UNITED STATES COURT OF APPEALS

FOR THE TENTH CIRCUIT

No. 13-2187

FRONT RANGE EQUINE RESCUE, THE HUMANE SOCIETY OF THE UNITED STATES, MARIN HUMANE SOCIETY, HORSES FOR LIFE FOUNDATION, RETURN TO FREEDOM, RAMONA CORDOVA, KRYSTLE SMITH, CASSIE GROSS, DEBORAH TRAHAN, and BARBARA SINK, SANDY SCHAEFER, TANYA LITTLEWOLF, CHIEF DAVID BALD EAGLE, CHIEF ARVOL LOOKING HORSE and ROXANNE TALLTREE-DOUGLAS,

Plaintiffs-Appellants,

and THE STATE OF NEW MEXICO,

Plaintiff-Intervenor-Appellant

v.

TOM VILSACK, Secretary U.S. Department of Agriculture; ELIZABETH A. HAGEN, Under Secretary for Food Safety, U.S. Department of Agriculture; and ALFRED A. ALMANZA, Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture,

Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

APPELLANTS' RULE 8(a) EMERGENCY MOTION FOR INJUNCTION PENDING APPEAL[1]

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November 2, 2013

[1] Counsel is filing this Motion in connection with its Notice of Appearance because the ECF system would not allow the filing of this Emergency Motion at this time. Because of the emergency nature of the motion, counsel is submitting it along with the Notice of Appearance, and will contact the Court as soon as possible to make arrangements to file the exhibits for the motion, and any further documents needed by the Court.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, Appellants Front Range Equine Rescue, The Humane Society of the United States, Marin Humane Society, Horses for Life Foundation, and Return to Freedom state they are non-governmental corporate parties. However, none of them issues stock of any kind, nor has parent or subsidiary corporations. Appellant the State of New Mexico is a government party.

/s/ Bruce A. Wagman
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MEMORANDUM OF POINTS AND AUTHORITIES

Pursuant to Rule 8(a) of the Federal Rules of Appellate Procedure and Rule 8 of the Tenth Circuit Local Rules, Appellants Front Range Equine Rescue, The Humane Society of the United States *et al*. (collectively "Appellants") move this Court for an emergency injunction to preserve the status quo, pending appeal of Appellants' claims that the USDA's reauthorization and oversight of domestic horse slaughter operations nationwide for the first time in more than six years requires environmental review under the National Environmental Policy Act, 42 U.S.C. § 4321, *et seq.* ("NEPA").[2]

I. INTRODUCTION

Plaintiffs-Appellants seek an emergency injunction to prevent potential irreversible environmental harm and violation of federal environmental laws before this appeal can be heard. Without the emergency relief, Appellees will allow horse slaughter operations to proceed nationwide for the first time in over six years,

[2] Pursuant to 10th Cir. R. 8.1(A), the District Court of New Mexico had subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because the case involved a federal agency as a defendant and arose under the laws of the United States, including the National Environmental Policy Act, 42 U.S.C. § 4321 *et seq*. and the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq*. This Court has jurisdiction over this appeal under 28 U.S.C. § 1291 because appellants appeal a final decision of the district court – specifically its November 1, 2013 Memorandum Opinion and Order, which dismissed this action with prejudice. Order, ECF No. 205 at 33, Ex. 1*; Notice of Appeal, ECF No. 206, Ex. 2. *References in this motion to "Ex." 1- 20 pertain to the Exhibits to this motion, filed concurrently herewith.

exposing the environment to the toxic byproducts created by the slaughter of animals raised outside a regulated industry and not meant to be processed for food.

Specifically, Appellants seek an emergency injunction to prohibit the United States Department of Agriculture ("Appellees" or "USDA") from carrying out federal meat inspections at three horse slaughter facilities without first performing the required environmental review under the National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4332(C). Without the requested stay, the first slaughter of horses for human consumption in more than six years will resume as early as Monday, November 4.

The district court below correctly recognized the likely irreparable harm that Appellants would suffer should Appellees' actions go forward pending resolution of the case, and found that the balance of hardships and public interest favored Appellants, when it entered a temporary restraining order against Appellees. But the district court erred when it reversed course on the merits and upheld Appellees' view that its actions are purportedly exempt from NEPA review. This Court should also preserve the status quo pending its *de novo* review, and prevent the irreparable harm that will likely befall Appellants while the district court's ruling is on appeal.

II. BACKGROUND

Appellants challenge USDA's grants of inspection under the Federal Meat Inspection Act ("FMIA") to horse slaughter facilities throughout the United States and the creation of a new horse meat drug residue testing plan, memorialized as Food Safety and Inspection Service Directive 6130.1, Ante-Mortem, Postmortem Inspection of Equines and Documentation of Inspection Tasks (the "Directive"),

without conducting the necessary environmental review required by NEPA. *See* Directive 6130.1, ECF No. 22-3, Ex. 3.

A. LEGAL FRAMEWORK

1. National Environmental Policy Act.

The National Environmental Policy Act, 42 U.S.C. § 4321 *et seq*. requires federal agencies to assess environmental impacts of regulatory actions. Under NEPA, federal agencies must take a "hard look" at the potential environmental consequences of their projects *before* taking action. *New Mexico ex rel. Richardson v. Bureau of Land Mgmt.*, 565 F.3d 683, 704 (10th Cir. 2009).

NEPA requires that federal agencies prepare one of the following three levels of documentation based on the significance of an action's possible impact on the environment: (1) an environmental impact statement ("EIS"); (2) an environmental assessment ("EA"); or (3) a categorical exclusion ("CE"). *See* 40 C.F.R. §§ 1507.3(b), 1501.4(a). An agency must prepare an EIS, or at minimum an EA, where a major federal action *may* significantly affect the environment. 42 U.S.C. § 4332(C); 40 C.F.R. § 1508.9. Alternatively, an agency may invoke a CE without conducting environmental review, but only for actions that do not "individually or cumulatively have a significant effect on the human environment and which have been found to have no such effect in procedures adopted by a Federal agency in implementing [the Commission on Environmental Quality] regulations." 40 C.F.R. § 1508.4.

An agency's procedures for determining categorical exclusions must "provide for extraordinary circumstances in which a normally excluded action may have a significant environmental effect." *See id.* § 1508.4. USDA regulations state that FSIS actions "are categorically excluded from the preparation of an EA or EIS unless the agency head determines that an action *may have a significant environmental effect*." 7 C.F.R. § 1b.4(a) (emphasis added); *see also* 40 C.F.R.

§ 1508.4. Because of the significant value given environmental protection, this "ensures that important effects will not be overlooked or underestimated only to be discovered after resources have been committed or the die otherwise cast." *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349 (1989).

2. Federal Meat Inspection Act.

The FMIA is a statutory inspection scheme designed to prevent "adulterated" meat products from entering the human food supply. 21 U.S.C. § 603. FSIS inspection is required to sell human-grade meat, and a horse slaughter facility must apply to FSIS for inspection in order to process meat for human consumption. Based on its discretionary evaluation of the applicant's history, operations and procedures, and management of waste-streams, including sewage and water, among other factors, 9 C.F.R. § 416.2, FSIS decides whether to grant inspection applications.[3] See 9 C.F.R. § 304.2.

B. FACTUAL BACKGROUND

1. Horse Slaughter Can Contaminate the Environment Because Horses Are Not Raised for Slaughter for Human Consumption.

Unlike traditional food animals such as cows, pigs, and chickens, horses are not raised in a regulated environment, but rather as pets, on racetracks, and as working animals. As a result, the vast majority of American horses are given a wide variety of drugs and other substances that render their blood and tissue contaminated and potentially dangerous to consume.[4] The Agency has repeatedly

[3] *If* in its discretion it grants an application for inspection, FSIS then "shall" inspect animals going to slaughter. 21 U.S.C. § 603(a).

[4] Undisputed evidence shows that virtually every American horse sent to slaughter has received substances that federal law specifically states cannot be used on animals intended to be eaten, in addition to other substances that have not been approved or even tested for use in horse meat. Rulemaking Petition, AR18, 35-38, Ex. 4; Banned and Dangerous Substances, AR95-123, Ex. 5; Declarations of

acknowledged that horses are different and that their slaughter poses risks of unknown environmental and public health dangers. Decision Memo, AR1828, 1825, Ex. 8; Petition Denial Letter, AR1855, Ex. 9; Valley Meat CE Decision Memo ("VM Memo"), ECF No. 22-4, at 5, Ex. 10.

2. Horse Slaughter Causes Significant Environmental Harm.

Even apart from the drugs and other toxins present in horse flesh, horse slaughter operations have in the past caused significant environmental impacts in surrounding communities. Before the last three American horse slaughter plants closed in 2007, they created extensive environmental harms, including the destruction of community members' ability to enjoy the area surrounding the slaughterhouse and the contamination of the waste management and disposal systems.[5] The environmental havoc caused by horse slaughter byproducts, such as blood, entrails, urine, feces, heads, and hooves, entering local water systems, overwhelming local waste water infrastructures, and causing numerous environmental violations, is well documented. *See, e.g.*, Ex. 11; Allin, *When Horse Slaughter Comes to Town*, Int'l Fund for Horses (Mar. 2011), AR391-92, Ex. 12. And, as noted, the environmental

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Wood, Larson, Pavlis, Parker, and Greger, ECF No. 8-1, Ex. 6; Declarations of Grover, Colella, Hoffman, Vaca, Newberry, Conner, Fitch, and Murphy, AR4034-48, Ex. 7.

[o] *See*, *e.g.*, Decl. of Robert Eldridge, ECF No. 13, at 2, Ex. 11 (Kaufman, Texas resident "unable to use [his] yard" because of stench of plant, seeing blood spills and animal parts, concerned for loss of property values); Decl. of Juanita Smith, Ex. 11 at 4-5 ("blood in my bathtub, sinks, and toilets," unable to have family over because of "severe stench on daily basis"); Decl. of Margarita Garcia, *id*. at 6 ("constantly exposed to the severe stench of the plant;" cannot open windows because "odor is unbearable"); Decl. of Mary Farley, *id*. at 8 (DeKalb, Illinois resident stating that "smell was so bad, and it would linger in my head for the rest of the day"); Decl. of Elizabeth Kershisnik, *id*. at 12 (describing "ongoing water pollution violations"; "polluted, green foam oozing from the plant's wastewater treatment tank").

harm caused by horse slaughter facilities is exacerbated because of the unregulated substances horses, as opposed to traditional food animals, receive throughout their lives. *See* Rulemaking Petition, AR17-27, 31-33, Ex. 4.[6]

3. For Six Years, There Has Been No Domestic Horse Slaughter.

Before 2007, FSIS inspected horse slaughter plants. In 2006, Congress withdrew funding for the inspection of horses, which effectively shut down horse slaughter plants. The funding prohibition was reinstated annually through 2011.[7]

4. Agency Actions to Authorize Horse Slaughter.

Congress failed to renew its ban on funding for FSIS's horse slaughter inspections in 2011, opening the door for horse slaughter to resume. Subsequently, the Agency granted applications for horse slaughter inspection to Valley Meat ("VM") and Responsible Transportation ("RT"), and stated that Rains Natural Meats ("RNM") has met all conditions to receive a grant, all without conducting any substantive environmental review pursuant to NEPA. VM Grant, Ex. 13; RT Grant, Ex. 14; Notice re: Grant of Inspection for RNM, ECF No. 154, at 2, Ex. 15.[8]

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[6] *See also* Song W. *et al*., *Selected Veterinary Pharmaceuticals in Agricultural Water and Soil from Land Application of Animal Manure*, 39 J. Environ. Qual. 4, 1211-17 (2010) (discussing long-term contamination from animal byproducts).

[7] After the 2006 defunding, USDA enacted a rule allowing "fee-for-service" horse slaughter inspections, to avoid Congress' decision to shut down horse slaughter. In *Humane Soc'y of U. S. v. Johanns*, 520 F. Supp. 2d 8, 34 (D.D.C. 2007), the court held that USDA had violated NEPA by doing so, stating that "any notion that USDA may avoid NEPA review simply by *failing* even to consider whether a normally excluded action may have a significant environmental impact flies in the face of the [Council on Environmental Quality] regulations." (emphasis in original) (internal quotation marks omitted).

[8] First and foremost, the USDA considered politics, not the environment, in making its decision to authorize horse slaughter without undertaking NEPA review. USDA

In response to the public health and environmental threats posed by the routine administration of prohibited, dangerous, and untested substances to horses who may end up at slaughterhouses, and based on Appellants' presentation to the Agency of proof of these threats, USDA implemented a new drug residue testing program via the Directive. VM Memo at 3, Ex. 10; RT Memo, ECF No. 22-5, at 3, Ex. 16; Directive, Ex. 3. The Directive was expressly incorporated into USDA's decisions to grant inspections, VM Memo at 3, Ex. 10; RT Memo at 3, Ex. 16, and the Directive instructs food safety inspectors on protocols associated with the Agency's "new drug residue testing program." VM Memo at 3, Ex. 10; RT Memo at 4, Ex. 16. The Agency devoted "a significant amount of time" to designing the Directive, *see* E-mail between FSIS officials and Ms. Sarah De Los Santos re: Request for third party review, AR3189, Ex. 17, but issued it without undertaking any NEPA review or even finding that the Directive is exempt from NEPA analysis pursuant to a CE.

As for the specific grants of inspection, the Agency decided that NEPA did not apply to them, concluding that they did not "constitute major federal action that will significantly affect the quality of the environment and thus [did] not trigger any requirements under NEPA." VM Memo at 3, Ex. 10; RT Memo at 3, Ex. 16. And it further determined that, even if NEPA applied to the grants of inspection, it could invoke a CE and thereby avoid environmental review. In invoking a CE, the Agency determined that the Directive would adequately protect the environment from the risks associated with horse slaughter, despite the fact that the Directive itself was never subjected to NEPA review. *See* VM Memo at 3, Ex. 10; RT Memo at 3, Ex. 16.

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ignored environmental concerns because some members of Congress thought USDA was "dragging its feet on the equine slaughter issue," and that further delay could result in "punitive congressional action." Decision Memo at 5, Ex. 8.

C. PROCEEDINGS BELOW

Appellants commenced this action on July 2, 2013, alleging that USDA violated NEPA and the APA by authorizing federal inspections at horse slaughter facilities and implementing a new drug residue testing program without undertaking that USDA violated NEPA and the APA by a NEPA review of the potential impacts of those actions. Compl., ECF No. 1. On August 2, the District Court held that Appellants established a substantial likelihood of success on the merits and rejected all of the Agency's excuses for failing to comply with that USDA violated NEPA and the APA by a NEPA. Order Granting in Part Plaintiffs' Motion for TRO and Preliminary Injunction, Aug. 2, 2013, ECF No. 94, Ex. 18 ("TRO Order"). Consequently, the Court ordered the status quo – no horse slaughter – to be preserved, and enjoined USDA from dispatching inspectors or carrying out inspection services at domestic horse slaughter facilities. TRO Order at 6-7, Ex. 18. Yet on November 1, 2013, after briefing on the merits, the district court reversed itself and upheld the Agency's grants of inspection and issuance of the Directive without substantive that USDA violated NEPA and the APA by a NEPA review.

III. ARGUMENT

The factors governing issuance of an emergency injunction pending appeal pursuant to Federal Rule of Appellate Procedure 8(a) are: (1) whether the applicant has made a strong showing that he is likely to succeed on the merits of the appeal; (2) whether the applicant will be irreparably injured if an injunction pending appeal is denied; (3) whether an injunction will substantially injure the other interested parties; and (4) where the public interest lies. *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); *Sec. Investor Prot. Corp. v. Blinder, Robinson & Co, Inc.*, 962 F.2d 960, 968 (10th Cir. 1992); Fed. R. App. 8(a); 10th Cir. R. 8.1. In the context of injunctions and stays pending appeal, the Tenth Circuit has held that

"where the moving party has established that the three 'harm' factors tip decidedly in its favor, the 'probability of success' requirement is somewhat relaxed." *F.T.C. v. Mainstream Mktg. Servs., Inc.*, 345 F.3d 850, 852-53 (10th Cir. 2003) (citation omitted). Therefore, an appellant raising "serious, substantial, difficult, and doubtful [questions] . . . deserving of more deliberate investigation" has shown a probability of success. *Id*. (quotation and citation omitted). As set out below, Appellants satisfy each of the four requirements for an injunction pending appeal.[9]

A. APPELLANTS ARE LIKELY TO SUCCEED ON THE MERITS

1. The Directive and Grants of Inspection May Have Significant Environmental Effects, so NEPA Review Is Required.

USDA acted arbitrarily and capriciously by failing to prepare an EIS or at least an EA prior to issuing the Directive and the Grants. The evidence of potential environmental impacts is well beyond the threshold to trigger the Agency's substantive environmental review obligations under NEPA. "An EIS is warranted where uncertainty [regarding proposed action] may be resolved by further collection of data, especially where such data may reduce the need for speculation." *Town of Superior v. U.S. Fish & Wildlife Serv.*, 913 F. Supp. 2d 1087, 1120 (D. Colo. 2012) (citation omitted) (internal quotation marks omitted).

The possible environmental effects of the Directive and the Grants cannot be passed over or dismissed by invocation of a CE, because NEPA review is required anytime a mere possibility of significant such effects exists. *See* 42 U.S.C.

[9] It is also clear that filing this motion in the district court would be impracticable. 10th Cir. 8(a)(2)(A)(i). Domestic horse slaughter for human consumption will commence immediately now that Appellant's claims have been dismissed. And the District Court rejected Appellants' claims on the merits – indeed reversing its own prior decision that Appellants were likely to succeed – so arguing Appellants' likelihood of success on the merits to the District Court would be futile, jeopardizing the little time Appellants have to secure the status quo.

§ 4332(C); *see also Wildearth Guardians v. U.S. Forest Serv.*, 668 F. Supp. 2d 1314, 1321-22 (D.N.M. 2009) (to determine whether use of a CE is precluded, the agency "must consider if the proposed action *may* have a potentially significant impact") (emphasis added); *id.* (no CE unless "an agency [determines] that extraordinary circumstances do not exist") (citing *Utah Envtl. Cong. v. Russell*, 518 F.3d 817, 821 (10th Cir. 2008)).

There can be no legitimate argument that there is no possibility of significant environmental effects resulting from the commencement of horse slaughter operations at at least three – and likely more in the coming months – horse slaughter facilities. Indeed, the only three recently existing horse slaughter facilities in this country wreaked havoc on the environment and surrounding community by dumping blood, entrails, urine, feces, heads, and hooves into local water systems, overwhelming local wastewater infrastructures, and causing numerous environmental violations. *See generally* Decls. of Robert Eldridge, Juanita Smith, Margarita Garcia, Mary Farley, and Elizabeth Kershisnik, Ex. 11. The fact that horse flesh and by products are likely to contain drug residues makes the environmental threat, including the potential contamination of groundwater and entry into the food chain, even more significant.

Moreover, several CEQ "significance" factors are present with respect to both the Directive and the Grants, *see* 40 C.F.R. § 1508.27, thus mandating preparation of an EIS, or at minimum an EA. *See Fund For Animals v. Norton*, 281 F. Supp. 2d 209, 235 (D.D.C. 2003) (presence of one or more of the CEQ significance factors normally requires preparation of an EIS). For instance, both the Grants authorizing horse slaughter inspections and the Directive regulating horse slaughter drug residues pose serious risks to public health and safety, as well as unique or unknown health and safety risks. *See* 40 C.F.R. § 1508.27(b)(2), (5); *Catron Cnty. Bd. of Comm'rs, New Mexico v. U.S. Fish & Wildlife Serv.*, 75 F.3d

1429, 1439 (10th Cir. 1996) (designating critical habitat for protection pursuant to the Endangered Species Act warrants at least an EA "[w]hen the environmental ramifications of such designation[ ] are unknown"); *San Luis Valley Ecosystem Council v. U.S. Fish & Wildlife Serv.*, 657 F. Supp. 2d 1233, 1243 (D. Colo. 2009) ("An agency must generally prepare an EIS if the environmental effects of a proposed action are highly uncertain.").

Thus, the Agency has stated that there is no danger to the environment or public health from drug residues present in horse flesh and by-products because of its drug residue testing program and other controls it claims will prevent such toxins from entering the environment or food supply. VM Memo at 3, Ex. 10; RT Memo at 3, Ex. 16. However, the Agency's Directive requires the testing of only a small sampling of the drugs typically administered to American horses, without any scientific evidence that this sampling represents the most common substances present in horses. *See Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1574 (10th Cir. 1994) (agency action is arbitrary and capricious where it has "failed to consider an important aspect of the problem" or "offered an explanation that runs counter to the evidence before the agency"). At an absolute minimum, therefore, the record reflects that the presence of residues in horse flesh and by products, and their effect on human health and the environment, remains highly uncertain and unknown. *See Fund for Animals v. Babbitt*, 89 F.3d 128, 130 (2d Cir. 1996) ("Categorical exclusions may never be invoked if the action at issue may have . . . highly uncertain and potentially significant environmental effects or involve unique or unknown environmental risks.").

For the same reasons, there is also a significant public controversy over the "size, nature, or effect" of the Agency's Grants and Directive. *Middle Rio Grande Conservancy Dist. v. Norton*, 294 F.3d 1220, 1229 (10th Cir. 2002) (substantial

dispute as to the effects of water reallocation and curtailment of river maintenance warranted an EIS).

Additionally, USDA's actions in this case will define the "degree to which the action may establish a precedent for future actions with significant effects." 40 C.F.R. § 1508.27(b)(6). Both the Directive and the Grants establish the template for horse slaughter plants, with wide-ranging future environmental consequences. Because the Agency has engaged in new, nationwide programmatic changes, a CE may not be applied. *See Sierra Club v. U.S. Dept. of Energy*, 255 F. Supp. 2d 1177, 1183 (D. Colo. 2002) (citing with approval *High Sierra Hikers Ass'n v. Powell*, 150 F. Supp. 2d 1023, 1044 (N.D.Cal.2001) (CE could not be used to renew long-term special-use permits for commercial trip operators in wilderness areas where the CE previously only applied to renewals of short-term permits).

Furthermore, the Grants and Directive implicate the CEQ significance factor regarding "[w]hether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment." 40 C.F.R. § 1508.27(b)(10); *see also Wyoming Outdoor Council, Powder River Basin Res. Council v. U.S. Army Corps of Eng'rs*, 351 F. Supp. 2d 1232, 1244 (D. Wyo. 2005) ("Impacts to water quality are impacts to the human environment and, if significant, could necessitate the preparation of an EIS."). Given VM's past environmental violations, *see, e.g.*, Letter from William C. Olson to Richard De Los Santos, May 7, 2010, Letter from Dr. Ron Nelson to Director, New Mexico State Government Health Department, Jan. 22, 2010, and Letter from George W. Akeley, Jr. to Ricardo and Sarah De Los Santos, Jan. 4, 2011, ECF No. 13, Ex. 19, and the last horse slaughter plants' disastrous contamination issues on USDA's watch, the Agency could not rationally find that there was no potential for their Grants to threaten a violation of environmental laws.

Any one of these several CEQ factors mandates substantive NEPA review, rather than invocation of a CE. *See Fund For Animals v. Norton*, 281 F. Supp. 2d 209, 235 (D.D.C. 2003) (presence of one or more of the CEQ significance factors normally requires preparation of an EIS); *California v. Norton*, 311 F.3d 1162, 1177 (9th Cir. 2002) ("the fact that the exceptions may apply is all that is required to prohibit use of the categorical exclusion"); *Brady Campaign to Prevent Gun Violence v. Salazar*, 612 F. Supp. 2d 1, 16, 23 (D.D.C. 2009) (agency violated NEPA in invoking a CE where it ignored information in the record concerning environmental impacts).[10]

Given the negative environmental, aesthetic, economic, and cultural effects that past horse slaughter facilities inflicted on their communities, USDA was required to prepare an EIS to "inform decisionmakers and the public of the reasonable alternatives which would avoid or minimize adverse impacts" of horse slaughter for human consumption. *Citizens' Comm. to Save Our Canyons v. Krueger*, 513 F.3d 1169, 1178 (10th Cir. 2008) (citing 40 C.F.R. § 1502.1). USDA violated NEPA by adopting the Directive and issuing the Grants without proper environmental review.

2. The Agency Has Discretion to Conduct NEPA Review.

The district court's ruling under review relies heavily on the mistaken conclusion that USDA decisions to authorize horse slaughter are "non-discretionary" and thus exempt from NEPA review. Order at 27-32, Ex. 1.

[10] USDA was also required to, and did not, perform a comprehensive analysis of *cumulative* impacts of the Directive and Grants. *See Sierra Club*, 255 F. Supp. 2d at 1182 (agencies must "analyze indirect and cumulative impact.") (citing 40 C.F.R. §§ 1508.7, 1508.8); *Wyoming Outdoor Council*, 351 F. Supp. 2d at 1241 (same for EA); *Fuel Safe Washington v. F.E.R.C.*, 389 F.3d 1313, 1329-30 (10th Cir. 2004) (same for EIS); 40 C.F.R. § 1508.25(a)(2), (c).

Appellants believe this is a clear error of law, and seek to preserve the status quo so this Court can render a correction. USDA is not required to grant applications for inspection, and its grants of slaughterhouse applications are clearly subject to NEPA review. While the FMIA requires FSIS to examine animals before entering the slaughterhouse, 21 U.S.C. § 603(a), the Agency weighs many environmental factors in deciding whether to grant inspections in the first place. It is the Agency's decision whether to grant inspection or not. *See* 9 C.F.R. §§ 304.2, 416.2.

FSIS regulations recognize the discretionary nature of its authority, stating that FSIS "*is authorized* to grant inspection upon [its] determination that the applicant and the establishment are eligible therefor." 9 C.F.R. § 304.2(b) (emphasis added); *see also Heckler v. Chaney*, 470 U.S. 821, 835 (1985) (use of the term "authorized" suggests discretion).

Indeed, the Agency "is authorized to . . . refuse to grant inspection at any establishment if [it] determines" the plant does not meet the requirements of the FMIA or the Agency's various regulations, including requirements related to sanitary conditions, unlawful discharge into navigable U.S. waterways, product adulteration, inhumane handling or slaughtering of livestock, an applicant's truthfulness in filling out his application, and an applicant's past criminal convictions. 9 C.F.R. § 304.2 (incorporating by reference various other FMIA regulations); *see also Sierra Club*, 255 F. Supp. 2d at 1185-86 (authority to limit mining activities constitutes discretion). The language of this regulation *specifically relates* to the impacts that Appellants have alleged will result from horse slaughter operations, including the likelihood that contaminated horse meat will enter the food supply and slaughter byproducts will threaten the natural environment.

USDA has clearly demonstrated its discretion to implement a whole range of residue testing or residue prevention options by way of its mandate to ensure that meat is not adulterated under the FMIA – and therefore to limit the risks and potential impacts to human health and the environment resulting from drug residues. *See* 21 U.S.C. §§ 603(a), (b), 604, 607. USDA cannot evade NEPA compliance by falsely claiming that it had no choice but to issue approvals of the Grants.

Because the Directive and Grants may have significant environmental effects and because the Agency possesses discretion in granting inspections, Appellants have demonstrated a likelihood of success on the merits of their appeal.

B. THE BALANCE OF HARM FAVORS AN INJUNCTION PENDING APPEAL.

1. Appellants Will Be Irreparably Harmed If An Injunction Pending Appeal is Denied.

Appellants seek this emergency injunction because they will be irreparably harmed if USDA's Directive and Grants are carried out before Appellants can meaningfully exercise their right to appeal. *See* Decls. of Smith, Trahan, Gross, Cordova, Sink, and Seper, ECF No. 13, Ex. 20. An "irreparable harm" requirement for injunctive relief is met if the applicants demonstrate a significant risk of harm that cannot be compensated after the fact by monetary damages. *Greater Yellowstone Coal. v. Flowers*, 321 F.3d 1250, 1258 (10th Cir. 2003) (plaintiffs sufficiently demonstrated risk of irreparable harm to bald eagles); *Comm. to Save the Rio Hondo v. Lucero*, 102 F.3d 445, 448–49 (10th Cir.1996) ("The injury of an increased risk of harm due to an agency's uninformed decision is precisely the type of injury [NEPA] was designed to prevent."). Appellants face the imminent prospect that horse slaughter inspections and operations will commence in less than 48 hours,

thereby irreparably injuring Appellants' aesthetic, environmental, cultural, health, informational, and public interests.

By mandating compliance with NEPA procedural requirements, "Congress has presumptively determined that the failure to comply with NEPA has detrimental consequences for the environment." *Davis v. Mineta*, 302 F.3d 1104, 1114 (10th Cir. 2002). Moreover, the named individual appellants have clearly demonstrated that they will be irreparably harmed if the Grants are not enjoined, as set out in detail in their declarations. *See* Decls. of Smith, Trahan, Gross, Cordova, Sink, and Seper, Ex. 20.

As the Supreme Court recognized in *Amoco Production Co. v. Village of Gambell*, "[e]nvironmental injury, by its nature, can seldom be adequately remedied by money" and, thus, "the balance of harms will usually favor the issuance of an injunction." 480 U.S. 531, 545 (1987). *See also Catron Cnty. Bd. of Comm'rs, New Mexico*, 75 F.3d at 1440 (environmental injury "generally considered irreparable"). Therefore, for NEPA violations, "there is a presumption that injunctive relief should be granted against continuation of the action until the agency brings itself into compliance." *Realty Income Trust v. Eckerd*, 564 F.2d 447, 456 (D.C. Cir. 1977). This presumption applies here, as Appellants will suffer irreparable harm if the Agency conducts federal horse slaughter inspections during the course of this appeal. Once horse slaughter has begun again, there will be nothing the Court or Appellants can do to restore the potentially ruined environment, or to stem the damage triggered as a result of the discharge of contaminated horse slaughter water.

Courts have found irreparable harm where issues similar to those raised here are presented. *See, e.g., United States v. Power Eng'g Co.*, 10 F. Supp. 2d 1145, 1165 (D. Colo. 1998) *aff'd*, 191 F.3d 1224 (10th Cir. 1999) (injunction warranted given presence of waste in the soil and groundwater raising concern for public

health and environment); *see also Davis*, 302 F.3d at 1115-16 (irreparable harm where highway project would "impair the aesthetic attributes associated with the [parkway] and [would] disrupt the natural setting and feeling of the park"); *Wilderness Workshop v. U.S. Bureau of Land Mgmt.*, No. 08-CV-00462-REBMEH, 2008 WL 1946818, at *6-*8 (D. Colo. Apr. 30, 2008) (irreparable harm from construction of pipeline).[11]

2. Neither the Agency Nor Horse Slaughter Inspection Grantees Will Be Irreparably Harmed By An Injunction Pending Appeal.

The emergency injunction that Appellants seek is necessary to preserve the status quo as it has existed for the last six years, with the absolute dormancy of the U.S. horse slaughter business. There is certainly no harm, irreparable or otherwise, to USDA if it is enjoined from inspecting domestic horse slaughter facilities during the pendency of this appeal, or indeed pending the completion of proper NEPA review. The injunction will merely "require the [federal] defendants to maintain a course of conduct that they have pursued for many years." *Nat'l Senior Citizens Law Center, Inc. v. Legal Serv. Corp.*, 581 F. Supp. 1362, 1373 (D.D.C. 1984); *see also Nat'l Ski Areas Ass'n, Inc. v. U.S. Forest Serv.*, 910 F. Supp. 2d 1269, 1290 (D. Colo. 2012) (harm to movants of allowing agency to carry out invalid directive outweighed any "inconvenience caused by requiring the agency to adhere with statutory requirements and mandatory procedures").

Even if VM, RT, or RNM could point to economic harm from an injunction pending appeal (which is not clear at all, given the unestablished and speculative

[11] *See also Humane Soc'y of the U.S. v. Bryson*, 2012 WL 1952329, at *6 (D. Or. May 30, 2012) (unreported) ("real emotional and aesthetic injury from the knowledge that [California Sea Lions] have been killed . . . "); *Animal Legal Def. Fund v. Glickman*, 154 F.3d 426, 433 (D.C. Cir. 1998) (*en banc*) ("cognizable interest in viewing animals free from inhumane treatment") (citations omitted).

nature of their proposed business), purely economic loss is not irreparable. *See, e.g.*, *Schrier v. Univ. of Colo.*, 427 F.3d 1253, 1267 (10th Cir. 2005) ("It is also well settled that simple economic loss usually does not, in and of itself, constitute irreparable harm; such losses are compensable by monetary damages.") (internal quotation marks omitted). Any harm that could be potentially claimed by VM, RT, or RNM certainly does not outweigh the irreparable harms that would be suffered by Appellants and the public in the absence of an injunction. *See Davis*, 302 F.3d at 1116 (balance of harms favored injunctive relief to block highway project since the environmental harm outweighed even "significant financial penalties" that would be incurred by delaying the project).

C. THE PUBLIC INTEREST WOULD BE SERVED BY AN INJUNCTION PENDING APPEAL.

An injunction pending appeal is in the public interest because this appeal seeks to ensure that the Agency complies with NEPA as intended by Congress, *before* rendering a decision that adversely affects the natural environment. *See Cottrell*, 632 F. 3d at 1138 ("This court has also recognized the public interest in careful consideration of environmental impacts before major federal projects go forward, and we have held that suspending such projects until that consideration occurs comports with the public interest.") (internal quotation marks omitted); *Nat'l Ski Areas Ass'n, Inc.*, 910 F. Supp. 2d at 1290 ("[T]here is public interest in ensuring that federal agencies adhere to rule-making processes in the APA [and other] statutes."); *Power Eng'g Co.*, 10 F. Supp. 2d at 1165 (injunction would serve the public interest in preventing violation of hazardous waste disposal law as local citizens "have a right to expect contamination-free groundwater and soils").

The public must have access to information regarding the detrimental environmental effects caused by prior USDA-monitored horse slaughter facilities

before residents start seeing horse blood in their faucets, piles of rotting carcasses at the slaughterhouse facilities, polluted waterways, and news that our meat supply has been contaminated by adulterated horse flesh. By neglecting to conduct NEPA review for the Directive and the Grants, USDA deprived Appellants and other members of the public of "critical evaluation of an agency's actions by those outside the agency," a key function of NEPA review. *Catron Cnty. Bd. of Comm'rs, New Mexico*, 75 F.3d at 1434.Accordingly, the public interests in carrying out NEPA as Congress intended it, guarding against environmental harms, and allowing public participation by access to planned agency actions all would be served by issuing an injunction pending appeal.

IV. CONCLUSION

For the foregoing reasons, Appellants have demonstrated that an emergency injunction pending appeal would prevent irreparable harm to Appellants without inflicting irreparable harm on others, would serve the public interest, and is appropriate because Appellants' NEPA claims have a likelihood of success.

Dated: November 2, 2013

Respectfully submitted,

/s/ *Bruce A. Wagman*

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RULE 8.2 EMERGENCY MOTION CERTIFICATE

The undersigned attorney hereby certifies that the foregoing Rule 8 Emergency Motion for Injunction Pending Appeal is being filed at the earliest possible time following the denial of Appellants' motion for declaratory judgment on November 1, 2013, which was immediately effective. Counsel for Appellants notified the Circuit Clerk on November 1, 2013 that Appellants anticipated filing for emergency relief. Counsel notified the counsel of record for the defendants and defendants-intervenors on November 2, 2013 that Appellants intended to seek emergency relief. Due to the expiration of the temporary restraining order and risk of irreparable harm, Appellants proceeded with filing for emergency relief. The undersigned attorney further certifies that contact information for all counsel of record from the district court proceedings is set out below. Pursuant to Fed. R. App. P. 25(a)(5), the undersigned certifies that all required privacy redactions have been made.

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CERTIFICATE OF SERVICE

I hereby certify that on November 2, 2013, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Tenth Circuit by using the appellate CM/ECF system.

I further certify that on November 2, 2013, I served the foregoing motion via the CM/ECF system and via e-mail on all counsel of record.

/s/ Bruce A. Wagman
BRUCE A. WAGMAN
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EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

FRONT RANGE EQUINE RESCUE,
et al.

Plaintiffs,

vs. No. 1:13-CV-00639-MCA-RHS

TOM VILSACK, Secretary U.S.
Department of Agriculture, *et al.*

Defendants.

MEMORANDUM OPINION AND ORDER

This case involves applications for grants of inspection for federal meat inspection services for commercial horse slaughter operations at Valley Meat Company, LLC (Valley Meat), Responsible Transportation, LLC (Responsible Transportation), and Rains Natural Meat. The Federal Meat Inspection Act (FMIA), 21 U.S.C. § 601 *et seq.*, regulates the inspection of meat and meat food products. The Food Safety Inspection Service (FSIS), as the delegate of the United States Department of Agriculture (USDA), is the agency responsible for conducting inspections and issuing grants of inspection to such facilities. The grants of inspection allow for facilities such as Valley Meat, Responsible Transportation, and Rains Natural Meats to engage in commercial slaughtering of horses intended for human consumption. Plaintiffs seek to have the Court permanently enjoin Valley Meat, Responsible Transportation, Rains Natural Meats, and the USDA from performing house slaughter inspections or utilizing a June 28, 2013 FSIS

Directive until the USDA has satisfied its obligations under the National Environmental Policy Act (NEPA) 42 U.S.C. § 4321 *et seq.*

This matter is before the Court on Plaintiffs' *First Amended Complaint for Declaratory and Injunctive Relief.* [Doc. 54] Consistent with Olenhouse v. Commodity Credit Corp., 42 F.3d 1560, 1580 (10th Cir. 1994), the Court has processed Plaintiffs' *First Amended Complaint for Declaratory and Injunctive Relief* [Doc. 54] as an appeal. [See Doc. 137] Having considered the submissions, the Administrative Record, the relevant case law, and otherwise being fully advised in the premises, the Court affirms the agency's decision.

I. BACKGROUND AND PROCEDURAL HISTORY

The FMIA governs the slaughter of "amenable species," including horses, see 21 U.S.C. § 601(w), and requires that all amenable species be examined and inspected "before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce . . . ," 21 U.S.C. § 603(a). The FMIA also requires "a post mortem examination and inspection of the carcasses and parts thereof of all amenable species to be prepared at any slaughtering, meat-canning, salting, packing, rendering, or similar establishment in any State, Territory or the District of Columbia as articles of commerce which are capable of use as human food . . .." 21 U.S.C. § 604. The FMIA prohibits the slaughter or preparation of "cattle, sheep, swine, goats, horses, mules, or other equines . . . which are capable of use as human food at any

establishment preparing any such article for commerce, except in compliance with the requirements of this chapter." 21 U.S.C. § 610(a).

For fiscal years 2006 through 2011, Congress prohibited the use of federal funds to "pay the salaries or expenses of personnel to inspect horses under section 3 of the Federal Meat Inspection Act (21 U.S.C. Sec. 603) or under the guidelines issued under section 903 the Federal Agriculture Improvement and Reform Act of 1996 (7 U.S.C. [§] 1901 note; Public Law [No.] 104–127)." Pub. L. No. 109-97, § 794 (2005); see also Pub. L. 110-1161, div. A, § 741(1) (2007); Pub. L. No. 111-80, div. A, tit. VII, § 744 (2009). As a consequence, horse slaughter in the United States ceased during this time period. However, the prohibition was not enacted for fiscal years 2012 or 2013. Because there is federal funding to pay the salaries and expenses of horse slaughter inspectors, commercial horse slaughtering may once again be carried out lawfully in the United States.

The USDA has received "[a]t least six applications for horse slaughtering inspections in five states . . . since Congress appropriated funding for inspections." [Doc. 54 at 3] Valley Meat, a slaughter facility located in Roswell, New Mexico, submitted an application dated December 13, 2011, to add equines to its preexisting grant of inspection. However, federal regulations require the slaughter of "horses, mules, or other equines" to be "done in establishments separate from any establishment in which cattle, sheep, swine, or goats are slaughtered or their products are prepared." 9 C.F.R. § 305.2(b). On March 2, 2012, Valley Meat submitted an amended application seeking "to modify its grant of inspection to receive inspection services for the commercial slaughter

of horses, mules, and other equines." [Doc. 66-2 at 2] On June 28, 2013, the Food Safety Inspection Service (FSIS) issued a decisional memorandum granting Valley Meat's modified application. [AR 2467]

Responsible Transportation, a facility located in Sigourney, Iowa, filed an application dated December 13, 2012, for a grant of inspection for equines. [Doc. 22-5 at 3] On July 1, 2013, FSIS issued a decisional memorandum granting Responsible Transportation's application. [AR 3282]

Rains Natural Meats, a facility located in Gallatin, Missouri, submitted an application dated January 15, 2013, for a grant of inspection for equines. [Doc. 201-1 at 2] Rains Natural Meat's application has been reviewed, a decisional memorandum granting Rains Natural Meat's application, and FSIS is in a position to issue a grant of inspection pending the resolution of this action. [Doc. 201-1 at 2; Doc. 154]

The three other establishments that have submitted applications for grants of inspection for equines are: American Beef Company/Unified Equine, LLC in Rockville Missouri, Oklahoma Meat Company in Washington, Oklahoma, and Trail South Meat Processing Company in Woodbury, Tennessee. [Doc. 54 at 3] None of these three companies have "actively pursued completion of the grant process after the first submission of their applications to FSIS." [Doc. 66-1 at 5]

The grants of inspection issued to Valley Meat and Responsible Transportation are conditional in nature and shall not "exceed 90 days, during which period the establishment must validate its HACCP [Hazard Analysis and Critical Control Point]

plan." 9 C.F.R. § 304.3(b); see 9 C.F.R. §§ 417.2 and 417.4 (discussing HACCP plans). After the successful validation of a HACCP plan, the conditional grants of inspection become permanent.

On June 28, 2013, FSIS issued FSIS Directive 6130.1 (the Directive) regarding "Ante-Mortem, Postmortem Inspection of Equines and Documentation of Inspection Tasks." [Doc. 22-3 at 2]

> This directive provides instructions to inspection program personnel (IPP) on how to perform ante-mortem inspection of equines before slaughter and post mortem inspection of equine carcasses and parts after slaughter. Additionally, this directive instructs Food Safety and Inspection Service (FSIS) Public Health Veterinarians (PHVs) making ante-mortem and post-mortem dispositions of equines how to perform residue testing, verify humane handling, verify marking of inspected equine products, and document results using the Public Health Inspection (PHIS) for equine when available.

[Id.] In the Directive, FSIS "recognizes that most equines presented for slaughter will likely not have been raised for human consumption" and that, therefore, there are "concerns regarding the potential presence of chemical residues from drugs not previously approved for use in all food animals including equine." [Id. at 7] In addition to following pre-existing residue testing policies, IPP are instructed to "conduct random residue testing of normal-appearing" horses at "at least the same rate as for show livestock." [Id. at 8] Thus, "IPP are to randomly select, on the slaughter floor from normal-appearing equine[s], "[a] minimum of 4 animals if there are more than 100 animals in the lot." [Id.]

On July 2, 2013, Plaintiffs Front Range Equine Rescue, the Humane Society of the United States, Marin Humane Society, Horses for Life Foundation, Return to Freedom, Ramona Cordova, Krystle Smith, Cassie Gross, Deborah Trahan, and Barbara Sink (collectively, "Plaintiffs") filed their *Complaint for Declaratory and Injunctive Relief* in the United States District Court for the Northern District of California. [Doc. 1] In their complaint, Plaintiffs allege that Defendants, Tom Vilsack, Secretary of the USDA, Elizabeth A. Hagen, USDA Under Secretary for Food Safety, and Alfred V. Almanza, USDA Administrator for FSIS (collectively, "Federal Defendants") "are proceeding with the inspection of horses under the [FMIA] without compliance with their federally mandated environmental review obligations." [Doc. 1 at 2; see also Doc. 54 at 2] Specifically, Plaintiffs allege that the Federal Defendants violated the NEPA and the Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(A), (C)), and (D), when it issued grants of inspection for horse slaughter and "adopt[ed] and implement[ed] a new residue testing plan applicable to all horse slaughter plants throughout the nation that may be authorized to operate by Defendants" without first preparing an environmental impact statement (EIS) or environmental assessment (EA) in accordance with the requirements of NEPA and its implementing regulations. [Doc. 1 at 3] As a remedy, Plaintiffs seek a declaratory judgment setting aside the grants of inspection and drug residue testing policy as "arbitrary and capricious, and without observance of procedure required by law" and a preliminary and permanent injunction enjoining Federal Defendants from "granting or conditionally granting any applications for inspection of horse slaughter facilities," or

"implementing the new drug residue testing plan for horse slaughterhouses nationwide, without performance of adequate NEPA review." [Doc. 1 at 35-36] On July 2, 2013, Plaintiffs also filed a motion for a temporary restraining order and preliminary injunction seeking to enjoin Federal Defendants "from authorizing horse slaughter at a domestic horse slaughter facility pending consideration of the merits of Plaintiffs' claims." [Doc. 16-1 at 37]

Pursuant to the stipulation of the parties, the case was transferred from the United States District Court of the Northern District of California to the District of New Mexico. [Doc. 31] After the transfer, Plaintiffs filed their *First Amended Complaint for Declaratory and Injunctive Relief*. [Doc. 54] The *First Amended Complaint* adds several new Plaintiffs, including Foundation to Protect New Mexico Wildlife, Sandy Schaefer, Tanya Littlewolf, Chief David Bald Eagle, Chief Arvol Looking Horse and Roxanne Talltree-Douglas. [Doc. 54 at 1] Otherwise, the *First Amended Complaint* mirrors the original complaint, in that it alleges that the Federal Defendants have violated NEPA and the APA by issuing grants of inspection for horse slaughter and implementing a drug residue testing policy for equines without first preparing an EIS or an EA.

Numerous parties have filed motions to intervene in the present proceedings, and the Court has granted the motions to intervene filed by the following interested parties: Valley Meat, Responsible Transportation, Rains Natural Meats, Chevaline, LLC, Confederated Tribes and Bands of the Yakama Nation, State of New Mexico, International Equine Business Association, New Mexico Cattlegrowers' Association,

South Dakota Stockgrowers Association, Ranchers-Cattlemen Action Legal Fund United Stockgrowers of America, Marcy Britton, Bill and Jan Wood, Leroy and Shirley Wetz, Doug and Judy Johnson, Kujyukuri, Ltd., United Horseman, and Scenic View Ranch. [See Docs. 43, 90, and 140]

On August 2, 2013, the Court conducted a hearing on Plaintiffs' motion for a temporary restraining order and preliminary injunction. [See Doc. 96] After the hearing, the Court granted Plaintiffs' request for a temporary restraining order concluding, in relevant part, that Plaintiffs had demonstrated a substantial likelihood of success on the merits of their NEPA and APA claims. With respect to the Directive, the Court provisionally determined that the Directive "constitute[d] final agency action as defined by the APA" and also "major Federal action[] significantly affecting the quality of the human environment under NEPA." [Doc. 94 at 2, 3] Because the grants of inspection issued to Valley Meat and Responsible Transportation "were based, in relevant part, on the existence of the FSIS Directive . . . to protect the public health and safety," the Court provisionally determined that the grants of inspection were also flawed. Furthermore, the Court determined that Plaintiffs had "fulfilled their burden to prove that environmental harm is likely to occur in the absence of the issuance of a temporary restraining order," that the potential environmental harm outweighed "the legitimately incurred costs to defendants resulting from a temporary restraining order," and that a temporary restraining order was not adverse to the public interest. [Id. at 5-6] Accordingly, Plaintiffs' request for a temporary restraining order was granted, and Federal Defendants were enjoined

"from dispatching inspectors to the horse slaughterhouse facilities operated by the Intervenor-Defendants Valley Meat and Responsible Transportation until further order of the Court." [Id. at 6-7] The Court further ordered Federal Defendants to "suspend or withhold the provision of meat inspection services to Valley Meat and Responsible Transportation until further order of the Court."[1] [Id. at 6-7] The Court also enjoined Valley Meat and Responsible Transportation "from commercial horse slaughter operations until further order of the Court," and stated that it would "set a hearing on Plaintiffs' request for a preliminary injunction within thirty (30) days." [Id. at 7]

On August 26, 2013, the Federal Defendants and Defendant-Intervenors (collectively, "Defendants") filed a *Joint Motion to Consolidate the Preliminary Injunction Hearing on the Merits, and For Expedited Briefing on the Merits*. [Doc. 131] Plaintiffs and Plaintiff-Intervenor, the State of New Mexico, "support[ed] Defendants' request that the Court expedite resolution of this case with briefing on the merits." [Doc. 133] Therefore, the Court consolidated "Plaintiffs' pending motion for preliminary injunction . . . with the hearing on the merits" and ordered briefing on an expedited basis. [Doc. 137] The Court also clarified that it would process Plaintiffs' *First Amended Complaint for Declaratory and Injunctive Relief* as an appeal consistent with Olenhouse, 42 F.3d at 1580, and that the parties would not be permitted to "submit additional

[1] Per an *Amended Order* filed on August 21, 2013, the Court clarified that its August 2, 2013 Order applied only to *horse* slaughter inspections and did not prohibit the dispatch of federal inspectors to Valley Meat or Responsible Transportation to inspect other amenable species under the Federal Meat Inspection Act. [See Docs. 124 and 125]

evidence in support of and in opposition to the substantive result of the Federal Defendants' NEPA process." [Doc. 137]

On September 13, 2013, Federal Defendants filed *Notice Regarding Grant of Inspection for Rains Natural Meats in Gallatin, Missouri*. [Doc. 154] The notice provided that "FSIS ha[d] completed an analysis of the proposed grant of inspection for the Rains Natural Meats facility in accordance with NEPA, [and] determin[ed] that the grant f[ell] under the USDA categorical exclusion for FSIS actions" and, therefore, FSIS was "presently in a position to issue the grant of inspection for Rains Natural Meats as required by the FMIA." [Doc. 154 at 2] As a result of Federal Defendants' *Notice Regarding Grant of Inspection for Rains Natural Meats in Gallatin, Missouri*, Plaintiffs filed an *Emergency Motion to Modify the Amended Temporary Restraining Order* [Doc. 156], requesting "that the Court modify its Order enjoining . . . [F]ederal [D]efendants from conducting horse meat inspections at [Rains Natural Meats]." [Id. at 4]

On September 20, 2013, the Court issued an Order enjoining Federal Defendants from dispatching inspectors to the horse slaughterhouse facility operated by Intervenor-Defendant Rains Natural Meats and referred the matter to the Honorable Robert H. Scott for an evidentiary hearing regarding whether the Order should be extended beyond October 4, 2013. [Doc. 168 at 2] On September 25, 2013, the Parties filed a *Stipulation and Joint Motion to Extend the Temporary Restraining Order Regarding Rains Natural Meats, to Modify Briefing Schedule and to Vacate October 1, 2013 Evidentiary Hearing*, [Doc. 178], in which the Parties agreed that the "Court's September 20, 2013 temporary

restraining order, [Doc. 168], will remain in effect until October 31, 2013, when the Court anticipates issuing its ruling on the merits of Plaintiffs' claims." [Doc 178 at 1]

Expedited briefing on the merits has now been completed and the matter is now ripe for adjudication.

III. STANDARD OF REVIEW

Because NEPA does not provide for a private right of action, the Court must review Plaintiffs' NEPA claims under the APA. Utah Envtl. Cong. v. Bosworth, 443 F.3d 732, 739 (10th Cir. 2006). Review under the APA is limited to final agency actions. See 5 U.S.C. § 704 ("Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review."). "[T]he finality requirement is concerned with whether the initial decisionmaker has arrived at a definitive position on the issue that inflicts an actual, concrete injury . . .." Darby v. Cisneros, 509 U.S. 137, 144 (1993) (internal quotation marks and citation omitted) (alteration in original).

> As a general matter, two conditions must be satisfied for agency action to be final: First, the action must mark the consummation of the agency's decisionmaking process, —it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow.

Bennett v. Spear, 520 U.S. 154, 177-78 (1997) (internal quotation marks and citations omitted). Our Tenth Circuit has interpreted the finality requirement in a flexible and

pragmatic manner. Center for Native Ecosystems v. Cables, 509 F.3d 1310, 1329 (10th Cir. 2007).

When examining agency action under the APA, the Court reviews the final agency action to determine whether it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This requires a reviewing court to determine whether the agency

> examined the relevant data and articulated a rational connection between the facts found and the decision made. In reviewing the agency's explanation, the reviewing court must determine whether the agency considered all relevant facts and whether there has been a clear error of judgment.

Olenhouse, 42 F.3d at 1574 (citation omitted). The agency's decision will be deemed arbitrary and capricious if

> the agency (1) entirely failed to consider an important aspect of the problem, (2) offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise, (3) failed to base its decision on consideration of the relevant factors, or (4) made a clear error of judgment.

New Mexico ex rel. Richardson v. Bureau of Land Mgmt., 565 F.3d 683, 704 (10th Cir. 2009) (internal quotation marks and citations omitted). The reviewing court "should not attempt to make up for such deficiencies; it *may not supply* a reasoned basis for the agency's action that the agency itself has not given." Olenhouse, 42 F.3d at 1574-75 (internal quotation marks and citation omitted) (emphasis in original). Moreover, when resolving issues that require a "high level of technical expertise, [the reviewing court]

must defer to the informed discretion of the responsible federal agencies." Marsh v. Oregon Nat'l Res. Council, 490 U.S. 360, 377 (1989) (internal quotation marks and citation omitted).

Notwithstanding the fact that this standard of review is very deferential to the agency, the Court's review must be thorough. Hillsdale Envtl. Loss Prevention, Inc. v. U.S. Army Corps of Engineers, 702 F.3d 1156, 1165 (10th Cir. 2012). "A presumption of validity attaches to the agency action and the burden of proof rests with the parties who challenge such action." Id. (internal quotation marks and citation omitted). Therefore, an agency's decision will not be overturned, unless the agency's decision is determined to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." Colorado Wild, Heartwood v. U.S. Forest Serv., 435 F.3d 1204, 1213 (10th Cir. 2006) (quoting 5 U.S.C. § 706(2)(A)).

III. STATUTORY FRAMEWORK: NEPA AND THE FEDERAL MEAT INSPECTION ACT

A. APPLICABILITY OF NEPA

NEPA is the "basic national charter for protection of the environment." 40 C.F.R. 1500.1(a). "NEPA was enacted to regulate government activity that significantly impacts the environment and 'to help public officials make decisions that are based on [an] understanding of environmental consequences and take actions that protect, restore, and enhance the environment.'" Colorado Wild, 435 F.3d at 1209 (quoting 40 C.F.R. § 1500.1(C)) (alteration in original). "NEPA dictates the process by which federal agencies

must examine environmental impacts, but does not impose substantive limits on agency conduct." Utah Envtl. Cong. v. Russell, 518 F.3d 817, 821 (10th Cir. 2008). As our Tenth Circuit Court of Appeals has observed, NEPA "does not require agencies to elevate environmental concerns over other appropriate considerations," but rather requires "that the agency take a 'hard look' at the environmental consequences before taking a major action." Utah Shared Access Alliance v. U.S. Forest Serv., 288 F.3d 1205, 1207 (10th Cir. 2002). "In other words, it prohibits uninformed-rather than unwise-agency action." Id. at 1207-08 (internal quotation marks and citation omitted).

NEPA "requires all federal agencies to consider the environmental consequences of 'major federal actions significantly affecting the human environment. . ..'" Goos v. Interstate Commerce Comm'n, 911 F.32d 1283, 1293 (8th Cir. 1990) (42 U.S.C. § 4332(2)(C)). In order to satisfy NEPA's procedural requirements, an agency must produce one of the following: "(1) an environmental impact statement (EIS), (2) an environmental assessment (EA), or (3) a categorical exclusion [(CE)]." Russell, 518 F.3d at 821 (internal quotation marks and citation omitted). "An EIS is required for 'major Federal actions significantly affecting the quality of the human environment.'" Colorado Wild, 435 F.3d at 1209 (quoting 42 U.S.C. § 4332(2)(C)).

> If an agency is uncertain whether a proposed action will significantly affect the environment, it may first prepare an EA, a concise public document that [b]riefly provide[s] sufficient evidence and analysis for determining whether to prepare' a more detailed EIS. If, pursuant to that EA, the agency determines that a more detailed EIS is not required, it must issue a finding of no significant impact (FONSI), which briefly presents the reasons why

> the proposed agency action will not have a significant impact on the human environment.

Russell, 518 F.3d at 821 (internal quotation marks and citation omitted).

In rare instances, however, an agency will not have to prepare an EA or an EIS. "Under regulations promulgated by the Council on Environmental Quality (CEQ), an agency is not required to prepare either an EIS or [an] EA if the proposed action does not 'individually or cumulatively have a significant effect on the human environment.'" Citizens' Comm. to Save Our Canyons v. U.S. Forest Service, 297 F.3d 1012, 1023 (10th Cir. 2002) (quoting 40 C.F.R. § 1508.4). "[F]ederal regulations delegate to individual agencies the responsibility [of] defining what types of actions may be categorically excluded from NEPA review." Citizens' Comm. to Save Our Canyons, 297 F.3d at 1023. Federal regulations define a categorical exclusion as follows:

> a category of actions which do not individually or cumulatively have a significant effect on the human environment and which have been found to have no such effect in procedures adopted by a Federal agency in implementation of these regulations (§ 1507.3) and for which, therefore, neither an environmental assessment nor an environmental impact statement is required. An agency may decide in its procedures or otherwise, to prepare environmental assessments for the reasons stated in § 1508.9 even though it is not required to do so. Any procedures under this section shall provide for extraordinary circumstances in which a normally excluded action may have a significant environmental effect.

40 C.F.R. § 1508.4. "Federal law limits categorical exclusions in one critical respect: a proposed action is precluded from categorical exclusion if 'extraordinary circumstances' exist such that 'a normally excluded action may have a significant environmental effect.'" Bosworth, 443 F.3d at 736 (quoting 40 C.F.R. § 1508.4).

The USDA has adopted federal regulations governing categorical exclusions, see 7 C.F.R. 1b.1, and pursuant to 7 C.F.R. § 1b.4, has found that certain "agencies and agency units," including FSIS, "conduct programs and activities that have been found to have no individual or cumulative effect on the human environment." Thus, FSIS is "excluded from the requirements of preparing procedures to implement NEPA" and its actions are "categorically excluded from the preparation of an EA or EIS unless the agency determines that an action may have a significant environmental effect." 7 C.F.R. § 1b.4.

Pursuant to 7 C.F.R. § 1b.3(c), agencies that have been categorically excluded from having to prepare an EIS or an EA "shall continue to scrutinize their activities to determine continued eligibility for categorical exclusion," and the "agency heads may determine that circumstances dictate the need for preparation of an EA or EIS for a particular action." Id.

B. Federal Meat Inspection Act

FMIA "regulates the inspection, handling, and slaughter of livestock for human consumption," Nat'l Meat Ass'n v. Harris, __ U.S.__, 132 S.Ct. 965, 968 (2012), and "applies to all slaughterhouses producing meat for interstate and foreign commerce," id. at 968 n.1(citing 21 U.S.C. § 601(a),(h)).

The FSIS is responsible for administering the FMIA and for "promot[ing] its dual goals of safe meat and humane slaughter." Harris, 132 S.Ct. at 968.

III. DISCUSSION

Plaintiffs challenge both the FSIS Directive and the grants of inspection issued to Valley Meat and Responsible Transportation. The Court will address each of these challenges in turn.

A. FSIS Directive 6130.1

FSIS "directives are instructions written to FSIS employees to implement the USDA's policies and procedures." FPL Food, LLC v. U. S. Dept. of Agric., 671 F.Supp. 2d 1339, 1344 (S.D. Ga. 2009). In this case, the FSIS's Directive contains information regarding the specific conditions that must be satisfied before a grant of inspection can be issued, how to ensure the humane handling of equines, how to conduct the ante-mortem and post-mortem inspection of equines, and how to conduct the drug residue testing of equines. [Doc. 22-3] The Directive explicitly sets forth the rules and regulations governing the ante-mortem and post-mortem inspection of equines, humane handling, and drug residue testing. [Doc. 22-3] It outlines the process by which inspection program personnel (IPP) are to select equines for random drug residue testing and the procedure for submitting residue samples and reporting violations. [Doc. 22-3] Pursuant to the Directive, the Public Health Veterinarian (PHV) "is to make final disposition on the carcass and parts and take any necessary regulatory actions based on the results." [Doc. 22-3 at 9] Any equine that tests positive for drug residues must be condemned and destroyed and regulatory action may be instituted. [Doc. 22-3 at 9]

Plaintiffs contend that FSIS's adoption of the Directive is "final agency action" and violates the APA and NEPA because Federal Defendants failed to conduct an EA or

EIS prior to adopting or implementing the Directive. [Doc. 54 at 3] Plaintiffs further contend that the fact that the USDA incorporated the Directive into its Categorical Exclusion memos and expressly relied on the Directive in its decision to issue the grants of inspection, demonstrates that the Directive contains the "FSIS's final statement regarding drug residue testing in equines." [Doc. 170 at 39] Both Plaintiffs and Intervenor-Plaintiff assert that the Directive constitutes a new agency plan, policy, or procedure, as defined by the CEQ regulations, that amounts to major federal action that may have a significant effect on the human environment and, therefore, the FSIS was required to prepare an EA or EIS. [Doc. 170 at 40-41]

In response, Defendants assert that the FSIS Directive does not constitute final agency action, and therefore that Plaintiffs' challenge to the Directive is without merit. [Doc. 185 at 29; Doc. 183 at 44] Defendant-Intervenors further contend that because the question regarding what constitutes final agency action is to be approached pragmatically, the Directive cannot be viewed as a consummation of the Agency's decision making process. [Doc. 183 at 45] Alternatively, Federal Defendants argue that even if the Directive does constitute final agency action, it is not the legally relevant cause of any alleged harm to the environment and that the environmental effects alleged by Plaintiffs are the result of horse slaughter operations, not the Directive and, therefore, the Directive does not trigger a NEPA review. [Doc. 185 at 29]

1. Final Agency Action

As discussed below, review under the APA is limited to final agency action. See 5 U.S.C. § 704. Agency action is considered final if it "mark[s] the consummation of the agency's decisionmaking process" and is an action "by which rights or obligations have been determined, or from which legal consequences will flow." Bennett, 520 U.S. at 177-78 (internal quotation marks and citations omitted). As the United States Court of Appeals for the District of Columbia observed in Munsell v. Dept. of Agriculture, 509 F.3d 572, 586 (D.C. Cir. 2007), "[i]t is not altogether clear whether" a FSIS directive "reflects a final agency rule that is subject to judicial review . . . or a nonreviewable policy statement." Id. (declining to decide whether an FSIS Directive constitutes final agency action).

Defendant-Intervenors rely on Lujan v. National Wildlife Federation, 497 U.S. 871 (1990), to support their assertion that the Plaintiffs and Plaintiff-Intervenor's challenge of the drug residue program contained in the Directive is not a discrete, identifiable action or decision and is nothing more than the type of broad generalized challenge that is expressly precluded by Lujan. [Doc. 183 at 41,43]

In Lujan, the United States Supreme Court held that the Bureau of Land Management's "so-called 'land withdrawal review program'" did not constitute "'agency action' within the meaning of § 702, much less a 'final agency action' within the meaning of § 704" because

> [t]he term 'land withdrawal review program' (which as far as we know is not derived from any authoritative text) does not refer to a single BLM order or regulation, or even to a completed universe of particular BLM

> orders and regulations. It is simply the name by which petitioners have occasionally referred to the continuing (and thus constantly changing) operations of the BLM in reviewing withdrawal revocation applications and the classifications of public lands and developing land use plans as required by the FLPMA. It is no more an identifiable 'agency action'—much less a 'final agency action'—than a 'weapons procurement program' of the Department of Defense or a 'drug interdiction program' of the Drug Enforcement Administration. As the District Court explained, the 'land withdrawal review program' extends to, currently at least, '1250 or so individual classification terminations and withdrawal revocations.'

Id. at 890. Unlike the broad ongoing national program challenged in Lujan, the FSIS Directive is an identifiable action or event, i.e., it is a discrete directive adopted by FSIS on a specific date, June 28, 2013, for a specific purpose. Accordingly, Lujan does not support Defendant-Intervenors' argument.

Defendants also rely on Schweiker v. Hansen, 450 U.S. 785 (1981) and W. Radio Services Co., Inc. v. Espy, 79 F.3d 896 (9th Cir. 1996), to support their contention that the Directive is an internal agency document that is not binding on the agency, nor legally enforceable in court. [Doc. 66 at 28; Doc. 183 at 33] However, these cases do not address the issue of "final agency action" under the APA and, therefore, are distinguishable. See Schweiker, 450 U.S. at 789 (holding that the Social Security Administration (SSA) was not estopped from denying retroactive benefits, even though the plaintiff had been advised, in violation of the SSA's Claims Manual and internal Administration handbook, that she was ineligible for such benefits); W. Radio Services Co., Inc., 79 F.3d at 901 (holding that the Forest Service's issuance of a special use permit was not arbitrary and capricious, despite alleged violations of the guidelines in the Service's Manual and

Handbook, because the Manual and Handbook are not a binding limitation on the Service's authority).

Because the Directive appears to be FSIS's final statement regarding drug residue testing in equines and because the policy was drafted to address the public health concerns posed by "the potential chemical residues from drugs not previously approved for use in all food animals including equine," [Doc. 22-3 at 7] the Court concludes that the Directive constitutes final agency action from which legal consequences flow. Moreover, in the grants of inspection issued to Valley Meat and Responsible Transportation, FSIS relied on the Directive to conclude that the risk to public health posed by commercial horse slaughter is not significant. Accordingly, the Directive satisfies the statutory definition of "final agency action" under the APA.

2. FSIS Directive 6130.1 is Excluded from the Requirement of an EIS and/or EA under NEPA

Plaintiffs assert that the Federal Defendants acted arbitrarily and capriciously, or not in accordance with the law, in violation of the APA when they adopted FSIS Directive 6130.1 and established a new drug residue testing program. [Doc. 170 at 12] They contend that Federal Defendants failed to comply with NEPA when adopting the Directive because they failed to prepare an EIS, an EA, or invoke a CE. [Doc. 170 at 12] Defendants contend that the adoption of Directive is not an action that would trigger any obligation under NEPA. [Doc. 183 at 54, 185 at 30] The Court agrees.

The USDA adopted regulations to supplement the CEQ regulations governing the implementation of the NEPA. See 7 C.F. R. § 1b.1. In those regulations, the USDA categorically excluded certain actions, as well as certain agencies that "conduct programs and activities that have been found to have no individual or cumulative effect on the human environment." 7 C.F. R. §§ 1b.3, 1b.4.[2] The USDA agencies and agency units, such as the FSIS, that are listed in 7 C.F.R. § 1b.4, "are excluded from the requirements of preparing procedures to implement NEPA . . . [and] are "categorically excluded from the preparation of an EA or EIS unless the agency determines that an action may have a significant environmental effect." 7 C.F.R. § 1b.4. Although Section 1b.4 categorically excludes agencies from the requirements of NEPA, unless the agency determines that an action may have a significant environmental effect, Section 1b.3(c) places an obligation on the excluded agencies to examine whether the activities taken by the agency should be categorically excluded. Section 1b.3(c) provides:

> Notwithstanding the exclusions listed in paragraphs (a) of this section and § 1b.4, or identified in agency procedures, agency heads may determine that circumstances dictate the need for preparation of an EA or EIS for a particular action. *Agencies shall continue to scrutinize their activities to determine continued eligibility for categorical exclusion*.

Reading Section 1b.4 in conjunction with Section 1b.3(c), the Court concludes that the regulations exclude FSIS from the requirements of NEPA, i.e. the preparation of an

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[2] The Court understands "activity" to be broader than an individual "action." For example, an "activity" is the granting of inspections. An "action" is the issuance of a specific grant of inspection.

EA, EIS, but place an affirmative duty on the agency to "continue to scrutinize [its] activities to determine continued eligibility for categorical exclusion." 7 C.F.R. § 1b.3 (c). The Court further concludes that FSIS did not have an affirmative obligation to expressly invoke a categorical exclusion for the Directive in the present case.

NEPA's CEQ regulations "instruct agencies to identify . . . categorical exclusions or CEs, which normally do not individually or cumulatively have a significant effect on the human environment and [which] are excluded from further NEPA review." Aquifer Guardians in Urban Areas v. Fed. Highway Admin, 779 F.Supp.2d 542, 563 (W.D. Tex 2011) (internal quotation marks omitted) (quoting 23 C.F.R. § 771.115(b); see 40 C.F.R. § 1507.3(b)(2), 40 C.F.R. § 1508.4). "Establishing and using CEs can reduce excessive paperwork by eliminating unnecessary preparation of environmental impact statements." Aquifer Guardians, 779 F.Supp.2d at 563; see 40 C.F.R. § 1500.1(c). Because USDA determined that the FSIS was categorically excluded from NEPA procedures unless the agency determined that an action may have a significant environmental effect, the Court concludes that FSIS does not have an obligation to affirmatively invoke a categorical exclusion before taking any action.

The Parties have pointed to only one case, Humane Society of the United States v. Johanns, that has examined NEPA obligations in the context of horse slaughter and 7 C.F.R. § 1b.4. Johanns, 520 F.Supp 2d 8, 11 (D.C. Cir. 2007). In Johanns, the Humane Society of the United States (HSUS) alleged that the United States violated NEPA and the CEQ's implementing regulations when it created a fee-for-service ante-mortem horse

slaughter inspection system without first conducting an environmental review under NEPA. 520 F.Supp 2d at 11. The Johanns court agreed with HSUS and found the interim-final rule to be a violation of NEPA and APA. "At the time [HSUS] filed their [c]omplaint, horses were slaughtered at three different facilities in the United States to provide horse meat for human consumption abroad and for use in zoos and research facilities domestically." Id. at 12. After Congress' amendment to the 2006 Agriculture Appropriations Act, which prevented any funds made available in the Act from being used to pay the salaries and expenses associated with horse slaughtering under 21 U.S.C. § 603, the FSIS amended "the Federal Meat Inspection regulations to provide for a voluntary fee-for-service program under which official establishments will be apply to apply for and pay for ante-mortem inspection." Johanns, 520 F.Supp 2d at 12-13.

The Johanns court, in examining whether a violation of NEPA had occurred, noted that although the adoption of the interim-final rule was clearly major federal action, "some environmental effect must be caused by the [interim-rule]for it to come within the rubric of NEPA." Johanns, 520 F.Supp 2d at 22. The court explained that "[t]here is a major federal action subject to NEPA review when an agency makes a decision which permits action by other parties which will affect the quality of the human environment." Johanns, 520 F.Supp 2d at 22-23. Whether the major federal action caused the environmental effect, requires examining whether the major federal action was the "'legally relevant cause' of the effect." Johanns, 520 F.Supp 2d. at 22-23. The Johanns court looked to Department of Transportation v. Public Citizen, 541 U.S. 752 (2004), for

guidance in how to determine whether major federal action caused the environmental effect, Johanns, 520 F.Supp 2d. at 22-23.

In Public Citizen, the United States Supreme Court held that "where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered the legally relevant cause of the effect . . . [and] need not consider the effects in its EA when determining whether its action is a 'major federal action.'" Id. at 770. The Johanns court distinguished Public Citizen, where the Court concluded that the FMCSA lacked any discretion not to act, from its case by emphasizing the discretion surrounding the promulgation of the interim-rule. Johanns, 520 F.Supp 2d at 27. The Johanns court held that the interim-rule was the legally relevant cause of the environmental effects of the horse slaughter facilities. Johanns, 520 F.Supp 2d at 27.

Here, the challenged action, i.e. adoption of the Directive and drug residue program, is not the legally relevant cause of the environmental effects of horse slaughter. Although the Directive contains information regarding conditions that determine whether a grant of inspection may be issued, the Directive's main focus is to inform FSIS employees how to conduct an inspection once a grant of inspection is already issued. Moreover, to the extent the Directive contains information regarding the conditions to grant inspection, FSIS's role in the process is akin to FMCSA's activity in Public Citizen, which was deemed not to be the legally relevant cause of the pollution.

Plaintiffs further assert that Federal Defendant's violated NEPA by not expressly invoking a categorical exclusion. The Court concludes that 7 C.F.R. § 1b.4 does not require FSIS to affirmatively invoke a categorical exclusion for its actions because the USDA has pre-determined that FSIS as a whole is categorically excluded from further compliance with NEPA procedures. Furthermore, although the agency head has a continuing duty to scrutinize its activities to ascertain if the categorical exclusion should still apply, see 7 C.F.R. § 1b.3, the record indicates that FSIS complied with that obligation. The Court views the Directive and the drug residue program to be evidence of FSIS's compliance with Section 1b.3(c). Therefore, reading 7 C.F.R. § 1b.4 in conjunction with 7C.F.R. § 1b.3, the Court concludes that FSIS complied with the relevant regulations.

B. Grants of Inspection

Plaintiffs and Intervenor-Plaintiff assert that "Federal Defendants were required to prepare at least an EA for their grants of inspection to Valley Meat and Responsible Transportation because the issuance of the grants of inspection are major federal actions that may have a significant effect on the human environment." [Doc. 170 at 43; Doc. 172 at 16] Plaintiffs contend that by failing to prepare an EA or an EIS prior to issuing the grants of inspection to Valley Meat and Responsible Transportation, Federal Defendants violated NEPA and the APA. [Id.]

Defendants respond by asserting that the issuance of grants of inspection are mandatory actions and are not subject to the procedural requirements of NEPA. [Doc.

185 at 33; Doc. 183 at 57] They contend that although FSIS prepared a CE decisional memorandum discussing the issuance of grants of inspection to Valley Meat, Responsible Transportation, and Rains Natural Meats, it did not believe NEPA was applicable to those actions and did not believe such documentation was required. [Doc. 185 at 34; Doc. 183 at 57] Defendants further assert that even if the grants of inspection were subject to NEPA, the categorical exclusion was properly applied insofar as the agency engaged in careful consideration of the potential effects of its action, and concluded that a categorical exclusion was appropriate. [Doc. 183 at 62]

1. NEPA Does Not Apply to FSIS' Grants of Inspection

NEPA applies only to discretionary agency actions, not to ministerial or mandatory actions." Nevada v. U.S., 221 F.Supp. 2d 1241, 1247 (D.Nev. 2002); see Sac & Fox Nation of Mo. v. Norton, 240 F.3d 1250, 1262 (10th Cir. 2001) (providing that "NEPA compliance is unnecessary where the agency action at issue involves little or no discretion on the part of the agency"). Defendants assert that because the decision to issue a grant of inspection is mandatory, NEPA does not apply. [Doc. 185 at 37, 43; Doc.183 at 56] The Court agrees.

"Several [district and circuit courts] have held that NEPA compliance is unnecessary where the agency action at issue involves little or no discretion on the part of the agency." Norton, 240 F.3d at 1262. Because the "primary purpose of the impact statement is to aid agency decisionmaking, courts have indicated that nondiscretionary acts should be exempt from the [NEPA's procedural] requirement." Goos, 911 F.2d at

1296. Therefore, "[m]inisterial acts . . . have generally been held outside the ambit of NEPA's EIS requirement." Id. (alterations in original).

In Nevada v.United States, the state alleged that the United States had failed to comply with NEPA. 221 F.Supp. 2d at 1241. The court explained that "NEPA applies to the action of federal agencies, and requires the preparation of an EIS when a federal agency engages in a major federal action that significantly affects the quality of the human environment." Id. at 1247. The court, however, noted that "NEPA applies only to discretionary agency actions, not to ministerial or mandatory actions." Id. Therefore, because the government's action was mandatory, the court concluded that NEPA was not triggered.

Our Tenth Circuit has reached the same conclusion when determining whether NEPA applies to a ministerial or mandatory action. In Sac & Fox Nation of Missouri v. Norton, the plaintiffs asserted that the secretary "violated the APA by determining it was unnecessary for the agency to comply with [NEPA]." 240 F.3d at 1262. The secretary responded by asserting that "NEPA analysis was unnecessary due to the mandatory nature of the [land] acquisition." Id. at 1262. In examining whether NEPA was triggered, the court determined that "NEPA compliance is unnecessary where the agency action at issue involves little or no discretion on the part of the agency." Id. at 1262.

In Department of Transportation v. Public Citizen (cited earlier), the United States Supreme Court held that because the Federal Motor Carrier Safety Administration (FMCSA) had limited discretion regarding motor vehicle carrier registration, NEPA did

not require it to evaluate the environmental effects of such operations. 541 U.S. at 768. In reaching this conclusion the Court discussed that the FMCSA was required to "grant registration to all domestic or foreign motor carriers that are willing and able to comply with the applicable safety, fitness, and financial-responsibility requirements" Public Citizen, 541 U.S. at 758-59 (citing 49 U.S.C. § 13902(a)(1)). Section 13902(a)(1) provides that "[e]xcept as otherwise provided in this section, the Secretary of Transportation shall register a person to provide transportation . . . as a motor carrier using self-propelled vehicles the motor carrier owns, rents, or leases only if the Secretary determines that the person" is willing and able to comply with the six requirements listed in subsection (A). See 49 U.S.C. § 13902(a)(1). The Court noted that under a reasonable reading of Section 13902(a)(1), FMCSA must "certify any motor carrier that can show that it is willing and able to comply with the various substantive requirements for safety and financial responsibility contained in the [Department of Transportation] regulations. . .." Public Citizen, 541 U.S. at 766. The Court, therefore, concluded that because FMCSA "has no statutory authority to impose or enforce emissions controls or to establish environmental requirements unrelated to motor carrier safety," Public Citizen, 541 U.S. at 758-59, the FMCSA "lacks the power to act on whatever information might be contained in the EIS," Public Citizen, 541 U.S. at 768. The Court discussed that if an agency's action is mandatory, the preparation of an EIS serves 'no purpose' in light of NEPA's regulatory scheme as a whole. Public Citizen, 541 U.S. at 767. Because the preparation of an EIS would be futile, FMCSA did not violate NEPA or the

accompanying regulations by failing to consider environmental effects, Public Citizen, 541 U.S. at 768 ("It would not. . .satisfy NEPA's 'rule of reason' to require an agency to prepare a full EIS due to the environmental impact of an action it could not refuse to perform.").

2. The Code of Federal Regulations Lend Further Support to the Court's Conclusion that the Decision to Issue Grants of Inspection is Mandatory.

In examining the Code of Federal Regulations, the Court is further persuaded that the grants of inspection are mandatory. The Code of Federal Regulations, 9 C.F.R. § 304.3, outlines the conditions for receiving grants of inspection, and provides:

> (a) Before being granted Federal inspection, an establishment must have developed written sanitation Standard Operating Procedures [SOP], as required by part 416 of this chapter, and written recall procedures as required by part 418 of this chapter.
>
> (b) Before being granted Federal inspection, an establishment shall have conducted a hazard analysis and developed and validated a HACCP plan, as required by §§ 417.2 and 417.4 of this chapter. A conditional grant of inspection shall be issued for a period not to exceed 90 days, during which period the establishment must validate its HACCP plan.
>
> (c) Before producing new product for distribution in commerce, an establishment shall have conducted a hazard analysis and developed a HACCP plan applicable to that product in accordance with § 417.2 of this chapter. During a period not to exceed 90 days after the date the new product is produced for distribution in commerce, the establishment shall validate its HACCP plan, in accordance with § 417.4 of this chapter.

The grant or refusal of inspection is governed by 9 C.F.R. § 304.2(b), which provides:

> The Administrator is authorized to grant inspection upon his [or her] determination that the applicant and the establishment are eligible therefor

> and to refuse to grant inspection at any establishment if he [or she] determines that it does not meet the requirements of this part or the regulations in Parts 305, 307, and Part 416, §§ 416.1 through 416.6 of this chapter or that the applicant has not received approval of labeling and containers to be used at the establishment as required by the regulations in Parts 316 and 317. Any application for inspection may be refused in accordance with the rules of practice in part 500 of this chapter.

9 C.F.R. § 304.2(b). Part 500 of Chapter III is titled "Rules of Practice" and governs various actions that the FSIS may take, including the withdrawal of a grant of inspection, notification of appeals, withholding of actions with and without notice, and the refusal to issue a grant of inspection, see 9 C.F.R. § 500.7. "Refusal to grant inspection," 9 C.F.R.§ 500.7, lists the instances in which the FSIS may refuse to grant Federal inspection., and provides

> (a) The FSIS Administrator may refuse to grant Federal inspection because an applicant:
>
> > (1) Does not have a HACCP plan as required by part 417 of this chapter;
> > (2) Does not have Sanitation Standard Operating Procedures as required by part 416 of this chapter;
> > (3) Has not demonstrated that adequate sanitary conditions exist in the establishment as required by part 308 or part 381, subpart H, and part 416 of this chapter;
> > (4) Has not demonstrated that livestock will be handled and slaughtered humanely; or
> > (5) Is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.
>
> (b) If the Administrator refuses to grant inspection, the applicant will be provided the opportunity for a hearing in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H.

These regulations, read in conjunction with FMIA, 21 U.S.C. § 601 *et seq.*, indicate that FSIS, much like the FMCSA in Public Citizen, has little to no discretion regarding whether to issue a grant of inspection. For example, the inspection of meat and meat food products is governed by FMIA, 21 U.S.C. Section 603(a) and provides:

> For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all amenable species before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce; and all amenable species found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other amenable species, and when so slaughtered the carcasses of said amenable species shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter.

21 U.S.C. § 603(a).

Furthermore, Federal Defendants are correct that the House and Senate Reports for the 1967 Amendments to the FMIA both indicate that 21 U.S.C. § 603(a), or Section 3, of FMIA was amended so as to remove discretion from the Secretary. [Doc. 185 at 36] The Amendments replaced the language "the Secretary of Agriculture, *at his discretion, may* provide inspectors," with "the Secretary *shall*' provide such inspectors." [Doc. 185-1]. Moreover, the House Report specifically states that this amendment "[m]akes ante mortem inspection mandatory rather than permissive." [Doc. 185-1] Therefore, because NEPA applies only to discretionary agency actions, [and] not to ministerial or mandatory actions," Nevada, 221 F.Supp. 2d at 1247, the Court concludes that NEPA does not apply

to grants of inspection. Therefore, the Court concludes that the grants of inspection were properly issued.

III. CONCLUSION

Based upon the review of the Administrative Record and in consideration of the applicable law, the Court concludes that the FSIS Directive 6130.1 and drug residue program did not require the agency to prepare an EIS, or EA, or affirmatively invoke a categorical exclusion under NEPA. Furthermore, the Court concludes that the issuing of a grant of inspection is a mandatory act not subject to NEPA review.

IT IS THEREFORE HEREBY ORDERED AND DECLARED that Plaintiffs' request for a permanent injunction is hereby **DENIED**. In accordance with this ruling, the agency action challenged in Plaintiffs' *First Amended Complaint for Declaratory and Injunctive Relief* [Doc. 54] is **AFFIRMED** and all claims asserted in Plaintiffs' *First Amended Complaint for Declaratory and Injunctive Relief* [Doc. 54] are **DISMISSED**.

IT IS FURTHER ORDERED that this action is **DISMISSED WITH PREJUDICE**.

SO ORDERED this 1st day of November, 2013, in Albuquerque, New Mexico.

M. CHRISTINA ARMIJO
Chief United States District Judge

EXHIBIT 2

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW MEXICO

FRONT RANGE EQUINE RESCUE, THE HUMANE SOCIETY OF THE UNITED STATES, MARIN HUMANE SOCIETY, HORSES FOR LIFE FOUNDATION, RETURN TO FREEDOM, FOUNDATION FOR THE PROTECTION OF NEW MEXICO WILDLIFE, RAMONA CORDOVA, KRYSTLE SMITH, CASSIE GROSS, DEBORAH TRAHAN, BARBARA SINK, SANDY SCHAEFER, TANYA LITTLEWOLF, CHIEF DAVID BALD EAGLE, CHIEF ARVOL LOOKING HORSE and ROXANNE TALLTREE-DOUGLAS, Plaintiffs, v. TOM VILSACK, Secretary U.S. Department of Agriculture; ELIZABETH A. HAGEN, Under Secretary for Food Safety, U.S. Department of Agriculture; and ALFRED A. ALMANZA, Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, Defendants.	Civil No. 1:13-CV-00639-MCA-RHS

PLAINTIFFS' AND PLAINTIFF-INTERVENOR'S NOTICE OF APPEAL

Notice is hereby given this 1st day of November, 2013, that Plaintiffs in the above-captioned case, Front Range Equine Rescue, The Humane Society of the United States, Marin Humane Society, Horses for Life Foundation, Return to Freedom, on their own behalf and on behalf of their members, and Ramona Cordova, Krystle Smith, Cassie Gross, Deborah Trahan, Barbara Sink, Sandy Schaefer, Tanya Littlewolf, Chief David Bald Eagle, Chief Arvol Looking Horse, and Roxanne Talltree-Douglass, on their own behalf, and the Plaintiff-Intervenor State of

New Mexico, hereby appeal to the United States Court of Appeals for the Tenth Circuit from the final judgment of this Court entered in this action on the 1st day of November, 2013, in favor of Defendants against said Plaintiffs and Plaintiff-Intervenor.

Respectfully submitted this 1st day of November 2013.

/s/ *Bruce A. Wagman*
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CERTIFICATE OF SERVICE

I hereby certify that on November 1st, 2013, I filed through the United States District Court ECF System the foregoing document to be served by CM/ECF electronic filing on all counsel of record.

/s/ Bruce A. Wagman
BRUCE A. WAGMAN (Admitted *Pro Hac Vice*)
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EXHIBIT 3

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE	6130.1	6/28/13

ANTE-MORTEM, POSTMORTEM INSPECTION OF EQUINES AND DOCUMENTATION OF INSPECTION TASKS

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) on how to perform ante-mortem inspection of equines before slaughter and post mortem inspection of equine carcasses and parts after slaughter. Additionally, this directive instructs Food Safety and Inspection Service (FSIS) Public Health Veterinarians (PHVs) making ante-mortem and post-mortem dispositions of equines how to perform residue testing, verify humane handling, verify marking of inspected equine products, and document results using the Public Health Inspection System (PHIS) for equine when available.

II. BACKGROUND

A. The Federal Meat Inspection Act (FMIA) provides that there is to be an inspection of horses and other equines, among other species, to assess whether the carcasses of these animals are not adulterated, can be passed for human consumption, and are eligible to bear the mark of inspection (21 U.S.C. 604).

B. The FMIA requires that the slaughter or preparation of products of equines be conducted under inspection. FSIS regulations require that horse slaughter and preparation of products of equines be done in establishments that are separate from any establishment in which cattle, sheep, swine, or goats are slaughtered or their products prepared (9 CFR 305.2 (b)).

C. The Humane Methods of Slaughter Act of 1978 and 9 CFR Part 313 require that all livestock, including horses, slaughtered under inspection be handled humanely. Equines must be rendered insensible to pain (i.e. unconscious) before being shackled, hoisted, thrown, cast, or cut.

III. BEFORE START OF OPERATIONS

A. GRANT OF INSPECTION

1. Before issuing a grant of inspection for equine slaughter, a representative of the District Office (DO) is to verify that the establishment has:

    a. Sanitation Standard Operating Procedures (SSOPs);

    b. Performed a hazard analysis with supporting documentation;

    c. Developed a Hazard Analysis and Critical Control Points (HACCP) plan per 9 CFR 304.3,; And

    d. A recall plan per 9 CFR 418.3.

2. The Frontline Supervisor (FLS) at or prior to the start of operations is to inform the establishment management of applicable Food Safety and Inspection Service (FSIS) regulatory requirements per 9 CFR 305.4.

3. Before recommending approval for the grant of inspection or the start of operations and as necessary, the FLS is to determine whether any modifications to establishment facilities or other conditions are necessary to meet regulatory requirements per 9 CFR 307.2. The FLS is to advise the establishment management that the establishment with deficiencies will not be issued a grant of inspection until specified changes necessary to meet regulatory requirements are made.

4. Upon acceptance and approval of the application for a grant of inspection, the DO is to issue a conditional grant, not to exceed 90 days, to allow the establishment time to validate its HACCP plan.

5. The DO through the FLS or the PHV is to ensure that IPP receive all equine-related training provided by the FSIS Center for Learning (CFL).

B. AWARENESS MEETING

1. Before the start of slaughter operations, the PHV-IIC is to review with the establishment the FSIS procedures used to verify humane handling (9 CFR Part 313), identification (9 CFR Part 320), inspection, and other regulatory requirements referenced in this directive. The PHV-IIC is to document the meeting in a Memorandum of Interview (MOI) with distribution to the establishment and government office files in accordance with FSIS PHIS Directive 5000.1, Ch. 1, VIII. *Weekly Meeting*.

2. In addition, before the start of slaughter operations, the PHV-IIC is to review the information from this awareness meeting with the IPP assigned to the establishment.

IV. HUMANE HANDLING AND ANTE-MORTEM INSPECTION OF EQUINES

A. HUMANE HANDLING

1. IPP are to follow instructions in FSIS Directive 6900.2 Rev. 2, *Humane Handling and Slaughter of Livestock*, for verifying establishment compliance with humane handling and slaughter requirements set forth in 9 CFR Part 313.

2. During official hours of operation and when performing official duties, IPP are to verify the humane handling of all equines on the official premises from the time of unloading up to the time of slaughter. IPP are to verify:

    a. Facilities and handling are maintained at a level to prevent equine injuries per 9 CFR 313.1.

    b. The humane handling, segregation, identification, and slaughter of equines identified as U. S. Suspects per 9 CFR Parts 309 and 313.

    c. The humane handling, identification, stunning, and disposal of equine identified as U. S. Condemned per requirements in 9 CFR Parts 309 and 313.

NOTE: IPP are to immediately contact the District Veterinary Medical Specialist (DVMS) or DO via the PHV or FLS regarding any questions regarding the humane handling of equines.

B. HUMANE ACTIVITIES TRACKING SYSTEM (HATS):

1. FSIS IPP are to follow instructions in FSIS Directive 6900.2 Rev. 2, *Humane Handling and Slaughter of Livestock*, to perform and document HATS activities. See Section VIII of this directive regarding instructions on how to document HATS activities.

2. IPP are to seek guidance and updated instructions from the DVMS on how to perform HATS activities at official establishments slaughtering equines.

C. ANTE-MORTEM INSPECTION OF EQUINES

PHVs or IPP under PHV supervision are to conduct ante-mortem inspection of equines. FSIS IPP are to follow the verification instructions for ante-mortem inspection that are found in FSIS Directive 6100.1, *Ante-Mortem Livestock Inspection*. IPP are to conduct such inspection per the direction in this directive.

1. IPP are to observe:

    a. Equines at rest from outside the pen; and

    b. Equines in motion.

2. IPP are to perform ante-mortem inspection and accept only animals capable of producing products acceptable for use as human food. IPP are to pass equines for regular slaughter when ante-mortem inspection does not reveal diseases or abnormalities.

3. IPP while conducting ante-mortem inspection are to direct establishment employees to segregate all equines found to have any abnormalities or disease conditions into designated (suspect) pens for further examination by a PHV. Such additional inspection ensures removal from human food channels of equines that are:

    a. Obviously unfit for human food because of diseases or abnormalities;

    b. Have diseases or conditions that are difficult to detect on routine post-mortem inspection (e.g., central nervous system disorders, lameness, and chemical poisoning). See 9 CFR Part 309;

    c. Febrile or appear to be ill, depressed, or with a fever; or

    d. Showing indications of zoonotic or reportable diseases as listed in *FSIS Directive 6000.1, Rev. 1, Responsibilities Related to Foreign Animal Diseases (FADs) and Reportable Conditions - Revision 1.*

4. PHVs are to pass for slaughter with restriction suspect equines eligible for slaughter as U. S. Suspects per requirements in 9 CFR 309. 2.

5. In accordance with FSIS Directive 6100.1, *Ante-Mortem Livestock Inspection*, PHVs are to identify as "U.S. Condemned" any equines that found on ante mortem inspection to be:

    a. Dead or in a dying condition when offered for slaughter on the premises of the official establishment;

    b. Plainly showing on ante-mortem inspection any disease or condition that, under 9 CFR Part 311, would cause the PHV to condemn the carcass when inspecting post-mortem;

    c. Febrile with a temperature of 105^{o}F or higher (9 CFR 309.3(c));

    d. In a comatose or semi-comatose condition; or

    e. Other condemnable condition per 9 CFR Part 309.

V. EQUINE POST-MORTEM INSPECTION

A. Head Inspection: IPP are to:

1. Observe head surfaces, and

2. Observe and palpate (incise when necessary) mandibular, pharyngeal, and parotid lymph nodes; guttural pouch; and tongue.

B. Viscera Inspection: IPP are to:

1. Observe and palpate lungs and bronchial and mediastinal lymph nodes (incise when abnormal);

2. Incise and observe heart as for cattle;

3. Observe and palpate spleen, liver (both surfaces), and portal lymph nodes;

4. Open the hepatic (bile) duct as for cattle; and

5. Observe remaining viscera including kidney if removed from the carcass and body cavities.

C. Carcass Inspection: IPP are to perform carcass inspection of equines using the same basic methodology used on cattle as described in FSIS Directive 6100.2, *Post-mortem Livestock Inspection*. IPP are to perform carcass inspection after carcass splitting and before washing. Depending upon facilities available and after approval by the FLS, IPP have two (2) approaches to carcass inspection. IPP may inspect equine carcasses by the quarters (i.e. hind quarters or forequarters; or high and low) or by the side (i.e. side by sides).

1. Carcass Inspection by the Quarters: Similar to inspecting beef carcasses on a high-low final rail, IPP inspect the carcass and viscera as follows:

    a. Hindquarter inspection. Used where viscera and carcass inspections are combined. For each hindquarter on each side:

        i. Observe back of skinned carcass after it has been eviscerated.

        ii. Palpate superficial inguinal, or supramammary, and internal iliac lymph nodes.

iii. Observe body cavities.

b. Perform viscera inspection per B. above.

c. Forequarter inspection. It completes carcass inspection started under "hindquarter inspection." For each forequarter on each side:

i. Observe cut surfaces of muscles and bones, peritoneum, and diaphragm's pillars;

ii. Observe and palpate kidneys and diaphragm in the carcass; and

iii. Observe pleura, neck, and carcass exterior.

2. Carcass inspection by the sides. Alternatively to inspection by the quarters, IPP inspect each side of the carcass to complete carcass inspection. This is typical with other livestock (e.g. cattle) carcass inspection on moving chains with separate carcass inspection stations. Carcass inspection is performed after viscera inspection and splitting of the carcass as follows:

a. Palpate superficial inguinal, or supramammary, and internal iliac lymph nodes;

b. Observe lumbar region;

c. Observe and palpate kidneys;

d. Observe diaphragm's pillars and peritoneum;

e. Observe and palpate diaphragm; and

f. Observe pleura, cut surfaces of muscles and bones, neck, and carcass exterior.

3. Additional carcass inspection. IPP perform the following additional inspections on all or particular retained equine carcasses. IPP are to observe (and incise when necessary):

a. The inner abdominal walls for encysted parasites when IPP observe inflammatory lesions as nodules in the equine stomach, ceacum, colon, or fat along the abdominal wall. IPP are to condemn and verify affected organs and parts are condemned and removed by trimming.

b. Observe after the carcass has been skinned, and before splitting the carcass, the “topped” withers. The upper third of the spinous processes of thoracic vertebrae two through nine are removed and presented for inspection. IPP verify there is no evidence of inflammation and infection that may be occasionally be found in the supraspinous bursa in the withers area.

NOTE: Lesions in this area (fistulous withers) are commonly the result of *Brucella abortus* infection*;* The incidence of brucellosis in these lesions is high and humans can contract brucellosis. The PHV is responsible to verify IPP and establishment employees maintain sanitary conditions, sanitary implements, and sanitary dressing procedures. IPP in contact with such lesions are to thoroughly wash hands and avoid placing their hands about their face. IPP are to always retain the carcass and parts for veterinary disposition when brucellosis is suspected.

c. Observe the axillary, perineal, and subscapular spaces of gray and white equines for melanosis and metastatic or invasive melanomas. To accomplish this observation effectively, the FLS and PHV are to arrange with the establishment procedures to identify carcasses of white and gray horses after the hide has been removed. To ensure detection of melanosis or metastatic melanoma lesions commonly seen in the axillary and subscapular areas of white or gray equines, per requirements in 9 CFR 305.4, 307.2, 310.2, and 310.3 and as requested by the FLS, the PHV may direct company personnel to routinely "drop the shoulders" of any or all white or gray equines. When "dropping the shoulders," the limb remains attached to the carcass. As usual, the PHV may perform other inspections as necessary at his or her discretion.

NOTE: The FLS or PHV may at the request of the establishment allow the dropping to be accomplished on the following day after the carcass has chilled. The carcasses must be under FSIS control (U.S. Retained) until after the inspection is completed.

VI. RESIDUE TESTING OF EQUINE

A. GENERAL

FSIS recognizes that most equines presented for slaughter will likely not have been raised for human consumption. Therefore, FSIS has concerns regarding the potential presence of chemical residues from drugs not previously approved for use in all food animals including equine. Because of these concerns about residues in horses, IPP should follow instructions in FSIS PHIS Directive 5000.1,*Verifying an Establishment's Food Safety System*, for verifying that the establishment that slaughters horses has addressed violative residues in its hazard analysis and that the establishment's HACCP system is effective in preventing horsemeat containing residues that would adulterate the meat under the FMIA from entering the human food supply.

In addition, FSIS expects many of the drugs used in working or pleasure horses are not antimicrobials and therefore would not be detected by FSIS in-plant antibiotic residue screening tests. Therefore, whenever IPP collect equine tissues for residue sampling as instructed below, IPP are to submit those tissues directly to the specified FSIS laboratory where a complete residue analysis can be conducted. IPP are to select carcasses for residue verification testing according to the two selection methods described below.

B. RESIDUE SAMPLING WHEN IPP FINDINGS SUGGEST INCREASED RISK OF DRUG RESIDUES

IPP are to select carcasses for residue testing when ante-mortem or post-mortem findings suggest an increased likelihood of recent drug treatment. IPP are to use the existing residue policies (including retaining of carcasses) in FSIS Directive 10,800.1, *Procedures For Residue Sampling, Testing, and Other Responsibilities for the National Residue Program*, for residue sampling, testing, and verification of the establishment's residue program and test every time the IPP suspect that there is an increased likelihood of a violative residue. Also, IPP are to use the list of pathologies and conditions in FSIS Directive 10,220.3, as a reference for conditions warranting residue testing. IPP are to retain any carcass suspected of containing a drug residue and follow the sample submission instructions described in part D. of this section for selected carcasses. The policy for testing animals from producers that are listed on the Residue Repeat Violator Lists as described in FSIS Notice 44-12 also applies to horse slaughter.

C. RANDOM RESIDUE SAMPLING OF NORMAL-APPEARING ANIMALS

Because equines are not generally raised as food animals, FSIS will conduct random residue testing of

normal-appearing animals to provide additional assurance that carcasses are free from drug residues. FSIS will conduct random testing of normal-appearing horses at least the same rate as for show livestock as described in FSIS Directive 10,800.1, *Procedures for Residue Sampling, Testing, and Other Responsibilities for the National Residue Program*. IPP are to randomly select, on the slaughter floor from normal-appearing equine, from every lot of animals that passes ante-mortem as follows:

1. A minimum of 1 animal if there are 1 to 10 animals in a lot;

2. A minimum of 2 animals if there are 11 to 50 animals in the lot;

3. A minimum of 3 animals if there are 51 to 100 animals in the lot; and

4. A minimum of 4 animals if there are more than 100 animals in the lot.

IPP are to retain the selected carcasses and follow the sample submission instructions in paragraph D. of this section

D. SUBMITTING RESIDUE SAMPLES

1. From each equine carcass selected for residue sampling under the two scenarios (i.e. Paragraphs B and C) above, IPP are to collect two (2) separate one pound muscle samples; and

    a. Submit one sample containing one pound of muscle to the Western Lab (WL) where it will be tested for pesticides; and

    b. Submit the other one pound sample from each carcass to the Eastern Lab (EL) where it will be tested for multiple chemical class residues and contaminants.

IPP are to follow the instruction provided in FSIS PHIS Directive 13,000.2, *Performing Sampling Tasks in Official Establishments using the Public Health Information System,* and FSIS Notice 58-12, *Scheduling and Submitting Lab Samples in PHIS,* on sample collection and submission of inspector-generated residue samples for laboratory testing. IPP are to create and schedule the sampling task in PHIS by selecting the following projects from the drop down menu in the Sample Management window of PHIS:

    a. Select project CG_EQUINE_EL for the one pound of muscle going to the Eastern Laboratory.

    b. Select project CG_EQUINE_WL for the one pound of muscle going to the Western Laboratory

2. Until the equine class is available in PHIS, unless directed by the DO otherwise, IPP are to verify that the establishment profile includes the slaughter class “GOAT” and enter equine data in PHIS using the goat slaughter class. If the establishment profile does not include the goat slaughter class, IPP are to add “GOAT” slaughter class to the plant profile.

NOTE: “GOAT” is being used at this time in order to capture necessary information in PHIS relative to equine. FSIS will manage PHIS results in a manner to discern goat data separately from equine data until such time that PHIS is modified to accommodate equine data entry. FSIS will rely upon the grant of inspection to discern which establishments in PHIS slaughter goat versus equine.

E. ACCESSING TEST RESULTS

1. IPP are to periodically access LEARN to check the status of tissue samples submitted for chemical residue testing. FSIS Directive 10,200.1, *Accessing Laboratory Sample Information via LEARN*, provides complete information on how to access LEARN on the FSIS intranet. Test results are reported in PHIS upon completion of the sample analysis. IPP can access test results in PHIS through the Laboratory Sample data field on the Inspector Home page.

2. IPP are to provide a printed copy of the test results from LEARN to establishment management and inform the establishment that it can receive sample results by email if it provides an email address to the IIC, who will enter it into the establishment profile information in PHIS. IPP are to advise establishments to add to their address book OPHSLearn@fsis.usda.gov to ensure the emails are not blocked. IPP are to provide a printed copy of sample results to the establishment regardless of whether they receive results via email.

3. Sample discard: If the FSIS Laboratory discards a sample submitted for chemical residue testing, IPP are to take appropriate action based on the reason for sample discard. IPP are to review the reason for sample discard, as indicated in LEARN, and make the necessary adjustments in how they collect, seal, and ship the samples to ensure that the laboratory does not discard future samples because of improper handling or packaging

F. IPP ACTIONS UPON REPORTING OF TEST RESULTS THROUGH LEARN

1. IPP are to check LEARN and review the test results. The PHV is to make a final disposition on the carcass and parts and take any necessary regulatory enforcement actions based on the results.

    a. For residue test results reported as ”Not Detected,” the PHV is to inform the establishment that the test result is “in compliance” and release the carcass and its parts.

    b. For residue test results reported as “Detected – violative,” the PHV is to condemn the carcass and all parts and notify the establishment of the results and the final disposition of the carcass and parts.

2. IPP are to notify the establishment of each new violation, any developing trends, and final disposition of any carcass and its parts at the next weekly meeting and document the meeting in a MOI.

3. IPP are to seek guidance through their supervisory chain of command for any questions regarding residue test results or action to take based on test results. IPP may also submit questions through AskFSIS, using the instructions provided in Section X of this directive.

NOTE: Additional information on how FSIS expects establishments to address residues in a HACCP environment is available in Federal Register: November 28, 2000 (Volume 65, Number 229).

VII. MARKING OF EQUINE CARCASSES, PARTS, AND PRODUCTS

A. IPP are to verify the official inspection legend used in the establishment. 9 CFR 312.3 identifies the official inspection legends that are to be used in equine slaughter establishments.

B. IPP are to verify the establishment uses green ink that is approved to mark equine carcasses and product per 9 CFR 316.5(e).

C. IPP are to verify that the establishment marks equine carcasses, parts, and product per 9 CFR 316.12.

VIII. PERFORMING AND DOCUMENTING INSPECTION TASKS

A. Where no comparable PHIS FSIS Directive is published, IPP are to follow the instructions in the standard (non-PHIS) FSIS Directives for inspection activities applicable to all livestock slaughter and processing.

http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/5000-series

B. When PHIS is not available, IPP are to contact the DO for additional instructions on how to determine what inspection tasks they are to perform, how often they perform the tasks, and how to document results.

C. Where FSIS Directives specifically provide instructions applicable to specific classes of livestock other than equine, and no specific direction is available for equine, IPP are to refer to and extrapolate instructions applicable to cattle when performing inspection procedures on horses after discussion with the PHV. The PHV may modify such instructions as appropriate. For example, IPP seeking guidance regarding sanitary dressing of horses are to refer to FSIS Directive 6410.1, *Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age - Revision 1*, until such information for equine is provided in a revised or new issuance.

IX. EXPORTS

IPP are to follow the instructions in FSIS Directive 9000.1, *Export Certification*, to certify exports of equine products for edible purposes. IPP are to refer to the FSIS Export Library opening page first for any general remarks about equine product exports, as well as the specific requirements for the country to which exports are being considered:

X. QUESTIONS

Refer questions regarding this directive to the Policy Development Staff through askFSIS or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter **Directive 6130.1**
Question Field:	Enter your question with as much detail as possible.
Product Field:	Select **General Inspection Policy** from the drop-down menu.
Category Field:	Select **Slaughter** from the drop-down menu.
Policy Arena:	Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue**.

(for) Assistant Administrator
Office of Policy and Program Development

EXHIBIT 4

PETITION

To Create Rules and Regulations Governing the Sale, Transport and Processing of Horses and Horse Meat Intended for Human Consumption

Before the United States Department of Agriculture
United States Food Safety Inspection Service

April 9, 2012

To:

Docket Clerk,
U.S. Department of Agriculture
Food Safety and Inspection Service
George Washington Carver Center, Room 2-2127
5601 Sunnyside Avenue
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On behalf of
FRONT RANGE EQUINE RESCUE
HUMANE SOCIETY OF THE UNITED STATES

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I. INTRODUCTION

Front Range Equine Rescue ("FRER") and The Humane Society of the United States ("HSUS") (collectively "Petitioners") petition the United States Food Safety and Inspection Service ("FSIS"), an agency of the United States Department of Agriculture ("USDA"), pursuant to the requirements for such petitions under the Federal Meat Inspection Act, 21 U.S.C. § 601, *et seq.* ("FMIA"), its accompanying regulations, 9 C.F.R. §§ 300, *et seq.*, and the Administrative Procedure Act, 5 U.S.C. § 553(e). Petitioners request the Secretary of the USDA, Tom Vilsack, and the Office of the FSIS Administrator, Alfred V. Almanza, to classify all horses who were formerly companion animals, wild horses, or work and sport horses (involved in ranching and competitions, including rodeos and racing), and any other horses without a proven lifetime medical history, as "Condemned" and adulterated, and unusable for the production of horse meat for human consumption. Petitioners also request that the FSIS engage in administrative rulemaking regarding horses intended for human consumption, in order to prevent against the risk that consumers of horse meat will have painful or prolonged adverse reactions or drug side effects, or contract serious, contagious, or fatal diseases, after they have eaten the meat of horses sent to slaughter, and to ensure that proper controls are in place to prevent horses whose meat would be adulterated from being slaughtered for food. Petitioners make this request because of the very real potential for consumers to experience such severe side effects and adverse reactions, unless adequate screening and verification demonstrates that the horses have not been exposed to any drugs, treatments or other substances that create the possibility of such problems.

In November 2011, after a roughly five-year period in which inspection of horses for slaughter for human consumption was prohibited, the FSIS was once again authorized to inspect horses destined for slaughter. If horse slaughter for human consumption begins in America, the horses' carcasses, if allowed to pass FSIS inspection, will eventually be sold as meat for human consumption in America and abroad. Historically, almost all horses who have been slaughtered for use as human food started their lives in one of three situations – as companions living with families across America and used for pleasure, recreation and work; as sport horses (involved in,

among other things, jumping, vaulting, racing, rodeos, dressage and other competitive activities); or as wild horses on the public and private lands. These animals are not raised for food in the way other animals, such as cows, pigs and chickens are, who from before conception are maintained within a regulated industry. The horses, throughout their lives, are not monitored or controlled by an agricultural industry aware of the legal restraints placed on the presence of contaminants in food animals. They have almost certainly ingested, or been treated or injected with, multiple chemical substances that are (1) known to be dangerous to humans if eaten, (2) untested on humans, or (3) specifically prohibited for use in animals destined to be slaughtered and turned into meat. These substances to which the horses have been exposed create the potential for great danger to humans if they are eaten. The presence of these substances in horse meat may cause a plethora of health problems, from the transient to the fatal, the acute to the chronic. Exposure to these substances puts consumers at the risk of cancer, life-threatening autoimmune diseases, or other illnesses of significant proportion.

The pharmacological history of horses turned into meat, and therefore the potentially toxic nature of the meat from those horses, is almost completely unknown. The horses are often sold from owner to auction and eventually, unbeknownst to the original owners, to slaughter by "killer-buyers" who have purchased them at auctions and from other sources, and then sell them to slaughterhouses. When the horses are finally transported and sold for slaughter, there is virtually no way to determine what substances they have been treated or injected with, or that they have eaten, over the course of their lives.

One thing is certain, though. Tainted by prohibited drugs and chemicals, horse meat from American horses is "adulterated" under the FMIA, and thus must be kept out of the food supply.[1] Since 1907, the FMIA has been focused on protecting the health and welfare of meat consumers and eliminating the harm caused by adulterated food.[2] The FSIS is responsible for

[1] 21 U.S.C. § 601(m).

[2] *Id.* at § 602.

inspecting meat under the FMIA and enacting regulations to carry out that authority.[3] Horses loaded up with dangerous and prohibited drugs must be stopped at the slaughterhouse gates, in order for FSIS to honor the language and spirit of the FMIA. Otherwise, FSIS will be sanctioning the dissemination of adulterated meat containing harmful additives with the potential for significant consumer harm.

The focus for FSIS is on the animals, and their flesh when it is turned into meat, and the condition of horses going to slaughter clearly fits within the FSIS definition of "adulterated" meat.[4] The horses themselves are laced with sufficient foreign and potential toxic substances so that their meat should never satisfactorily pass any inspection that complies with the FMIA. Exhibit 1 to the Petition, "Banned And Dangerous Substances Commonly Given To Horses Sent To Slaughter," provides a nonexhaustive list of examples of drugs and other substances to which American horses are routinely exposed throughout their lives, through injection, ingestion or topical application.[5] Exhibit 1 includes (1) drugs that expressly prohibited (by law or by label) from use in food animals; (2) drugs and other substances that are known to be harmful to humans when eaten; and (3) drugs and other substances that have never been tested in humans, so that the potential dangers from ingestion of horse meat laced with the residue of these substances creates a frightening unknown possibility of medical consequences. It is important for the agency and the public to appreciate that the substances listed on Exhibit 1 are only illustrations of some of the more commonly used drugs and additives that may potentially be lurking poisons in horse meat. There are multiple products and brand name compounds that may incorporate many of the items listed on Exhibit 1.

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[3] *See*, *e.g.*, 7 C.F.R. §§ 2.53, 2.7; 9 C.F.R. § 300.2.

[4] *See*, *e.g.*, 9 C.F.R. § 301.2(2)(iii) (meat with unsafe food additives is adulterated); 9 C.F.R. § 318.20 (meat with unapproved animal drug residues is adulterated).

[5] *See* Exhibit 1; Declaration of Hilary Wood ("Wood Dec."), attached hereto as Exh. 2, ¶¶ 6-7; Declaration of Peggy W. Larson ("Larson Dec."), attached hereto as Exh. 3, ¶ 7; Declaration of Joanne Pavlis ("Pavlis Dec."), attached hereto as Exh. 4, ¶¶ 4-5; Declaration of Randy Parker, D.V.M. ("Parker Dec."), attached hereto as Exh. 5, ¶¶ 7-9.

This situation is solidly within FSIS jurisdiction, and current FSIS regulations do not address the very real problem of horse meat, because procedures established for the inspection of other food animals cannot determine the presence of the multitude of prohibited drugs and potentially dangerous substances given to American horses during their lifetime. FSIS should be aware of the potential for drastic consequences from humans' ingestion of meat from these animals.

The chance of tragic human reactions should guide the agency's decisionmaking process with respect to the use of horses for human consumption. Because there is no realistic way to fully assess the risks of eating horse meat, and because all horse meat is potentially dangerous in many ways, there is no other course than for the FSIS to ban the sale of horse meat from American horses, unless the agency can reach a level of certainty about the substances these horses have eaten or to which they have been exposed. Petitioners are doubtful that the FSIS can invoke rules that will provide the level of certainty needed for American horses to be turned into meat, but have provided a list of proposed rules that, if placed in effect and fully enforced, could meet that challenge.

II. INTERESTS OF THE PETITIONERS

Petitioner FRER is a Colorado-based nonprofit group incorporated under Section 501(c)(3) of the Internal Revenue Code. FRER is dedicated to stopping cruelty and abuse of horses through rescue and education.[6] FRER is actively involved in the rescue, rehabilitation and adoption to good homes of domestic and wild horses found at auctions and horses destined for slaughter; and in educational efforts regarding responsible horse ownership, the cruelty of horse slaughter and wild horse roundups.[7] FRER has assisted thousands of horses through its rescue and educational programs.[8] While some of FRER's horses are surrendered by their

[6] Wood Dec., Exh. 2, ¶ 2.
[7] *Id.*
[8] *Id.*

owners or rescued when abandoned, many are rescued from livestock auctions; others are purchased at feed lots before they are sent to slaughter.[9]

Petitioner The Humane Society of the United States (HSUS) is a non-profit organization that promotes the protection of all animals.[10] The HSUS maintains its headquarters in Washington, DC and is the largest animal protection organization in the United States, with more than eleven million members and constituents.[11] The HSUS actively advocates against practices that injure or abuse horses and opposes the slaughter of horses for human consumption.[12] The HSUS has been actively involved in litigation and the support of legislation directed at the prohibition of horse slaughter and the transport of horses for slaughter.[13] Furthermore, the HSUS offers information regarding the inhumane treatment of animals on a wide spectrum of topics, including the process of slaughtering horses for their meat.[14]

III. ACTION REQUESTED[15]

Based on the facts and law presented here, Petitioners request that the FSIS issue a rule that renders any horse "U.S. Condemned" for use as food for human consumption, unless the slaughterhouse (or its agent) receiving or buying the horse obtains (1) an accurate record of all of the horse's prior owners, (2) a record of all drugs, treatments and substances administered to the horse since birth, and (3) verification that the horse has at no time been exposed to any substances prohibited for use in animals intended for use as food. Petitioners also request that,

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[9] *Id.*

[10] Declaration of Keith Dane, attached hereto as Exh. 7, at ¶ 2.

[11] *Id.*

[12] *Id.* ¶ 3.

[13] *Id.* ¶ 4.

[14] *Id.*

[15] On March 27, 2012, Petitioners filed a Petition with the Department of Health and Human Services and the Food and Drug Administration ("FDA"), requesting the FDA to enact certain rules and regulations regarding horses and horse meat intended for human consumption. *See* FDA Docket Number FDA-2012-P-0299-0001/CP. The prior Petition requests separate actions based on different legal authority under the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and FDA regulations under that law. The acts and rules requested in this Petition are solely within the jurisdiction of the FSIS, separate and apart from any FDA action, and are necessary regardless of the FDA's response to the prior Petition.

for any horses that do satisfy those three criteria, the FSIS adopt rules and regulations that mandate the testing of the flesh and organs of all such horses going to slaughter. The required tests should examine the horses for all substances listed on Exhibit 1 to the Petition, unless such substances have been subjected to sufficient human testing to ensure no danger in ingestion of that substance to any human.

Because of the elevated chance that these horses have been exposed to a myriad of substances prohibited for use in food animals, the only way to protect the food supply and the consuming public is for the FSIS to be able to provide this level of reassurance. Based on the Factual and Legal Background and Statement of Grounds below, Petitioners request that the FSIS adopt the following regulations:

1. Certification of Horse Meat as Approved. No horse or horse meat shall be approved for human consumption in America, or for export intended for human consumption elsewhere, unless the following criteria are all met: (1) Written records shall accompany the horse or horse meat attesting to the ownership of the horse at all times from birth until the horse's death; (2) Written records shall accompany the horse or horse meat that provide a complete list of all drugs, treatments and other substances that have been administered to the horse during the course of the horse's life, from birth until the time of the horse's death, in connection with any medical care, prophylactic treatment of diseases, vaccination, pest control, growth promotion or regulation, reproductive or hormone therapy, including but not limited to all prescription and over-the-counter medications, pain medication, sedatives, anesthetics, antibiotics, hormones (synthetic or natural), steroids, dewormers, fly or pest sprays, ointments, liquids or applications; (3) Prior to slaughter, an FSIS inspector shall review the written records accompanying each horse intended for slaughter for human consumption and verify that no prohibited or potentially dangerous substances have been administered to the horse during the course of the horse's life, from birth until the time of certification or the horse's death.

2. Potentially Dangerous Substances in Horse Meat. All substances, including "new animal drugs" and other veterinary drugs, shall be considered "potentially dangerous substances"

if there is scientific evidence that ingestion of horse meat containing these substances, by any significant percentage of the human population, could cause detrimental health consequences to that group of individuals.

3. Unqualified Horses or Horse Meat. Any horse meat or horse intended for human consumption shall be labeled and certified as "U.S. Condemned," if all the criteria listed in 1. above are not met. "U.S. Condemned" horses and horse meat shall be prohibited from sale or transport to slaughter for human consumption, and labeled as such. Any horse determined to be "U.S. Condemned" under this rule shall be returned to the transporter.

4. Testing of Horses and Horse Meat. Any horse or horse meat intended for human consumption, and that meets all the criteria listed in 1. above, shall be tested for the presence of all potentially dangerous substances in a manner that ensures discovery of the presence of any residue of any potentially dangerous substances in the horse or horse meat. If any potentially dangerous substance is found, or if testing is not available to determine the presence of any prohibited substances, the horse or horse meat shall be certified as "USDA Condemned," and labeled as such.

5. Destruction of Unqualified Horse Meat. All horse meat that is labeled and certified "USDA Condemned" shall be safely decontaminated and disposed of in a manner that ensures it does not contaminate the environment.

IV. FACTUAL BACKGROUND

A. Americans Love Horses.

Americans have a long relationship with horses. From parades, search and rescue teams, and competitions to police and military support, advertisements, and summer camps, Americans use horses for a vast array of purposes. We keep them as companions. They have stood by, loyal as dogs, during every war from the American Revolution up to the present day. They shoulder the burdens to work for farmers and ranchers. We cheer them on as they race and watch them in the Olympics. We admire their wildness and herd cultures where they are left alone in nature on the open range.

There are approximately nine million horses in the U.S. and two million horse owners,[16] and tens of thousands of wild horses. Of the nine million owned horses, a 2005 study concluded that almost four million are used for recreation, three million for "showing," eight hundred thousand for racing, and two million for activities ranging from farm and ranch work to police work and rodeos.[17] A 2007 study by the federal government found that almost forty-six percent of horses are used for pleasure, twenty-five percent for farm and ranch work, sixteen percent for breeding, and ten percent for show and competition.[18]

B. American Horses Are Not Intended to Be Meat.

One purpose horses do not currently serve in America is as a source of meat.[19] Because of the way Americans treat their horses – as companions, sources of recreation, and tools of labor – they neither raise horses for human consumption nor consume horse meat. Americans treat their horses more like their dogs and cats than other commercial animals. They give them whatever drugs and substances they need to keep them healthy, strong, and free of pests. Horses' place in American culture makes their slaughter something that, so far, has never received much support.

Nevertheless, when Americans have lost interest in their horses (whether companions, competitors, or racehorses), or when we capture the wild horses on public land, the profiteers buy them and send them off to be killed. Horses are transported to Canada and Mexico, where they are slaughtered, butchered, and their meat eaten. Horse meat is a common food, even a

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[16] Study by Deloitte Consulting LLP for the American Horse Council Foundation (2005), http://www.horsecouncil.org/national-economic-impact-us-horse-industry (attached hereto as Exh. 8).

[17] *Id.*

[18] USDA Animal and Plant Health Inspection Service Info Sheet (Mar. 2007), http://www.aphis.usda.gov/animal_health/nahms/equine/downloads/equine05/Equine05_is_Demographics.pdf (attached hereto as Exh. 9).

[19] *See, e.g., Cavel Int'l., Inc. v. Madigan*, 500 F.3d 551, 545 (7th Cir. 2007) ("Americans do not eat horse meat. . . ."); *see also* Terry L. Whiting, *The United States' prohibition of horse meat for human consumption: Is this a good law?*, 48 CANADIAN VET. J. 1173, 1174 (Nov. 2007) ("A commercial market for horse meat as food has never emerged in the USA."), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2034431/ (attached hereto as Exh. 10).

staple, in many regions, from China to Southeast Asia to Europe.[20] It regularly appears on menus and in markets. Between 100,000 and 200,000 American horses, from a variety of sources, are slaughtered outside of the United States and end up in restaurants and markets each year, and hundreds of thousands of people are eating American horse meat annually.

Because Americans view horses as somewhat totemic or "sacred" animals, horse slaughter for human consumption is overwhelmingly unpopular in the U.S.[21] A January 2012 poll confirmed that eighty per cent of Americans are strongly opposed to horse slaughter.[22] The survey found that "Americans oppose horse slaughter overwhelmingly regardless of their gender, political affiliation, whether they live in an urban or rural area, or their geographic location," or whether they own horses themselves.[23]

Americans revere horses and oppose horse slaughter and consumption for a variety of reasons. Some attribute this opposition to culture.[24] Others attribute it to the role of horses in American history, from the founding era to westward expansion.[25] Another factor deterring American consumption of horse meat is the level of animal cruelty connected with the slaughter

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[20] *Id.* at 552.

[21] Christa Weil, *We Eat Horses, Don't We?*, NY Times, March 5, 2007 ("*Weil*"), www.nytimes.com/2007/03/05/opinion/05weil.html (attached hereto as Exh. 11); Josh Ozersky, *The Case for Eating Horse Meat*, TIME (Dec. 28, 2011), http://ideas.time.com/2011/12/28/the-case-for-eating-horse-meat/ (attached hereto as Exh. 12).

[22] http://www.prnewswire.com/news-releases/aspca-research-confirms-americans-strongly-oppose-slaughter-of-horses-for-human-consumption-138494089.html ("*ASPCA Survey*") (attached hereto as Exh. 13); *see also* Press Release, The Humane Society of the United States, USDA Threatened with Suit if Court Order Not Followed Before Horse Slaughter Resumes (Feb. 3, 2012) *available at* http://www.humanesociety.org/news/press_releases/2011/11/usda_threatened_02032012.html (attached hereto as Exh. 14).

[23] *ASPCA Survey, supra* Note 22.

[24] Nicholas Day, *They Eat Horses, Don't They?*, CHOW (Nov. 17, 2006), http://www.chow.com/food-news/53692/they-eat-horses-dont-they/ (attached hereto as Exh. 15); Dan Flynn, *Horse Slaughter Issue Won't Go Away* (Oct. 25, 2011), http://www.foodsafetynews.com/2011/10/horse-slaughter-issue-wont-go-away/ (attached hereto as Exh. 16) (attributing Americans' opposition to eating horse meat to its "Cowboy Culture").

[25] Brian Palmer, *The Delicious Mr. Ed*, SLATE MAGAZINE (Oct. 24, 2011), http://www.slate.com/articles/health_and_science/explainer/2011/10/slaughtering_horses_for_meat_is_banned_in_the_u_s_why_.html (attached hereto as Exh. 17).

of horses, who are especially combative and frightened in slaughterhouses.[26] Yet others do not even attempt to explain their view, simply calling the eating of horse meat "repulsive[]" and "gross."[27]

Regardless of the rationale – from the "transcendent relationship" a rider forms with her horse to the popularity of movies like *Seabiscuit* and *War Horse* – Americans do not eat horse meat.[28] And they do not want their companions slaughtered and exported for others to eat either.

Americans did eat horses in decades past, but consumption has dropped off to almost nothing in the past thirty or forty years.[29] At this point, horse meat is almost never eaten in America. But because of recent legal changes (discussed in this Petition) and a business desire to slaughter horses for profit, it may soon be served again in restaurants and homes across the nation, and American horses will continue to be shipped over our borders, north and south, for foreign markets.

Although meat from slaughtered American horses has been shipped overseas for years, American horses have never been bred, borne, or raised specifically as food animals. As described below, the horses who end up as meat come from varied backgrounds and have been exposed to a multitude of identifiable and unknown drugs, substances, and treatments that have been applied to, injected in, and ingested by the horses. Many of those substances may be dangerous or even fatal to humans who ingest them. When meat from horses who have been exposed to those substances is eaten, there is a real potential for extreme consequences.[30] Because of the impossibility of knowing these horses' histories, every bite of American horse meat includes the potential for death and disease for the consumer; the chance of liability for the

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[26] *See* Larson Dec., Exh. 3, ¶¶ 11-21.

[27] *Weil, supra* Note 21.

[28] *Weil, supra* Note 21.

[29] *Cavel Int'l., supra* Note 19, 500 F.3d at 552.

[30] *See* Larson Dec., Exh. 3, ¶ 8-11, 14, 16; Declaration of Michael Greger ("Greger Dec."), attached hereto as Exh. 6, ¶¶ 13-15.

manufacturer, producer and seller; and the corollary need for all involved government agencies to ensure the safety of horse meat to the greatest possible degree.

C. Horses Used as Food Come from Sources Where They Are Regularly Exposed to the Substances in Exhibit 1 to the Petition.

As discussed above, and as proven by the evidence submitted with the Petition, American horses who end up as meat almost all begin their lives in factual settings that do not contemplate their ultimate end. Horses who become meat are of all breeds and ages, though most of them are young and healthy.[31] The horses come from several sources that can first be split into two larger categories – carefully-maintained and cared-for, privately-owned horses; and wild horses, who then often become privately-maintained horses for some time before their sale at auction that sends them on to slaughter. Almost every American horse sent to slaughter fits into one of these categories.[32]

A majority of the horses for slaughter, who end up being bought at auction by "killer-buyers" (who often act as middlemen to the final auctioneer or stockyard), spend most of their lives in highly-managed, highly-medicated home and stable environments. Their lives, before their final weeks or months as commodities in the slaughter industry for meat production, are both privately controlled out of the public eye, and almost completely unregulated.[33] They are treated as pets or as valuable commodities, and they are therefore given a series of medications, and treated with a number of substances, identical or similar to those listed in Exhibit 1 and identified in the following section of the Petition. Some, but not all of these are *per se* dangerous

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[31] Larson Dec., Exh. 3, ¶ 22. The USDA has reported that 92.3 percent of horses arriving at slaughterhouses were in "good" condition. http://www.humanesociety.org/issues/horse_slaughter/facts/facts_horse_slaughter.html

[32] Larson Dec., Exh. 3, ¶¶ 20-21, 24-25.

[33] There are rules and regulations that limit the use of certain drugs in connection with some competitive use, but most of the substances listed on Exhibit 1 are approved for use in competitive horses. Competitive horses may be treated even with banned substances when they are not actively in competition. It is also the case that abuse of even prohibited drugs in the racing industry is an ongoing problem. Joe Drape, *At Breeders' Cup, a Volatile Mix of Speed and Drugs*, NY Times, Nov. 3, 2010 ("Numbers suggest there is, indeed, a culture in American horse racing that ultimately rewards those who seek any means, legal and otherwise, to gain an edge."), *available at* http://www.nytimes.com/2010/11/04/sports/04racing.html (attached hereto as Exh. 18).

to humans. All of the Exhibit 1 drugs may be harmful if ingested by at least some portion of the human population, and over the course of her life, each horse is exposed to likely hundreds of applications of drugs, substances and treatments that could lead to detrimental side effects in the humans who eventually eat them.

The use of many of these products cannot be avoided in caring for horses, and often the use of these substances is necessary to provide for the health, safety and comfort of the horses. The substances fall into a number of identifiable categories, each category including tens, if not hundreds, of individual generic or brand names, which are regularly and routinely used on American horses.[34] First, in order to control common pests such as flies, ticks and other insects, horses are regularly treated with a number of substances, either topically or systemically.[35] Many of these treatments are specifically labeled with a warning that the treatments should not be used on animals who are intended to be used for food.[36] Second, in order to treat many ailments and medical problems, horses are injected with medications, many of which also are banned from use in animals who will become meat.[37] Third, many horses are treated with antibiotic and antibacterial compounds that are banned for use in food animals, and that could have a variety of negative health impacts if ingested by humans.[38] Fourth, various hormones and

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[34] *See* Exhibit 1; Wood Dec., Exh. 2, ¶¶ 6-7; Larson Dec., Exh. 3, ¶ 7; Pavlis Dec., Exh. 4, ¶¶ 4-5; Parker Dec., Exh. 5, ¶¶ 7-9.

[35] Examples include butoxy polypropylene glycol (fly spray), di-n-propyl isocinchomeronate (fly control products), n-(2-ethylhexyl)-5-norbornene-2,3-dicarboximide (fly control), and N-Octyl Bicycloheptene Dicarboximide (fly spray). *See* Exhibit 1; Wood Dec., Exh. 2, ¶¶ 6-7; Larson Dec., Exh. 3, ¶ 7; Pavlis Dec., Exh. 4, ¶¶ 4-5; Parker Dec., Exh. 5, ¶¶ 7-9.

[36] Examples include ponazuril (for treatment of equine protozoal myeloencephalitis) and eucalyptus oil (for dressing wounds). *See* Exhibit 1.

[37] Examples include moxidectin (a dewormer) and ceftiofur crystalline free acid (for treatment of lower respiratory tract infections). *See* Exhibit 1.

[38] *See Natural Resources Defense Council v. U.S. Food & Drug Administration*, No. 11 Civ. 3562 (THK), Memorandum Opinion and Order (Mar. 22, 2012) (granting summary judgment for plaintiff; noting that "[f]or over thirty years, the FDA has taken the position that the widespread use of antibiotics in livestock for purposes other than disease treatment poses a threat to human health"). Examples of antibiotics given to horses include entamicin sulfate solution (for the control of bacterial infections in the uterus and for improving conception), olaquindox (for growth promotion), and furazolidone (for treating wounds and sores). *See* Exhibit 1; Greger Dec., Exh. 6, at ¶¶ 11-12.

steroids are used on competition and companion horses for various reasons. Even where they are not expressly banned or even approved for human use, the ingestion of these substances could have dramatic effects on all humans, and especially on women of child-bearing age and the unborn.[39] Fifth, many over-the-counter medications used on horses are expressly banned, in federal regulations enacted by the Food and Drug Administration ("FDA"), from use in food animals – something the FDA would not have done without a concern about humans eating meat infected with those medications.[40] Sixth, many drugs that are approved for use on horses are specifically excluded from use in food animals, because of the need for all prescription drugs to be given under the direction and supervision of a physician.[41] It is a matter of common understanding that drugs of any kind, but especially prescription medications, should not be anonymously or secretly given to people.[42] But if those substances are in horse meat, that is exactly what will happen.

D. There are Over 110 Toxic Substances, Many Prohibited for Use in Animals Who Are Made Into Food – All of Which are Used on Horses.

The FSIS, the FDA, and private industry have recognized that many of the drugs, treatments and other substances that are regularly applied to, injected in or ingested by American horses create grave dangers if eaten by humans. Because of the possibility of unpleasant to fatal side effects, and the potential for crippling or chronic illnesses or even death that may result from ingestion of meat tainted with these toxic chemicals, literally hundreds of products are clearly labeled "Not for use in animals used for food" or "Not to be given to animals that will be eaten by humans" or some similar language.[43] The message is clear – once a horse (or any animal) has

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[39] *See* Exhibit 1; Greger Dec., Exh. 6, at ¶ 13.

[40] It is illegal to administer over fifty of the drugs listed on Exhibit 1 to animals intended to be used as food. Exhibit 1 also includes citations to the corresponding Code of Federal Regulations sections, which exclude animals who have received those drugs from slaughter for human consumption.

[41] Examples include dimethylsulfoxide (to reduce swelling), xylazine (a common sedative used in veterinary medicine) and prednisone (an anti-inflammatory agent). *See* Exhibit 1.

[42] Greger Dec., Exh. 6, at ¶ 3.

[43] Exhibit 1 includes examples of many such drugs only with respect to horses.

been exposed to even one of these chemicals, the horse must be permanently excluded from any possibility of being used for food. They cannot be slaughtered for human consumption and their flesh cannot be turned into meat. This determination, whether made by the agency or by the industry, is a potent declaration that horse meat from horses who have had one of these substances may be dangerous, unhealthy, even deadly.

Exhibit 1 to the Petition is an illustrative, but not complete, list of substances that are routinely given to American horses – and proof positive of the inherent problems in horse meat. Virtually every single substance on the list is used on American horses who may end up as horse meat, sometimes routinely, sometimes by prescription.[44] And a majority of the substances on the list is actually banned for use on animals who will be consumed by humans – regardless of when, over the course of their lives, the horses were exposed to that substance. There is good reason for the bans, given the potential consequences from human ingestion. Petitioners provide illustrations below:

1. *Acepromazine* is used as a sedative and antiemetic in horses. Its use has been discontinued in humans. While it was previously used in humans, its ingestion can still be harmful or fatal, or cause neurologic symptoms.[45] Other sedatives have been expressly banned from use in horses who will become food, but they continue to be used by horse owners.[46]

2. *Acetazolamide* is a diuretic commonly used in horses, and appropriate for use in some humans.[47] However, for many humans, it can cause serious health consequences, up to and including death.[48]

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[44] *See* Exhibit 1; Wood Dec., Exh. 2, ¶¶ 6-7; Larson Dec., Exh. 3, ¶ 7; Pavlis Dec., Exh. 4, ¶¶ 4-5; Parker Dec., Exh. 5, ¶¶ 7-9.

[45] See further detail included on Exhibit 1.

[46] *See, e.g.*, 21 C.F.R. § 522.2662 (xylazine, marketed as Anased, a sedative, is prohibited for use in horses who will become food, but its use on horses is allowed).

[47] Many drugs that are used by humans are also banned for use in animals who will be eaten. This may be because the drugs may be extremely dangerous to some humans, whether because of particular allergies/sensitivities or because they are taking other medications; because the drugs have not been tested on humans who take them orally; or because no tests have ever been done to see what byproducts of the drugs may end up in the meat of animals who take them. Since there is no way of filtering the consuming population to avoid adverse reactions, and no way to identify meat from animals who have had specific substances, the fact that a drug may be safe for some humans does not assure its safety for the consuming public.

[48] See further detail included on Exhibit 1; *Acetazolamide* (*sulfonamide*) is contraindicated in patients with hyperchloremic acidosis, angle-closure glaucoma, kidney and liver disease, and in

(Footnote continued on next page)

3. *Blue Kote* is a topical ointment, antiseptic, and protective wound dressing used by many horse owners. Its active ingredient is *acriflavine*. The Material Data Safety Sheet (MSDS)[49] for this substance states that it is "[h]azardous in case of . . . ingestion" and is "toxic to lungs [and] mucous membranes."[50]

4. *Adequan*, a commonly-used drug for degenerative and traumatic joint problems, and containing the active ingredient *polysulfated glycosaminoglycan*, cannot legally be given to horses used for food.[51] *Adequan* has never been tested on humans, so that its potential toxicity and adverse reactions to its use by humans are completely unknown.[52]

5. *Altrenogest* is the active substance in *Regu-Mate*, an artificial hormone and growth promoter. Even skin contact with the chemical is unsafe, and it is especially dangerous to pregnant women and women of child-bearing age, as it can disrupt biological function.[53] Unsurprisingly, the federal government has expressly forbidden its use in animals used for meat.[54]

6. *Amikacin* is used for the treatment of genital tract infections in mares. Use of *amikacin* has been expressly prohibited by law for "in horses intended for human consumption."[55]

7. Many different *antibiotics*, which help fight infection and the microorganisms that cause infection, are used in horses, in the companion, sport, and wild horse areas. While many of them are the same drugs used in humans, they are potentially dangerous to humans who either have allergies or sensitivities to them. Because of the unknown administration of antibiotics over the course of a horse's life, this problem cannot be avoided.[56] Additionally, the use of antibiotics in food animals, and the

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(Footnoted continued from previous page)

patients with Addison's disease. Many adverse side effects have been reported. *See* http://www.drugs.com/pro/acetazolamide.html.

[49] Material Safety Data Sheets are used in industries around the world to provide vital information about the safety, composition and other aspects of products on the market. They are generally considered conservative reports of the important information on a product, and are relied on by legislatures, courts, and administrative agencies.

[50] http://www.sciencelab.com/msds.php?msdsId=9927421. See further detail included on Exhibit 1.

[51] 21 C.F.R. § 522.1850.

[52] See further detail included on Exhibit 1.

[53] http://www.drugs.com/vet/regu-mate-solution.html.

[54] 21 C.F.R. § 520.48 ("Do not use in horses intended for human consumption."); see further detail included on Exhibit 1.

[55] 21 C.F.R. § 529.56; see further detail included on Exhibit 1.

[56] *See, e.g.*, 21 C.F.R. § 522.90c (Ampicillin Sodium: "Do not use in horses intended for human consumption."); *see also* http://www.drugs.com/vet/equifur-can.html (*Nitrofurantoin*, marketed as *Equifur* and used for bacterial infections of the urinary tract, "is not to be administered to horses that are to be slaughtered for use in food."); 21 C.F.R. § 524.1580b (*Nitrofurazone*, used as

(Footnote continued on next page)

subsequent ingestion by humans of those animals, has the potential to create antibiotic resistance in humans, which can cause significant problems for humans upon subsequent illness.[57]

8. *Antiseptic* compounds are often considered dangerous to humans upon ingestion, and are used regularly to clean horses' skin and wounds. Some of those substances are also expressly labeled to indicate that, as a matter of federal law, they cannot be used in animals who will become food.[58]

9. *Avermectin* is a common chemical component in dewormers used on American horses. Dewormers are part of typical routine care for most horses, in order to prevent worm infestation and the problems related with infestation. The MSDS for this substance directs that upon any human ingestion of the drug, immediate medical attention is required. The MSDS, like the label, also states without limitation that it is not to be used on horses who will be eaten.[59] The deworming products *Agri-mectin, Bimectin, Equell, Equimax, Exodus, Farnam Ivercare, Horse Health, Ivercare, Prometin E,* and *Zimecterin* all contain substances prohibited under federal law for use in "horses intended for human consumption."[60]

10. *Equipoise* is an injectable form of *boldenone undecylenate* and is used popularly to treat horses who are debilitated, in order to bolster their physical condition. When men use it (illegally), it has been known to cause blood dyscrasias, psychological aberrations, "sleeplessness, chills, vomiting, diarrhea, hypertension, [and] prolonged blood clotting time." When women use it, hormonal effects occur, including but not limited to menstrual irregularities and post-menopausal bleeding.[61] Probably because of all those potential problems, horses who have received the drug cannot be used for meat,[62] but its use on horses otherwise is legal.

11. *Butorphanol* is a commonly-used drug for pain relief in a wide variety of situations involving horses. Its effectiveness makes it a regular choice, but, probably because of its severe side effects (see Exhibit 1), federal law forbids the use or sale for human consumption of meat from any horse who has had it.[63]

12. *Carbadox* is a growth-enhancing antibiotic. If ingested, it can cause

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(Footnoted continued from previous page)

antibacterial on surface wounds but not "for use in horses intended for human consumption" – "Federal law prohibits the use of this product in food-producing animals.").

[57] Parker Dec., Exh. 5 at ¶ 7; see further detail included on Exhibit 1.

[58] *See, e.g.*, 21 C.F.R. § 524.402 (*Chlorhexidine* topical antiseptic not to be used on horses intended for human consumption); see further detail included on Exhibit 1.

[59] http://msds.farnam.com/m001116.htm.

[60] *See* 21 C.F.R. §§ 520.1192, 520.1194, 520.1195, 520.1198, 520.2044; see further detail included on Exhibit 1.

[61] http://www.anabolicsmall.com/equipoise.html.

[62] 21 C.F.R. § 522.204; see further detail included on Exhibit 1.

[63] 21 C.F.R. § 522.246; see further detail included on Exhibit 1.

serious health problems or even be fatal. Even a single exposure could cause irreversible mutations of human chromosomes.[64]

13. *Excede*, an antibiotic drug containing *ceftiofur cystalline free acid*, is "[n]ot for use in humans" and that if a person is exposed, that a physician should be consulted.[65]

14. *Chloramphenicol* is a topical antibiotic ointment. If ingested by humans, it can cause tragic consequences, including death and severe blood disorders.[66] In some forms, it is wholly prohibited for use on animals who become food.[67] In others, it is allowed without condition.[68]

15. *Kopertox* is used to treat thrush (a common bacterial infection of the hoof) in horses. Its active ingredient is *copper naphthenate* which, if eaten, may cause vomiting, shock, jaundice, and liver, kidney or central nervous system failures.[69] The law forbids the use of horses for meat, if they have been treated with *copper naphthenate*.[70]

16. *Cupric sulfate* is the active ingredient in *Proudsoff*, used to treat certain types of unwanted granulation tissue (proud flesh"). If eaten by humans, *cupric sulfate* can cause gastrointestinal tract problems including bleeding, liver damage, anemias, urinary system problems, and cardiovascular problems.[71]

17. *Farnam Repel* and other fly sprays used to control flies on horses contain *deodorized kerosene*. If any of that substance was in horse meat, the potential problems upon ingestion could include pulmonary edema, central nervous system depression, convulsions and loss of consciousness.[72]

18. *Deslorelin* is used in order to induce ovulation, as a regular tool for successful horse breeding. Federal regulations forbid its use in horses who will be eaten.[73] This is undoubtedly because the drug can cause serious

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[64] http://datasheets.scbt.com/sc-204668.pdf; see further detail included on Exhibit 1.

[65] http://animalhealth.pfizer.com/sites/pahweb/US/EN/Products/Documents/Combined%20Full%20PI%20(8_5x11)%20-%20EXEQ0110014.pdf. *See also* 21 C.F.R. §§ 522.313a, 522.313c (not to be used in horses who are eaten); see further detail included on Exhibit 1.

[66] http://www.drugs.com/cdi/chloramphenicol.html.

[67] 21 C.F.R. § 524.390 (Chloramphenicol ointment).

[68] See further detail included on Exhibit 1.

[69] http://www.sciencelab.com/msds.php?msdsId=9923553.

[70] 21 C.F.R. § 524.463; see further detail included on Exhibit 1.

[71] http://www.sciencelab.com/msds.php?msdsId=9923598; see further detail included on Exhibit 1.

[72] http://www.sciencestuff.com/msds/C1955.html; see further detail included on Exhibit 1.

[73] 21 C.F.R. § 522.533.

adverse reactions related to hormonal effects.[74]

19. *Dexium (dexamethasone)* injection and tablets are used as anti-inflammatory agents in horses, but are expressly banned from use in food animals because of the great danger from ingestion. *Dexium* is a steroid that is very hazardous if eaten.[75] Any use of it is banned by law for horses "intended for food."[76] *Methylparaben*, also in *Dexium* injections, is used as a preservative in cosmetic products, and its toxicity is established, but the exact scope and nature of the toxicity in humans is unknown.[77]

20. *Diclofenac sodium* (marketed as *Surpass*) is used for pain associated with arthritis in horses. While it is also used in human medicine, the drug is very dangerous, used only when necessary, and in the shortest duration possible. There are many known adverse reactions and side effects,[78] and the FDA prohibits its use in animals who become food.[79]

21. *Dormosedan*, the brand name for *detomidine hydrochloride*, is a common sedative and analgesic for many routine procedures performed on mature horses. No animal that has been administered this drug can legally be used for food.[80]

22. *Doxycycline*, an antibiotic also used in humans, has several severe side effects for humans who have sensitivities or compromised health that would indicate that they should not take the drug. The potential adverse effects include fetal injury, damage to tooth development in children, kidney problems, and bacterial resistance.[81]

23. Injectable *enrofloxacin* can cause significant problems if animals who have been treated with this antibiotic are eaten by humans. The Center for Veterinary Medicine specifically directed that the drug should be removed from use on chickens because chickens treated with the drug, who were then eaten by humans, passed on drug-resistant bacteria, a significant health hazard to humans.[82]

24. *Eucalyptus oil* is used as a topical treatment for horses (also known as "Scarlet Oil") for small wounds. Despite use in some compounds

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[74] *See, e.g.*, http://www.pdr.net/drugpages/concisemonograph.aspx?concise=2848; see further detail included on Exhibit 1.

[75] http://www.drugs.com/vet/dexium-injection.html.

[76] 21 C.F.R. § 522.540.

[77] http://www.sciencelab.com/msds.php?msdsId=9926083; see further detail included on Exhibit 1.

[78] http://www.pdr.net/search/searchResult.aspx?searchCriteria=Diclofenac+Sodium; see further detail included on Exhibit 1.

[79] 21 C.F.R. § 524.590.

[80] 21 C.F.R. §§ 522.536, 529.536; see further detail included on Exhibit 1.

[81] http://www.drugs.com/cdi/doxycycline-capsules.html; see further detail included on Exhibit 1.

[82] http://www.fda.gov/AnimalVeterinary/SafetyHealth/RecallsWithdrawals/ucm042004.htm; see further detail included on Exhibit 1.

marketed to humans, eucalyptus is a known extreme human toxin if eaten.[83]

25. *Flunixin*, the active compound found in many equine pain medications, is a *non-steroidal anti-inflammatory drug*, or NSAID. NSAIDs cause severe and dangerous reactions in some humans. While many NSAIDs are used by people, the NSAIDs have significant potential adverse effects when combined with other drugs. There are also serious contraindications for use of NSAIDs in humans who have heart, liver, or kidney problems; who are taking other types of pain relievers, steroids or anticoagulants; and in third-trimester pregnancies. Several other NSAIDs are on the list as well, all of which could lead to the same problems,[84] and federal law has banned all of them in horses used for food.[85]

26. *Furaltadone*, a common antibacterial used in horses, is definitely "harmful if swallowed," has carcinogenic effects and, of even greater concern, the actual detrimental effects of the drug on humans who eat it has not been studied and is not known.[86] Other antibacterials also threaten human health if ingested, and are banned by law.[87]

27. *Furazolidone* is an antibacterial drug that is used in both horses and humans. Its use is carefully restricted in humans, however, because of the dangerous side effects from ingestion. For example, severe hypertension can result from the combination of furazolidone and certain food and drink, including alcoholic beverages.[88] It is also banned for use in horses who will be eaten.[89]

28. *Gentamicin sulfate* is used in humans and horses as an antibacterial. However, when prescribed for humans, doctors are careful to ensure that their patients are not taking other medications which can combine with gentamicin and cause severe kidney and hearing problems.[90] There are many other side effects of gentamicin ingestion that patients are warned

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[83] See further detail included on Exhibit 1.

[84] *See, e.g.*, http://www.drugs.com/vet/ketofen.html.

[85] *See, e.g.*.. 21 C.F.R. § 522.1225; 21 C.F.R. §§ 520.930; 522.930 (*Equioxx*, containing the substance *firocoxib* – "Do not use in horses intended for human consumption"); 21 C.F.R. §§ 520.970; 522.970 (*Banamine*, *Flunazine*, and *Flunixamine* products, containing *Flunixin*); see further detail included on Exhibit 1.

[86] http://www.chemblink.com/MSDS/MSDSFiles/139-91-3_Sigma-Aldrich.pdf; see further detail included on Exhibit 1.

[87] *See, e.g.*, 21 C.F.R. § 520.2215 (*Sulfadiazene*, marketed as *Tribrissen 400*, an antibacterial oral paste, not to be used in horses intended for human consumption). *See also* 21 C.F.R. §§ 520.2611, 520.2613 (*Trimethoprim*, found in multiple products including both *Uniprim* antibiotic powder and *Tribrissen*, is banned by the FDA for use in food animals).

[88] http://msds.farnam.com/m000394.htm; see further detail included on Exhibit 1.

[89] 21 C.F.R. § 524.1005.

[90] http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682275.html; see further detail included on Exhibit 1.

about, including vomiting, fatigue, and muscle weakness, among others,[91] which is probably also why it has been banned for use in animals intended to be food.[92]

29. *Hyaluronate Sodium*, marketed as *Legend*, is used to treat an arthritic condition in horses. It is illegal to use this drug on horses who will be food.[93]

30. The use of *isoflurane*, a commonly used anesthetic gas for humans and horses, renders horses unfit for human consumption.[94] Federal law has barred other anesthetic compounds as well.[95] Studies have not addressed the effect of these drugs on the flesh of horses, and so the consequences for humans who eat those horses are completely unknown.

31. *Levothyroxine Sodium* (marketed as Thyro-L) is a thyroid-replacement hormone. The thyroid gland is a very sensitive, vital regulator of various bodily functions. Administration of even small amounts of thyroid replacement hormones can have detrimental effects on humans, including systemic toxicity, cardiovascular problems, aggravation of diabetes problems, and other hormonal effects.[96]

32. *Luprostiol*, a female hormone used in horses to manipulate estrus cycles and to chemically terminate pregnancies, cannot legally be used in food horses.[97] There is of course a potential for hormonal effects in women who eat horse meat from horses who have been given *luprostiol*.

33. *Methylandrostenediol* is an anabolic steroid used for a variety of reasons for sport horses, and by humans, often in the bodybuilding setting. The use in humans is highly controversial and the effects of exposure potentially detrimental to multiple body systems. Another drug in the same group, *Stanozolol*, is banned in food animals, by law.[98] Other steroids, perhaps even more dangerously, have no restrictions at all, are

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[91] http://www.drugs.com/pro/gentamicin-sulfate.html.

[92] 21 C.F.R. § 529.1044a.

[93] 21 C.F.R. § 522.1145. *See also* http://www.medi-vet.com/Polyglycan.aspx (Hyaluronic acid sodium salt for use "only in animals not intended for food use."); see further detail included on Exhibit 1.

[94] 21 C.F.R. § 520.186.

[95] *See, e.g.*, 21 C.F.R. § 522.1372 (*mepivicaine*).

[96] http://www.drugs.com/vet/thyro-l.html; see further detail included on Exhibit 1.

[97] 21 C.F.R. § 522.1290. The drug is so dangerous to humans that the FDA requires that the product include a label that says, among other things, that "[w]omen of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early states, women may be unaware of their pregnancies. Luprostiol is readily absorbed through the skin and can cause abortion and/or bronchiospasms." See further detail included on Exhibit 1.

[98] 21 C.F.R. § 522.2150.

used in horses, and can have severe detrimental effects on humans.[99]

34. *Methylprednisolone* and *prednisone* are used regularly in horses, while use in humans must be undertaken only with careful physician's supervision and with a prescription. The requirement for a physician's approval, coupled with the deleterious side effects, are likely what caused the federal government to ban the drugs for use in horses used for food.[100]

35. *Moxidectin* is used as a dewormer and marketed as *Quest*. And like most of the drugs on this list, its sellers must label the product as "[n]ot for horses or ponies intended for human consumption."[101]

36. *N-(2-Ethylhexyl)-5-norbornene-2,3-dicarboximide*, an active ingredient in "*Bug Block*" fly control, is "harmful if swallowed [and m]ay cause gastric distress, stomach pains, vomiting and diarrhea."[102]

37. *Neomycin sulfate* and many other antibiotic ointments are used on horses, just as they are on humans. But the strong caution with the use of such substances is that they should not be used unless there is an active infection – otherwise bacterial resistance and other serious side effects can occur.[103] Additionally, because they are ointments, they are not intended for oral ingestion.

38. *Omeprazole*, marketed as *Gastrogard*, is a commonly-used drug to aid in the protection and relief of stomach ulcers. Though also used in human drugs, its use in horses intended for food is expressly prohibited under federal regulations.[104]

39. *Phenylbutazone*, marketed as *Butazone*, *Bute* and *Butequine*, is barred by

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[99] *See, e.g.*, http://www.drugs.com/vet/uni-bol-can.html (*Uni-Bol*, containing *testosterone enanthate*, an anabolic steroid simulating a male hormone, used on horses with multiple adverse reactions in humans).

[100] 21 C.F.R. §§ 522.1410 (methylprednisolone), 522.1890 (prednisone); see further detail included on Exhibit 1.

[101] *See* 21 C.F.R. §§ 520.1452, 520.1463; see further detail included on Exhibit 1; *see also generally* FDA Directive 7371.006, Illegal Residues in Meat, Poultry, Seafood, and Other Animal Derived Foods, (H.H.S. 2005), *available at* http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UCM113433.pdf (attached hereto as Exh. 19); 21 C.F.R. § 520.905a (common dewormer *Panacur* (*fenbendazole*) cannot be used on any horse who will be eaten). *See also* 21 C.F.R. § 520.1638 (*Oxibendazole*, active ingredient in the dewormer *Anthelcide EQ*).

[102] http://www.statelinetack.com/ContentFiles/Associated_Content/absorbinebugblockMSDS.pdf; see further detail included on Exhibit 1.

[103] *See, e.g.*, http://www.pdr.net/drugpages/concisemonograph.aspx?concise=3174; http://www.drugs.com/vet/equifur-can.html (Nitrofurantoin); http://www.drugs.com/vet/niderm-ointment-can.html (*Nitrofurazone*, an active ingredient in *Nitroderm* ointment, an antibacterial ointment that "[f]ederal law prohibits the administration of this preparation to animals that produce food or that are intended for consumption as food.").

[104] 21 C.F.R. § 520.1615; see further detail included on Exhibit 1.

law from use in horses who are eaten,[105] undoubtedly because of its significant adverse effects on humans.[106]

40. Horses are regularly treated with *insecticides* with known health risks for humans and others. For example, *Mosquito Halt*, containing the substance *Prallethrin*, can cause serious problems affecting multiple body systems.[107]

41. A series of drugs that affect thyroid function in horses, known as *thyrostats*, are used without significant control in America. However, the European Union has permanently banned the importation, purchase or sale of animals or meat of any animal that has been treated with these substances, because of their adverse characteristics.[108]

42. *Triamcinolone acetonide*, an ingredient in popular topical creams and liquids, is applied regularly to American horses in products such as *Animax*. It is specifically prohibited for use in horses who will become meat.[109]

43. Many other drugs used on horses for various medical treatments and problems are also directly banned by a series of federal regulations. Because of the FMIA's concern for public safety, and the FSIS' mandate to protect the public from animals or meat that have the potential for consumer harm, any horse who receives these prohibited drugs should be certified "USDA Condemned," and that horse's meat should be deemed adulterated by the FSIS. The meat of those horses should be excluded, permanently and as a matter of law, from the food supply.[110]

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[105] 21 C.F.R. §§ 520.1770a.

[106] *See, e.g.*, Nicholas Dodman, Nicolas Blondell, Ann M. Marini, "*Association of phenylbutazone usage with horses bought for slaughter: A public health risk*", FOOD AND CHEMICAL TOXICOLOGY 48 (2010) 1270–74, *available at* http://www.equinewelfarealliance.org/uploads/Food_and_Chemical_Toxicology_FINAL.pdf (attached hereto as Exh. 20) ("*Phenylbutazone Health Risks*"); U.S. Food & Drug Administration, "FDA Order Prohibits Extralabel Use of Phenylbutazone in Certain Dairy Cattle," *available at* http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm124078.htm (accessed Feb. 9, 2012) (attached hereto as Exh. 21) ("Phenylbutazone is known to induce blood dyscrasias, including aplastic anemia, leukopenia, agranulocytosis, thrombocytopenia and deaths . . . [and] is a carcinogen, as determined by the National Toxicology Program."); see further detail included on Exhibit 1.

[107] *See, e.g.*, http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC35755; see further detail included on Exhibit 1.

[108] *See, e.g.*, Directive 2008/97/EC (2008) http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=EN&numdoc=32008L0097 (attached hereto as Exh. 22); see further detail included on Exhibit 1.

[109] 21 C.F.R. §§ 520.2483, 522.2483.

[110] *See, e.g.*, Larson Dec., Exh. 3, ¶¶ 8-11. *See also* 21 C.F.R. § 520.606 (Diclazuril, used for treatment of a form of myeloencephalitis); § 520.1855 (Ponazuril, marketed as Marquis, also used for myeloencephalitis treatment, with no information known on human toxicity); § 520.766 (Domperidone, used for toxicity in pregnant mares); 21 C.F.R. § 520.784 (Doxylamine succinate: used as an antihistamine substitute); 21 C.F.R. § 522.2063 (Pyralamine maleate).

44. Other drugs listed on Exhibit 1 are also used by humans, and may even be safe for a significant portion of the human population – but the dangers of ingestion to humans who may have allergies, sensitivities, and adverse reactions to those drugs, have also led to the absolute legal prohibition on use of those drugs in food animals.[111]

The list above represents only some examples of the substances listed on Exhibit 1, and Exhibit 1 is itself just a sampling of the drugs and substances that American horses are constantly treated with, fed, or injected with during their lives.[112] An accurate list cannot be compiled without an extensive review of every equine products catalogue, equine supply store and equine product website containing the various substances and drugs commonly used on horses in America – and that is without considering all the homemade remedies that are undoubtedly used on horses around the country. The illustrations here and on Exhibit 1 are telling, however, since they present a long list of substances which, if ingested, could cause a parade of problems and adverse reactions, illnesses and potential fatalities, if American horses continue to be slaughtered for food.[113]

E. Commercial Horse Slaughter Cannot Be Accomplished Without Horrendous Treatment of the Horses.

From their acquisition at livestock auctions and other sources to the slaughterhouse, horses destined for human consumption are subject to mistreatment and cruelty.[114] Their transportation from the livestock auction to the slaughter facility is often long and grueling, because they are cramped in trucks that do not accommodate their physical requirements and unique temperaments.[115] At slaughter facilities, horses are often subject to appalling abuse

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[111] *See, e.g.*, Larson Dec., Exh. 3, ¶¶ 8-11. *See also* 21 C.F.R. §§ 524.660a, 524.660b (Dimethylsulfoxide solution and gel, regularly used for topical relief of swelling due to trauma).

[112] Exhibit 1; Wood Dec., Exh. 2, ¶¶ 6-7; Larson Dec., Exh. 3, ¶ 7; Pavlis Dec., Exh. 4, ¶¶ 4-5; Parker Dec., Exh. 5, ¶¶ 7-9.

[113] *See, e.g.*, Larson Dec., Exh. 3, ¶¶ 8-11.

[114] *See* Larson Dec., Exh. 3, ¶¶ 12-13, 15-16, 18-19, 25.

[115] Larson Dec., Exh. 3, ¶¶ 12-13, 16, 25; *see* C.L. Stull, *Response of Horses to Trailer Design, Duration, and Floor Area During Commercial Transportation to Slaughter*, J. ANIM. SCI. 77:2925-2933 (1999) ("Horses tend to travel longer distances to slaughter than other livestock, because there is a limited number of equine slaughterhouses.") *available at* http://jas.fass.org/content/77/11/2925 (attached hereto as Exh. 23).

before and during their slaughter.[116] Some horses may even be slaughtered while still conscious.[117] Each aspect of this treatment increases the possibility that their meat is inappropriate for consumption under the FMIA and FSIS regulations discussed in Section V. below.[118]

Poor conditions during the transportation of horses result in slaughter facilities filled with frightened, food- and water-deprived, sick and injured horses.[119] Federal law usually requires transported horses to be off-loaded for food and water every twenty-eight hours, but horses are often transported continuously for over thirty hours.[120] Traveling in double-deck trailers meant for cows and pigs until late in 2011, some horses were unable to hold their heads in a natural position.[121] Some horses arrive at slaughterhouses with their backs broken or with other serious injuries.[122] And the lack of proper food and water in already weakened horses can lead to further injuries and death during extended transport. According to a 1999 study of sixty horses transported for slaughter, one animal had to be removed from the transport trailer after twelve hours of transport, dying two days later.[123] The fifty-nine arriving horses sustained a total of eighty-one injuries.[124]

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[116] *See* Larson Dec., Exh. 3, ¶¶ 15, 18-19.

[117] *Id.* at ¶ 18.

[118] *Id.* at ¶¶ 14, 16.

[119] *Id.* at ¶¶ 16, 18.

[120] T.H. Friend, *A Review of Recent Research on the Transportation of Horses*, J. ANIM. SCI. 79:E32-E40 (2001) ("Continuous transport of slaughter horses for 30 hours is common, and some trips last 36 hours or longer.") *available at* http://jas.fass.org/content/79/E-Suppl/E32 (attached hereto as Exh. 24).

[121] Larson Dec., Exh. 3, ¶ 13. In September 2011, the USDA announced a new rule which closed a loophole that allowed double-decker transport to continue for horses being driven to slaughter. 76 Fed. Reg. 55213. A bill is currently pending in Congress that would make that rule a matter of statutory law.

[122] *See* Larson Dec., Exh. 3, ¶ 13; *see also* 151 CONG. REC. H4247 (horses are "transported in excess of 1,000 miles in the most inhumane conditions perceived").

[123] C.L. Stull, *Response of Horses to Trailer Design, Duration, and Floor Area During Commercial Transportation to Slaughter*, J. ANIM. SCI. 77:2925-2933 (1999), *supra* Note 115.

[124] *Id.*

The arduous trip to slaughter facilities is frightening for most horses but is especially traumatic for wild horses, who resist handling during gather and transport operations.[125] Because of their wildness, the fear they display in response to proximity to people in strange environments, and their resistance to handling and transport, wild horses experience extremely high levels of distress and injury during the events leading up to slaughter.[126]

The mistreatment continues at the end of the transport phase. Many horses are not given hay or water in overnight holding pens.[127] Many of the horses in holding pens are "downers" – animals too sick or injured to stand up and walk, some of whom may be dragged or pushed into the pen.[128] Some of these ill, diseased, and injured animals are unfit for food under the FMIA and should not be slaughtered for human consumption.[129]

Because they frighten more easily than cows, horses are unsuited to be processed at a slaughter plant.[130] As horses are more sensitive to odors than cows, the scent of blood that necessarily exists in the slaughter facility exacerbates their fright.[131] Some horses slip and fall in

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[125] Larson Dec., Exh. 3, ¶ 25.

[126] *Id.*

[127] *See Pasture to Plate: A Report by the Canadian Horse Defence Coalition on Equine Slaughter*, p. 5 (July 2011), *available at* http://canadianhorsedefencecoalition.files.wordpress.com/2011/12/pasture-to-plate.pdf ("*Pasture to Plate*") (attached hereto as Exh. 25).

[128] Larson Dec., Exh. 3, ¶ 14; *see also* Gary D. Anderson & Don R. Lee, *Salmonella in Horses: A Source of Contamination of Horse Meat in a Packing Plant Under Federal Inspection*, 31 Applied and Environmental Microbiology 661 (1975) ("[S]laughter horses have usually been trucked for extensive distances. Many times they are injured or unhealthy, housed poorly, fed and watered improperly, and sometimes held for long times, as much as a week, in dirty confined pens at the slaughter plant.") *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC291172/ (attached hereto as Exh. 26).

[129] *See* 21 U.S.C. § 601(m)(3), (4) (defining "adulterated" to include animals or meat that are (a) "for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food," or (b) "held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health"). The FMIA is discussed in detail in Section V.A., *infra*.

[130] *See* Larson Dec., Exh. 3, ¶¶ 18, 25.

[131] *See* Larson Dec., Exh. 3, ¶ 18.

the stun box.[132] As a result of their keen perception and subsequent fear, horses are more likely to injure themselves trying to escape the slaughter plant.[133]

Under federal law, horses must be rendered unconscious prior to slaughter,[134] but because of their natural agility and flight instinct, many horses are improperly stunned and remain conscious when they are hoisted to have their throats cut.[135] According to a recent report, almost half of the horses going to slaughter had to be stunned more than once.[136] The desire to slaughter as many horses as quickly as possible inevitably contributes to the inaccuracy and cruelty of the slaughtering process.

FSIS and USDA are aware of and have documented appalling cruelty at slaughter plants, including gruesome descriptions and photographs of the mistreatment inherent in horse slaughter.[137] The mistreatment seems to be an inevitable occurrence anytime that horses are slaughtered, as documented most recently in Canada.[138] The examples cited in this section, which are only those that were discovered and occurred in a small sampling of plants, speak

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[132] *See id.* at 4.

[133] *See id.* at 5.

[134] *See* Humane Methods of Slaughter Act, 7 U.S.C. § 1902(a).

[135] *See* 151 CONG. REC. S10,220 (daily ed. June 8, 2005) ("horses sometimes remain conscious throughout the slaughter process"). *See also* Larson Dec., ¶ 18.

[136] *Pasture to Plate, supra* Note 127, at 4.

[137] *See, e.g.*, USDA, Food Safety & Inspection Service, Noncompliance Record No. 0019-2005-8243 (Apr. 13, 2005) (attached hereto as Exh. 27); *see also, e.g.*, Noncompliance Record Nos. 0018-2005-8243 (Apr. 4, 2005) (attached hereto as Exh. 28) ("Nine horses were overcrowded in the alleyway causing undue excitement which was further exacerbated when two more employees from the kill floor began yelling and hitting these horses causing the one in the end of the line to slip and fall."); 0013-2006-8243 (Oct. 9, 2006) (attached hereto as Exh. 29) ("horse was down" . . . "in the upper middle compartment of a pot bellied trailer" and "[o]ther horses within the compartment were trampling the downed horse"); 0006-2007-8243 (Jan. 24, 2007) (attached hereto as Exh. 30) ("two downed horses being trampled upon by the other horses as well as the front horse being kicked with the hind feet from another horse"); Press Release, Animals' Angels (Nov. 2008), *available at* http://www.kaufmanzoning.net/nov24/pressrelease.pdf (attached hereto as Exh. 31); *see also* Mary Nash's Horse Meat Website, *available at* http://www.kaufmanzoning.net/foia.htm (attached hereto as Exh. 32) (making available for download USDA documents describing and depicting regulatory violations, mistreatment, and cruelty).

[138] *See generally Pasture to Plate, supra* Note 127.

volumes for the absolute terror that slaughterhouses are for horses, and the danger to them and to the public in processing them for meat.

F. Horse Slaughter Leads to Other Public Health Problems.

Not only does horse slaughter pose danger to those who consume horse meat, and inflict cruelty upon the horses, but horse slaughter facilities – to a greater degree than other slaughterhouses – also harm the environment, overwhelm local governments, diminish quality of life, and threaten public health. There has been a growing and "overwhelming public sentiment that horse slaughter for human consumption should be ended,"[139] and to prohibit activities which "have detrimental impacts on the health, safety, environment, and welfare of" humans living in proximity to horse slaughter plants.[140] These problems are exacerbated by nonresident owners of slaughterhouses who have no reason or motivation to be concerned about the community in which their facilities are located. For example, the company that owned the last of the Texas horse slaughter facilities demonstrated "extreme disregard" towards the local citizenry and government.[141]

Every one of the last three American horse slaughterhouses[142] wreaked environmental havoc by dumping blood, entrails, urine, feces, heads, and hooves into local systems, overwhelming waste water infrastructures and leading to numerous environmental violations.[143]

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[139] Ltr. From Hon. Robert S. Molaro (June 11, 2007) ¶ 3, in support of Illinois law banning slaughtering of horses for human consumption, 225 ILCS § 635 ("*Molaro Letter*"). *See also ASPCA Survey*, *supra* Note 22.

[140] *Molaro Letter*, *supra* Note 139, ¶ 5.

[141] Jane Allin, *When Horse Slaughter Comes to Town*, p. 3 (Mar. 2011), *available at* http://www.horsefund.org/resources/When_Horse_Slaughter_Comes_to_Town_Updated_March_2011.pdf ("*When Slaughter Comes to Town*") (attached hereto as Exh. 33); *Life In A Slaughter Town: Kaufman, Texas*, pp. 4, 10, *available at* http://galleries.forbes.com/gallery/Life_in_a_Slaughter_Town%3A_Kaufman,_Texas#image=03PB6Ww0dV53u&view=filmstrip ("*Life In A Slaughter Town*") (attached hereto as Exh. 34).

[142] The last three horse slaughterhouses in America, which closed in 2007, were in DeKalb, Illinois (Cavel), Kaufman, Texas (Dallas Crown), and Fort Worth, Texas (Beltex).

[143] *See When Slaughter Comes to Town, supra* Note 141, at 3. *See also* Eckhoff, Vickery, "Horse Slaughterhouse Investigation Sounds Food Safety and Cruelty Alarms," *Forbes*, Dec. 6, 2011, available at http://www.forbes.com/sites/vickeryeckhoff/2011/12/06/horse-slaughterhouse-investigation-sounds-food-safety-and-cruelty-alarms/ (accessed Jan. 15, 2012) ("*Slaughterhouse Food Safety & Cruelty*") (attached hereto as Exh. 35).

According to the former mayor of Kaufman, Texas, where the Dallas Crown plant was located, the problems were epidemic, including (1) a pervasive and horrible odor in the vicinity of the plant; (2) multiple violations of the plant's industrial waste permit; (3) denial of access to city inspectors for waste water testing; (4) transportation of slaughter refuse in leaking containers without covers, leading to horse parts falling into the road; (5) blood flowing in nearby ditches; and (6) bones and blood in front of the facility and in neighboring yards, attracting dogs and other animals.[144] Dallas Crown also left a 600-gallon container filled with blood and horse parts outside its facility, generating a stench and attracting flies and vermin.[145] In 2003, the container spilled outside the plant, emptying blood into a ditch, and, from there, into the ground.[146]

The frequency and magnitude of Dallas Crown's environmental damage and legal breaches devastated the community. The cost of enforcing all violations for which Dallas Crown was cited would have consumed the city's entire legal budget for the year, and the company simply ran the legal expenses up so that the city was unable to adequately respond.[147] This included the costs of the twenty-nine individual jury trials requested by Dallas Crown for its waste water violations, each of which resulted in a $2,000 fine.[148]

Due to its lack of funds, Kaufman was unable to prosecute and collect on those fines.[149] Even so, the city spent over twice as much on legal fees related to Dallas Crown's violations as the company paid in property taxes.[150] Overall, the horse slaughter business nearly destroyed the

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[144] Former Mayor Paula Bacon, Open Letter to State Legislatures Considering Pro-Horse Slaughter Resolutions (Feb. 2009), *available at* http://www.animallawcoalition.com/horse-slaughter/article/686 ("Paula Bacon Letter") (attached hereto as Exh. 36); *see also* Eckhoff, Vickery, "Texas Mayor Paula Bacon Kicks Some Horse Slaughter Tail," *Forbes*, Jan. 10, 2012, *available at* www.forbes.com/sites/vickeryeckhoff/2012/01/10/texas-mayor-paula-bacon-kicks-some-tail/ (accessed Jan. 15, 2012) (attached hereto as Exh. 37).

[145] *Life In A Slaughter Town, supra* Note 141, at 9.

[146] *See id.*

[147] Paula Bacon Letter, *supra* Note 144.

[148] *Id.*

[149] *Id.*

[150] *Id.*

town – breaking laws, paying virtually no taxes, forcing the city to use valuable resources to protect the environment, and overwhelming the city's water system.[151]

In addition to endangering the ultimate consumer of the meat, horse slaughter facilities also diminish the quality of life and threaten public health. The omnipresent putrid air of the slaughterhouse dampens communities, drives citizens away, and depresses real estate values.[152] In Kaufman, Texas, the ultimate insult came when, on multiple occasions, residents' faucets delivered blood and horse tissue instead of water.[153] Most notably here, even the Sanitation Group of DeKalb, Illinois described the discharge from the Cavel facility as "uniquely acute," given that horses are given a "wide range of drugs" that are "clearly labeled NOT FOR USE IN HORSES INTENDED FOR HUMAN CONSUMPTION."[154] Horse blood disposal presents a similar and related problem: with horses having twice as much blood as cows, the bacterial agents used to neutralize cows' blood are insufficient to treat horse blood due to the antibiotics in it.[155] Moreover, the byproducts of horse slaughter – especially blood, sludge, and waste water – may contaminate groundwater used for consumption and even enter the food chain when sludge is distributed on crops.[156] Consequently, even individuals who choose not to eat horse meat may unintentionally be exposed to the drugs, treatments and substances listed on Exhibit 1 – all potentially harmful and all possibly entering the food and the water supply.[157]

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[151] *When Slaughter Comes to Town, supra* Note 141, at 5 ("It is entirely foreign owned, and pays no corporate taxes or export tariffs. The horse slaughter industry is economically insignificant.").

[152] *See, e.g., Life In A Slaughter Town, supra* Note 141, at 5, 10, 13.

[153] *When Slaughter Comes to Town, supra* Note 141, at 3.

[154] *Id.* at 4 (emphasis in original).

[155] *Id.*

[156] *Id.*

[157] *See generally* Section V.C, *infra*.

V. LEGAL BACKGROUND

A. Federal Regulation of Horses Slaughtered for Human Consumption Under the Federal Meat Inspection Act, 21 U.S.C. §§ 601, *et seq.*

Congress enacted the Federal Meat Inspection Act ("FMIA") in 1907 in order to protect the food supply and ensure people do not experience any untoward effects from eating meat.[158] The FMIA prohibits the sale, receipt, and transport of "adulterated" carcasses and meat.[159] Several factors that render meat legally adulterated are prevalent in American horses, and as a consequence of horse slaughter practices, as explained in detail here and in Section VI.A. below.[160]

The Secretary of Agriculture has delegated to the FSIS the authority to exercise USDA's functions under the FMIA.[161] The FSIS primarily fulfills those duties by performing mandatory inspections of all animals processed at U.S. slaughterhouses, before and after slaughter, to ensure that no adulterated meat enters the human food supply.[162] Meat that does not pass inspection cannot be sold, received or transported.[163] If horse slaughter begins again in America, each horse presented for slaughter will need to be screened for exposure to the many banned and dangerous substances listed in Exhibit 1, as well as other drugs and conditions that could render them adulterated under the FMIA.[164]

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[158] 21 U.S.C. § 602.

[159] *Id.* § 610(c).

[160] *Id.* § 603(m)(1),(2)(A),(C),(3).

[161] 9 C.F.R. § 300.2. Pursuant to this delegation, the FSIS Administrator may take any action, authorize any expenditure, and promulgate any rule, regulation, or order that is lawful under the FMIA, Humane Slaughter Act, 7 U.S.C. §§ 1901-1906, and related statutes. *See* 7 C.F.R. §§ 2.18, 2.53.

[162] 9 C.F.R. § 302.1 (mandating inspection, with a few exceptions, of every establishment "in which livestock are slaughtered for transportation or sale as articles of commerce . . ."); 21 U.S.C. § 603 (mandating ante-mortem examination and inspection of animals intended for use as food); 21 U.S.C. § 604 (mandating post-mortem examination and inspection of animals intended for use as food).

[163] 21 U.S.C. § 610(c)(2).

[164] *Id.* § 601(j) (defining "meat food product" to include equines).

1. Meat from Horses Administered Certain Drugs or That Contains Certain Food Additives or Drug Residues Is Adulterated and Cannot Be Sold Legally.

Under the FMIA, "adulterated" meats are unsafe and cannot be sold to the public.[165] The FSIS establishes, and enforces, standards for determining whether meat is adulterated.[166] For purposes of the Petition's requests, horse meat is adulterated under the FMIA if it (1) contains any added substance that may render it "injurious to health,"[167] (2) has any added substance that may make it "unfit for human food,"[168] or (3) it is "otherwise unfit for food."[169]

These definitions apply directly to horse meat and the requests in this Petition. Under the FMIA definitions just stated and FSIS regulations, horse meat will be adulterated if (1) it comes from a horse who was directly administered any of the products on Exhibit 1 that are prohibited for use in horses who will become food, unfit for use in horses, and illegal for use in horses;[170] (2) it bears or contains any food additive declared unsafe by the FDA;[171] (3) it contains a veterinary drug residue in an amount that exceeds FDA tolerance levels;[172] or (4) it is from a

[165] *Id.* § 610(c).

[166] 9 C.F.R. § 300.2; 7 C.F.R. § 2.7, 2.18, and 2.53.

[167] 21 U.S.C. § 601(m)(1) (Meat is adulterated "if it bears or contains any [added] poisonous or deleterious substance which may render it injurious to health. . . .").

[168] *Id.* § 601(m)(2)(A) (Meat is adulterated "if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food. . . .").

[169] *Id.* § 601(m)(3) (meat is adulterated if it is "for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food. . . .").

[170] *See* 21 C.F.R. §§ 520, 522, 524, 526, 529 (prohibiting the use of dozens of "new animal drugs" in animals intended for human consumption); 21 U.S.C. § 601(m)(2)(A) (establishing that meat is adulterated if "unfit for human food"), (m)(3) (establishing that meat is adulterated if "otherwise unfit for human food"); *see also* FSIS Notice 14-11, Inspection Responsibilities When a Chemical Residue Does Not Have an Established Tolerance (USDA 2011) (attached hereto as Exh. 38) (requiring that an entire carcass must be condemned if a muscle tissue residue sample tests positive for a substance for which there is no established tolerance).

[171] 21 U.S.C. § 601(m)(2)(C); *id.* § 348(a)(2); *see also* FDA Food Additive Status List, (H.H.S. 2012), *available at* http://www.fda.gov/food/foodingredientspackaging/foodadditives/foodadditivelistings/ucm091048.htm (listing all FDA food additives and their status) (attached hereto as Exh. 39).

[172] 9 C.F.R. § 318.20 (adopting drug residue tolerance levels established by the FDA); 21 C.F.R. §§ 520, 522, 524, 526, 529 (establishing drug residue tolerance levels); *see also* FSIS Notice 14-11, *supra* Note 170.

horse who was administered a substance, including those listed in Exhibit 1, that renders it "injurious to health" and unsafe for human consumption.[173]

The FSIS' findings regarding adulterated meat rely, in large part, on the FDA's determinations about the safety of certain drugs and chemicals.[174] One highly relevant group, identified throughout the Petition and in greater detail in Exhibit 1, is those substances which under federal law absolutely *cannot legally be administered* to food animals in any amount.[175] If an animal has been given any of those identified products, at any time, that animal cannot be turned into meat.[176] Any meat from such animals cannot be legally sold, is unfit for human food, and *must* be condemned.

Another relevant group of products is "food additives." Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a "food additive" is, broadly, any substance that is intended for use in the production or manufacture of a food like horse meat, unless the substance is already generally recognized as safe, or is one of the substances enumerated in 21 U.S.C. § 321(s), including a "new animal drug."[177] Meat that contains an additive is presumed unsafe and its sale

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[173] *See* 21 U.S.C. § 601(m)(1) ("injurious to health"); 21 C.F.R. §§ 520, 522, 524, 526, 529 (prohibiting the use of dozens of "new animal drugs" in animals intended for human consumption); FSIS Notice 14-11, *supra* Note 170 (requiring condemnation of meat from horses in whom substances in 21 C.F.R. §§ 520, 522, 524, 526, and 529 are present in *any* amount); Exhibit 1.

[174] *See, e.g.*, United States National Residue Program, 2011 Scheduled Sampling Plans, p. vi (USDA 2011) (attached hereto as Exh. 40) (explaining that the FSIS relies on tolerances established by the FDA); 21 U.S.C. § 601(m)(2)(C) (adopting the FDA standard for unsafe food additives); 9 C.F.R. § 318.20 (adopting drug residue tolerance levels established by the FDA).

[175] *See* C.F.R., Title 21 ("Food and Drugs"), Parts 520, 522, 524, 526, and 529.

[176] FSIS Notice 14-11, *supra* Note 170. One example of the many drugs in this category is phenylbutazone, which has five separate sections of the C.F.R. identifying different forms of the drug that are completely barred from any use in animals who become food. *See* 21 C.F.R. § 520.1720a (tablets and boluses of phenylbutazone cannot be used "in horses intended for human consumption"); *id.* § 520.1720b (granules: "Treated animals should not be slaughtered for food use."); *id.* § 520.1720c (paste: "Do not use in horses intended for human consumption."); *id.* § 520.1720d (gel: not for animals used as food); *id.* § 520.1720e (powder: cannot be used on horses used for human consumption).

[177] 21 U.S.C. § 321(s) (defining food "additive" as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing [or] manufacturing . . .), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety,

(Footnote continued on next page)

is prohibited *unless* the FDA has expressly approved all additives that may be in it.[178] If a food such as horse meat contains an additive, the FDCA and FMIA automatically deem it adulterated and unsafe unless there is in effect a regulation prescribing the conditions under which the additive may be safely used and the additive is used in conformity with the regulation.[179]

A third class of products that may render meat adulterated are those drug residues which under FSIS regulations absolutely cannot be *present* in food animals or their meat in any amount.[180] Many of the substances in Exhibit 1 also fit in this category.[181] If a horse tests positive for any of those identified drug residues, that horse cannot be turned into meat.[182] And under FSIS rules, that meat *must* be condemned.[183]

(Footnoted continued from previous page)

as having been adequately shown through scientific procedures to be safe under the conditions of its intended use").

Contrary to the facial meaning of "generally recognized as safe and effective" ("GRASE"), drugs do not easily qualify as GRASE, which requires a finding by experts based on substantial evidence – evidence of adequate and well-controlled investigations by qualified experts backed by substantial support in scientific literature – plus a determination by the fact-finder that there is a general recognition of safety and effectiveness among the qualified experts. *See, e.g.*, *United States v. Pro-Ag, Inc.*, 796 F. Supp. 1219, 1229-30 (D. Minn. 1991), *aff'd*, 968 F.2d 681 (8th Cir. 1992). All drugs approved by the FDA for some use but that fail to qualify as GRASE are "new animal drugs." *See id.* at 1230. New animal drugs are subject to the FDA's premarketing clearance process. *See id.* New animal drugs can only be marketed for purposes expressly approved by the FDA. *See* 21 U.S.C. § 360b(a)(1)(A)-(C).

[178] *See id.* § 342(a) (food additives). All drugs approved by the FDA for some use but that fail to qualify as GRASE are "new animal drugs." *See Pro-Ag, Inc.*, 796 F. Supp. at 1230. New animal drugs are subject to the FDA's premarketing clearance process. *See id.* New animal drugs can only be marketed for purposes expressly approved by the FDA. *See* 21 U.S.C. § 360b(a)(1)(A)-(C).

[179] *Id.* § 348(a)(2).

[180] 9 C.F.R. § 318.20.

[181] *See* Exhibit 1.

[182] *See* 9 C.F.R. § 318.20; C.F.R., Title 21 ("Food and Drugs"), Parts 520, 522, 524, 526, and 529.

[183] FSIS Notice 14-11, *supra* Note 170; 9 C.F.R. § 318.20; *id.* § 603(m)(1), (2)(A), (2)(C), (3); *id.* § 603(c).

A final relevant group of products is those, identified throughout the Petition, which render meat unsafe for human consumption or "injurious to health."[184] Many of the drugs and substances on Exhibit 1 qualify, as set out in the descriptions of the drugs in Exhibit 1. If an animal has ever been given any of those identified products, that animal cannot be turned into meat.[185] And under the FMIA, that meat *must* be condemned.[186]

2. The FSIS Screens Food Animals for Disease and Exposure to Dangerous Substances.

The FSIS, along with the FDA, is responsible for inspecting animals and their flesh to protect consumers from harmful residues.[187] Specifically, the FSIS conducts its investigations of potentially harmful residues, including food additives and veterinary drugs,[188] in animals who will be used for food, to help the FDA determine the parties responsible for violations and for introducing adulterated food into interstate commerce.[189] When conducting ante-mortem inspections and examinations, FSIS inspectors observe the animals at rest and in motion, focusing on their overall condition, their behavior, and the existence of any swelling or external abnormalities.[190] If an animal does not show signs of disease or abnormality and appears fit for

[184] *See* 21 U.S.C. § 601(m)(1) ("injurious to health"); C.F.R., Title 21 ("Food and Drugs"), Parts 520, 522, 524, 526, and 529 (listing tolerances for dozens of veterinary drugs, including those banned from use in "horses intended for human consumption"); Exhibit 1.

[185] *See* 21 U.S.C. § 601(m)(1) ("injurious to health"); C.F.R., Title 21 ("Food and Drugs"), Parts 520, 522, 524, 526, and 529 (listing tolerances for dozens of veterinary drugs, including those banned from use in "horses intended for human consumption"); Exhibit 1.

[186] *See* 21 U.S.C. § 601(m)(1); *id.* § 610(c)(2).

[187] FDA Directive 7371.006, *supra* Note 101 (explaining that the FSIS is responsible for initial inspections and then reports drug residue violations to the FDA to follow up). FSIS jurisdiction over the safety of all meat sold to the public extends not only to meat but also to live animals who will become meat. 21 U.S.C. § 603 (granting jurisdiction over food animals); *id.* § 604 (granting jurisdiction over flesh of food animals).

[188] All "new animal drugs" are "veterinary drugs."

[189] FDA Directive 7371.006, *supra* Note 101, at 6. The FSIS also obtains names of producers and other parties involved in the sale of the animal at issue, informs producers of violations, and maintains Residue Repeat Violator Lists. Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs, p. 68 (USDA 2011). (attached hereto as Exh. 41); United States National Residue Program, *supra* Note 174, at vi.

[190] FSIS Directive 6100.1, Ante-Mortem Livestock Inspection, p. 4 (USDA 2009) (attached hereto as Exh. 42).

slaughter, the animal can be slaughtered.[191] And when conducting post-mortem inspections and examinations, FSIS inspectors inspect and observe the carcasses' physical condition, looking for (among other things) inflammation or swelling, pathology in the lymph nodes, cysts, and parasites,[192] and examine various organs and body parts.[193]

To ensure that slaughter establishments control harmful drug residues and keep the food supply safe, the FSIS executes the National Residue Program (the "NRP").[194] Under the NRP, the FSIS is responsible for collecting tissue samples at the ante- and post-mortem inspection stages to screen for contamination, comparing the amounts of detected substances to tolerances (if any exist) established by the FDA and EPA, and preventing adulterated meat from entering the food supply.[195] The FSIS engages in two types of testing – (1) "Scheduled Sampling," in which inspectors apply statistical sampling methods and randomly collect tissue samples from a pre-designated number of different types of animals who have passed ante-mortem inspection,[196] and (2) "Inspector Generated Sampling," in which inspectors collect tissue samples when they have reason to believe that a violative residue is present.[197]

Each calendar year, various federal agencies, including the FSIS, FDA, and EPA, create the Scheduled Sampling Plan,[198] deciding "which chemical compounds are tested in which food animals" and weighing practical considerations such as FSIS laboratory capacity and analytical

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[191] *Id.* at 5.

[192] FSIS Directive 6100.2, Post-Mortem Livestock Inspection, p. 6 (USDA 2007) (attached hereto as Exh. 43) (describing post-mortem inspection of cattle).

[193] *Id.* at 7.

[194] FSIS Directive 10,800.1, Procedures for Residue Sampling, Testing, and Other Responsibilities for the National Residue Program, p. 2 (USDA 2007) (attached hereto as Exh. 44); United States National Residue Program, *supra* Note 174, at vii.

[195] Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs, *supra* Note 189, at 67.

[196] *Id.* at 69; FSIS Notice 40-11, Instructions for Carcass Selection for the National Residue Program Scheduled Samples (attached hereto as Exh. 45).

[197] FSIS Directive 10,800.1, *supra* Note 194, at 10; FSIS Notice 40-11, *supra* Note 196. A "violative residue" is residue from a substance in excess of the permitted amount under the FMIA, FDCA, or related FSIS or FDA regulations.

[198] The FSIS publishes finalized Scheduled Sampling Plans each year in the "Blue Book."

methods.[199] The agencies devise the plan based on samples from the NRP, information accumulated during previous investigations, and veterinary inventories completed during on-farm visits.[200] The agencies determine which chemical compounds put the human food supply at risk, use algorithms to rank the compounds, pair the compounds with appropriate products derived from food animals, and establish the number of samples to collect.[201] Because statistical evidence of violation rates is not available for many potentially tested compounds, the FSIS must estimate the overall violation rates for these compounds.[202] The program is inexact, even for its most controlled subjects. Many dangerous substances are not tested for at all. In 2006 and 2007, when horses were slaughtered for human consumption and tested under the Scheduled Sampling Plan, horses were only tested for *11 of the 115* commonly administered drugs listed in Exhibit 1.[203]

The Inspector Generated Sampling Program complements the Scheduled Sampling Program, requiring inspectors to collect tissue samples every time there is reason to believe that a violative residue is present.[204] If a concern arises about a violative residue, the FSIS conducts rapid, in-plant screening tests of the suspicious tissue.[205] This review is limited to triggers such as evidence of acute disease, questionable production practices, known herd history, relevant

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[199] United States National Residue Program, *supra* Note 174, at vi, 25.

[200] *Id.* at vi.

[201] *Id.* at 1.

[202] *Id.* at 21.

[203] *See* 2006 FSIS National Residue Program Data (USDA 2007) (attached hereto as Exh. 46); 2007 FSIS National Residue Program Data (USDA 2008) (attached hereto as Exh. 47); Exhibit 1.

[204] *See* FSIS Directive 10,800.1 *supra* Note 194, at 11 ("There are no exceptions to this direction. Inspection program personnel are to take a sample of any tissue that they believe may contain a violative level of chemical residue.").

[205] FSIS Directive 10,800.1, *supra* Note 194, at 11. Inspectors administer the Fast Antimicrobial Screen Test ("FAST") when they suspect illegal levels of antimicrobial drug residues and the Kidney Inhibition Screen (KIS™ Test) when they suspect illegal levels of antibiotics. Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs, *supra* Note 189, at 69-70. The FAST and KIS™ Test are "used to more closely monitor producers and others who are known historically to have marketed animals with violative concentrations of antimicrobial residues." *Id.*

environmental exposure, and threats to homeland security.[206] Further, FSIS inspectors must collect and test tissue from all animals identified as "U.S. Suspect" during ante-mortem inspection.[207]

If an in-plant screening is positive, the inspector sends the liver, kidney, and muscle tissues to an FSIS laboratory for further analysis.[208] If the in-plant screening is negative, the inspector must determine whether there is a reason to suspect that a violative residue other than an antimicrobial drug residue is present in the tissue.[209] Notably, the in-plant screen tests do not detect non-steroidal anti-inflammatory drugs, many of which can never be given to food animals.[210] Accordingly, only if inspectors suspect the use of these drugs, must they take tissue samples and retain the carcasses until receiving laboratory testing results.[211] If an animal's tissue tests positive for violative residues, the inspectors must condemn the carcass and all parts from an animal whose muscle tissue or fat contains a residue violation.[212] Moreover, FSIS inspectors must condemn the entire carcass if a sample collected and analyzed under the NRP is positive and "there is no FDA or EPA established tolerance for the identified residue in muscle,"[213] which describes over fifty of the drugs listed on Exhibit 1.

The slaughter establishments themselves are also responsible for ensuring the safety of the food supply. Every slaughterhouse must conduct a hazard analysis to determine the food

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[206] FSIS Directive 10,220.3, Using the Fast Antimicrobial Screen Test (FAST) to Detect Antimicrobial Drug Residues in Cattle and Swine, p. 2 (attached hereto as Exh. 48). Additional indicia of the need to test include mastitis, metritis, peritonitis, surgery, injection sites, pneumonia, pleuritis, pericarditis, endocarditis, septicemia, pyemia, or generalized disease, injury or inflammatory conditions, acute cellulitis or other acute inflammations, beta-agonist, signs of treatment. *Id.* at 3-4.

[207] *Id.* at 2.

[208] FSIS Directive 10,800.1, *supra* Note 194, at 11.

[209] *Id.*

[210] *See, e.g.*, FSIS Directive 10,800.1, *supra* Note 194, at 11; Exhibit 1 (Firocoxib, Flunixin, Ketoprofen, Phenylbutazone).

[211] FSIS Directive 10,220.3, *supra* Note 206, at 4.

[212] FSIS Directive 10,800.1, *supra* Note 194, at 17.

[213] FSIS Notice 14-11, *supra* Note 170.

safety hazards reasonably likely to occur in the production process and identify measures to prevent those hazards from occurring.[214] Examples of food safety hazards include the presence of drug residues and unapproved food additives in food animals and their meat.[215] After conducting a hazard analysis, each establishment must produce a Hazard Analysis and Critical Control Points ("HACCP") plan that lists food safety hazards which it must prevent or minimize and the processes or steps it can take to control each hazard.[216] The facilities are responsible not only for food safety hazards they introduce to the production process but also those introduced outside the establishment, including those that occur before entry into the establishment.[217] Failure to develop and implement an HACCP plan may render meat products produced by an establishment adulterated.[218]

3. Agency Reports Describe FSIS Screening of Animals and Flesh for Banned Substances as Inadequate.

In multiple respects directly relevant to the Petition and horse slaughter issues, current NRP sampling is inadequate. The scheduling algorithm is based on a "one size fits all" strategy and has not been updated for almost a decade.[219] And although the NRP is "resource intensive," it provides the FSIS with minimal information on the "true chemical residue burden" in inspected meat.[220] Further, the NRP is "slow to respond to emerging residue issues."[221] In sum, according to the USDA's own report on the primary residue inspection program for which FSIS is responsible, the sampling regime that American consumers rely on to keep unsafe drug residues and food additives out of their meat is both expensive and ineffective, yields insufficient

[214] 9 C.F.R. § 417.2(a)(1).

[215] *Id.* § 417.2(a)(3)(v), (ix).

[216] *Id.* § 417.2(c).

[217] *Id.*

[218] *Id.* § 417.2(e).

[219] Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs, *supra* Note 189, at 71.

[220] *Id.*

[221] *Id.*

information on risks to meat in the nation's food supply, and has not been updated in response to evolving threats.[222]

FDA investigations based on FSIS reports of tissue residue violations are also inadequate. The FSIS reports tissue residue violations to the FDA on a "single-animal basis,"[223] providing very limited information on a very limited number of animals. Because FSIS analysis of tissue samples may be restricted to the identification of only a single drug, food animals that (1) contain violative residues of multiple drugs (like horses often will), (2) have been exposed to hundreds of drugs, such as those listed in Exhibit 1, that are either banned completely and/or that are not tested for by FSIS at all, and (3) are tested by the FSIS, may not be reported to the FDA to pursue enforcement measures.[224] Put differently, meat from an animal that contains residue of a dangerous violative drug and is tested by the FSIS for a tissue residue violation is unlikely to be discovered under the "single-drug" testing, which means there may never be an FDA investigation or enforcement action against the producer.[225]

If the FSIS is aware of a first-time violation that does not evidence the presence of particularly dangerous drugs, the intentional misuse of a drug, or a complete disregard for withdrawal periods, "*resource constraints do not allow for an FDA investigation.*"[226] In other words, there are an endless number of situations – known and unknown – where animals will be contaminated with toxic drugs, the FSIS will have knowledge of the contamination, and the FDA will have no ability to evaluate the dangers for consumers.[227] There are certainly an equally

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[222] *See id.*

[223] FDA Directive 7371.006, *supra* Note 101, at 18 (H.H.S. 2005).

[224] *See id.*

[225] The assurance of health threats under this testing regime is apparent with respect to horses based on the facts presented in the Petition, because every horse is given a long list of substances, on a regular basis, that are absolutely prohibited, not tested for, or undetectable. The current protocols, and likely any affordable and workable process, virtually guarantee that adulterated horse meat would travel through the slaughterhouses without detection, if the requested rules are not put in place.

[226] FDA Directive 7371.006, *supra* Note 101, at 10 (emphasis in original).

[227] *See id.* at 18.

great number of circumstances that the FSIS will never be able to identify, and that involve animals whose meat is destined for human consumption.

The FSIS is currently – even before any horses are added to the slaughter lines – unable to adequately monitor most animals slaughtered for human consumption in a manner that provides any assurance of a safe food supply. According to a 2010 report from the USDA's Office of the Inspector General, the FSIS NRP for cows was not "accomplishing its mission of monitoring the food supply for harmful residues."[228] Not only did the FSIS, FDA, and EPA fail to establish thresholds for many dangerous substances which have been found in meat, but the FSIS failed to recall meat when tests confirmed the presence of excessive amounts of veterinary drugs.[229] According to the Report, the FSIS' failure to recall adulterated beef makes it clear that the responsible federal agencies must strengthen preventative controls over contaminated animals currently traveling through the system.[230] Consequently, the Inspector General made multiple recommendations to the FSIS, FDA, and EPA, including the following: improve coordination among the agencies, develop plans to ensure adequate resources for the NRP, improve sampling and testing methodologies, canvass the drug industry and other experts for new substances to test for, develop incentives to prevent slaughter facilities from releasing potentially adulterated meat and to get plants to voluntarily trace and recall tainted meat, and modernize the testing process.[231]

The lack of a reliable identification system for food animals further hinders the ability of the FSIS to perform its mandate. In noting that a significant portion of violations results from slaughter facilities purchasing animals from sources with a history of providing animals with "drugs in their system," the Report recommended that slaughter plants be required to identify the

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[228] USDA Office of the Inspector General, Audit Report 24601-08-KC, FSIS National Residue Program for Cattle ("*OIG Report*"), p. 1 (2010), *available at* http://www.usda.gov/oig/webdocs/24601-08-KC.pdf (attached hereto as Exh. 49).

[229] *Id.* at 1.

[230] *Id. at* 28.

[231] *Id.* at 5-6.

producers of their cows.[232] Without knowledge of the cows' origins, the inspectors are unable to identify the source of the violation, trace the violation to the producer's practices, and preclude purchases of animals from repeat violators.[233] Thus, even with cows, raised in a regimented and highly-regulated system from birth, it is quite difficult to identify the source of adulterated animals, and meat, because the animals (especially dairy cows) pass between several buyers before their slaughter.[234] And while the FSIS recently posted a list on its website identifying suppliers of tainted cows, this list is of little use to slaughter facilities when their animals' records are insufficient or nonexistent, and because the intervening livestock auctions, sales facilities, and trading eliminate the ability to assuredly list slaughtered animals' prior owners.[235] If slaughter facilities do not receive producer identification for each animal before slaughter, they do not know which animals to subject to additional testing.[236] This failure of identification results in wasted resources and a greater likelihood of adulterated meat entering the marketplace and being purchased and consumed.[237]

This is the situation now, *without* horses in the slaughter mix. It requires no speculation to see that the facts of American horses' lives (documented in detail in Sections III.A.-D.) will decimate any possibility of adequate screening, testing, and investigation for adulterated horse meat by the FSIS under the FMIA.

4. Congress Prohibited FSIS Inspections of Horse Slaughter Plants from 2006 to 2011.

Until 2006, FSIS carried out inspections of horse slaughter plants. In an amendment to the 2006 Agricultural Appropriations Act, on November 10, 2005, Congress withdrew funding for the inspection of horses transported for slaughter, and at slaughterhouses where horses were

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[232] *Id.* at 26-27.
[233] *Id.* at 27.
[234] *Id.* at 27
[235] *Id.*
[236] *Id.*
[237] *See id.*

going to be slaughtered for human consumption.[238] This was intended to effectively end horse slaughter for human consumption in America.[239] The funding prohibition was reinstated annually through 2011.

The horse slaughter industry first responded by trying to circumvent the Congressional act, working together with the FSIS to establish a set of "fee-for-service" inspections, which would allow the slaughter to continue.[240] Even though Congress plainly wanted to end horse slaughter in America, not just save some money, the slaughterers convinced FSIS to take their money and continue the inspections.[241]

The fee-for-service program did not last. First a federal court held that the program was invalid,[242] once again ending horse slaughter for human consumption in America. In 2007, the last three American facilities slaughtering horses for human consumption were shut down,[243] and in 2008 the fee-for-service inspections formally ended when Congress withdrew funding even for that program.[244]

Since 2006, when the in-country commercial processing of horses for human food production in America was prohibited, American horses have continued to be turned into meat. Trucked across the borders, American horses are now slaughtered for meat in Canadian and Mexican slaughterhouses in greater numbers than before the ban on in-country slaughter. But

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[238] Pub. L. 109-97, § 794, 119 Stat. 2120, 2164 (A.R. 51).

[239] *The Humane Society of the United States v. Johanns*, 520 F. Supp. 2d 8, 19, (D.D.C. 2007); *see discussion* Note 239.

[240] *Id.* at 11. The USDA program was part of the Agricultural Marketing Act, which has been used for inspection of wild animals. United States Government Accountability Office, Report to Congressional Committees, "Horse Welfare: Action Needed to Address Unintended Consequences From Cessation of Domestic Slaughter," GAO-11-228 (June 2011) ("*GAO Report*"), at 3 n.2 (attached hereto as Exh. 50).

[241] *Id.*

[242] *Id.* at 12.

[243] *Cavel Int'l., Inc. v. Madigan, supra* Note 19; *Empacadora de Carnes de Fresnillo, S.A. de C.V. v. Curry,* 476 F.3d 326 (5th Cir. 2007).

[244] *GAO Report, supra* Note 240, at 3.

that could soon change, given the recent appropriation of funds for inspection of horses going to slaughter for human food purposes, discussed in more detail in the following Section.

5. In 2011, Congress Removed Its Prohibition on Inspections of Horse Slaughter Facilities

In November 2011, at least partly in response to an inconclusive report by the federal Government Accountability Office,[245] Congress removed the prohibition on funding of FSIS inspections for horse slaughter within America.[246] For the first time in approximately five years, funding is available to inspect horse slaughter operations, despite a growing national revulsion of the possibility.[247] But it is also clear that if any horse slaughter plant desires to open, or any existing facility wants to convert to begin slaughtering horses as part or all of its business, the FSIS must engage in a thorough environmental assessment process before the plant begins its horse slaughter operations.[248]

Regardless of whether slaughter of horses begins in earnest in America, Petitioners have filed this Petition because of the immediate need for rules to be adopted to remove the danger of the potential adverse health consequences described above. American horses continue to be eaten in other countries, and the FSIS should create rules to be sure we are not exporting death and disease around the globe.

6. Pending Legislation May Permanently Ban Horse Slaughter for Human Consumption

The national attention on the horse slaughter issue is indisputable. In reaction to the appropriations bill, the horse slaughter industry began to mobilize in order to begin the killing of

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[245] *See generally id.*

[246] 2011 FD H.B. 2112 (NS) (H.R. 2112).

[247] *See, e.g., ASPCA Survey, supra* Note 22.

[248] This issue is discussed in detail in Section V.C., *infra*. This is the holding of *The Humane Society of the United States v. Johanns*, *supra* Note 239, discussed in greater detail below. *See also* Letter from Jonathan R. Lovvorn, Senior Vice President, The Humane Society of the United States, to Secretary of Agriculture Thomas J. Vilsack (Feb. 1, 2012), *available at* http://www.humanesociety.org/assets/pdfs/horse/usda_horse_slaughter_let_020112.pdf ("*Lovvorn Letter*") (attached hereto as Exh. 51).

American horses on American soil, maybe even for Americans to consume.[249] At the same time, the opposition legislation is mounting. For example, Congress is considering a bill to end horse slaughter completely,[250] and a different bill to limit the cruel conditions of transport for horses destined for foreign slaughter.[251] Even in Canada, where horse slaughter is ongoing and big business, a bill has been introduced which would prohibit import or export of horse meat, or of horses for slaughter for human consumption, as well as the transport of horses across province borders, where the horses are to be slaughtered for human consumption.[252]

B. Federal Regulation of Horses Slaughtered for Human Consumption under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*

Congress enacted the FDCA in order to guarantee the safety of food for the consuming public, and created the FDA to fulfill this purpose.[253] As compared with FSIS, the FDA agency maintains an independent and parallel set of obligations with respect to food animal and meat safety. FDA and FSIS have separate but equal responsibilities in connection with animals who will become meat, and in connection with the meat if it is produced.[254] When harmful substances are present in foods, the FDA must enact rules and regulations that provide procedures to determine which foods contain these substances or are otherwise unsafe.[255] Among other responsibilities, the FDA must approve all food additives.[256] If food additives

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[249] Besides forming a group ready to begin organizing the industry, the horse slaughter proponents introduced bills like Oklahoma's HB 2758, which would allow a tax credit for construction of new horse slaughterhouses, or modification of existing slaughterhouses to accommodate horse slaughter.

[250] American Horse Slaughter Prevention Act of 2011, SB 1176/H.R. 2966.

[251] Horse Transportation Safety Act of 2011, SB 1281/H.R. 7.

[252] Bill C-322 ("An Act to amend the Health of Animals Act and the Meat Inspection Act (slaughter of horses for human consumption)").

[253] 21 U.S.C. § 393.

[254] FDA Directive 7371.006, *supra* Note 101, p. 6.

[255] 21 U.S.C. at § 342.

[256] *See id.* at § 348; *see also* 21 C.F.R. § 570.38 (explaining the process for determining whether a substance is a food additive); FDA Food Additive Status List, (H.H.S. 2012), *supra* Note 171.

cannot be safely used, then the FDA must prohibit their presence in food or remove the offending products from the marketplace.[257]

The FDA also must identify and distinguish between drugs which are allowed, and prohibited, for use in animals that will be slaughtered for meat.[258] For example, 21 C.F.R. Sections 520.23-520.264 list dosage limits for drugs administered orally to animals. Many of the drugs listed have *no* dosage limits because they are completely prohibited and can never be administered to animals intended for human consumption. Exhibit 1 to the Petition provides a list of dangerous, unsafe, or potentially harmful drugs, many of which fall into the "completely prohibited" category; that is, once a horse has been treated with one of these chemicals, that horse can *never* be used for meat, because of the potential dangers to consumers. As previously mentioned, phenylbutazone has five different regulations prohibiting its use in animals who become food.[259] A large number of animal drugs regulated by the FDA and included on Exhibit 1 simply cannot, under any circumstances, be administered to animals slaughtered for human consumption. Exhibit 1 includes notations of over fifty drugs that have been so identified. As explained above, most of these drugs are commonly given to companion horses and horses used in sport and competition, throughout their lives, without consideration of their ultimate end as meat.[260]

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[257] 21 U.S.C. §§ 331(a)-(c), § 348.

[258] *See, e.g.*, 21 C.F.R. §§ 520, 522, 524, 526, 529; FDA Green Book On-Line, (H.H.S. 2012), *available at* http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/ucm042847.htm (attached hereto as Exh. 52).

[259] *See* 21 C.F.R. § 520.1720a (tablets and boluses of phenylbutazone cannot be used "in horses intended for human consumption"); *id.* § 520.1720b (granules: "Treated animals should not be slaughtered for food use."); *id.* § 520.1720c (paste: "Do not use in horses intended for human consumption."); *id.* § 520.1720d (gel: not for animals used as food); *id.* § 520.1720e (powder: cannot be used on horses used for human consumption).

[260] Wood Dec., Exh. 2, ¶¶ 6-7; Larson Dec., Exh. 3, ¶ 7; Pavlis Dec., Exh. 4, ¶¶ 4-5; Parker Dec., Exh. 5, ¶¶ 7-9.

1. Horse Meat is Adulterated under the FDCA and Cannot Be Sold Legally.

The FDA, like the FSIS, is tasked within its own regulatory sphere with keeping harmful foods from the consuming public.[261] And like the FSIS, the FDA prohibits "adulterated" foods, which are unsafe and cannot be sold to the public.[262] The FDCA establishes the FDA standard for adulteration and the basis upon which the FDA may make a finding of adulteration.[263] Food is adulterated if, among other reasons, "it is or if it bears or contains . . . any food additive that is unsafe" or if it contains "any new animal drug (or conversion product thereof) that is unsafe" or "if it is otherwise unfit for food. . . ."[264] For purposes of the FDCA, a food "additive" is, broadly, any substance that may be used in such a way that it becomes a component part of the food, unless (1) the substance is already generally recognized as safe; or (2) it is one of the substances enumerated in the statute, 21 U.S.C. § 201(s), including a "new animal drug." Specifically, a food "additive" is

> any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . , if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures to be safe under the conditions of its intended use.[265]

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[261] The Food Safety Modernization Act ("FSMA"), a part of the FDCA, adds a further level of protection under FDA's jurisdiction. Pub. Law 111-353 (2011); 21 U.S.C. § 350c, *et seq.* The FSMA amends the FDCA and "aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it." FDA, "About FSMA," *available at* http://www.fda.gov/Food/FoodSafety/FSMA/ucm247546.htm (last accessed March 22, 2012) (attached hereto as Exh. 53). To that end, the FSMA contains a number of provisions aimed at improving FDA's ability to stop food safety problems before they occur, by constructing additional safeguards at the level of food manufacturing, packaging and processing plants. In the context of horse slaughter, this will entail registration of horse slaughter facilities and the creation of special protocols and procedures just for those operations.

[262] 21 U.S.C. §§ 331(a), 342.

[263] *Id.*; *see also id.* § 348 (establishing the process for regulating food additives); 21 C.F.R. § 570.38(r).

[264] 21 U.S.C. § 342(a)(2)(C)-(a)(3); *see also id.* § 348 (food additives); § 360b (new animal drugs).

[265] *Id.* § 321(s).

"New animal drugs" are defined as drugs intended for use for nonhuman animals that are not "generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof."[266]

Horse meat that contains an additive or comes from a horse that was treated with a new animal drug is presumed unsafe under the FDCA, and its sale is prohibited unless the FDA has expressly approved all the additives or new animal drugs that may be present in the meat.[267] If a food like horse meat contains an additive, the FDCA *automatically* deems it unfit for human food unless there is in effect a regulation prescribing the conditions under which the additive may be safely used and the additive is used in conformity with that regulation.[268] Similarly, if horse meat contains a new animal drug, it is *automatically* deemed adulterated and unsafe unless there is in effect an approved application for use of the drug and the use conforms to the approved application.[269]

For food additives and new animal drugs to be approved by the FDA, they must satisfy a myriad of procedural requirements (described in the following text) prescribed by FDCA and FDA regulations. Any person may petition the Secretary of the Department of Health and Human Services ("HHS Secretary") for issuance of a regulation prescribing the conditions under which an additive may be safely used.[270] The HHS Secretary may not issue a regulation until determining that the proposed use of the food additive will be safe, based on consideration of the probable consumption of the additive, the cumulative effects of the additive in the diet of persons and animals, and other safety factors used by experts in reaching such conclusions.[271]

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[266] *Id.* § 321(v)(1); *see also id.* § 360b(a)(1). *See supra* Note 177, for detailed discussion of "GRASE" products.

[267] *See* 21 U.S.C. § 342(a) (food additives); § 360b(a)(1) (new animal drugs).

[268] *Id.* § 348(a)(2). Other exceptions (irrelevant to the issues raised in the Petition) exist for additives "intended solely for investigational use by qualified experts" and additives that are "food contact substances." *Id.* § 348(a)(1), (3).

[269] *Id.* § 360b(a)(1)(A). Exceptions also exist for conditionally approved applications, which are available only for "a minor use or a minor species," *id.* § 360ccc, neither of which are at issue here. *See id.* § 360b(a)(B)-(C); *id.* § 321(oo) (horses are not a "minor species").

[270] *Id.* § 348(b)(1).

[271] *Id.* § 348(c)(3)(A), (c)(5).

Similarly, any person may file an application with the HHS Secretary for use of a new animal drug.[272] If the HHS Secretary makes any one of nine types of findings, including findings of inadequate testing, inadequate methods of production, inadequate information in the application, lack of proof of safety, or inducement of cancer, the HHS Secretary must deny the application.[273]

2. The FDA Screens Animals for Exposure to Banned Substances.

The FDA has jurisdiction over the safety of all food sold to the public, including meat and the live animals[274] who will become meat.[275] The FDA conducts investigations of potentially harmful residues in animals who will be used for food, including new animal drugs, to determine the parties responsible for any tissue residue violation and for introducing the adulterated food into interstate commerce.[276]

According to the FDA, most violations involving illegal drug residues result from animal producers' failure to comply with label warnings, such as those absolute prohibitions on the use of certain drugs for food animals identified in Exhibit 1, and their use of drugs for unapproved

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[272] *Id.* § 360b(b)(1).

[273] *Id.* § 360b(c)(1). For detailed procedures on new animal drug applications, see 21 C.F.R. § 514.

[274] *See* 21 U.S.C. § 321(f)(1), (3) (defining "food" to include "articles used for food or drink for man" and "articles used for components of any such article"); *Otis McAllister & Co. v. U.S.*, 194 F.2d 386, 387 (5th Cir. 1952) (holding that unprocessed coffee beans are food); *United States v. Tuente Livestock*, 888 F. Supp. 1416, 1423 (S.D. Ohio 1995) (holding that the FDA has the authority under the FDCA to inspect live hogs).

[275] 21 U.S.C. § 679 (declaring that the FDA has the full authority conferred by the FDCA to regulate food, notwithstanding the FMIA's conferral of authority over meat inspection to the USDA and FSIS). The FDA and FSIS share responsibility for the safety of meat, including horse meat, intended for human consumption, and it is the FDA that is responsible for ensuring that meat is safe before, and once, it enters the marketplace. *See* , *e.g.*, FDA Directive 565.100, FDA Jurisdiction Over Meat and Poultry Products (H.H.S. 2005), *available at* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074588.htm (attached hereto as Exh. 54) (explaining that food additives used in meat are subject to both FDA and USDA jurisdiction); FSIS Factsheet, Additives in Meat and Poultry Products (USDA 2008), *available at* http://www.fsis.usda.gov/Factsheets/Additives_in_Meat_&_Poultry_Products/index.asp (attached hereto as Exh. 55) (explaining that the FSIS and FDA share responsibility for the safety of food additives used in meat); FDA Directive 7371.006, *supra* Note 101, at 49, 50 (prescribing guidelines for FDA inspection of food animals).

[276] FDA Directive 7371.006, *supra* Note 101, p. 6.

purposes.[277] Consequently, the FDA focuses on obtaining evidence of "poor husbandry practices," which would presumably include the use of substances prohibited for use in food animals.[278]

In conducting on-site investigations of potentially harmful residues in animals intended for human consumption, the FDA focuses mainly on repeat violators.[279] If resources allow, the FDA also conducts on-site inspections of first-time violators in response to FSIS reports of violative tissue residues demonstrating(1) the presence of particularly dangerous drugs in food animals, (2) the intentional misuse of a drug, or (3) a complete disregard for the withdrawal period (the "criteria").[280] If the FDA is aware of an initial residue violation but the violation does not satisfy the above criteria, FDA does not investigate.[281] Thus, FSIS is essential to preventing the dissemination of dangerous meat to the public.

3. The FDA Will Be Unable to Properly Screen Horses and Horse Meat for Exposure to Banned Substances.

As discussed in Section V.B. with respect to the FSIS, if horses are slaughtered for human consumption, it will be incumbent on the FDA to inspect the horses and their meat to ensure food safety. But success at the task will be unattainable. FDA procedures simply cannot meet the challenge, because of the untold number of exposures experienced by each horse going to slaughter, and the laundry list of prohibited and dangerous drugs to which they may have been exposed. As established above, current FDA protocols are inadequate to ensure the safety of horse meat. That is because, unlike most other animals inspected by the FDA for tissue residue violations, American horses are not raised as food, are not overseen by anyone familiar with drug prohibition and the danger of certain drugs, and their intake and exposure to drugs and other chemicals is not adequately monitored.

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[277] *Id.*

[278] *Id.* at 19.

[279] *Id.* at 10.

[280] *Id.*

[281] *Id.* (emphasis in original).

Moreover, the FDA's requirement to identify evidence of, and sanction, "poor husbandry practices," presents another insurmountable barrier with horses, as opposed to all the other species raised for human consumption.[282] Poor husbandry practices, including indiscriminate use of prohibited drugs, are certainly a cause of concern with horses as with other animals inspected by the FDA. But violations of FDA regulations will go unnoticed and forever unknown with respect to horses. Because horses are not in the market stream for most of their lives, they will be given substances unsafe for human consumption throughout their lives, while they are owned by people who do not consider their horses to be potential food. In short, the important evidence FDA needs to make its evaluations will be plainly inaccessible for horses going to slaughter.

C. Establishment of Horse Slaughter Plants Requires Environmental Review Under The National Environmental Policy Act

The National Environmental Policy Act ("NEPA") is the "basic national charter" for protecting the environment, intended to minimize risk to human health and safety, assure beneficial uses of the environment without degradation, and balance resource uses with high standards of living.[283] NEPA ensures consideration of these policy goals by requiring federal agencies to follow certain procedures in evaluating the environmental consequences of their projects prior to taking action.[284] Because of the exceptional potential for disruption of the environment caused by horse slaughter facilities, NEPA review is mandated for the establishment of new horse slaughterhouses, as well as for the conversion of existing slaughterhouses, currently processing other species, into operations involving horses.

Agencies generally must include an environmental review for every recommendation for "major Federal actions significantly affecting the quality of the human environment."[285]

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[282] *See* FDA Directive 7371.006, *supra* Note 101, pp. 19-20.

[283] 42 U.S.C. § 4331, *et seq.*; 40 C.F.R. § 1500.1.

[284] *See* 42 U.S.C. § 4332(2)(C); *City of Alexandria, Va. v. Slater*, 198 F.3d 862, 866 (D.C. Cir. 1999).

[285] 42 U.S.C. § 4332(C); *Humane Soc. of U.S. v. Johanns*, 520 F. Supp. 2d 8, 19 (D.D.C. 2007). Under the most rigorous type of review, an agency must prepare an Environmental Impact

(Footnote continued on next page)

"Actions" include adoption of official policy, such as rules and regulations, and approval of specific projects – like horse slaughter facilities – by permit or other regulatory decision.[286] Whether an action "significantly" impacts the environment depends on "context" and "intensity," including its effect on public health and safety and the degree to which the effects are controversial, among other factors.[287] Agency action "affects" the quality of the human environment if the action is the foreseeable, "legally relevant," or proximate cause of the effect.[288]

The FSIS' actions regarding horse slaughter are major Federal actions that significantly affect the quality of the human environment because (1) as established by Exhibit 1 and the Petition, most horse meat contains chemicals that are harmful to humans,[289] (2) horse slaughter operations cannot be carried out without significant negative impacts on the local environment, including the water supply,[290] (3) horse slaughter facilities detract from the quality of life in surrounding areas,[291] and (4) horse slaughter for human consumption is controversial nationally.[292]

(Footnoted continued from previous page)

Statement ("EIS"), identifying the effect of the proposed action, unavoidable adverse environmental effects, and available alternatives, among other factors. 42 U.S.C. § 4332(C); 40 C.F.R. § 1505.2. In some circumstances, an agency need not prepare a full EIS but may determine based on an "Environmental Assessment" ("EA"), a document more concise than an EIS, that the proposed action would not have a significant impact on the environment. *Pub. Citizen*, 541 U.S. at 758-59; 40 C.F.R. § 1501.4(a)-(b).

[286] 40 C.F.R. § 1508.18(b)(1), (4).

[287] *Id.* § 1508.27(a)-(b).

[288] *Dep't of Transp. v. Pub. Citizen*, 541 U.S. 752, 769 (2004) (legally relevant cause); *Metro. Edison Co. v. People Against Nuclear Energy*, 460 U.S. 766, 774 (1983) (proximate cause).

[289] *See, e.g.*, Wood Dec., Exh. 2, ¶¶ 6-7; Larson Dec., Exh. 3, ¶ 7; Pavlis Dec., Exh. 4, ¶¶ 4-5; Parker Dec., Exh. 5, ¶¶ 7-9.

[290] Sanitation workers in DeKalb, Illinois identified the Cavel plant's effluent as especially problematic, expressly because of the presence of all the drugs and dangerous substances that horses are given, such as those in Exhibit 1, that are prohibited from use in horses used for meat. *When Slaughter Comes to Town, supra* Note 141, at 4. The efforts to eliminated the byproducts of horse slaughter – blood, entrails and body parts – have led to hundreds of violations of local wastewater and environmental laws. *Id.*

[291] *See* Section IV.F., *supra*. *See also Lovvorn Letter, supra* Note 248.

[292] *ASPCA Survey, supra* Note 22.

In the *Johanns* case, the court held that "the environmental effects of horse slaughter operations themselves should have been assessed pursuant to NEPA. . . ."[293] That court's conclusion that the establishment of a horse slaughter facility merited environmental review is especially notable, because that case did not even address the core and compelling environmental concerns raised by this Petition. That is, the *Johanns* court did not have any information before it regarding the uncontrolled administration of prohibited and dangerous drugs and substances to horses throughout their lifetimes. Specifically because of the multitude of drugs given to horses during their lifetimes, both their meat and the waste created by horse slaughter creates a significant potential for a negative impact on both the environment and public health and safety. Thus, that court's determination is greatly amplified and underscored by the facts presented here: that horse slaughter involves the dissemination of an endless array of drug residues in virtually every slaughtered animal which represents an undeniable basis for triggering NEPA review. Building on the prior ruling, NEPA clearly mandates that slaughter facilities cannot begin slaughtering horses for human consumption until the FSIS prepares an EIS or EA for each facility.[294]

NEPA review is also required, as a separate matter, because the renewal of horse slaughter operations, if it occurs, will result in a change of the status quo, which is that horse slaughter has been prohibited and currently is not occurring on American soil.[295] FSIS issuance of updated rules to ensure the efficient execution of the FMIA, and FSIS approval of horse slaughter facility permit applications, if adopted, will constitute a new regulatory framework.[296]

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[293] *Johanns*, 520 F. Supp. 2d at 27.

[294] *See, e.g., id.* at 38.

[295] *See id.*

[296] *Id.*

D. European Union Laws on Horses and Horse Meat Demonstrate the Dangerous Nature of Horse Meat from American Horses

1. The European Union's Regulations Meant to Ensure the Safety of Horse Meat Illustrate the Inadequacy of American Law.

Because horses in most countries, including the United States, are not raised for food production, nations whose citizens do consume significant amounts of horse meat are concerned that imported horses and horse meat may be unsafe. In the European Union, considerable restrictions are placed on such imports.[297] In order to protect public health and avoid environmental contamination, in May 2009 the European Parliament and the Council of the European Union ("EU") adopted a regulation with respect to the importation of food-producing animals and their meat.[298] This regulation bans horse meat from horses that have been treated with any of a list of identified prohibited substances. The regulation also establishes maximum residue limits of pharmacologically active substances permitted in food-producing animals, and sets up procedures for testing those animals to ensure compliance with the regulation.[299] Pursuant to this regulation and related regulations and directives, countries exporting horses and horse meat to the EU must submit to the European Commission (the "Commission") (1) a "residue control plan" setting out guarantees equivalent to those applicable to EU member states and (2) an "action plan" with information sufficient to assess whether the importer has implemented specific measures to ensure that it does not export any contaminated animals or meat.[300]

This rule is supposed to apply to any horses for human consumption, or horse meat, sent from the U.S. and destined for the EU market. At this point, the U.S. has not put a system in place to comply with the EU requirements for an action plan. As discussed throughout the

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[297] *Residues of Veterinary Products, Third Countries*, Europa Website, *available at* http://ec.europa.eu/food/food/chemicalsafety/residues/third_countries_en.htm ("*Residues of Veterinary Products*") (attached hereto as Exh. 56).

[298] Council Regulation 470/2009, 2009 O.J. (L 152) (EC) (attached hereto as Exh. 57).

[299] *Id.* at 11, 14-15.

[300] The former requirement is derived from a 1996 Council Directive (96/23/EC), whereas the latter was established in the 2009 Regulation.

Petition, the U.S. probably cannot comply with the EU requirements because of the sources from which the American horses who become meat originate, and the impossibility of providing the required proof of medical, and medication, history.

In its residue control plan, the U.S. will be required to submit to the Commission a description of how it will ensure that horse meat and horses meant for human consumption that enter the EU market meet safety standards at least as stringent at those applicable within the EU. The EU explicitly prohibits importation of horses and horse meat that fail to meet these standards.[301]

Many of the drugs listed on Exhibit 1 to the Petition, which are regularly used on American horses without documentation, are also "prohibited substances" in the EU.[302] If American horses have ever been exposed to these substances, as well as other identified classes of drugs (certain steroid hormones and beta-agonists used for growth purposes), those horses need to be completely excluded from the food supply.[303] The Commission will only approve America's new residue control plan if the U.S. establishes a "split system" to separate horses who have been treated with those substances from those destined for export to Europe.[304] Because there is no such system in place, and because there is no way of controlling the use of these substances, meat from American horses cannot legally enter the EU or be sold there at this point in time.

If American exporters are to comply with the EU's requirements, the U.S. will need to enact detailed new legislation and regulations that meet the EU standards and govern authorization, distribution, and provision of veterinary products that may be used on all horses, at

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[301] Council Directive 96/22/EC, art. 11 (2), 1996 O.J. (L 125) 3, 7 (EC) (attached hereto as Exh. 58); Council Directive 96/23/EC, art. 29, 30, 1996 O.J. (L 125/10) (attached hereto as Exh. 59).

[302] *See* Commission Regulation (EU) No. 37/2010, Table 2 (prohibited substances include chloramphenicol, chloroform, colchicine, metronidazole).

[303] Council Directive 96/22/EC, Annexes II, III. *supra* Note 306.

[304] Council Directive 96/22/EC, art. 11 (2), 1996 O.J. (L 125) 3, 7 (EC), *supra* Note 306; *Residues of Veterinary Products, supra* Note 302.

all stages of their lives. The actual U.S. "residue control plan" will have to be submitted to the EU and must include five general elements. First, the plan must describe how the U.S. will assign the coordination and implementation of inspections to a central governmental agency that will be responsible for monitoring, data collection, and data submission to the Commission.[305] Second, the U.S. must describe for the Commission the laws governing veterinary medical products.[306] Third, the plan must list approved laboratories for residue controls, as well as the accreditation status of these laboratories.[307] Fourth, the plan must describe the rules covering collection of official samples.[308] Finally, the plan must contain details on measures to be taken in the event of infringement of the U.S. pharmacological substance limits and inspection regime.[309]

In addition to establishing a residue control plan and monitoring its results, the U.S. will also need to submit to the Commission an action plan explaining how it will implement several measures to prevent the export of unapproved horse meat. The U.S. will need to make significant changes to its regulatory framework governing the treatment, identification, and inspection of horses slaughtered and intended to be slaughtered for human consumption before resuming exportation of horse meat to the EU.

In order to comply with the EU's requirements, the U.S. must have in place or implement the five following measures. First, the U.S. must establish an identification and verification system for *all* horses intended for food production.[310] Second, horses given anabolic steroids for growth purposes, and other prohibited substances, must be identified and segregated from horses to be exported to Europe for human consumption.[311] Third, only horses with known medical

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[305] Council Directive 96/23/EC, art. 4, 1996 O.J. (L 125) 10, 12 (EC), *supra* Note 306).

[306] *Id.* art. 7 (1), 1996 O.J. (L 125) 10, 13 (EC).

[307] *Residues of Veterinary Products, supra* Note 302.

[308] Council Directive 96/23/EC, art. 7 (6), 1996 O.J. (L 125) 10, 13 (EC) *supra* Note 306.

[309] *Residues of Veterinary Products, supra* Note 302.

[310] *Id.*

[311] *Id.*

treatment histories may be slaughtered and exported to Europe as consumer-grade meat.[312] All horses must be accompanied by an identification document, which the Commission calls "passport," on which each horse's owner records all veterinary medical treatments received by each horse.[313] While the EU has given the U.S. and other horse and horse meat exporters a three-year transition period in which veterinary records need only guarantee that a horse has not been administered a banned substance (something the U.S. cannot even do now, as explained in the Petition), by 2014 all horses meant for human consumption in Europe must be accompanied by medical treatment records which span their entire life. Fourth, the U.S. must guarantee that each horse slaughtered for human consumption has never received banned substances and is free from restricted substances for the required withdrawal periods.[314] And fifth, the U.S. must regularly inspect collection centers and slaughter facilities to ensure that exporters are adhering to EU regulations on the use of veterinary products and banned substances.[315]

It is unfathomable that the U.S. regulatory regime will ever be able to track horses' lifetime medical records. American suppliers do not and cannot meet the treatment, identification, and inspection requirements established by the EU. It is impossible, based on current testing and verifications protocols, for the U.S. to guarantee that horses treated with banned or restricted substances do not enter the food supply.[316] As demonstrated by Exhibit 1 and discussed elsewhere in the Petition, hundreds of substances are banned in all animals intended for human consumption, but there is no "pre-slaughter mechanism" to identify and

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[312] *Id.*

[313] *Id.*

[314] *Residues of Veterinary Products, supra* Note 302.

[315] *Id.*

[316] *See, e.g., Phenylbutazone Health Risks, supra* Note 106. *See also* European Commission Food and Veterinary Office, Final Report of an Audit Carried Out In Canada From 23 November to 6 December 2010, Ares(2011)1101887, 12-16 ("*Canada Report 1*") (attached hereto as Exh. 60); European Commission Food and Veterinary Office, Final Report of a Mission Carried Out in Mexico From 22 November to 3 December 2010, Ares(2011)398056, 6-9 ("*Mexico Report*") (attached hereto as Exh. 61); European Commission Food and Veterinary Office, Final Report of an Audit Carried Out In Canada From 13 to 23 September 2011, Ares(2012)257268 ("*Canada Report 2*") (attached hereto as Exh. 62); *infra* Section VI.B.5.

exclude horses who have been exposed to those substances from the food supply.[317] Even if the U.S. enacts a myriad of regulatory measures to try to conform to EU regulations, it will surely fall short of the mark set by the EU, which would require the tracking of every horse sent for human consumption from the date of their birth. Because virtually no horses in America are identified as potential meat until late in their lives, when it is not feasible or possible to trace backwards, only a crystal ball can solve this problem. This bar with respect to the EU requirements is also a clear illustration of the inadequacy of current rules and regulations to protect consumers of horse meat from significant danger.

2. Certification of Horses Exported to Mexico and Canada for Slaughter under European Rules is Unreliable and Threatens the Food Supply.

Since 2007, over 100,000 American horses have been exported to slaughter facilities in Canada and Mexico each year. Those two border countries exponentially increased their imports of American horses in response to the defunding of FSIS inspections discussed in Section V.A.4. Most of the horses slaughtered in Canada and Mexico are sold to overseas markets in Europe and Asia, where horse meat is an expensive commodity. As exporters of horse meat to EU nations, the Canadian and Mexican slaughterhouses have presumably made efforts to comply with the EU regulations just discussed, which restrict imports based on the prior exposure of the horses to a variety of substances including many of those on Exhibit 1 to the Petition, as well as on the quality of the meat. But the border countries' efforts have not been enough to meet the reasonable European standards. Neither can American agencies like FSIS, which are intended to protect the consuming public from health problems arising as a result of eating problematic horse meat, fill the gap in information that jeopardizes the food supply.

The Commission recently published the results of audits undertaken in order to evaluate Canadian and Mexican compliance with EU regulations. These audits revealed that both

[317] In a recent study of phenylbutazone treatment of thoroughbred race horses, eighteen of eighteen thoroughbred horses intended for slaughter for human consumption tested positive for phenylbutazone. *Phenylbutazone Health Risks*, *supra* Note 106, at 1271. In the five-year period over which the authors examined data, over 90,000 thoroughbred race horses were sent to slaughter. *Id.*

countries' controls over the production of horse meat are inadequate to protect consumers.[318] In particular, the auditors criticized both Canada and Mexico for relying on a system that permits the American killer-buyers, typically the last owners of American horses, to certify that the horses they are selling have never been administered banned veterinary drugs and other harmful substances without providing medical records or any kind of formal guarantee.[319] This inadequate certification system, which is an unavoidable consequence of slaughtering American horses, results in the export of tainted horse flesh from the United States, through Canadian and Mexican slaughter facilities, to EU consumers.

Though almost all horses raised in the United States are administered substances listed in Exhibit 1 which render their flesh unsafe for human consumption, Canada and Mexico continue to import these horses, slaughter them, and export their meat to foreign nations. As discussed in the prior Section of the Petition, the EU currently requires horses raised in EU member states and intended for human consumption to be accompanied by a "passport," which identifies the animal's complete medical history, including the administration of veterinary drugs.[320] And (until 2014) the EU requires Americans who sell horses to Canadian or Mexican parties for slaughter to issue a declaration stating that (1) no drug or other substance that the EU prohibits for use on food animals has ever been administered to the horse and (2) withdrawal limits for other drugs administered to their horses have been met.[321] Even this limited standard provides no protection, because the person making the certification is the horse's last owner – often an individual who purchased the horse only a few days before the sale, and who bought the horse

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[318] *Canada Report 1*, *supra* Note 321; *Mexico Report*, *supra* Note 321, 6-9; *Canada Report 2*, *supra* Note 321 (stating that "for those horses imported from the United States of America for direct slaughter, the equine identification documents received were not reliable, with verification only being possible by means of residue testing.") All U.S. horses imported into Canada were for direct slaughter. *Id.* at 29. Notably, of the 30,000 horses slaughtered in Canada in 2011, 85% were from the U.S., 90% of slaughtered horses were exported, and half of all horse meat exported went to the EU. *Id.*

[319] *See generally Canada Report 1, supra* Note 321; *Mexico Report, supra* Note 321.

[320] *See* Section V.D.1, *supra; Residues of Veterinary Products, supra* Note 302.

[321] *See id.*

solely for the purpose of selling for slaughter. That recent purchaser issues an affidavit to accompany the horse in which he declares that the horse has not been administered any banned substances – but those statements are often made without knowledge of their accuracy.[322] These assertions are also made, without confirmation, by a party whose primary interest is in being able to sell the horses for profit, and whose profit would disappear if the horses had ever been administered any of the prohibited substances. And even if the final purchasers/sellers are able to provide an accurate statement regarding their knowledge of the horses' exposure to certain drugs, they cannot possibly know what drugs the horses were given over the course of their lives. Since it is a known fact that many of those drugs and substances render the horses' meat *permanently* unfit for human consumption, the system of sending American horses for slaughter, in its present form, is hopelessly, and almost irreparably, flawed and dangerous.

The sworn statements currently required under U.S., Canadian and Mexican law are completely insufficient to guarantee the fitness of the horse's flesh for human consumption.[323] While the FSIS issues an export certificate for each horse, which certifies the horse's identification, the FSIS does not require horse owners to maintain their medical records, guarantee the origin of the horse, or take responsibility for the accuracy or authenticity of the sworn statements.[324] And there is no system to verify or trace back the accuracy or authenticity of declarations accompanying horses who Mexican or Canadian border inspectors previously rejected for illness, later appear before the same inspectors as healthy, and may have just been treated with banned substances to overcome their recent illness.[325] Consequently, the interim system mandated by the EU and established by Canada and Mexico almost guarantees that American horses slaughtered for human consumption, who have been administered banned substances, will end up as dangerous food.

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[322] *Canada Report 1, supra* Note 321 at 15; *Mexico Report, supra* Note 321 at 7.

[323] *See, e.g., Canada Report 2, supra* Note 321, at 28 (describing exclusion of animals from European Union market who do not have complete drug histories prepared).

[324] *Canada Report 1, supra* Note 321, at 15; *Mexico Report, supra* Note 321, at 7.

[325] *See Mexico Report, supra* Note 321, at 7.

The potential for both inadvertence and fraud that will lead to unsafe food being consumed by purchasers is clear. Commission auditors have expressed concern over the lack of responsibility taken by the United States government over the safety of horse meat derived from American horses.[326] The potential for slaughtered horses to have been given significant amounts of dangerous substances is high, based on the origins of the horses, discussed in Sections IV.A-D. above.

Additionally, private individuals have also uncovered proof of fraud among Americans who sell horses for slaughter. At one horse export market selling horses to be exported to and slaughtered in Canada, blank declarations (besides signatures) were randomly matched with horses sold for slaughter; there was no actual reference to the specific horse, and no accurate information about that horse was passed along.[327] These declarations purportedly certified that the horses they accompanied had never been administered any prohibited substances when, in reality, they were prepared and applied to horses without regard to their accuracy or the identity of the horse.[328] Other individuals have witnessed auction houses complete the declarations for owners – even though the auction houses obviously knew nothing about the animals.[329] Given the lack of any viable controls on the quality of horses and horse meat being exported, the FSIS should immediately amend its policies, procedures, rules and regulations to address these issues and ensure unadulterated meat for the consuming public.

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[326] *Canada Report 1*, *supra* Note 321, at 15; *Mexico Report*, *supra* Note 321, at 7.

[327] *See Investigation on horse meat entering Europe from America*, ITALIAN HORSE PROTECTION ASSOCIATION, *available at* http://www.horseprotection.it/dett_articolo.asp?id_a=379 (attached hereto as Exh. 63); *see also* Photographs of the New Holland Auction, *available at* http://www.horseprotection.it/docs/eid/album/index.html (attached hereto as Exh. 64).

[328] *See id.*

[329] *See Pasture to Plate*, *supra* Note 127 ("After reviewing all the EIDs [Equine Information Documents] it is apparent that some auction houses are helping to complete the documents on behalf of some owners or agents. Consistent statements such as "Drug-free Six Months" in the same hand writing, and the same red pen colour, are written across the top.").

VI. STATEMENT OF GROUNDS

A. American Horses Are Unfit for Human Consumption Because They Are Not Raised for Food and Create the Potential for Myriad Health Hazards upon Ingestion of Their Flesh.

There is an important health and food safety distinction to be made between *horses* sent to slaughter and eventual human food production, and the several other, more commonly eaten species, such as cows, pigs, chickens, turkeys and sheep. Those more traditional livestock/food animals are, from before birth, raised in an environment that contemplates their growth and eventual transformation into meat products that will be consumed here and abroad. The individuals who are involved in the breeding, raising, and killing of those animals are aware, every step of the way, that the animals they are using are destined for human consumption. But this is not the case with horses, who come from a variety of factual settings, *none of which* necessarily involve contemplation of the horses' ultimate end as being human food. This fundamental distinction between horses and all other animals that humans eat creates a severe, drastically increased, and particularized danger connected to the eating of horse meat that does not exist for other food animals.[330]

The reason that horse meat carries such an escalated risk of health danger and negative consequences is, as explained throughout the Petition, that horses who eventually become meat are given multitudes of drugs over the course of their lives. The drugs given to horses lead to these health and safety concerns because of a number of considerations that may not be immediately obvious, but that are explained in this Petition and in the following sections.

1. Horses Receive Many Drugs Known to Be Dangerous.

Many drugs commonly administered to horses are proven to be unsafe for human use – so that ingestion in horse meat creates great cause for alarm.[331] These include drugs that are prohibited for use on humans, as well as those that humans take only in very controlled

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[330] As discussed in Section V.A.3., *supra*, even the federal government's ability to adequately monitor the safety of those more commonly eaten, regulated-from-birth animals is limited, which may endanger the consuming public.

[331] *See* Exhibit 1; *see generally* Greger Dec., Exh. 6.

situations, with knowledge of potential severe side effects.[332] Nitrofurazone, for example is used to treat bacterial infections in horses but is toxic to humans' respiratory and nervous system.[333] Trimethoprim kills and controls bacteria in horses with respiratory tract infections; in humans, it causes a number of adverse effects and interferes with the important metabolism of folic acid, which can lead to blood dyscrasias.[334] And dexamethasone, an anti-inflammatory agent for horses, causes muscle weakness, osteoporosis, peptic ulcer, pancreatitis, growth suppression (in children), glaucoma, and weight gain in humans.[335]

These are only a few select examples from Exhibit 1. There are dozens of other drugs commonly used on horses on a regular basis, that likely cannot be identified in their tissues, and that create great danger for human use. Many, but not all, of the drugs and other substances that fit into this category have been consequently banned by the FDA for use in horses intended for human consumption. The message is clear – there is an identified significant danger if humans are exposed to these products, and the scientists responsible for making these decisions have concluded unequivocally that under no circumstance can exposure or ingestion of these products be safe. Nevertheless, because American horses *not* raised to be consumed by humans end up as horse meat, these drugs are ingested by humans who eat horse meat from American horses.

2. Horses Receive Many Drugs That Have Never Been Tested on Humans.

Other drugs commonly administered to horses *have never been tested on humans*. So while those drugs are not at this point known to be unsafe when used by humans, there is absolutely no evidence that they are safe, either. Because there has never been any expectation that humans would be exposed to or ingest these drugs, there has simply been no testing. This does not make these drugs safe; to the contrary, it makes every piece of horse meat a potential health time bomb for unsuspecting humans eating horses who have been treated with these

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[332] *See* Exhibit 1; *see generally* Greger Dec., Exh. 6.

[333] *See* Exhibit 1.

[334] *See* Exhibit 1.

[335] *See* Exhibit 1.

drugs. Clenbuterol, for example, is used for growth promotion purposes in horses but has not been approved for human use.[336] Similarly, equine influenza vaccine helps healthy horses avoid contracting the equine influenza, but it is not intended for human use and has not been tested on humans.[337] A third example is n-octyl bicycloheptene disarboximide, which enhances the pesticidal properties of other active ingredients but could cause cancer in humans, based on increased rates of tumors in lab rats.[338] While it is unclear whether drugs unintended for human use are harmful when ingested by humans who consume horse meat, certainly it would be unreasonable and arbitrary and capricious for FSIS to take the risk of approving this meat, knowing it will mean that people will be ingesting drugs that are untested on, and not meant for, human consumption. Such a risk certainly makes meat containing those substances "unfit for human food."[339] The FSIS cannot treat virtually identical situations differently, and it has appropriately enacted regulations to minimize the small risk of beef that might carry bovine spongiform encephalopathy ("mad cow disease") from ever getting into the food supply. The agency cannot ignore the many potential disasters presented here, which may have an even greater chance of occurring, without acting contrary to that prior determination.

3. Even Drugs That Are Safe for Humans May Be Unsafe for Horse Meat.

Many of the drugs on Exhibit 1 – and many additional drugs given to horses regularly but not on Exhibit 1 – are also approved for human use, and may be used regularly by many humans. Amoxicillin is an antibiotic often prescribed for humans. Prednisone is a powerful steroid also used in human medicine. Many people take nonsteroidal anti-inflammatory drugs ("NSAIDs") for a variety of symptoms.[340] And while the human uses may be for the same or different reasons that they are given to horses, this categorically does *not* provide assurance that the drugs

[336] *See* Exhibit 1.

[337] *See* Exhibit 1.

[338] *See* Exhibit 1.

[339] *See* 21 U.S.C. § 601(m)(3).

[340] Other NSAIDs, like phenylbutazone, are prohibited for use by humans. *See* Exhibit 1.

are safe when given to horses, who become meat, that humans then eat.[341] First, as with any drug prescribed or recommended for humans, there will be a certain percentage of the population that has mild to severe (including fatal) allergic reactions to some drugs.[342] It is also well-known that many drugs, such as the commonly used antibiotics, are safe for most individuals under most conditions; but for humans with allergies or drug sensitivities to those antibiotics (for example, penicillin), these drugs can lead to anaphylactic shock, injury and even death.[343] Therefore any meat that comes from an animal who may pass on that drug could lead to terrible effects on consumers.[344]

Thus, even the substances commonly administered to horses that are FDA-approved for use in humans could be harmful to some humans who ingest them.[345] If drugs are invisibly present in horse meat, and people eat them unknowingly, the meat (and the hidden drugs) may cause significant harm.[346] These otherwise approved drugs can be problems because there is a substantive distinction between a doctor intentionally recommending a drug for an identified problem, after evaluation of her patient and the presenting issue, and that same person not having a problem, not talking to a doctor, and unintentionally and unknowingly ingesting a drug embedded in horse meat.

Sucralfate, for example, is commonly administered to horses and approved for use in humans for short-term treatment of ulcers – but it may cause humans numerous adverse reactions, including diarrhea, pruritus, rash, and dizziness.[347] Similarly, humans may use

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[341] *See* Exhibit 1; Greger Dec., Exh. 6.

[342] Greger Dec., Exh. 6, ¶¶ 5-6.

[343] *See id.*

[344] *See id.*

[345] *See* Exhibit 1; Greger Dec., Exh. 6.

[346] Even aspirin, routinely used and prescribed, can cause hives, facial swelling, asthma, and shock when ingested by someone allergic to it. *See* Exhibit 1. Cimetidine, also used by humans, can cause a series of unpleasant sequelae, and other drugs may cause bleeding in those humans who have particular susceptibilities or immune-mediated conditions affecting the blood system. *See* Exhibit 1.

[347] *See* Exhibit 1.

praziquantel, which is commonly administered to horses to treat worm infections near the liver, but praziquantel may cause dizziness, fever, nausea, and hives.[348] Horses may also be given drugs which affect the clotting mechanisms; if people with blood disorders ingest even a small amount of such substances, the consequences could be tragic. Just because these drugs are useful to some humans under some conditions does not make them safe when present in horse meat that will be consumed by humans who are not aware of their presence, and who are unprepared to deal with the drug's adverse reactions or unexpected and unknown allergic reactions. In short, it depends on the individual: drugs that are safe when taken by most individuals are unsafe when taken by those same individuals under certain conditions and unsafe when taken by other individuals under any conditions.[349]

In addition to the potential allergic responses, many drugs ingested by humans who consume horse meat may ordinarily be safe for human use, but may be especially dangerous upon interaction with other drugs commonly taken by humans.[350] Physicians routinely inquire about medications patients are currently taking before prescribing new medicine, because many drugs have the potential to combine with, exaggerate the effects of, or nullify other medications.[351] The dangers of taking two different drugs without consulting a doctor are well understood. But because there is no way of controlling what drug residues might be in horse meat, and because there is such a wide variety of potential drugs in horse meat, it must logically be considered unfit for human food.

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[348] *See* Exhibit 1.

[349] Greger Dec., Exh. 6, ¶¶ 5-9. And while small doses of drugs unexpectedly ingested by at-risk individuals may not initially cause them harm, the accumulation of small doses of these drugs over time can cause problems that a single small amount usually would not. This, too, depends on the individual. *Id.*

[350] Greger Dec., Exh. 6, ¶ 4. Hydroxyzine pamoate, for example, becomes more potent when taken by someone who also takes antidepressants. *See* Exhibit 1.

[351] Greger Dec., Exh. 6, ¶ 4.

B. Horse Meat Containing Certain Food Additives and Veterinary Drugs Is Adulterated and Unsafe for Human Consumption.

As established above, most of the horses who end up being slaughtered for meat are of three identified types – companion horses (including pleasure and work functions), horses involved in sports and competitions, and wild horses who are funneled into one of those first two categories – and the use, by those horses, of the drugs and substances listed in Exhibit 1 is widespread among all three groups. As also established above, the indiscriminate use of substances listed in Exhibit 1 occurs because the owners of the horses who end up in production for meat have no intention or expectation that their horses will someday be food. Accordingly, virtually all horse meat is "adulterated" under the FMIA because (1) many of the substances listed in Exhibit 1 are explicitly banned as unfit for use in horses intended for human consumption, and thus any horse who has had those substances cannot legally be used for meat,[352] (2) many of the substances listed in Exhibit 1 are food additives declared unsafe by the FDA,[353] (3) horses often contain animal drug residues, including those listed in Exhibit 1, in amounts exceeding FDA tolerance levels,[354] and (4) other substances listed in Exhibit 1, some of which are approved for use for humans, can be harmful to humans who ingest them, depending on a variety of factors that cannot be predicted, controlled for, or eliminated in the class of individuals who may be horse meat consumers.[355]

Therefore, virtually all horse meat is unfit for food and cannot be transported or sold for human consumption under the FMIA without (1) an overhaul and infusion of significant

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[352] *See* 21 U.S.C. § 601(m)(2)(C), (m)(3); 21 C.F.R. §§ 520, 522, 524, 526, 529 (prohibiting the use of dozens of "new animal drugs" in animals intended for human consumption as unsafe); Exhibit 1.

[353] *See* 21 U.S.C. § 601(m)(2)(C) (adopting the FDCA provision on food additives, 21 U.S.C. § 348); *id.* § 348 (declaring food additives unsafe unless "there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used. . . ."); Exhibit 1.

[354] *See* 9 C.F.R. § 318.20 (adopting drug residue tolerance levels established by the FDA); Exhibit 1.

[355] *See* 21 U.S.C. § 601(m)(2)(C) ("unfit for human food"); § 601(m)(1) ("may render it injurious to health"); Exhibit 1.

resources for the National Residue Program ("NRP") to provide for the systematic inspection of horses for whom there is reason to believe that a violative residue is present and (2) adequate monitoring and oversight of the horses who become meat, including a reliable lifetime history of each horse's exposure to drugs, treatments, and other potentially harmful substances.[356]

1. The Variety of Drugs Administered to American Horses Makes Their Meat Adulterated and Unsafe for Human Consumption.

Virtually all horse meat derived from American horses is adulterated under the FMIA because many of the veterinary drugs listed in Exhibit 1 are unfit for use in food consumed by humans.[357] Over fifty of the substances listed in Exhibit 1 can not under any circumstances be used in horses intended for human consumption, making horse meat from horses treated with those substances adulterated and illegal as a meat product.[358] These substances are so dangerous that if any trace of them appears in a muscle tissue residue test, the FSIS automatically condemns the carcass and all parts.[359] Drugs commonly administered to horses but which may render their meat unfit and illegal include the following: boldenone undecylenate (used for physical improvement in debilitated horses),[360] butorphanol (used for pain relief),[361] ceftiofur crystalline free acid (used to treat lower respiratory tract infections),[362] ceftiofur sodium (used to treat respiratory infections),[363] and copper naphthenate (used to treat sores on the mouth and tongue).[364] This list of substances only includes drugs on Exhibit 1 beginning with the letters 'b' and 'c,' all of which are commonly administered to horses but must not be administered to horses intended for human consumption.[365] Meat from any horse that has ever been

[356] *See* discussion of NRP, *supra* Section V.A.2.

[357] *See* 21 U.S.C. § 601(m)(2)(c); 21 C.F.R. §§ 520, 522, 524, 526, 529; Exhibit 1.

[358] *See* 21 U.S.C. § 601(m)(2)(c); 21 C.F.R. §§ 520, 522, 524, 526, 529; Exhibit 1.

[359] *See* FSIS Notice 14-11, *supra* Note 170.

[360] 21 C.F.R. § 522.204(c) ("Do not administer to horses intended for human consumption.").

[361] 21 C.F.R. § 522.246(d)(3)(iii) ("Do not use in horses intended for human consumption.").

[362] 21 C.F.R. § 522.313a(e)(3)(iii) ("Do not use in horses intended for human consumption.").

[363] 21 C.F.R. § 522.313c(e)(7)(iii) ("Do not use in horses intended for human consumption.").

[364] 21 C.F.R. § 524.463(c)(3) ("Do not use in horses intended for human consumption.").

[365] *See* Exhibit 1.

administered any of the above prohibited substances, in addition to all of the other banned substances listed in Exhibit 1, "is unfit for food" and "may render it injurious to health," is adulterated, and may not be sold or transported for human consumption under the FMIA.[366]

2. The Presence of Prohibited Drug Residues in Horses Makes Horse Meat Adulterated and Unsafe for Human Consumption.

Not only is most horse meat adulterated under the FMIA due to the administration of drugs absolutely prohibited for use on horses intended for human consumption, but some of this meat is also adulterated, as a separate matter, due to the presence of excessive drug residues.[367] The FDA prohibits the administration of many of the veterinary drugs listed in Exhibit 1 to horses intended for human consumption in any amount,[368] and the FSIS has adopted the drug residue tolerance levels established by the FDA.[369] Therefore, residue tests that reveal even trace amounts of these banned substances in horses or horse meat render the meat adulterated.[370] Consequently, if traces of the above drugs from Exhibit 1 that begin with the letters 'b' and 'c' – boldenone undecylenate,[371] butorphanol,[372] ceftiofur crystalline free acid,[373] ceftiofur sodium,[374] and copper naphthenate,[375] all drugs that may not be administered to horses intended for human consumption – are found in tissue collected and tested by FSIS inspectors, all meat from that horse is adulterated.[376] The same applies to each of the other dozens of veterinary drugs

[366] *See* 21 U.S.C. § 601(m)(2)(c); § 601(m)(1); 21 C.F.R. §§ 520, 522, 524, 526, 529; 21 U.S.C. § 610(c) (prohibiting the sale, transport, offer for sale or transport, or receipt for transport of any carcasses, parts of carcasses, meat, or meat products from animals that are capable of use for food and adulterated); Exhibit 1.

[367] 9 C.F.R. § 318.20 (adopting drug residue tolerance levels established by the FDA).

[368] *See* 21 C.F.R. §§ 520, 522, 524, 526, 529; Exhibit 1.

[369] *See* 9 C.F.R. § 318.20.

[370] *See* 9 C.F.R. § 318.20 (explaining that drug residues in excess of FDA tolerance levels are not permitted in meat and meat food products).

[371] 21 C.F.R. § 522.204(c) ("Do not administer to horses intended for human consumption.").

[372] 21 C.F.R. § 522.246(d)(3)(iii) ("Do not use in horses intended for human consumption.").

[373] 21 C.F.R. § 522.313a(e)(3)(iii) ("Do not use in horses intended for human consumption.").

[374] 21 C.F.R. § 522.313c(e)(7)(iii) ("Do not use in horses intended for human consumption.").

[375] 21 C.F.R. § 524.463(c)(3) ("Do not use in horses intended for human consumption.").

[376] *See* 9 C.F.R. § 318.20; 21 C.F.R. §§ 520, 522, 524, 526, 529; Exhibit 1.

commonly administered to horses that are prohibited for use in horses intended for human consumption.[377]

3. Food Additives Render Horse Meat Adulterated and Unsafe for Human Consumption.

Other substances listed in Exhibit 1 are food additives under the FDCA (as opposed to "new animal drugs") because they are intended or reasonably expected to become "a component or otherwise affect[] the characteristics of any food … including any substance intended for use in producing [or] manufacturing. . . ."[378] Many of these food additives are unsafe for administration to food animals under the FDCA, and consequently, adulterated under the FMIA.[379] There can be no doubt that the substances described on Exhibit 1 and throughout the Petition, once given to horses, meet the statutory definition of "additive" under 21 U.S.C. § 321(s). For example, many of the substances on Exhibit 1 are growth hormones, substances intended to alter body chemistries, or to improve body quality, muscle mass, or growth rates. Clearly they "affect the characteristics" of the meat – indeed that is their sole purpose.[380] Likewise, they are "intended for use in" the production and manufacturing of the meat, and unquestionably both directly and indirectly "affect[] the characteristics of" horse meat.[381] As a matter of food safety, they are not guaranteed as safe by scientists or by long-term usage. As such, they are food additives that are deemed unsafe under both the FMIA and FDCA.[382]

Exhibit 1 to the Petition provides an extensive list of drugs that fit this profile and render horse meat, with its guaranteed but unknown quantities of these drugs, unsafe.[383] By way of brief example, olaquindox, an antibiotic used to promote the growth of horses, is a food additive

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[377] *See* 9 C.F.R. § 318.20; 21 C.F.R. §§ 520, 522, 524, 526, 529; Exhibit 1.

[378] *See* 21 U.S.C. §§ 321(s), 342(a)(2)(A); Exhibit 1.

[379] *See* 21 U.S.C. § 601(m)(2)(C) (adopting the FDA list of unsafe food additives); 21 U.S.C. § 348(a)(2) (establishing which food additives are unsafe under the FDCA); *see also* FDA Food Additive Status List, (H.H.S. 2012), *supra* Note 171.

[380] 21 U.S.C. § 321(s).

[381] *Id.*

[382] *See* 21 U.S.C. § 601(m)(2)(C) (FMIA); *id.* § 348(a)(2) (FDCA).

[383] Exhibit 1.

for which the FDA has not issued a regulation prescribing conditions under which it may be safely used.[384] Accordingly, any horse meat containing olaquindox is adulterated and cannot be sold or transported for human consumption.[385] This is just one of many on the list that similarly fit into this class.

4. The FSIS' National Residue Program Is Unable to Protect the Food Supply if Horse Slaughter Begins Again.

If American horses are slaughtered for human consumption, the FSIS will be responsible for inspecting hundreds of thousands of additional animals before and after slaughter, testing them for a vast array of drugs known to be administered to most American horses, devising new analytical methods, establishing new sampling plans, updating inspection and testing protocols, performing additional tests for tissue residue violations, and collaborating more with other agencies to accomplish their shared mission. All this will need to be done in the shadow of nationwide (and the agency's acknowledged) resource constraints, for a product that most Americans firmly detest. Even if the FSIS successfully implements these steps, it will only be able to inspect and test horses as it does other animals, based on its established programs discussed below. The FSIS has already had significant problems protecting the food supply from adulterated meat from animals who are already raised in regimented fashion to become food. For all the reasons stated in the Petition and this Section, it will be eminently more difficult for the FSIS to protect the food supply from adulterated meat from horses, who are not raised to become food and whose prior owners are not known.

FSIS, FDA, and EPA have been unable to accomplish their mission of monitoring the food supply for harmful residues in cows under the NRP; this finding calls into question their

[384] *See* 21 C.F.R. § 510.110(f) (explaining that antibiotics "are deemed to be new drugs as well as food additives"); 21 U.S.C. § 342(a), § 348 (food additives); FDA Food Additive Status List, (H.H.S. 2012) (omitting olaquindox); Exhibit 1.

[385] *See* 21 U.S.C. § 610(c) (prohibiting the sale, transport, offer for sale or transport, or receipt for transport of any carcasses, parts of carcasses, meat, or meat products from animals that are capable of use for food and adulterated); 21 U.S.C. § 601(m)(2)(C) (food additives deemed unsafe by the FDA are adulterated under the FMIA); 21 U.S.C. § 348(a)(2) (declaring, with a few irrelevant exceptions, that food additives for which there is no regulation prescribing the conditions under which they may be used safely are unsafe); Exhibit 1.

ability to do so with horses. As documented in the recent Report from the Office of the Inspector General on the NRP for cows, the FSIS failed to adequately monitor the presence of banned and limited substances in animals intended to be slaughtered for human consumption even when the agency was focused directly on those substances.[386] And the FSIS failed to recall tainted meat when tests confirmed the presence of excessive amounts of harmful substances.[387] Monitoring the known food supply is easier than monitoring the unknown food supply, but the Inspector General's Report demonstrates that the FSIS was unable to do the former adequately.[388]

Moreover, the lack of a mandatory identification system for horses, as with cattle, will make it virtually impossible for slaughter facilities and inspectors to identify the source of adulterated horse meat.[389] While identifying the source of violations in cattle is difficult enough because they are passed between several buyers before slaughter, identifying the source of violations in horses is virtually impossible. Horses are not only passed between several owners, but many of the initial owners may often be untraceable. Even if found, it is unlikely that early owners kept records of drug administration that would affect the safety of their horses' meat – because they did not intend or expect their horses to one day become food.[390] Just as livestock auctions, cattle sales facilities, and cattle traders often fail to completely list their animals' prior owners, the problem will be hopelessly compounded when adding in the unknowns of early owners of horses.[391] The federal agencies will need to expend infinite resources in the identification process, and still there will be an almost insurmountable chance that adulterated horse meat, tainted with multiple dangerous substances, will enter the marketplace and be purchased and consumed.[392]

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[386] *See* USDA Office of the Inspector General, Audit Report 24601-08-KC, FSIS National Residue Program for Cattle, *supra* Note 208.

[387] *See id.* at 1.

[388] *See id.*

[389] *See id.* at 26-27.

[390] *See id.*

[391] *See id.*

[392] *See id.*

5. FSIS Inspection and Testing Protocols Are Insufficient to Prevent the Entry of Adulterated Horse Meat into the Food Supply.

The unique nature of horse meat from American horses (given their origins and histories prior to slaughter) means that the FSIS will have to take additional steps to protect the food supply from adulterated horse meat. At a minimum, the FSIS must devote additional resources to the inspection and testing of horses and horse meat to account for the administration of substances, including those listed in Exhibit 1, which may render horse meat unsafe for food.

The current NRP testing regime cannot ensure the safety of meat from horses specifically because, unlike most other animals inspected and tested by the FSIS for tissue residue violations, horses are not raised for human consumption. Horses who are *eventually* eaten are not raised in a regulated industry, and their exposure to drugs will not be monitored (if ever) until very shortly before they are sent to slaughter. During their existence as companion/work/sport horses, there are no controls in place to track their medical and drug histories, or to prevent their exposure to drugs and other substances that render them wholly unfit to become food. The horses' owners for most of their lives will have no reasonable expectation that the horses they are riding or training will end up as meat. Those owners and caretakers will have no need or desire in complying with FSIS restrictions on the amounts and types of drugs administered to horses who will become meat. Consequently, the horses will be given many of the substances listed in Exhibit 1 that are so dangerous that they do not have withdrawal times or tolerance levels but are prohibited for food animals, rendering horse meat unfit for food, injurious to health, and adulterated.

Specifically, the current NRP testing regime is inadequate to meet the particular challenges posed by horses because the two testing models were not designed to screen animals that are not raised to become food.[393] The first model, Scheduled Sampling, is of minimal use in

[393] *See* discussion of NRP testing *supra* Section V.A.2. That the NRP focus on drugs that *can* be given to horses at some point, as long as withdrawal times have been met, is further evidence that the current testing regime is inadequate to prevent adulterated horse meat from entering the food supply. Due to the important distinction between horses and animals actually raised to become food, a testing regime geared toward monitoring tissue residue violations in the latter is necessarily inadequate to meet the risks posed by the former. For horses, one of the biggest

(Footnote continued on next page)

screening random samples of horses for particular chemical residues because (1) the data upon which the annual Scheduled Sampling Plans are based is both outdated and collected too long after horses are treated with banned substances,[394] (2) the algorithm used to create the Scheduled Sampling Plans is outdated and inflexible,[395] and (3) the lack of data on chemical compounds that should be tested makes it likely that the FSIS will underestimate – and under-test – these compounds, which are commonly administered to horses.[396] Moreover, while random testing based on algorithms may be both efficient and precise when applied to a relatively uniform, known quantity of commercially raised food animals and production facilities, it is imprecise and

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(Footnoted continued from previous page)

problems is the administration of prohibited drugs, which may never show up under the current testing regimen.

[394] Data used to devise the annual Scheduled Sampling Plans comes from prior investigations of residue violations for each animal-compound combination and veterinary inventories completed during on-farm visits. *See* United States National Residue Program, *supra* Note 174, at vi. This means that data on horses is *at least* five years old. Moreover, even if the data was more recent, evidence collected on farm visits reveals little, if any information on the drugs administered to horses by the myriad of potential previous owners they had, who include *mostly non-farm situations*. Thus, the data both will not detect the inherent problems described in the Petition, and cannot be done at the proper source of potential exposures.

[395] According to the USDA Report on the FSIS' Microbiological and Residue Sampling Programs, the algorithm "has been unchanged for approximately ten years and contains variables . . . that may no longer be appropriate measures for prioritizing hazards" and "is a 'one size fits all' strategy that determines the number of samples collected, regardless of the product class/compound pairing, geographical or seasons trends." Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs, *supra* Note 189, p. 71.

[396] Because statistical evidence of violation rates for the administration of many of the Exhibit 1 compounds to horses is not available, the FSIS will use this absent, and therefore misleading, estimate of their violation rates if it decides to test for them. *See* United States National Residue Program, *supra* Note 174, at 21. The FSIS only tested horses for *11 of the 115* drugs listed in Exhibit 1 in 2006 and 2007, when horses were last slaughtered for human consumption. *See* 2006 FSIS National Residue Program Data, *supra* Note 203; 2007 FSIS National Residue Program Data, *supra* Note 203; Exhibit 1. And even if the FSIS looks at data from FSIS tests of other food animals to help determine which drugs to test in horses, it only has test data for 2006 through 2009 (the year of the most recent published test data) on 68 of the 115 drugs listed in Exhibit 1. *See* 2006 FSIS National Residue Program Data, *supra* Note 203; 2007 FSIS National Residue Program Data, *supra* Note 203; Exhibit 1; 2008 FSIS National Residue Program Data (USDA 2009) (attached hereto as Exh. 65); 2009 FSIS Residue Sample Results (USDA 2011) (attached hereto as Exh. 66). Given that the NRP views horses the same as they view animals raised for food from birth, it is likely that the FSIS will underestimate violation rates for these substances and, consequently, under-test them. *See generally* 2006 FSIS National Residue Program Data, *supra* Note 203; 2007 FSIS National Residue Program Data, *supra* Note 203.

inefficient when applied to horses, for whom the number of owners, drugs, and drug combinations is nearly infinite.

Under this first testing model, horses whose tissue is tested may only be tested for a *single drug*.[397] Given the unreliable NRP algorithm; the nonuniform manner in how horses are raised, treated, and administered veterinary drugs; and the plethora of drugs listed in Exhibit 1 that are commonly administered to horses, it is likely that most horses contain violative residues of multiple drugs that, like those listed in Exhibit 1, are particularly dangerous. Yet even animals who are selected for a tissue residue test by the FSIS are often still not identified by the FSIS or reported to the FDA for enforcement. Further, when the FSIS tested horses under the 2006 and 2007 Scheduled Sampling Programs (before horse slaughter was effectively banned), it only tested horses for *11* of the 115 drugs listed in Exhibit 1, which are commonly administered to horses and pose danger to humans who consume meat from those horses.[398]

In contrast to the Scheduled Sampling Program, the FSIS' second testing model, the Inspector Generated Sampling Program, would be beneficial if applied properly to horses but is too expensive to be applied as needed. For this program, FSIS inspectors must collect tissue samples *every time* there is reason to believe that a violative residue is present, without exception.[399] This would apply to every American horse, given the reasons for conducting an in-plant test, which include evidence of suspect "production practice" and "herd history."[400] As described in the Petition, even a basic understanding of how most American horses who end up as meat are raised – especially knowledge of the information in Exhibit 1 and supporting

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[397] *See* FDA Directive 7371.006, Illegal Residues in Meat, Poultry, Seafood, and Other Animal Derived Foods (H.H.S. 2005), *supra* Note 101, at 18.

[398] *See* 2006 FSIS National Residue Program Data, *supra* Note 203; 2007 FSIS National Residue Program Data, *supra* Note 203; Exhibit 1. In 2006, the FSIS included horses in the Scheduled Sampling Program but did not test them for phenylbutazone, even though "musculoskeletal injuries are frequent in horses and are treated commonly with [phenylbutazone] to ameliorate the pain associated with these injuries." *Phenylbutazone Health Risks, supra* Note 106, at 1273.

[399] *See* FSIS Directive 10,800.1, Procedures for Residue Sampling, Testing, and Other Responsibilities for the National Residue Program, (USDA 2007), *supra* Note 194, p. 11 (emphasis added).

[400] FSIS Directive 10,220.3, *supra* Note 206, p. 2.

declarations – is more than sufficient to raise suspicions that multiple violative residues, that would render meat adulterated, are present on a regular basis.[401] Similarly, a fundamental understanding of the history of certain types of horses, such as companion and race horses, for whom the use of anti-inflammatory drugs and steroids is well-known,[402] is more than sufficient to give reason to believe that violative residues would be found.[403]

Even this screening model, if done constantly and diligently, will not identify many problems. These in-plant screenings do not detect non-steroidal anti-inflammatory drugs such as flunixin and phenylbutazone. In order to perform that kind of assay, the FSIS inspectors would need to take further tissue samples for laboratory testing if they suspect the use of this category of drugs.[404] Yet these drugs are widely used for virtually all horses who go to slaughter.[405] Based on their "production practice" and "herd history," inspectors will need to perform tests to determine if these kinds of violative residues are present in a substantial percentage of horses.[406] Accordingly, faithful application of the Inspector Generated Sampling Program to horses would result in the expenditure of vastly more funds than Congress appropriates for the entire NRP, much less one testing model for application to a single species. But if the FSIS did not effectively apply the Inspector Generated Sampling Program to horses, it would be knowingly permitting the entry of adulterated horse meat into the food supply and the potential infliction of illness and possibly even death on consumers.

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[401] *See* FSIS Directive 10,800.1, *supra* Note 194, p. 11; FSIS Directive 10,220.3, *supra* Note 206, p. 2; Exhibit 1.

[402] *See Phenylbutazone Health Risks*, *supra* Note 106, pp. 1270-73. According to the authors of that article, of 18 race horses in a study who were sent for intended slaughter, all 18 were administered phenylbutazone, 6 of them within a month of slaughter. *Id.* at 1271. Over 90,000 race horses were slaughtered in the five years over which the authors examined data. *Id.*

[403] *See* FSIS Directive 10,800.1, *supra* Note 194, p. 11; FSIS Directive 10,220.3, *supra* Note 206, p. 2.

[404] *See* FSIS Directive 10,800.1, *supra* Note 194, p. 11.

[405] Wood Dec., Exh. 2 at ¶¶ 6-7; Larson Dec., Exh. 3 at ¶ 7; Pavlis Dec., Exh. 4 at ¶¶ 4-5; Parker Dec., Exh. 5 at ¶¶ 7-9.

[406] *See* FSIS Directive 10,220.3, *supra* Note 206, p. 2.

Slaughter establishments are similarly obliged under FSIS regulations to prevent, eliminate, and minimize food safety hazards, including the slaughter and sale of horse meat from horses (1) treated with prohibited veterinary drugs, (2) containing excessive amounts of drug residue, or (3) containing unsafe food additives.[407] And like FSIS, their current programs simply cannot provide any satisfactory level of protection. That these prohibited veterinary drugs and food additives are usually administered to horses before they enter a slaughter facility does not reduce the obligation of slaughter establishments.[408] If slaughter establishments do not develop and implement a Hazard Analysis and Critical Control Points ("HACCP") plan that accounts for these known food safety hazards, which at the very least would require them to refuse groups of horses for slaughter based on their "herd history," their horse meat products should be deemed adulterated.[409] In other words, just like FSIS, without significant additional resources and a major overhaul of their testing processes, there is simply no way slaughterhouses can be expected to detect all the hidden problems with horse meat described in the Petition, and so it all must be deemed adulterated. As currently set up, the HACCP program is born to fail, for the same reasons that are stated in the Petition in connection with FSIS' obligations to detect these substances and eliminate adulterated meat from the marketplace.

6. Adulterated Horse Meat Can Be Excluded from the Food Supply Only if Complete Treatment Histories Are Kept for All Horses Slaughtered for Human Consumption.

Just because a horse's tissue residue test results for a given drug are negative, that does not mean that the horse has never been administered that drug or even that the tissue does not contain the drug. Even the most thorough testing regime is unlikely to uncover which horses have been administered substances that must never be used "in horses intended for human consumption"[410] and that render the horses' meat adulterated. Consequently, implementing and

[407] *See* 9 C.F.R. § 417.2(a)(1), (3)(v), (ix), (b)(i), (c)(1)-(4).

[408] *See* 9 C.F.R. § 417.2(c).

[409] *See* 9 C.F.R. § 417.2(e).

[410] *See, e.g.*, 21 C.F.R. § 520.1720a (declaring that tablets and boluses of phenylbutazone cannot be used "in horses intended for human consumption").

rigorously enforcing a "passport system" that requires horse owners to keep a verifiable lifetime medical treatment history for each horse is the only way the FSIS can prevent the entry of adulterated horse meat into the nation's food supply.

Individuals who administer banned substances to their horses are often unaware that their horses will become food, and the FSIS is unlikely to detect and prevent the administration of these banned substances, especially since these individuals are largely unknown and effectively unidentifiable. Moreover, the FSIS will be unable to determine the presence of the banned substance in the horse and its flesh when the drug remains in the horse but is undetectable via residue tests – or when, as demonstrated above, the drug is never even in the list of FSIS' tested substances. This is especially true given the relatively wide dispersal of the administration of banned substances to horses – at stables and farms, in competitions and at racetracks across the country[411] – and the passage of time between a horse's treatment with banned substances and slaughter. And this would be true *even if* the FSIS faithfully applied the Inspector Generated Sampling Program to horses, as discussed in the previous Section.

The primary types of evidence gathered by FSIS inspectors engaged in ante-mortem and post-mortem inspections – observations of horses just before slaughter, tissue from horses just before slaughter, and observations of and tissues from horses carcasses after slaughter – do not address the time periods in which horses have been administered prohibited substances.[412] Without a drug and dangerous substance exposure list that is kept for horses' entire lives, and that can be reviewed and scrutinized by FSIS inspectors and slaughterhouse personnel at the time of their slaughter, there is no possible way to determine the likely inevitable conclusion – that American horses, and their meat, are "adulterated" and should not be allowed to proceed to slaughter. Certainly the current practice, which provides only for a limited determination of drugs and prohibited substances used on horses in their last few days or weeks, cannot come

[411] Wood Dec., Exh. 2 at ¶¶ 6-7; Larson Dec., Exh. 3 at ¶ 7; Pavlis Dec., Exh. 4 at ¶¶ 4-5; Parker Dec., Exh. 5 at ¶¶ 7-9.

[412] *See* FSIS Directive 6100.1, Ante-Mortem Livestock Inspection, *supra* Note 190; FSIS Directive 6100.2, Post-Mortem Livestock Inspection, *supra* Note 192.

close to telling the full story the FSIS needs to ensure the public is safe when it eats the flesh of those horses. In order to protect the public and the market and the food supply, the FSIS needs to know about *all* the drugs and drug-containing products administered to the horse *before* the horse was sent off to be slaughtered.

Comprehensive medical records from birth are the only way to ascertain drug exposures, and given the various purposes for which humans own horses before they enter the slaughter pipeline, those records are unlikely to exist and virtually impossible to locate. Put differently, the evidence currently collected by FSIS inspectors does not and cannot provide the necessary drug history of an animal such as a horse who has had multiple owners, especially where the animals were never contemplated as meat and those prior owners are unknown and effectively unidentifiable. As the necessary data to ensure public safety is simply unascertainable when horses are the species being slaughtered, FSIS inspection procedures are unable to capture the necessary information. Without comprehensive treatment records, adulterated horse meat will enter the food supply and cause harm, disease, or even death to unsuspecting consumers.

C. The Treatment of Horses Going to Slaughter and the Processing of the Horses Increases the Chance the Horse Meat is Adulterated and Unfit for Food

As documented in Sections IV.E and IV.F above, the procedures of horse transport and slaughter, for the horses and the communities involved, also brings into question the unhealthy and unsafe nature of horse meat. Because of the documented suffering of horses shipped to slaughter, and the treatment of the horses while they are at the slaughter house, the potential for the spread of bacterial diseases, blood-borne infecting agents, and other health hazards is high.[413] Because of the ingestion by the horses of a long list of dangerous, often toxic, substances, the entire environment around a horse slaughter plant is in danger. In addition to the unpredictable and unidentifiable presence of the substances on Exhibit 1 in horse meat, the potential that they

[413] *See, e.g.*, Larson Dec., Exh. 3, ¶¶ 12-13, 15-16, 18-19, 25.

are also sick presents a further reason for the FSIS to seriously consider the use of American horses for meat at any juncture.[414]

VII. CONCLUSION

American horses are cared for, used and treated as companions, as competitors, as work partners. Their owners, caregivers and veterinarians administer a wide array of drugs and other substances to keep the horses healthy, strong, and productive. Most, if not all, of these substances are either prohibited by federal law for use in animals who will become meat, or are potentially dangerous to a significant percentage of humans who eat these substances. Not only do Americans not eat horses, their horses are not meant to be meat, and any American horse that becomes meat is a danger to the consuming public. It is imperative that the FSIS eliminate the threat created by the slaughter of American horses for food, in order to prevent the spread of unsafe meat in America and throughout the world.

VIII. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioners which are unfavorable to the Petition.

Dated: April 6, 2012

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[414] *See* Wood Dec., Exh. 2 at ¶ 9.

CITATIONS, BIBLIOGRAPHY, AND EXHIBIT LIST

CASES

STATUTES

REGULATIONS

REGULATIONS (*Continued*)

EXHIBIT 5

BANNED AND DANGEROUS SUBSTANCES COMMONLY GIVEN TO HORSES SENT TO SLAUGHTER

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
1.	**Acepromazine**	Anti-anxiety/tranquilizer Previously used in humans, but use discontinued	*See also* Citak A, Soysal DD, Uçsel R, Karaböcüoglu M, Uzel N., *Seizures associated with poisoning in children: tricyclic antidepressant intoxication*, PEDIATR INT. 48(6):582-585 (2006) (Two children suffered cardiac arrest from intoxication from acepromazine and died.).
2.	**Acetazolamide**	Diuretic for horses. Used to treat epilepsy and benign intracranial hypertension in children and adults.	Acetazolamide (sulfonamide) induces metabolic alkalosis and is contraindicated in patients with hyperchloremic acidosis, angle-closure glaucoma, kidney and liver disease, and in patients with Addison's disease. Fatalities have occurred (rare) due to Stevens-Johnson syndrome (diffuse rash that sloughs), toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, and other blood dyscrasias. Sensitizations may recur when a sulfonamide is readministered irrespective of the route of administration. If signs of hypersensitivity or other serious reactions occur, discontinue use of this drug. Caution is advised for patients receiving concomitant high-dose aspirin and Acetazolamide, as anorexia, tachypnea, lethargy, coma and death have been reported. http://www.drugs.com/pro/acetazolamide.html
3.	**Acriflavine**	Blue-Kote (topical ointment, antiseptic, protective wound dressing) http://www.drugs.com/vet/dr-naylor-blu-kote.html Not for use on animals intended for food. http://www.horsesuppliesplus.com/antiseptics.html	Acriflavine is an ingredient found in Blue-Kote, which is itself labeled "not for use on animals intended for food." The dangers for humans who ingest this substance are unknown.
4.	**Altrenogest**	Regu-Mate (altrenogest/oral progestin) (growth promoter) 21 CFR § 520.48: - "Do not use in horses intended for human consumption." "Do Not Use In Horses Intended For Human Consumption." http://www.drugs.com/vet/regu-mate-solution.html	Active harmful ingredients (residue): Progestin. Progestin is used in the mini-pill to prevent contraception so progestin could result in an aborted fetus in a pregnant woman. Progestin along with estrogens are pro-thrombotic meaning that they cause deep blood clots, including venous thrombosis and cerebral thrombosis. http://www.nejm.org/doi/full/10.1056/NEJM200105173442007 Combined with estrogens, progestin increases the risk of breast cancer and cardiovascular problems.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
			http://www.whi.org/findings/ht/eplusp_3yr.php Increased stroke risk. http://www.whi.org/findings/ht/ealone_stroke.php HUMAN WARNINGS Skin contact must be avoided as Regu-mate® (altrenogest) Solution 0.22% is readily absorbed through unbroken skin. Protective gloves must be worn by all persons handling this product. Pregnant women or women who suspect they are pregnant should not handle Regu-mate® (altrenogest) Solution 0.22%. Women of child bearing age should exercise extreme caution when handling this product. Accidental absorption could lead to a disruption of the menstrual cycle or prolongation of pregnancy. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water. http://www.drugs.com/vet/regu-mate-solution.html
5.	**Aluminum hydroxide**	Strepvax II (component in equine vaccine) Used in humans for gastrointestinal problems, ulcers. http://www.drugs.com/vet/strepvax-ii.html	WARNINGS/PRECAUTIONS May cause constipation. Caution with renal failure; prolonged use may result in or worsen dialysis osteomalacia. Elevated tissue aluminum levels contribute to the development of dialysis encephalopathy and osteomalacia syndromes. Caution with normophosphatemic patients; prolonged use may result in hypophosphatemia if phosphate intake is inadequate. ADVERSE REACTIONS Constipation, dialysis osteomalacia, hypophosphatemia. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=1544 Can cause constipation, confusion, loss of appetite, and muscle weakness. http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001056/
6.	**Amikacin**	Antibiotic 21 CFR § 529.56 - "Do not use in horses intended for human consumption"	Antibiotics are potentially dangerous to humans who either have allergies or sensitivities to them. Additionally, the use of antibiotics in food animals, and the subsequent ingestion by humans of those animals, has the potential to create antibiotic resistance in humans, which can cause significant problems for humans upon subsequent illness.
7.	**Amoxicillin**	Antibiotic	Infections and Infestations: Mucocutaneous candidiasis. Gastrointestinal: Nausea, vomiting, diarrhea, black hairy tongue, and hemorrhagic/pseudomembranous colitis. Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment. Hypersensitivity Reactions: Anaphylaxis Serum sickness-like reactions, erythematous maculopapular rashes, erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis, toxic epidermal necrolysis, acute generalized exanthematous pustulosis, hypersensitivity vasculitis and urticaria have been reported. Liver: A moderate rise in AST (SGOT) and/or ALT (SGPT) has been noted, but the significance of this finding is unknown. Hepatic dysfunction including cholestatic

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
			jaundice, hepatic cholestasis and acute cytolytic hepatitis have been reported. Hemic and Lymphatic Systems: Anemia, including hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis have been reported during therapy with penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. Central Nervous System: Reversible hyperactivity, agitation, anxiety, insomnia, confusion, convulsions, behavioral changes, and/or dizziness have been reported rarely. Miscellaneous: Tooth discoloration (brown, yellow, or gray staining) has been rarely reported. Most reports occurred in pediatric patients. Discoloration was reduced or eliminated with brushing or dental cleaning in most cases. http://www.drugs.com/sfx/amoxicillin-side-effects.html
8.	**Ampicillin sodium**	Antibiotic for treatment of respiratory tract infections (pneumonia and strangles) and skin and soft tissue infections (abscesses and wounds), when caused by susceptible organisms. 21 CFR § 522.90c - "Do not use in horses intended for human consumption."	COMMON SIDE EFFECTS Inflammation and redness of the tongue; irritation of mouth or throat; mild diarrhea; nausea; second infection; vomiting. SEVERE SIDE EFFECTS Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); bloody stools; severe diarrhea; stomach pain/cramps; vaginal irritation or discharge. http://www.drugs.com/sfx/ampicillin-side-effects.html See also side effects for ampicillin injection: •upset stomach, diarrhea, vomiting, mild skin rash More severe: •severe skin rash, itching, hives, difficulty breathing or swallowing, wheezing, unusual bleeding or bruising, headache, dizziness, seizures, sore mouth or throat http://www.nlm.nih.gov/medlineplus/druginfo/meds/a601133.html Material Safety Data Sheet ("MSDS") for ampicillin sodium salt: Toxic Effects on Humans: Hazardous in case of ingestion, of inhalation. http://www.sciencelab.com/msds.php?msdsId=9925610
9.	**Aspirin**	Aspir-paste http://www.drsfostersmith.com/1/1/10913-aspir-paste-by-oral-x.html Reduces joint, muscle, and lameness pain.	WARNINGS/PRECAUTIONS Avoid in children or teenagers for chickenpox or flu symptoms; Reye's syndrome may occur. May cause severe allergic reaction (hives, facial swelling, asthma, shock) and stomach bleeding. Avoid in asthma, stomach problems that persist or recur, ulcers, or bleeding problems. ADVERSE REACTIONS Allergic reaction, hives, facial swelling, asthma, shock. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=195

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
			Can cause excessive bleeding in those taking warfarin; http://stroke.ahajournals.org/content/40/5/1944.full Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); black or bloody stools; confusion; diarrhea; dizziness; drowsiness; hearing loss; ringing in the ears; severe or persistent stomach pain; unusual bruising; vomiting. http://www.drugs.com/sfx/aspirin-side-effects.html
10.	**Avermectin A1a, 5-O-demethyl-25-de(1-methylpropyl)-22,23-dihydro-25-(1-methylethyl)-**	Farnam Ivercare (dewormer) http://msds.farnam.com/m001116.htm Ivercare Paste is labeled "Do not use in horses intended for food purposes." http://www.drugs.com/vet/ivercare-paste-1-87.html	A hazardous component of the Farnam Ivercare dewormer product. http://msds.farnam.com/m001116.htm Links to the toxicological literature here: http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?sid=14145#x50 http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+toxline:@term+@rn+65195-51-9+@OR+@all
11.	**Benzyl alcohol**	Equipoise Equipoise Injectable http://www.drugs.com/vet/equipoise-injectable-can.html	ADVERSE REACTIONS Pruritis, erythema, pyoderma, ocular irritation. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Benzyl+alcohol
12.	**Boldenone undecylenate**	Equipoise injectable 21 CFR § 522.204 - "Do not administer to horses intended for human consumption." Equipoise injectable (boldenone undecylenate injection) is recommended as an aid for treating debilitated horses when an improvement in weight, haircoat or general physical condition is desired. http://www.drugs.com/vet/equipoise-injectable-can.html	Boldenone undecylenate is a steroid ingredient in Equipose (for horses). It is not indicated for use in humans but appears to have off-label uses as a bodybuilding steroid. Known side effects consist of: nausea, leukopenia, symptoms resembling a peptic ulcer, acne, excitation (commonly referred to as roid rage), sleeplessness, chills, vomiting, diarrhea, hypertension, prolonged blood clotting time, increase in libido. Females had reported menstrual irregularities, post-menopausal bleeding, increased sex drive, swelling of the breasts, hoarseness or deepening of the voice, and enlargement of the clitoris. Men had reported acne, gynocomastia, and increased aggression. http://www.anabolicsmall.com/equipoise.html Steroids should be taken under a doctor's supervision and have multiple significant adverse affects including severe allergic reactions, hormonal changes, changes in menstrual functions, mental and mood changes, respiratory problems, nausea and vomiting, joint swelling, vision changes, and unusual weight gain.
13.	**Butorphanol**	For the relief of pain associated with colic and postpartum pain in adult horses and yearlings.	COMMMON SIDE EFFECTS Dizziness; drowsiness; dry mouth; light-headedness; nasal irritation; nausea; runny nose; sore throat; stuffy nose; trouble sleeping; unpleasant taste; vomiting.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		21 CFR § 522.246 - "Do not use in horses intended for human consumption."	SEVERE SIDE EFFECTS Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); blurred vision; burning, numbness, or tingling; change in the amount of urine produced; chest pain; confusion; ear pain; fainting; fast, slow, or irregular heartbeat; flushing; hallucinations; mental or mood changes (agitation, anxiety, depression); restlessness; ringing in the ears; seizures; severe or persistent dizziness, drowsiness, or light-headedness; severe or persistent headache or trouble sleeping; shortness of breath; slow, shallow, or difficult breathing; tremors; unusual swelling. http://www.drugs.com/sfx/butorphanol-side-effects.html
14.	**Butoxy Polypropylene Glycol**	Farnam Bronco Gold (fly spray) http://msds.farnam.com/m001650.htm Farnam Endure Fly Spray http://msds.farnam.com/m000080.htm Farnam Endure Sweat-Resistant http://msds.farnam.com/m001046.htm Farnam Tri-Tec 14 http://msds.farnam.com/m000490.htm Farnam Wipe (fly control	In 2002, a woman in Oklahoma was hospitalized after using Pyranha fly spray on horses. Her face was distorted, and her words slurred. She reportedly had leg problems, tremors, memory problems. The medical toxicologist's conclusion was that the patient, a professional horse trainer, developed a complex neurotoxic movement disorder following sensitization to a product that contained 33% /butoxypolypropylene glycol/ BPG. Adverse reactions and side effects of ingestion are unknown.
15.	**Carbadox**	Antibiotic used for growth promotion purposes (generic)	Not permitted for use in food-producing animals in Australia (http://www.apvma.gov.au/registration/not_permitted.php) Or in Canada, or the European Union. (http://www.hc-sc.gc.ca/dhp-mps/vet/faq/faq_mrl-lmr-eng.php#a6) Not for human use. http://www.drugs.com/pro/mecadox.html Chronic health effects, including cancer, mutagenic effect, changes in lung function. Accidental ingestion may cause serious harm or be fatal. MSDS SUPPLIER http://datasheets.scbt.com/sc-204668.pdf
16.	**Ceftiofur Crystalline Free Acid**	Excede (antibiotic) For the treatment of lower respiratory tract infections in horses. 21 CFR § 522.313a	Intended for use in horses which are non-food animals. Because this indication for this new animal drug is not intended for use in food producing animals, there is no data pertaining to drug residues in food (i.e., human food safety). WARNINGS

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		- "Do not use in horses intended for human consumption." http://www.excede.com/Excede.aspx?country=US&drug=XT&sec=100&species=EQ	Not for use in humans. For use in animals only. Consult a physician in case of accidental human exposure. Do not use in horses intended for human consumption. http://animalhealth.pfizer.com/sites/pahweb/US/EN/Products/Documents/Combined%20Full%20PI%20(8_5x11)%20-%20EXEQ0110014.pdf
17.	**Ceftiofur Sodium**	Ceftiflex powder For treatment of respiratory infections in horses. 21 CFR § 522.313c - "Do not use in horses intended for human consumption." http://www.drugs.com/vet/ceftiflex.html	Penicillins and cephalosporins can cause allergic reactions in sensitized individuals. Topical exposure to such antimicrobials, including ceftiofur, may elicit mild to severe allergic reactions in some individuals. Repeated or prolonged exposure may lead to sensitization. Avoid direct contact of the product with the skin, eyes, mouth, and clothing. http://www.drugs.com/vet/ceftiflex.html
18.	**Chloramphenicol**	Chlor-500 Chlor-1000 Chloramphenicol 1% Ointment "Not for use in animals that are raised for food production. Must not be used in meat, egg, or milk-producing animals. 21 CFR § 520.390a; 520.390c; 522.390; 524.390. http://www.drugs.com/vet/chlor-500-can.html http://www.drugs.com/vet/chlor-1000-can.html http://www.drugs.com/cdi/chloramphenicol.html http://www.drugs.com/vet/chloramphenicol-1-ophthalmic-ointment-can.html	Some medicines may interact with Chloramphenicol: •Anticoagulants (e.g., warfarin) because side effects, including risk of bleeding, may be increased. •Hydantoins (e.g., phenytoin) or sulfonylureas (e.g., glyburide) because the actions and side effects of these medicines may be increased. •Medicines that may decrease your bone marrow (e.g., cancer chemotherapy) because the risk of serious side effects, such as low blood platelet levels and low white blood cell counts, may be increased. Chloramphenicol has caused severe and sometimes fatal blood problems (e.g., anemia, low blood platelets, low white blood cell counts). Leukemia has also been reported after use of Chloramphenicol. Blood problems have occurred after both short-term and long-term use of Chloramphenicol. Do not use chloramphenicol if safer, effective medicines can be used. http://www.drugs.com/cdi/chloramphenicol.html Prohibited for use in food-producing animals in the European Union.
19.	**Chloroform**	Anesthetic	The IARC (International Agency for Research on Cancer) classifies chloroform as possibly carcinogenic to humans. http://monographs.iarc.fr/ENG/Monographs/vol73/mono73.pdf
20.	**Cimetidine**	Prevention and prophylaxis of	ADVERSE REACTIONS

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		gastrointestinal irritation and ulcers	Diarrhea, headache, dizziness, somnolence, reversible confusional states, reversible impotence, increased serum transaminases, rash, gynecomastia, blood dyscrasias. WARNINGS/PRECAUTIONS Reversible confusional states reported, especially in severely ill patients. Increased risk of developing confusional states with advancing age (≥50 yrs), renal and/or hepatic impairment. Risk of hyperinfection of strongyloidiasis in immunocompromised patients. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=1440
21.	**Clenbuterol**	Beta-agonists used for growth promotion purposes Prohibited from any use in any food-producing animal. http://www.farad.org/eldu/prohibit.asp	Not approved for human use. http://www.deadiversion.usdoj.gov/drugs_concern/clenbuterol.htm
22.	**Copper Naphthenate**	Kopertox Treatment of thrush. 21 CFR § 524.463 - "Do not use in horses intended for human consumption." http://www.drugs.com/vet/kopertox.html http://www.sciencelab.com/msds.php?msdsId=9923553	Toxic to central nervous system, blood, and kidneys. May produce vomiting, headache, shock, jaundice, kidney damage, nervous system damage, liver damage.
23.	**Crude Liver Extract**	Liver 7 injection http://www.drugs.com/vet/liver-7-injection.html	FDA cautions against the use by humans of any animal organ extract. http://www.healthline.com/natstandardcontent/liver-extract
24.	**Cupric Sulfate**	Proudsoff (ointment for control and removal of proud flesh) Not for use on animals intended for food. http://www.drugs.com/vet/proudsoff.html	Harmful if swallowed. May cause gastrointestinal tract irritation with nausea, vomiting, diarrhea, metallic taste, burning sensation in the stomach or epigastrum, abdominal pain, and possible gastrointestinal tract bleeding. May affect metabolism, liver (liver damage, jaundice), blood, urinary system (kidney damage, hematuria, hemoglobinuria, albuminuria), behavior/nervous systems (somnolence, tremor, psychosis, muscle weakness, coma), cardiovascular system (lowering of blood pressure, dysrhythmia).
25.	**Cypermethrin**	Farnam Endure Sweat-Resistant (fly spray http://msds.farnam.com/m000080.ht	"Pyrethroid ingestion gives rise within minutes to a sore throat, nausea, vomiting and abdominal pain. There may be mouth ulceration, increased secretions and/or dysphagia. Systemic effects occur 4-48 hours after exposure. Dizziness, headache and fatigue are common, and palpitations, chest tightness and blurred vision less

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		m	frequent. Coma and convulsions are the principal life-threatening features. Most patients recover within 6 days. . . ." S.M. Bradberry *et al.*, *Poisoning Due to Pyrethroids*, Toxicol Rev. 24(2):93-106 (2005) (quoting abstract). Potential organ damage. http://pmep.cce.cornell.edu/profiles/extoxnet/carbaryl-dicrotophos/cypermet-ext.html
26.	**Dapsone**	Dermatitis skin problems in horses. Acne treatment in humans.	Adverse effects include agranulocytosis, aplastic anemia, leucopenia, thrombocytopenia, hemolysis, and other blood dyscrasias have been reported after treatment. It may cause significant reduction in leukocytes, platelets, or hemopoiesis. Caution with glucose-6-phosphoate dehydrogenase (G6PD) deficiency, methemoglobin reductase deficiency, or hemoglobin M, and those who are exposed to other agents or conditions such as infection or diabetic ketosis capable of producing hemolysis. Toxic hepatitis and cholestatic jaundice reported after use. Liver function tests must be monitored if there are any abnormalities. Can cause muscle weakness. Peripheral neuropathy, nausea and vomiting, abdominal pain, and pancreatitis may occur. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Dapsone
27.	**Deodorized Kerosene**	Component in Farnam Repel Xp (fly spray). http://msds.farnam.com/m000031.htm	Ingestion may cause aspiration hazard, nausea, fatigue, pulmonary edema, central nervous systemepression, convulsions and loss of consciousness. http://www.sciencestuff.com/msds/C1955.html
28.	**Deslorelin**	Used for inducing ovulation within 48 hours in ovulating mares. 21 CFR § 522.533 - "Do not use in horses intended for human consumption."	Deslorelin stops the production of certain sex hormones in horses, and has never been approved for use on humans. If it was approved, it would be for a small targeted complement of the human population with identified diseases related to the production of too much of certain sex hormones, but could otherwise produce unwanted hormonal effects and responses.
29.	**Detomidine Hydrochloride**	Dormosedan Pain relief and sedative for minor surgery. Also used in humans for sedation in intensive care and surgery conditions. 21 CFR § 522.536; 529.536 - Not for use in horses intended for food." - "Do not use in horses intended for human consumption." http://www.dormosedan.com/	Can cause hypotension, hypertension, bradycardia, dry mouth, respiratory depression, tachycardia, nausea and vomiting, atrial fibrillation, fever, hyperglycemia, anemia, hypovolemia, hypoxia, atelectasis. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=2848

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
30.	**Dexamethasone**	Dexium injection Anti-inflammatory drug. 21 CFR § 522.540 - (d)(4) (sterile aqueous solution). "Not for use in horses intended for food." - (e)(5) (sterile aqueous solution). "Not for use in horses intended for food." 21 CFR § 522.542 - "Not for use in horses intended for food." http://www.drugs.com/vet/dexium-injection.html Steroid for humans.	Adverse reactions include fluid/electrolyte disturbances, muscle weakness, osteoporosis, peptic ulcer, pancreatitis, ulcerative esophagitis, impaired wound healing, headache, psychic disturbances, growth suppression (pediatrics), glaucoma, hyperglycemia, weight gain, nausea, malaise. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=798 Steroids should be taken under a doctor's supervision and have multiple significant adverse affects including severe allergic reactions, hormonal changes, changes in menstrual functions, mental and mood changes, respiratory problems, nausea and vomiting, joint swelling, vision changes, and unusual weight gain.
31.	**Dichloromethane**	Furall Antibacterial http://msds.farnam.com/m000394.htm	If eaten, this drug can cause gastrointestinal irritation with nausea, vomiting and diarrhea. May cause kidney damage. May cause central nervous system depression, characterized by excitement, followed by headache, dizziness, drowsiness, and nausea. Advanced stages may cause collapse, unconsciousness, coma and possible death due to respiratory failure. May cause carboxyhemoglobinemia. Dichloromethane has been treated as a carcinogen in California since 1988 and it may also have adverse reproductive effects. http://www.sciencelab.com/msds.php?msdsId=9948&code=SLM2677
32.	**Diclazuril**	Clinacox Antiprotozoal Used to treat infections leading to myoencephalitis. 21 CFR § 520.606 - "Do not use in horses intended for human consumption."	Administered to some AIDS patients, but effects in humans largely unknown.
33.	**Diclofenac Sodium**	Surpass (topical) Arthritis treatment in humans and horses. 21 CFR § 524.590 - "Do not use for horses intended for human consumption." http://www.drugs.com/vet/surpass-	May cause hypertension, edema, or heart failure. Some individuals with prior gastrointestinal disease may be hypersensitive to the drug's effects. Potential kidney failure and danger for patients with renal disease. May cause anaphylactic reactions; may harm fetus in utero. Maycause liver problems. May cause anemia and affect blood. May cause abdominal pain, constipation, diarrhea, dyspepsia, flatulence, gross bleeding/perforation, heartburn, nausea and vomiting, gastrointestinal ulcers, renal function abnormalities, anemia, dizziness, edema, elevated liver enzymes. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Diclofenac+Sodium

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		topical-cream.html	
34.	**Diflubenzuron**	Equitrol II Fly control http://www.drugs.com/vet/equitrol-ii-feed-thru-fly-control.html	May cause anemia.
35.	**Dimethylsulfoxide**	Topical application for sprains, soreness; may also be injected or combined with other drugs for administration. Limited treatment use in humans -- used as a topical application to reduce acute swelling due to trauma. 21 CFR § 524.660a - Dimethyl sulfoxide solution - "Not for use in horses and dogs intended for breeding purposes nor in horses slaughtered for food." 21 CFR § 524.660b - Dimethyl sulfoxide gel - "Do not use in horses and dogs intended for breeding purposes or in horses slaughtered for food." http://www.webmd.com/vitamins-supplements/ingredientmono-874-DMSO%20(DIMETHYLSULFOXIDE).aspx?activeIngredientId=874&activeIngredientName=DMSO%20(DIMETHYLSULFOXIDE)	May cause headache, dizziness, drowsiness, nausea, vomiting, diarrhea, constipation, breathing problems, vision problems, blood problems, and allergic reactions. Also may harm the liver and kidneys. http://www.webmd.com/vitamins-supplements/ingredientmono-874-DMSO%20(DIMETHYLSULFOXIDE).aspx?activeIngredientId=874&activeIngredientName=DMSO%20(DIMETHYLSULFOXIDE) MSDS available here: http://www.sciencelab.com/msds.php?msdsId=9927347
36.	**Dimetridazole** (generic)	Bactericidal Antibacterial	Withdrawn from European market because of dangers of gastrointestinal problems, potential for cancer. http://www.bioagrimix.com/msds/36/36280/3628007.pdf
37.	**Di-n-propyl isocinchomeronate**	Fly control products:	High toxicity – classified as a carcinogenic Pesticide Action Network (PAN) "Bad Actor".[1]

[1] "PAN Bad Actor pesticides" belong to a "most toxic" set of pesticides identified by the Pesticide Action Network and Californians for Pesticide Reform (CPR). These pesticides are at least one of the following: known or probable carcinogens, as designated by the International Agency for Research on Cancer (IARC), U.S. EPA, U.S. National Toxicology Program, and the state of California's Proposition 65 list; reproductive or developmental toxicants, as designated by the state of

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		Flysect Super-7 repellent spray Flysect Super-C Mosquito Halt http://www.drugs.com/vet/flysect-super-7.html http://msds.farnam.com/m000811.htm http://www.drugs.com/vet/flysect-super-c.html http://www.drugs.com/vet/mosquito-halt-repellent-spray-for-horses.html	www.pesticideinfo.org/Detail_Chemical.jsp?Rec_id=PC2798
38.	**Dipropyl isocinchomeronate**	Farnam Roll-On Repellent (fly spray) http://msds.farnam.com/m000018.htm	High toxicity – PAN Bad Actor. Carcinogenic. www.pesticideinfo.org/Detail_Chemical.jsp?Rec_id=PC2798
39.	**Domperidone**	In horses, used for treatment of toxicity from fescue grass that affects pregnancies. In humans, used to increase bowel contractions and combat nausea and vomiting caused by other drugs. 21 CFR § 520.766 - "Do not use in horses intended for human consumption." http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm235691.htm	FDA has warned that this drug passes into breast milk and should not be used in nursing human mothers. Side effects include dizziness, dry mouth, nervousness, flushing, irritability, insomnia, stomach cramps, hot flashes and leg cramps, chest pain, slow/fast/irregular heartbeat, swelling of the feet or ankles, difficulty urinating, swelling of the breasts or discharge from the nipple in men or women, menstrual changes, sexual difficulties. May affect absorption and action of other drugs, and interact with other drugs. http://www.medicinenet.com/domperidone-oral/article.htm
40.	**Doxycycline**	Antibiotic for horses and humans. http://www.drugs.com/cdi/doxycycline-capsules.html	Dangerous for pregnant women; may cause tooth problems, gastrointestinal symptoms, autoimmune syndrome, renal problems.

California's Proposition 65 list; neurotoxic cholinesterase inhibitors, as designated by California Department of Pesticide Regulation, the Materials Safety Data Sheet for the particular chemical, or PAN staff evaluation of chemical structure (for organophosphorus compounds); known groundwater contaminants, as designated by the state of California (for actively registered pesticides) or from historic groundwater monitoring records (for banned pesticides); pesticides with high acute toxicity, as designated by the World Health Organization (WHO), the U.S. EPA, or the U.S. National Toxicology Program.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
41.	**Doxylamine succinate**	Antihistamine Anticholinargic 21 CFR 520.784 - "Not for use in horses intended for food."	Not to be combined with other antihistamines. Can cause multiple adverse side effects.
42.	**Equine Influenza vaccine**	Killed virus vaccine	Not intended for human use and no testing on human ingestion of this vaccine.
43.	**Equine Rhinopneumonitis – Influenza vaccine**	Killed virus vaccine Prestige II with Havlogen (vaccine) http://intervetus.naccvp.com/?m=product_view&id=1047348	Not intended for human use and no testing on human ingestion of this vaccine.
44.	**Estradiol**	Female hormone for management of reproductive functions in horses, and for relief of menopausal symptoms in humans Estradiol Cypionate in Oil Estradiol enanthate; Estradiol benzoate	Risk of cancer is among the multiple potential negative side effects related to the unapproved and uncontrolled use of this synthetic female hormone. Other side effects include headaches, dizziness, breast pain, increased risk for yeast infections, flu-like symptoms, arthritic pain, hair loss, gastrointestinal problems including nausea or vomiting, and incidences of spotting in between periods or other menstrual irregularities. May be unsafe for people with blood disorders, heart disease, obesity, seizure disorders or certain allergies.
45.	**Eucalyptus Oil**	Scarlet Oil Wound Dressing http://www.drugs.com/vet/scarlet-oil.html Labeled "Not for use on animals intended for food."	Potential side effects include seizures, poisoning, drowsiness, morbidity in children, central nervous system, depression.
46.	**Fenbendazole**	Dewormer (Panacur) Equi-bits Panacur Paste Panacur Power Pac Panacur Suspension Safe-Guard Safe-Guard Power-Dose 21 CFR § 520.905a - "Do not use in horses intended	No human formulation, and adverse effects on humans who eat this dewormer, that directly affects the gastrointestinal tract, are unknown.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		for human consumption."	
47.	**Firocoxib**	Equioxx Non-steroidal anti-inflammatory drug (NSAID). 21 CFR § 520.930; 522.930 - Firocoxib paste. - "Do not use in horses intended for human consumption." http://www.equioxx.com/	There is no approved use of this drug for humans and so any adverse effects on humans who ingest this drug are completely unknown. Firocoxib is one of the NSAIDs, all of which have extensive potential adverse side effects in humans including cardiovascular, gastrointestinal, kidney and eye problems. The NSAIDs can be dangerous for individuals with blood disorders. They are also contraindicated during pregnancy. They also present significant risk for people with a history of ulcers or gastrointestinal bleeding. Can cause nausea, abdominal pain, diarrhea, headaches, excitability, and nervous system problems.
48.	**Flunixin**	NSAID: Banamine (solution or paste) (pain killer) Flunazine injectable Flu-nix D injection Flunixamine 21 CFR § 520.970 - Granules - "Do not use in horses intended for human consumption." 21 CFR § 522.970 - Injectible - "Do not use in horses intended for human consumption."	Flunixin is one of the NSAIDs, all of which have extensive potential adverse side effects in humans including cardiovascular, gastrointestinal, kidney and eye problems. The NSAIDs can be dangerous for individuals with blood disorders. They are also contraindicated during pregnancy. They also present significant risk for people with a history of ulcers or gastrointestinal bleeding. Can cause nausea, abdominal pain, diarrhea, headaches, excitability, and nervous system problems.
49.	**Flunixin Meglumine**	NSAID: Flunazine injectable Flu-nix D injection Flunixamine Labeled: Not for use in horses intended for food. http://www.drugs.com/vet/flunixin-meglumine-injection.html http://www.drugs.com/vet/flunazine-injectable-solution.html http://www.drugs.com/vet/flu-nix-d-	This is also one of the NSAIDs, all of which have extensive potential adverse side effects in humans including cardiovascular, gastrointestinal, kidney and eye problems. The NSAIDs can be dangerous for individuals with blood disorders. They are also contraindicated during pregnancy. They also present significant risk for people with a history of ulcers or gastrointestinal bleeding. Can cause nausea, abdominal pain, diarrhea, headaches, excitability, and nervous system problems.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		ivx.html http://www.drugs.com/vet/flunixamine.html	
50.	**Furaltadone**	Antibacterial http://www.chemblink.com/MSDS/MSDSFiles/139-91-3_Sigma-Aldrich.pdf	May cause cancer in humans, but very little known about effect on humans because the drug has not been tested on humans and the potential side effects upon ingestion are unknown.
51.	**Furazolidone**	Antibacterial: Furall Furox Aerosol Powder Used in humans as an anti-diarrheal 21 CFR § 524.1005 - "Not for use in horses intended for food." http://msds.farnam.com/m000394.htm http://www.drugs.com/vet/furazolidone-aerosol-powder.html Federal law prohibits the use of this product in food-producing animals.	Contains chemicals known to the state of California to cause cancer. Should only be taken under strict medical oversight; dangerous if taken with alcohol, when pregnant, or for individuals with certain blood disorders. Adverse effects include headache, stomach upset, nausea, vomiting, dizziness or weakness, fever, skin rash, itching, muscle aches, flushing, breathing trouble. This medication may cause the urine to turn brown in color.
52.	**Furosemide**	Diuretic: Lasix Used in humans and horses	May cause pancreatitis, jaundice, anorexia, paresthesias, ototoxicity, blood dyscrasias, dizziness, rash, urticaria, photosensitivity, fever, thrombophlebitis, restlessness. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Furosemide
53.	**Gentamicin sulfate solution**	Antibiotic: Gentamicin solution Do not use for horses intended for human consumption. http://www.drugs.com/vet/gentamicin-sulfate-solution.html 21 CFR § 529.1044a - "Do not use in horses intended for human consumption."	Can cause severe hearing and kidney problems. May cause dizziness, vertigo, ringing in the ears, hearing loss, numbness, muscle twitching or weakness, difficulty breathing, decreased urination, rash, itching, or sore throat. Interaction and potential harm with other drugs can cause adverse reactions.
54.	**Gentian violet**	Blue-Kote	Usually used topically on humans. Unknown side effects upon ingestion.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		Topical ointment, antiseptic, protective wound dressing. Not for use on food producing animals. http://www.drugs.com/vet/dr-naylor-blu-kote.html http://www.drnaylor.com/index.php?option=com_content&task=blogcategory&id=20&Itemid=47 "Not for use on animals intended for food." http://www.horsesuppliesplus.com/antiseptics.html	
55.	**HCl**	Component of Dexium injection http://www.drugs.com/vet/dexium-injection.html	Very hazardous if touched; not fully tested on humans; may be fatal if inhaled or swallowed. Causes irritation and burning, ulceration, or perforation of the gastrointestinal tract and resultant peritonitis, gastric hemorrhage and infection. Can also cause nausea, vomiting (with "coffee ground" emesis), diarrhea, thirst, difficulty swallowing, salivation, chills, fever, uneasiness, shock, strictures and stenosis (esophogeal, gastric, pyloric). May affect behavior (excitement), the cardiovascular system (weak rapid pulse, tachycardia), respiration (shallow respiration), and urinary system (kidneys- renal failure, nephritis). Acute exposure via inhalation or ingestion can also cause erosion of tooth enamel.
56.	**Hyaluronate sodium**	Arthritis treatment Legend Legend injectable 21 CFR § 522.1145 - "Do not use in horses intended for human consumption." - "Not for use in horses intended for food." http://www.bayerdvm.com/products/legend/legend.cfm http://www.drugs.com/vet/legend-multi-dose-hyaluronate-sodium-injectable-solution.html	May cause gastrointestinal tract information with nausea and vomiting. It may affect blood (normocytic anemia, change in leukocyte count), metabolism, behavior (ataxia, convulsions), respiration (respiratory stimulation), and urinary system. The toxicological properties of this substance have not been fully investigated. http://www.sciencelab.com/msds.php?msdsId=9924276
57.	**Hyaluronic acid sodium salt**	Polyglycan	May cause gastrointestinal irritation, affect blood, metabolism and behavior. The dangers upon ingestion by humans has not been fully investigated.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		For use only as a surgical lavage in animals not intended for food use. http://www.medi-vet.com/Polyglycan.aspx Also used in race horses prior to a race.	
58.	**Hydroxyzine Pamoate**	Anti-anxiety in humans and preoperative sedation. Antihistamine, anti-itching and sedative in animals. http://www.drsfostersmith.com/product/prod_display.cfm?pcatid=20678	May impair mental and physical abilities in elderly, may potentiate other medications, and not for use by pregnant or nursing mothers. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=1096
59.	**Hyoscine butylbromide**	Buscopan Scopolamine Antispasmodic; colic pain relief. http://www.drugs.com/vet/buscopan-sterile-solution-can.html	Potential adverse effects include blurred vision, severe allergic reactions, confusion, urinary problems, and mood changes. www.drugs.com/sfx/scopolamine-side-effects.html
60.	**Isoflurane**	Surgical anesthetic 21 CFR § 529.1186 - "Do not use in horses intended for human consumption."	MSDS reports no information on toxicity upon ingestion.
61.	**Isoparaffinic Petroleum Solvent**	Fly Control: Farnam Bronco Gold (spray) Farnam Wipe http://msds.farnam.com/m001650.htm http://msds.farnam.com/m000490.htm	Unknown human toxicity and side effects after ingestion.
62.	**Ivermectin**	Dewormers: Agri-mectin Paste Bimectin Paste Equell Paste	Can act for up to twelve months; carcinogenicity not studied; not recommended for pregnant women; distributes into breast milk. Adverse reactions include pruritus, edema, papular/pustular/frank urticarial rash, fever, axillary/cervical/inguinal lymphadenopathy, arthralgia/synovitis, limbitis, tachycardia, peripheral edema, leukopenia, eosinophilia

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		Equimax Farnam Ivercare Horse Health Ivermectin Ivercare paste ProMetin E™ Paste Zimecterin Gold Zimecterin Paste Also found in human anthelmintic compounds 21 CFR § 520.1192 - Paste - "Do not use in horses intended for human consumption." 21 CFR § 1194 - Meal - "Do not use in horses intended for human consumption." 21 CFR § 1195 - Liquid - "Do not use in horses intended for human consumption." 21 CFR §1198 - Ivermectin and praziquantel paste - "Do not use in horses intended for human consumption." http://www.drugs.com/vet/agri-mectin-paste-1-87.html http://www.drugs.com/vet/agri-mectin-paste-1-87.html http://www.davisandlawrence.com/1-x-6-08-g.html http://www.horsehealthusa.com/details/Equell-Paste/37-105.html http://www.equimaxhorse.com/	http://www.pdr.net/search/searchResult.aspx?searchCriteria=ivermectin

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
63.	**Ketoprofen**	NSAID: Ketofen Used as NSAID in horses and humans. 21 CFR § 522.1225 - "Not for use in horses intended for food." http://www.drugs.com/vet/ketofen.html	Ketoprofen is one of the NSAIDs, all of which have extensive potential adverse side effects in humans including cardiovascular, gastrointestinal, kidney and eye problems. The NSAIDs can be dangerous for individuals with blood disorders. They are also contraindicated during pregnancy. They also present significant risk for people with a history of ulcers or gastrointestinal bleeding. Can cause nausea, abdominal pain, diarrhea, headaches, excitability, and nervous system problems.
64.	**Levothyroxine Sodium**	Thyro-L Thyroid replacement hormone. http://www.drugs.com/vet/thyro-l.html	This artificial thyroid hormone can exacerbate thyroid and hypertension problems in susceptible individuals. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Levothyroxine+Sodium
65.	**Luprostiol**	For control of reproductive cycles and inducing termination of pregnancy. 21 USC § 522.1290 - solution - "Do not use in horses intended for human consumption." - "Labeling shall bear the following statements: Warning: Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early states, women may be unaware of their pregnancies..."	Dangerous for children, pregnant and lactating mothers, individuals with respiratory problems. Can cause hormonal effects when taken.
66.	**Mepivacaine**	Anesthetic 21 CFR § 522.1372 - "Not for use in horses intended for human consumption."	Because this is an injectable drug, studies have not been done on the dangers of ingestion.
67.	**Methocarbamol**	Robaxin Muscle relaxant in animals and humans.	Potential adverse reactions include lightheadedness, dizziness, drowsiness, nausea, urticaria, pruritus, rash, conjunctivitis, nasal congestion, blurred vision, headache, fever, seizures, syncope, flushing. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Methocarbamol

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		http://www.petplace.com/drug-library/methocarbamol-robaxin-v/page1.aspx	
68.	**Methyl Salicylate**	Scarlet Oil Wound dressing for horses. Muscle and joint pain relief in humans. Not for use on animals intended for food. http://www.drugs.com/vet/scarlet-oil.html	"When ingested, the highly concentrated liquid methyl salicylate in the form of wintergreen oil, as with other volatile oils, can induce vomiting and is a notorious source for severe, often fatal poisonings." http://www.drugs.com/npp/wintergreen.html Dangerous if used in conjunction with other analgesics, anticoagulants, steroids, NSAIDs, alcohol, and diuretics. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Methyl+Salicylate
69.	**Methylandrostenediol**	Methandriol Anabolic steroid Used as growth stimulator and steroid in horses and humans. http://www.drugs.com/international/methandriol.html	Can cause estrogenic (female hormone) and androgenic (male hormone) effects. Steroids should be taken under a doctor's supervision and have multiple significant adverse affects including severe allergic reactions, hormonal changes, changes in menstrual functions, mental and mood changes, respiratory problems, nausea and vomiting, joint swelling, vision changes, and unusual weight gain.
70.	**Methylprednisolone**	Human and horse steroid 21 CFR § 522.1410 - "Do not use in horses intended for human consumption."	Steroids should be taken under a doctor's supervision and have multiple significant adverse affects including severe allergic reactions, hormonal changes, changes in menstrual functions, mental and mood changes, respiratory problems, nausea and vomiting, joint swelling, vision changes, and unusual weight gain.
71.	**Metronidazole**	Antibiotic in humans and horses (Flagyl) http://www.wedgewoodpetrx.com/learning-center/professional-monographs/metronidazole-for-veterinary-use-ab.html	This drug can cause gastrointestinal problems, serious allergic reactions in sensitive individuals, flu-like symptoms, seizures, encephalopathy, aseptic meningitis, peripheral neuropathy, nausea and vomiting, headache, anorexia and neutropenia. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Metronidazole
72.	**Moxidectin**	Quest Gel Quest Plus Antiparasitic (dewormers) Not for horses or ponies intended for human consumption. http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/	Very limited testing on humans – potential adverse effects still unknown.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		ComplianceEnforcement/ucm168782.htm 21 CFR § 520.1452; 520.1463 - Gel - "Not for use in horses and ponies intended for food." http://www.drugs.com/vet/quest-plus-equine-oral-gel.html	
73.	**N-(2-Ethylhexyl)-5-norbornene-2,3-dicarboximide**	Bug Block (fly control) http://absorbine.org/products/flycontrol/bug-block-insecticide-repellent http://www.statelinetack.com/ContentFiles/Associated_Content/absorbinebugblockMSDS.pdf	"Harmful if ingested." Bug Block fly control has multiple adverse effects if swallowed by humans. http://www.statelinetack.com/ContentFiles/Associated_Content/absorbinebugblockMSDS.pdf
74.	**N-acetyl-D-glucosamine 10%**	Polyglycan Post-surgical lavage of joint compartments. "Do not administer to animals that are to be slaughtered for food." www.arthrodynamic.com/polyglycan/	Ingredient in Polyglycan, which includes warning: "For use only as a surgical lavage in animals not intended for food use." http://www.medi-vet.com/Polyglycan.aspx
75.	**Neomycin Sulfate**	Animax ointment Human and animal antimicrobial, anti-fungal steroid drug	May cause nausea and vomiting, diarrhea, malabsorption syndrome, nephrotoxicity, ototoxicity, neuromuscular blockage, neurotoxicity, fetal harm. Especially dangerous for individuals with certain diseases of the muscles. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=3174
76.	**Nitrofurantoin**	Equifur Antibacterial for urinary tract infections in horses and humans. This drug is not to be administered to horses that are to be slaughtered for use in food. http://www.drugs.com/vet/equifur-can.html	Adverse effects include hypersensitivity reactions, pulmonary/hepatic/psychotic reactions, peripheral neuropathy, nausea and vomiting, anorexia, dizziness, exfoliative dermatitis, anaphylaxis, hematologic abnormalities, cyanosis, angioedema, asthenia. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=383

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
77.	**Nitrofurazone**	Niderm Ointment Antibacterial ointment, burns, skin grafts. 21 CFR § 524.1580b - "Do not use in horses intended for human consumption." - "Federal law prohibits the use of this product in food-producing animals." Federal law prohibits the administration of this preparation to animals that produce food or that are intended for consumption as food. http://www.drugs.com/vet/niderm-ointment-can.html	Very toxic to humans. http://www.sciencelab.com/msds.php?msdsId=9926271
78.	**N-Octyl Bicycloheptene Dicarboximide**	Farnam Roll-On Repellent Fly spray http://msds.farnam.com/m000018.htm	According to the manufacturer, Farnam Roll-On Repellent is "harmful if swallowed."
79.	**Nystatin**	Antimicrobial, antifungal and steroid Animax ointment Mycostatin Bio-Statin For use in humans and horses with thrush.	Adverse reactions include oral irritation, sensitization, diarrhea, nausea and vomiting, gastrointestinal disturbances, rash, urticaria, Stevens-Johnson syndrome. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Nystatin See also: http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000767/ http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682758.html
80.	**Omeprazole**	Treatment for ulcers in horses and humans. Gastrogard 21 CFR § 520.1615 - "Do not use in horses intended for human consumption." http://gastrogard.us.merial.com/faq.shtml	Adverse reactions include headache, diarrhea, abdominal pain, nausea and vomiting, fever, respiratory disorders, severe allergic reactions, irregular heartbeat, bruising and bleeding. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Omeprazole
81.	**Oxibendazole**	Anthelcide dewormer	"Do not allow product to enter drinking water supplies, waste water or soil."

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		21 CFR § 520.1638 - paste - "Not for use in horses intended for human consumption." 21 CFR § 520.1638 - Suspension - "Not for use in horses intended for human consumption." Not for use in horses intended for human consumption. http://www.drugs.com/vet/anthelcide-eq-equine-wormer-paste.html	http://www.seqchem.com/safetysheet.php?SQIndex=SRP012491o
82.	**Parachlorometaxylenol**	Scarlet Oil Not for use on animals intended for food. http://www.drugs.com/vet/scarlet-oil.html	May cause burning of mouth, throat and stomach, if ingested. http://surfactantsinc.com/pdf/Surcide%20PCMX-USP%20MSDS.pdf
83.	**Phenol**	Red-Kote Not for use on animals intended for food. http://www.drugs.com/vet/dr-naylor-red-kote.html	Phenol is considered to be quite toxic to humans via oral exposure. Anorexia, progressive weight loss, diarrhea, vertigo, salivation, a dark coloration of the urine, and blood and liver effects have been reported in chronically (long-term) exposed humans. Animal studies have reported reduced fetal body weights, growth retardation, and abnormal development in the offspring of animals exposed to phenol by the oral route. http://www.epa.gov/ttn/atw/hlthef/phenol.html
84.	**Phenylbutazone**	NSAID: Butazone 400 Butazone 1000 Butazone Concentrate Bute paste Butequine 21 USC §520.1770a - Tablets and boluses - Dogs and horses - "Do not use in horses intended for human consumption.." 21 USC § 522.1720	Serious and fatal adverse effects have been reported from ingestion of Phenylbutazone, including bone marrow suppression and aplastic anemia. Banned in America for human use. Nicholas Dodman, Nicolas Blondell, Ann M. Marini, "Association of phenylbutazone usage with horses bought for slaughter: A public health risk", FOOD AND CHEMICAL TOXICOLOGY 48 (2010) 1270–74. "Phenylbutazone is known to induce blood dyscrasias, including aplastic anemia, leukopenia, agranulocytosis, thrombocytopenia and deaths. Hypersensitivity reactions of the serum-sickness type have also been reported. In addition, phenylbutazone is a carcinogen, as determined by the National Toxicology Program." http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm124078.htm Phenylbutazone is especially problematic for patients with a history of asthma attacks, hives, or other allergic reactions to aspirin or other NSAIDs. It also should be avoided by patients with peptic ulcer disease or poor kidney function, since this medication

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		- Injection - Dogs and horses - "Not for use in animals intended for food." http://horsebackmagazine.com/hb/archives/13184 http://www.farmvet.com/pc-1500-163-bute-paste-12-gm.aspx http://www.drugs.com/vet/butequine-can.html http://tuesdayshorse.wordpress.com/tag/cfia/	can aggravate both conditions. Phenylbutazone is generally used with caution in patients taking blood thinning medications (anticoagulants), such as warfarin (Coumadin), because of an increased risk of bleeding. Patients taking lithium can develop toxic blood lithium levels. Additionally, patients taking cyclosporine (Sandimmune) can develop kidney toxicity.
85.	**Piperonyl Butoxide**	Repel-XP Fly control Do not use on horses intended for human consumption. http://www.drugs.com/vet/repel-xp-emulsifiable-fly-spray.html	Potential dangers to humans are unknown: "Data are not available from accidental poisonings, occupational exposures, or epidemiological studies regarding the reproductive and developmental toxicity of piperonyl butoxide." npic.orst.edu/factsheets/pbotech.pdf Ingestion can cause vomiting and diarrhea. Pesticide Action Network North America. Piperonyl Butoxide, http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC33240 The EPA classifies piperonyl butoxide as a group C carcinogen, a possible human carcinogen. Environmental Protection Agency. Reregistration Eligibility Decision for Piperonyl Butoxide. (June 2006). http://www.epa.gov/opp00001/reregistration/REDs/piperonyl_red.pdf
86.	**Polysulfated Glycosaminoglycan**	Adequan Joint treatment. 21 USC § 522.1850 - "Do not use in horses intended for human consumption."	Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of this supplemental new animal drug. The drug is approved for use only in horses that are not to be used for food and is to be labeled "'Not for use in horses intended for food.'" http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm054846.htm Based on the formulation of the drug, humans could develop anaphylaxis or excessive bleeding as the sulfated proteoglycans are anticoagulants.
87.	**Ponazuril**	Antiprotozoal Marquis paste; Marquis 21 CFR § 520.1855 - Horses only - "Not for use in horses intended	Unknown side effects and adverse reactions in humans ingesting Ponazuril. "Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of this supplemental new animal drug. The drug is approved for use only in horses that are not to be used for food and is to be labeled 'Not for use in horses intended for food.'" Freedom of Information Summary, Original New Animal Drug Application, NADA

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		for food." "Not for use in horses intended for food." http://www.drugs.com/vet/marquis-15-w-w-ponazuril-antiprotozoal-oral-paste.html	141-188 (Marquis), www.fda.gov/downloads/AnimalVeterinary/.../ucm117581.pdf
88.	**Prallethrin**	Insecticide Mosquito Halt Fly spray http://www.drugs.com/vet/mosquito-halt-repellent-spray-for-horses.html	Potential poisoning, headache, dizziness, nausea, and seizure. http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC35755 "Pyrethroid ingestion gives rise within minutes to a sore throat, nausea, vomiting and abdominal pain. There may be mouth ulceration, increased secretions and/or dysphagia. Systemic effects occur 4-48 hours after exposure. Dizziness, headache and fatigue are common, and palpitations, chest tightness and blurred vision less frequent. Coma and convulsions are the principal life-threatening features. Most patients recover within 6 days. . . ." S.M. Bradberry *et al.*, *Poisoning Due to Pyrethroids*, Toxicol Rev. 24(2):93-106 (2005) (quoting abstract).
89.	**Praziquantel**	Dewormer For horses and humans Equimax Quest Plus Zimecterin Gold http://www.equimaxhorse.com/ http://www.drugs.com/vet/quest-plus-equine-oral-gel.html "Not for use in humans." (Zimecterin) http://www.zimecterin.com/ZimecterinGold/index.html?=50	Available by prescription only and to be taken only under the monitoring of a physician. Contraindicated for people with pre-exiting conditions involving the liver, kidney, or heart. Praziquantel may cause side effects including headache, dizziness, stomach pain, nausea, fever, itching, hives (especially serious). http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000474/ http://www.rxlist.com/biltricide-drug/patient-images-side-effects.htm
90.	**Prednisone**	Human and horse steroid 21 USC § 522.1890 - Horses, dogs and cats - "Not for use in horses intended for human consumption."	Steroids should be taken under a doctor's supervision and have multiple significant adverse affects including severe allergic reactions, hormonal changes, changes in menstrual functions, mental and mood changes, respiratory problems, nausea and vomiting, joint swelling, vision changes, and unusual weight gain.
91.	**Prostaglandin**	Lutalyse solution Horse and human use – regulation of	Can cause unknown and unwanted hormonal effects, including termination of pregnancy, to individuals who ingest without knowing.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		female reproduction and other uses. This drug is not to be administered to horses that are to be slaughtered for use in food. http://www.drugs.com/vet/lutalyse-sterile-solution-can.html	
92.	**Pseudoephedrine HCl**	Tri-Hist Granules Not for use in horses intended for food. http://www.drugs.com/vet/tri-hist-granules.html	Can cause central nervous stimulation, insomnia, anxiety, dizziness, blurred vision, colitis, and psychosis when combined with other drugs.
93.	**Pyrantel Pamoate**	Exodus Paste Dewormer 21 CFR § 520.2044 - Horses and ponies - "Do not use in horses intended for human consumption." 21 CFR § 520.2043 - Horses and ponies - "Do not use in horses intended for human consumption." http://www.drugs.com/vet/exodus-paste.html	Adverse reactions include abdominal cramps, nausea and vomiting, diarrhea, headache, dizziness. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=2985
94.	**Pyridoxine HCl**	Liver 7 injection	Potential health effects after ingestion unknown. http://www.sciencelab.com/msds.php?msdsId=9924765
95.	**Pyrilamine Maleate USP**	Tri-Hist Granules Antihistamine (human and horse use) 21 CFR § 522.2063 - "Do not use in horses intended for food purposes." Not for use in horses intended for food. http://www.drugs.com/vet/tri-hist-granules.html	Many individuals with identified health conditions have hypersensitivities to antihistamines and the use of antihistamines is contraindicated in that portion of the population. http://www.drugs.com/pro/poly-hist-pd.html

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
96.	**Rabies vaccination**	Imovax Rabies Vaccine	The dangers of human ingestion are unknown.
97.	**Ractopamine hydrochloride**	Optaflexx 100 Premix Beta-agonist used for growth promotion purposes	A January 2012 article reported that ractopamine hydrochloride is "[f]ed to an estimated 60 to 80 percent of pigs in the United States, [and has] has sickened or killed more of them than any other livestock drug on the market." While the FDA has approved the drug for use in cows and pigs, many countries have banned it from food-producing animals, and the drug has never been tested on horses intended for human consumption. http://bottomline.msnbc.msn.com/_news/2012/01/25/10220221-dispute-over-drug-in-feed-limiting-us-meat-exports
98.	**Rhinopneumonitis vaccine**	5-way (vaccination) http://www.alpineanimal.net/page6263a3c5.html?inc=na	Unknown consequences for humans.
99.	**Ronidazole**	Antiprotozoal agent http://www.wedgewoodpetrx.com/items/ronidazole-capsule.html	Does not appear to have any human applications. Dangerous side effects in animals. Toxicity information and potential health effects are unknown. https://www.reagentworld.com/products/msds2.asp?proid_2=23072
100.	**Selenium**	Trace mineral supplement 21 USC § 522.2100 - "Do not use in horses intended for food."	Rare but potential side effects include nausea, vomiting, abdominal pain, hearing loss, fatigue, weight loss, muscle tenderness, heart failure, and allergic reactions.
101.	**Stanozolol**	Anabolic steroid Used in both animals and humans. 21 USC 522.2150 - "Not for use in horses intended for food." http://www.petplace.com/drug-library/stanozolol-winstrol/page1.aspx	Potential side effects of anabolic steroids are well-documented. Steroids should be taken under a doctor's supervision and have multiple significant adverse affects including severe allergic reactions, hormonal changes, changes in menstrual functions, mental and mood changes, respiratory problems, nausea and vomiting, joint swelling, vision changes, and unusual weight gain
102.	**Stilbenes**	Used in estrogen-related substances	Animals treated with these drugs are banned from meat production in the European Union. http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=EN&numdoc=32008L0097
103.	**Strangles vaccine (Streptococcus Equi vaccine)**	Vaccination for *streptococcus equi* http://www.aaep.org/strangles.htm Pinnacle I.N. (strangles)	Dangers of human ingestion unknown.

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		http://www.drugs.com/vet/pinnacle-i-n.html	
104.	**Sucralfate**	Used to aid in healing gastrointestinal tract, ulcers, for humans and animals.	Adverse reactions include constipation, diarrhea, nausea and vomiting, pruritus, rash, dizziness, insomnia, back pain, headache, dry mouth, flatulence, gastric discomfort, indigestion, sleepiness. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Sucralfate
105.	**Sulfadiazine**	Tribrissen (oral) 400 paste 21 CFR § 520.2215 - "Do not use in horses intended for human consumption." 21 CFR § 520.2260a - "Do not use in horses intended for human consumption." http://www.drugs.com/vet/tribrissen-400-oral-paste.html	Sulfadiazine has potential cross-sensitivity with other drugs in the same class. Some individuals will have blood cell destruction from the drug. It can also cause transient leukopenia, skin necrosis, skin discoloration, burning sensation, rash, interstitial nephritis, and other systemic reactions. http://www.pdr.net/search/searchResult.aspx?searchCriteria=Sulfadiazine
106.	**Sulfamethoxazole Trimethoprim**	Antibacterial Bactrim, Septra	While these drugs are approved for human use, unnecessary ingestion of antibiotics is medically contraindicated. Additionally, adverse reactions include nausea and vomiting, anorexia, allergic skin reactions (*e.g.*, rash, urticaria), agranulocytosis, aplastic anemia, hepatitis, renal failure, hyperkalemia, aseptic meningitis, arthralgia, convulsions, cough.
107.	**Sunscreens**	Components in various fly spray products http://www.horse.com/ContentFiles/Associated_Content/ultrashieldexlabel.pdf	While sunscreens are used by humans, there is no substantial literature or studies on ingestion of sunscreens or their byproducts and metabolites.
108.	**Testosterone enanthate**	Uni-Bol Male sex hormone http://www.drugs.com/vet/uni-bol-can.html	The ingestion of male hormones, when not medically indicated, can create hormonal imbalances. Additionally, use may cause dangerous reactions in hypersensitive individuals or those with other illnesses. Can increase prostate and other problems in elderly men. Can also cause hormone-mediated reactions, fluid and electrolyte disturbances, nausea, cholestatic jaundice, alterations in liver function, headache, and anxiety. It is also designated as "not for use" in nursing mothers. http://www.pdr.net/drugpages/concisemonograph.aspx?concise=2017
109.	**Thiamine HCl**	Included in liver 7 injection http://www.drugs.com/vet/liver-7-injection.html	Hazardous in case of ingestion. http://www.sciencelab.com/msds.php?msdsId=9925232

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
110.	**Thyrostats**	Thyroid-related growth promotion Antithyroid agents for the purpose of growth promotion	Animals treated with these drugs are banned from meat production in the European Union. http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=EN&numdoc=32008L0097.
111.	**Topazone Aerosol Powder**	Antibacterial Topazone Furox http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm137145.htm	Contains chemicals known to the state of California to cause cancer. Should only be taken under strict medical oversight; dangerous if taken with alcohol, when pregnant, or for individuals with certain blood disorders. Adverse effects include headache, stomach upset, nausea, vomiting, dizziness or weakness, fever, skin rash, itching, muscle aches, flushing, breathing trouble. This medication may cause the urine to turn brown in color.
112.	**Triamcinolone Acetonide**	Component in Animax ointment Antimmicrobial, anti-fungal, steroid (for thrush treatment) 21 CFR § 520.2483 - tablets - "Do not use in horses intended for human consumption." 21 CFR § 522.2483 - Suspension - "Do not use in horses intended for human consumption."	Steroids should be taken under a doctor's supervision and have multiple significant adverse affects including severe allergic reactions, hormonal changes, changes in menstrual functions, mental and mood changes, respiratory problems, nausea and vomiting, joint swelling, vision changes, and unusual weight gain.
113.	**Trimethoprim**	Uniprim antibiotic Powder For treatment of *Streptococcus equi* ("Strangles") 21 CFR § 520.2611 - "Do not use in horses intended for human consumption." 21 CFR § 520.2613 - Trimethoprim and sulfadiazine powder - "Not for use in horses intended for food." "Do not use in horses intended for human consumption."	Trimethoprim is a strong antibiotic with multiple potential adverse reactions, adverse interactions with other drugs and hypersensitivities noted in individuals with various diseases and metabolic conditions. http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000813/

	Drug	Product/Type/Warnings	Potential problems from human ingestion of residue or metabolites
		http://www.drugs.com/vet/tribrissen-400-oral-paste.html http://www.drugs.com/vet/uniprim-powder.html	
114.	**West Nile virus**	Recombitek West Nile Vaccine http://www.drugs.com/vet/recombitek-equine-west-nile-virus-can.html	This vaccine has only been approved for use in horses and no data exists with respect to the safety of humans eating it, or meat from animals who have received it.
115.	**Xylazine**	Sedative Anased 21 CFR § 522.2662 - "Not for use in horses intended for food. - "Do not use in domestic food-producing animals."	Xylazine poisoning causes hypotension, bradycardia, and respiratory depression. Ocular administration can cause sinus bradycardia, hypotension and decreased mental status. Velez LI, Shepherd G, Mills LD, Rivera W., *Systemic toxicity after an ocular exposure to xylazine hydrochloride,* J. EMERG. MED. 30(4):407-10 (2006).

EXHIBIT 6

DECLARATION OF HILARY WOOD

I, Hilary Wood, declare as follows:

1. I am the President and Founder of Front Range Equine Rescue ("FRER"), a 501(c)(3) nonprofit organization incorporated in Colorado. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection. If called, I could and would testify to these facts in a court of law.

2. Petitioner FRER is a Colorado-based nonprofit group incorporated under Section 501(c)(3) of the Internal Revenue Code. FRER is dedicated to stopping cruelty and abuse of horses through rescue and education. FRER is actively involved in the rescue, rehabilitation and adoption to good homes of domestic and wild horses found at auctions and horses destined for slaughter; and in educational efforts regarding responsible horse ownership, the cruelty of horse slaughter and wild horse roundups. FRER has assisted thousands of horses through its rescue and educational programs. While some of FRER's horses are surrendered by their owners or rescued when abandoned, many are rescued from livestock auctions; others are purchased at feed lots before they are sent to slaughter.

3. FRER directly rescues approximately 100 – 120 new horses per year. FRER horses live at facilities owned by FRER, at private foster homes, or at other privately contracted facilities.

4. One of FRER's primary goals is to purchase horses destined for slaughter for human consumption. Once rescued, FRER provides for the direct care and rehabilitation of these horses, provides training assessment, and then adoption into permanent and suitable homes for them.

5. I have personally been housing and providing for the care of horses for over twenty years.

6. In connection with my work with FRER and my own personal ownership of horses, I have become intimately familiar with the drugs, treatments and substances used by horse owners in America.

7. I assisted in the preparation of and have reviewed Exhibit 1 to the Petition for Rulemaking being submitted by FRER. Every item on that list is either commonly found in barns housing horses, and is used on those horses, or is found in catalogues and supply stores, for sale to private horse owners in America or available with a veterinarian's prescription. I am personally familiar with and use or have used at least 50 of the substances on that list, and am informed and believe that all of those substances are used regularly on companion, pleasure and recreation, and competition/show horses.

8. FRER has rescued horses from auction lots who were born as wild horses, captured by the federal Bureau of Land Management ("BLM"), and eventually ended up for sale. I have also directly adopted wild horses from the BLM. Records that accompanied these horses showed that they received some of the drugs on Exhibit 1, including but not limited to a series of vaccinations for many diseases, dewormers, which are labeled as prohibited for use in animals which will be eaten.

9. As part of FRER's mission, I have participated in the purchase of slaughter-bound horses directly from lots that were the horses' last stop before slaughter. Many of those horses, who would have entered the slaughter process otherwise, were sick with contagious respiratory illnesses. Many others developed serious illnesses, such as *Streptococcus equi* ("strangles"), a virulent and highly contagious equine infection, within a week of our acquisition.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 19th day of March, 2012, in Larkspur, Colorado.

Hilary Wood

DECLARATION OF PEGGY W. LARSON, DVM, MS, JD

I, Peggy W. Larson, declare as follows:

1. I am a doctor of veterinary medicine, currently practicing in Vermont. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection.

2. As described in the attached Curriculum Vitae, I am a licensed large animal veterinarian and have been practicing veterinary medicine for over 45 years. I received a Doctorate of Veterinary Medicine from the University of Ohio in 1965, a Masters of Science in comparative pathology from the University of California at Davis in 1968, and a Juris Doctorate from Vermont Law School in 1988.

3. From 1968 to 1978, I was a practicing large animal veterinarian in North Dakota, focusing on food animal and equine medicine and surgery. I performed diagnosis, treatment, and surgery, and frequently assessed, observed, and treated horses in my professional capacity.

4. I served as a Veterinary Medical Officer for the United States Department of Agriculture (USDA) from 1979 to 1985. In this capacity, I managed federal livestock disease control programs in Vermont, performed animal welfare inspections at circuses and research facilities, and issued federal health certificates on export animals.

5. In 1984, I was appointed by the Governor of Vermont to the position of Vermont State Veterinarian and Acting Chief of Livestock and Meat Inspection. In this position, I managed ongoing livestock and meat inspections programs and rewrote Vermont's meat and poultry inspection regulations. For approximately four months, I inspected all of Vermont's slaughter facilities until a permanent veterinary meat inspector was hired.

6. As a veterinarian and a former USDA employee, I am familiar with the variety of drugs, substances and treatments given to American horses. I also have personal

knowledge regarding the issues surrounding the slaughtering of horses for human consumption, including the sources from which horses for human consumption originate, and horse slaughter welfare issues in general. As a large animal veterinarian, I have observed horses first hand in small and large communities throughout the country.

7. I have reviewed Exhibit 1 to the Petition for Rulemaking submitted by Front Range Equine Rescue. Based on my experience and knowledge of the industry, I am informed and believe that many of the drugs, substances and treatments listed on Exhibit 1 are commonly used on American horses in the companion, competitive and sport areas. Many of those drugs are prohibited for use in horses intended for human consumption, and others have never been tested on humans to determine the effect of ingestion, or the degree to which any residue of these drugs, treatments and substances remains in horses who have been exposed to them.

8. Based on longstanding medical and scientific principles, it is impossible to declare horse meat safe for human consumption when the horses who are slaughtered for that meat have been exposed to an unidentified (and unidentifiable) number of drugs, treatments and substances, in unknown (and unknowable) quantities, at various times during their life.

9. In order for horse meat to be safe for human consumption, each of these drugs will have to be identified and the following will have to be determined: the length of time the drug is present in the horse after the last administration of the drug, what drug residuals remain after a specified waiting period, how much residue is allowable in the meat, and the toxic effects of the drug in humans, including humans who may have special sensitivities or medical conditions that may make them more susceptible to these drugs.

10. In order for horse meat to be safe for human consumption, a testing method will have to be developed to identify and quantify each of the drugs, treatments and

substances commonly used on American horses. Until these criteria are met, horse meat has to be deemed unsafe for human consumption.

11. Based on the foregoing and my training and experience, it is my professional opinion that American horses who are sent to slaughter for human consumption have potentially been treated with a variety of drugs, treatments and substances that potentially renders their flesh dangerous to people who eat horse meat and makes the horses' meat unsafe for human consumption.

12. Horses bound for slaughter are frequently shipped for long distances, and sometimes in a manner that fails to accommodate their unique temperaments and physical requirements. See C.L. Stull, *Response of Horses to Trailer Design, Duration, and Floor Area During Commercial Transportation to Slaughter*, J. ANIM. SCI. 77:2925-2933 (1999). Transported horses are often not given food and water every 28 hours, despite the federal law. T.H. Friend, *A Review of Recent Research on the Transportation of Horses*, 79 J. ANIMAL SCI. E32 (2001) ("Continuous transport of slaughter horses for 30 hours is common, and some trips last 36 hours or longer.").

13. Because of the methods of transport, horses often suffer a variety of injuries and illnesses during transport. *See, e.g.*, K.A. Houpt & S. Lieb, *Horse Handling and Transport*, LIVESTOCK HANDLING AND TRANSPORT (2000) (describing "moderately severe back injuries" in transported horses); G. Giovangnoli, M. Trabalza Marinucci, A. Bolla & A. Borghese, *Transport Stress in Horses: An Electromyographic Study on Balance Preservation*, 73 LIVESTOCK PRODUCTION SCIENCE 247 (2002). The lack of proper food and water in already weakened animals can lead to further injuries, illness and death during extended transport.

14. Consequently, many horses may arrive at the slaughterhouse too sick or injured to stand up and walk. If they are ill, the microorganisms and other infecting agents would taint their meat and render it unsafe for human consumption.

15. The horses that survive transport are put into holding pens at the slaughter plant. These pens often lack shelter and expose the horses to extreme temperatures, rain and snow. This further increases the chances of disease and infection, and the possibility that the horses' meat will have dangerous microorganisms or other problems that could make their flesh dangerous if it was turned into meat.

16. As summarized in one study, "slaughter horses have usually been trucked for extensive distances. Many times they are injured or unhealthy, housed poorly, fed and watered improperly, and sometimes held for long times, as much as a week, in dirty confined pens at the slaughter plant." Gary D. Anderson & Don R. Lee, *Salmonella in Horses: A Source of Contamination of Horsemeat in a Packing Plant Under Federal Inspection*, 31 APPLIED AND ENVIRONMENTAL MICROBIOLOGY 661 (1975). This type of situation creates great potential for the growth of bacteria that can lead to severe health problems in humans who eat the meat of these horses.

17. During my tenure as a meat inspector in Vermont, I inspected slaughter animals, mostly dairy cattle. I became quite familiar with the behavior of these animals as they proceeded through the slaughter process. Even tame dairy cattle can become quite agitated in a slaughter plant. These animals are away from familiar surroundings, often for the first time in their lives, and they are often forced to move with an electric prod and they react accordingly.

18. Horses are more easily frightened than cattle. Horses can become particularly frightened, because they are historically prey animals. Consequently, based on my experience with large domestic animals, I believe that horses are uniquely unsuited to processing at a slaughter plant. It is very difficult to secure a horse's head which diminishes the effectiveness of the captive bolt. Sometimes horses have to be hit several times with the captive bolt, causing tremendous suffering before they are effectively rendered unconscious. Subsequently, it is highly probable that some horses may not be rendered unconscious when hung and bled.

Horses are also more likely to injure themselves trying to escape the runway in the slaughter plant.

19. According to USDA documents, there are numerous documented cases of inhumane slaughter of horses, ranging from improper handling to outright abuse. As explained by a USDA inspector working at the Cavel plant in Illinois:

> I observed the plant manager herding horses into the alley way to the knock box. Nine horses were overcrowded in the alleyway causing undue excitement which was further exacerbated when two or more employees from the kill floor began yelling and hitting these horses causing the one in the end of the line to slip and fall.

Likewise, on March 13, 2005, a USDA inspector at the Cavel plant reported:

> Eight horses were in the alleyway leading directly to the knock box. The employee who is routinely assigned to work on the kill floor, hanging the horses on the rails, was using a riding crop to whip the horse in the alleyway closest to the knock-box. This horse continued to move backwards, away from the knock-box causing the other horses behind it to be overcrowded. As the whipping continued the horses in the alleyway became extremely excited. I immediately told the employee to stop but he did not listen to me. During this time, the last horse in the alleyway attempted to jump over the alleyway wall and became stuck over the top of the wall. Eventually it had flailed around enough to fall over to the other side of the wall.
>
> * * *
>
> Meanwhile two more horses fell down in the alleyway. The first was the second horse in the line to the knock box. It had fallen forward and the horse behind it began to walk on top of it as the downed horse struggled to get up. The second horse to fall was the fourth horse in the line. It had flipped over backwards due to the overcrowding and was subsequently trapped and trampled by the fifth and sixth horse in the line in their excitement to move forward. Attached to this declaration are true and correct copies of the relevant USDA reports describing these incidents. In my professional opinion, this document illustrates the inhumane treatment of horses.

20. As companion animals, horses are not suited for this kind of inhumane treatment. An alternative for unwanted horses is euthanasia by a trained and licensed veterinarian. As with unwanted dogs and cats, the process of professional euthanasia quickly and painlessly ends the animal's life without the pain and suffering of long-distance transport, handling, and slaughter for human consumption. All equine veterinarians are capable of humanely euthanizing horses. I euthanized horses when I was a large animal practitioner, and it can be done in a quiet, safe and nonfrightening way. The horse does not struggle, is not fearful and dies a quiet and certain death.

21. Horses that eventually make their way to slaughter are taken to large horse auctions where they are purchased by "killer buyers." Some of these horses are healthy retired or unsuccessful race horses. Others are surplus riding school and camp horses. Many were companion animals whose owners gave them up for sale. Wild horses removed from public lands also constitute a percentage of the horses sent for human consumption, as do foals from mares whose urine is collected for the production of hormone replacement therapy drugs.

22. Many of the horses slaughtered are young and healthy, because they have been raised as companion or competitive horses, and treated with all the drugs and substances with which such animals are treated.

23. Many horses who are slaughtered for human consumption are also lame, blind, starved and/or show evidence of lack of care such as saddle sores, overgrown hooves, bad teeth, and injuries. These horses thus also show signs of having been used in the companion and competitive sectors before being sold for meat.

24. In addition, there is believed to be "a thriving trade in stolen horses going to slaughter." C.L. Stull, *Evolution of the Proposed Federal Slaughter Horse Transport Regulations*, 79 J. ANIMAL SCIENCE E12 (2001). The stolen horses presumably come from the sources identified above.

25. Transportation to a slaughter facility, especially in a multiple horse transport

vehicle, is frightening for most horses but is especially traumatic for wild horses, who resist handling during gather and transport operations. Because of their wildness, the fear they display in response to proximity to people in strange environments, and their resistance to handling and transport, wild horses experience high levels of distress and therefore the risk of injury is greater during the events leading up to slaughter.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge, and as to those matters, I believe them to be true.

Executed this 15 day of March, 2012, in Williston, Vt.

Peggy W Larson DVM, MS, JD

Peggy W. Larson, DVM, MS, JD

DECLARATION OF JOANNE PAVLIS

I, Joanne Pavlis, declare as follows:

1. I am a professional horse trainer with Milemakers, LLC of Larkspur, Colorado. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection.

2. Milemakers LLC provides training for horses and specializes in the education, training and condition of Endurance and Pleasures Distance horses and riders. We also provide conditioning for Arabian race horses who will be used on the racetrack, a beginning program for junior riders, and coaching for trail rides.

3. I have been training horses for eighteen years and have worked as a trainer with Milemakers for the last sixteen years. In the course of my work I have seen hundreds of horses, gotten to know hundreds of their owners, and am familiar with the drugs, treatments and substances used by owners of companion horses, sporting and competitive horses, and horses destined for racing.

4. I have reviewed Exhibit A to the Petition for Rulemaking being submitted by Front Range Equine Rescue. I am familiar with virtually all the drugs, treatments and substances listed on Exhibit A.

5. The drugs, treatments and substances listed on Exhibit A are all very commonly used by owners of companion horses and competition horses. Virtually all such owners would either have these drugs, treatments and substances on hand and use them on their horses, or would have access to the drugs treatments and substances, and be able to easily get them from their local veterinarian.

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6. I am also familiar with and have had experience with wild horses who have been captured and placed in holding pens. These horses are given some of the drugs, substances and treatments on Exhibit A, including many commonly-used veterinary drugs.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 19 day of March, 2012, in Larkspur, Colorado.

Joanne Pavlis

DECLARATION OF RANDY PARKER, D.V.M.

I, Randy Parker, declare as follows:

1. I am a veterinarian and own and manage Range View Equine Associates in Elbert, Colorado. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection.

2. I am a 1989 graduate of Tufts University School of Veterinary Medicine, and have been practicing veterinary medicine for twenty-three years. After graduation from Tufts, I did an internship on Prince Edward Island, focusing on large animal, food animal and equine practice.

3. After my internship I moved to Colorado where I have been in practice ever since. My veterinary practice focuses almost exclusively (greater than ninety percent) on the care of companion horses, and horses used in competition, show and sporting events.

4. I see an average of thirty horses every week as part of my practice.

5. In the course of my practice I prescribe medications needed by the horses I treat. I also visit the barns, tack rooms, and treatment areas in which my clients' horses live, and regularly observe the kinds of drugs, substances, and treatments my clients use for their horses, whether prescribed or acquired elsewhere.

6. I have reviewed Exhibit 1 to the Petition for Rulemaking submitted by Front Range Equine Rescue. I am familiar with the large majority of the drugs, treatments and other substances on Exhibit 1, which I have either prescribed myself or seen at the barns of and in use by my clients for their horses.

7. Many of the drugs on this list are harmful to humans. For example, chloramphenicol is known to cause aplastic anemia and other problems. Nitrofurazone, which is commonly used, is a human carcinogen. Additionally, the administration of any antibiotic to horses, if those horses were then eaten, could lead to the development of antibiotic resistances in humans.

8. The majority of drugs, treatments and substances on Exhibit 1 to the Petition are regularly and routinely used by owners of horses in the areas where I work, and I believe this practice to be common throughout the country.

9. Based on my training and experience, it is my professional opinion that an alarming majority of American horses who are sent to slaughter for human consumption may have been treated with a variety of drugs, treatments and substances that renders their flesh dangerous to people who eat horse meat and makes the horses' meat unsafe for human consumption.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 19 day of March, 2012, in Elbert, CO

Randy Parker, D.V.M.

DECLARATION OF MICHAEL GREGER, M.D.

I, Michael Greger, declare as follows:

1. I serve as the Director of Public Health and Animal Agriculture for the Humane Society of the United States ("HSUS"). I have held this position since 2005. I have lectured internationally, and have presented at the Conference on World Affairs, the National Institutes of Health, and the International Bird Flu Summit. I have an M.D. degree from the Tufts University School of Medicine. For more information regarding my credentials, see my *curriculum vitae*, which is attached to this declaration as Exhibit 1. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection. If called, I could and would testify to these facts in a court of law.

2. I have reviewed Exhibit 1 to the Petition for Rulemaking prepared by Front Range Equine Rescue and The Humane Society of the United States, as well as the declarations of Hilary Wood, Joanne Pavlis, Randy Parker and Peggy Larson, D.V.M. being submitted in support of the Petition. I understand from the declarations that most, if not all, of the drugs, treatments and substances listed on Exhibit 1 are routinely, and without adequate control, given to American horses who may end up as horse meat for human consumption. Exhibit 1 also accurately describes many of the adverse reactions and side effects of the drugs and substances listed there.

3. The substances listed on Exhibit 1, if ingested by humans, present a variety of potential health problems and adverse reactions, which can range from benign to fatal. While some of the substances are approved for use in humans, none of them are approved for use in humans who are not aware they are ingesting the substances. It is a matter of common sense and standard medical practice not to give drugs to individuals who are unaware they are receiving the drugs. Yet that is exactly what would be happening if horse meat that is eaten by humans contains residue of any of the substances listed on Exhibit 1.

4. It is a foundational medical treatment principle that patients are not given any drugs without first ascertaining if the patients are taking any other drugs at the time. A patient's current

drug and medication regime is important because it may limit the type of drugs that may be recommended or prescribed, based on the negative or potentiating reactions between drugs that may occur. Adverse drug reactions between different medications can be extremely severe and must be avoided to the extent possible.

5. It is also a foundational medical principle that patients must be asked about their prior experience with medications before prescribing or recommending new drugs for treatment. Taking such a history from a patient is vital, in order to determine if they may have allergies to certain specific drugs or groups of drugs. Patients may have known allergies to certain drugs, which can cause severe reactions, including anaphylactic shock or even death.

6. If drug residues in horses are unknown, individuals consuming horse meat will be unaware of what drugs and substances they may be eating. If consumers have drug allergies, there is a potential for individuals who eat horse meat to have serious negative reactions if any of the drugs that remain in horse meat that they eat are drugs to which they are allergic. There is the potential for an allergic reaction, made even worse because the consumer will not know that they have taken any drugs. Unless all horses are tested for all potential dangerous drug residues, and unless it can be guaranteed that horse meat comes only from horses who have never had any potentially dangerous substances to which humans are known to develop allergies, there is no way to eliminate the potential for such an adverse, and potentially severe, reaction. Additionally, since there is no way of filtering the consuming population to avoid adverse reactions, and no way to identify meat from animals who have had specific substances, the fact that a drug may be safe for some humans does not assure its safety for the consuming public or the market.

7. It is also a foundational medical principle that patients must be asked about their past family and personal medical history, and current medical conditions, before prescribing most drugs, in order to determine if the patients may have sensitivities to certain specific drugs. Patients may have particular genetic predispositions, or current illnesses or diseases, that preclude or limit the use of certain drugs. (For example, individuals with bleeding disorders are generally restricted

from their intake of drugs that may act as blood thinning agents, and must exercise extreme caution if they do take such drugs.)

8. If drug residues in horses are unknown, individuals consuming horse meat will be unaware of what drugs and substances they may be eating. If any of those drug residues would be contraindicated for use by the consumer because of sensitivities they have to certain drugs, based on genetic disposition, temporary conditions, or current illnesses, there is a potential for individuals who eat horse meat to have serious negative impacts. Unless all horses are tested for all potential dangerous drug residues, and unless it can be guaranteed that horse meat comes only from horses who have never had any potentially dangerous substances, there is no way to avoid the potential for such a negative reaction. Additionally, since there is no way of filtering the consuming population to avoid adverse reactions, and no way to identify meat from animals who have had specific substances, the fact that a drug may be safe for some humans does not assure its safety for the consuming public or the market.

9. It is a matter of undisputed medical science that pregnant and nursing women are strongly cautioned to avoid many drugs, including some listed on Exhibit 1, which could have harmful effects on their fetus or nursing babies. If drug residues in horses are unknown, there is a chance that such drugs could exist in horse meat, and there is a potential for pregnant and nursing women who eat horse meat to have serious negative impacts on their unborn, or nursing babies. Unless all horses are tested for all potential dangerous drug residues, and unless it can be guaranteed that horse meat comes only from horses who have never had any drugs or substances that would be dangerous for pregnant or nursing women, there is no way to avoid the potential for such a negative reaction.

10. The use of steroids by humans should be very carefully monitored and controlled, overseen by a physician. Steroids can have significant detrimental effect on a number of body systems. Exhibit 1 contains a number of steroids that, if taken by humans, would affect humans in many ways, including notable effects on human reproductive systems and sexual hormone production. Steroids such as prednisone and methylprednisolone, which are both on Exhibit 1 and

given to horses, should only be used under the careful monitoring and recommendation of a physician, and have a long list of potential negative, and serious, side effects.

11. I understand from the declarations of Hilary Wood, Joanne Pavlis, Randy Parker and Peggy Larson that many antibiotics, such as those listed on Exhibit 1, are given to American horses. The unknown and unmonitored use of antibiotics in horses that may be eaten creates the potential for adverse effects on the humans who eat those horses. Because of the dosing of horses with antibiotics, unknown amounts of antibiotics and antibiotic residue may be ingested by humans. This is problematic, and potentially harmful, for two reasons. First, it is a generally-accepted scientific principle that the use of antibiotics in food-producing animals leads to the growth of antibiotic-resistant pathogens, which negatively affect tens of thousands of Americans each year. Second, it is standard medical practice that humans should only take antibiotics when necessary and indicated, in order to prevent the development of new antibiotic-resistant bacteria. Inappropriate use of antibiotics, including use when no such treatment is indicated, leads to drug-resistant bacteria. *See* http://www.niaid.nih.gov/topics/antimicrobialResistance/Understanding/Pages/causes.aspx.

12. If drug residues in horses are unknown, there is a potential for individuals who eat horse meat to ingest antibiotics that they do not need, and to be exposed to or develop antibiotic-resistant bacteria which could potentially lead to severe illnesses that could not be treated with standard antibiotic therapy. Unless all horses are tested for all potential antibiotic residues, and unless it can be guaranteed that horse meat comes only from horses who do not have significant antibiotic residues and have not developed antibiotic-resistant strains of bacteria, there is no way to avoid the potential for a significant adverse effect on human health.

13. I am informed and believe that many of the drugs and other substances on Exhibit 1 have never been tested on humans, and that no studies have determined the potential health risks and dangers associated with ingestion of those drugs and substances. It is a strong ethical and medical principle that unsuspecting humans should not be treated as random experimental subjects and be indiscriminately given drugs and other substances that they are unaware they are taking.

14. With respect to the drugs and other substances given to horses who become meat, there is a very real potential for danger to humans who eat that meat, because of the lack of any information about the consequences of ingesting those substances, or the nature of the residue or metabolites of those substances. If drug residues in horses are unknown, there is a potential for individuals who eat horse meat to have serious negative impacts from ingestion of drugs and substances that have never been tested on humans and that they do not even know they are taking. Unless all horses are tested for all potential dangerous drug residues, and unless it can be guaranteed that horse meat comes only from horses who have never had any potentially dangerous substances, there is no way to avoid the potential for such a negative reaction.

15. Many of the drugs and substances listed on Exhibit 1 are known to be harmful to, and unsafe for, humans to ingest. If drug residues in horses contain substances that are known to be harmful or unsafe for human consumption, there is a potential for individuals who eat horse meat to have serious negative impacts from ingestion of that meat. Unless all horses are tested for all potential dangerous drug residues, and unless it can be guaranteed that horse meat comes only from horses who have never had any potentially dangerous substances or do not have any drug residues from of any drugs or substances known to be harmful to humans, there is no way to avoid the potential for such a negative reaction.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 19 day of March, 2012, in Madrid, Spain.

Michael Greger, M.D.

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MICHAEL GREGER, M.D.
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EDUCATION:

- *M.D.* – Tufts University School of Medicine; Boston, MA; May 1999 with honors
- *B.S. Biology* – Cornell University College of Agriculture; Ithaca, NY; May 1995

LICENSURE:

- Maryland Board of Registration in Medicine license #D0064571 (active)
- Massachusetts Board of Registration in Medicine license #206106 (inactive)

POSITIONS:

- *Director*. Public Health and Animal Agriculture, Humane Society International (since 2009)
- *Director*. Public Health and Animal Agriculture, The Humane Society of the United States (since 2005)
- *Guest Lecturer*. Cornell University Department of Nutrition (Fall 2004)
- *Public Speaker*. Speaking schedule posted at http://www.DrGreger.org/dates.html (since 2002)
- *Coordinator--Infectious Disease*. Organic Consumers Association; Marais, MN (2001-2005)
- *Chief Medical Investigator*. Farm Sanctuary; Watkins Glen, NY (1993-2005)

SELECTED PUBLICATIONS:

- Greger M. 2012. The Welfare of Transgenic Farm Animals. In *Biotechnology - Molecular Studies and Novel Applications for Improved Quality of Human Life*. InTech, 2012.
- Greger M. 2010. Transgenesis in animal agriculture and zoonotic disease resistance. *Centre for Agriculture and Biosciences (CAB) Reviews* 6(41):1-6.
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EXHIBIT 7

DECLARATION OF SANDRA GROVER, D.V.M.

I, Sandra Grover, declare as follows:

1. I am a veterinarian and own and manage Exclusive Equine Dentistry and Chiropractic in Black Forest, Colorado. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection.

2. I am a 1999 graduate of Colorado State University School of Veterinary Medicine, and have been practicing veterinary medicine since my graduation.

3. My practice has always included a significant percentage of horses, and in the last seven years over ninety percent of my practice has involved the treatment of equines.

4. I see approximately thirty to forty horses each week in my practice, for an average of 1500 visits per year.

5. I have worked with and around horses all my life, and have been extensively involved in showing horses since I was a teenager.

6. In the course of my practice I prescribe medications needed by the horses I treat. I also visit the barns, tack rooms, and treatment areas in which my clients' horses live, and regularly observe the kinds of drugs, substances, and treatments my clients use for their horses, whether prescribed or acquired elsewhere.

7. I have reviewed Exhibit 1 to the Petition for Rulemaking submitted by Front Range Equine Rescue. I am familiar with the large majority of the drugs, treatments and other substances on Exhibit 1, which I have either prescribed myself or seen at the barns of and in use by my clients for their horses.

8. Many of the drugs on this list are harmful to humans.

9. The majority of drugs, treatments and substances on Exhibit 1 to the Petition are regularly and routinely used by owners of horses in the areas where I work, and I believe this practice to be common throughout the country.

10. Based on my training and experience, it is my professional opinion that an alarming majority of American horses who are sent to slaughter for human consumption may have been treated with a variety of drugs, treatments and substances that renders their flesh dangerous to people who eat horse meat and makes the horses' meat unsafe for human consumption.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 25 day of January 2013, in Elbert, CO.

Sandra Grover, DVM

Sandra Grover, D.V.M.

DECLARATION OF HOLLY COLELLA, D.V.M.

I, Holly Colella, declare as follows:

1. I am a veterinarian and own and manage a solo mobile veterinary practice. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection.

2. I am a 2001 graduate of Colorado State University School of Veterinary Medicine, and have been practicing veterinary medicine for twelve years. After graduation from veterinary school, I began working with a veterinary practice and have specialized in general equine medicine for my entire career. Prior to admission to veterinary school, I worked as a veterinary assistant/technician for approximately 6 years, mostly focused on the equine industry.

3. My veterinary practice focuses almost exclusively on the care of companion horses, rodeo horses, hunter-jumper competition horses, and ranch horses.

4. I see more than 100 horses per month and 1200 horses per year, and have done so throughout the course of my career, as part of my practice.

5. I have always been around horses, since I was a young girl, and have used horses for pleasure, including trail riding, during that time.

6. In the course of my practice I prescribe medications needed by the horses I treat. I also visit the barns, tack rooms, and treatment areas in which my clients' horses live, and regularly observe the kinds of drugs, substances, and treatments my clients use for their horses, whether prescribed or acquired elsewhere.

7. I have reviewed Exhibit 1 to the Petition for Rulemaking submitted by Front Range Equine Rescue. I am familiar with the large majority of the drugs, treatments and other substances on Exhibit 1, which I have either prescribed myself or seen at the barns of and in use by my clients for their horses.

8. The majority of drugs, treatments and substances on Exhibit 1 to the Petition are regularly and routinely used by owners of horses in the areas where I work, and I believe this practice to be common throughout the country.

9. Based on my training and experience, it is my professional opinion that an alarming majority of American horses who are sent to slaughter for human consumption may have been treated with a variety of drugs, treatments and substances that renders their flesh dangerous to people who eat horse meat and makes the horses' meat unsafe for human consumption.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 10th day of February, 2013, in Cave Springs.

Holly Cotella, D.V.M.

DECLARATION OF SHIRLEY S. HOFFMAN

I, Shirley S. Hoffman, declare as follows:

1. I am the owner of HiView Acres of Longmont, Colorado, and also the founder of Horses Forever, a 501(c)(3) nonprofit corporation of Colorado, dedicated to the rescue of horses in need. The facts set forth are true to the best of my knowledge and recollection. If called, I could and would testify to these facts in a court of law.

2. I have been a horse owner for over thirty years, and have been actively involved in the breeding and showing of American Saddlebred Horses.

3. I have had as many as 100 horses at a time when I was involved in breeding and showing horses. I currently have approximately thirty horses.

4. The horses that Horses Forever rescues come from a variety of sources, including victims of animal cruelty cases and discarded horses from the horse training and competition industry.

5. I was involved in owning and showing American Saddlebred Horses in the 1980s and 1990s. The American Saddlebred Registry is the oldest horse registry in the United States and the breed is popular in the horse show world as well as the world of equine versatility. I was an active participant in shows and competitions involving American Saddlebred horses until the 1990s, when I discovered, from the inside, that trainers were giving these horses many types of prohibited drugs, including acepromazine and phenylbutazone.

6. I started the Rocky Mountain Horse Expo, a well-known equine educational event under the auspices of the Colorado Horse Council, a horse industry group.

7. I have been involved with hundreds of horses over the course of my experience with the show world and the rescue group. I am very familiar with the medications and other drugs given to horses in the performance and private sectors.

8. I have reviewed Exhibit 1 to the Petition for Rulemaking submitted by Front Range Equine Rescue, and have consulted with the veterinarian who cares for my horses. Almost all of

the drugs on the list, which I understand federal law states are not to be used in horses "intended for food," were or are given to some of my horses. Several of the drugs on the list, which I understand federal law states are not to be used in horses "intended for food," were or are given to 90 per cent or more of my horses, and I understand that usage to be common among other horse owners.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 17th day of January, 2013, in Boulder County, Colorado

Shirley S. Hoffman

DECLARATION OF GAIL VACCA

I, Gail Vacca, declare as follows:

1. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection. If called, I could and would testify to these facts in a court of law.

2. I have been a licensed trainer of horses for competition and shows since 1984. I have an extensive background in the horse racing industry, as further established below. I am also intimately aware of the way in which racehorses are treated, on and off the racetrack.

3. I am currently the President of the Illinois Equine Humane Center ("ILEHC"), a 501(c)(3) nonprofit organization that provides humane treatment and shelter while working as a clearinghouse to seek adoptive homes for Illinois' unwanted equines, and also provides public education to raise awareness about responsible equine ownership so that less horses end up in crisis. ILEHC has been involved with the rescue of hundreds of horses on their way to slaughter over the years, and ninety per cent of those horses were former racehorses.

4. I became a professional horsewoman almost thirty years ago. I have been a nationally licensed thoroughbred trainer, and have been involved with top level show horses, in both the hunter and jumper categories. I am also a licensed owner of racehorses.

5. I was actively involved in the horseracing industry, as a trainer and owner of horses, from the 1980s until 2002, after which I focused my efforts on rescue and rehabilitation of equine welfare issues. As a trainer I was at the track every day, working long hours. I worked with an average of ten horses at a time, and provided therapies and treatments and medications to the horses. I was also familiar with the practices of other trainers at the track, and so am fully aware of the kinds of substances, drugs and treatments most racehorses receive.

6. In the 1980s, trainers used phenylbutazone indiscriminately, and there was no restriction on the amount of phenylbutazone they administered or that the horses received. There

are more significant restrictions on the use of phenylbutazone now, but it is still frequently used on racehorses.

7. Based on my personal observation, racehorses involved in the breeding process, while they are in production, are given large amounts of hormones and antibiotics and anti-inflammatory drugs. These drugs are used to treat the normal medical and metabolic consequences and sequelae of multiple inseminations, pregnancies, and births.

8. From personal experience and observation, I know that many racehorses go from the racetrack to "kill buyers" who sell them for slaughter. These include horses who are injured in a race or are no longer top performers.

9. I was directly involved in a television production for a piece on Real Sports with Bryant Gumbel, which accurately portrayed the path of many racehorses to slaughter for food production.

10. I have been visiting auctions where horses are being sold for slaughter for approximately thirty years. Based on the information I have obtained in connection with that extensive experience, as well as with the television production and my professional career, I am informed and believe that approximately ten to fifteen percent of American horses that go to slaughter are former racehorses. I am informed and believe that more than 20,000 American racehorses go to slaughter each year.

11. When I have observed the pens at auctions of horses heading to slaughter, there are always thoroughbreds seen in virtually every pen.

12. I have reviewed the chart attached to this declaration. I am familiar with the vast majority of the drugs listed on the chart, in connection with their use on horses both by myself and by others who I have observed over the course of the last three decades.

13. Over the course of the time I have owned horses, my veterinarians and/or I have given most of the drugs on the chart to the horses I have owned, cared for, and trained.

14. Every item on the attached chart is either commonly found in racetrack and racehorse barns and other barns housing horses, and is used on those horses, or is found in

catalogues and supply stores, for sale to private horse owners in America or available with a veterinarian's prescription. I am personally familiar with and use or have used at least 98 of the substances on that list, and am informed and believe that all of those substances are used regularly on racehorses, companion, pleasure and recreation, and competition/show horses.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 16th day of January, 2013, in Plano, IL

Gail Vacca

Gail Vacca

DECLARATION OF CYNTHIA NEWBERRY

I, Cynthia Newberry, declare as follows:

1. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection. If called, I could and would testify to these facts in a court of law.

2. I am the owner and head trainer at Corgi Glen Farm in Beallsville, Maryland. I have over forty years of experience with horses, including extensive training and judging. I have been riding and caring for horses since I was six years old, and have shown horses nationally.

3. I am a graduate of Virginia Intermont College, where I obtained a degree in Equine Studies and Business Management, while continuing to ride on the intercollegiate riding team. I have also served as an officer with several equestrian organizations in the past ten years.

4. In my work as a trainer at Corgi Glen Farm, I deal on a regular basis with approximately thirty horses, about half of which are owned by clients and the other half by Corgi Glen Farms. I have trained approximately 100 horses over the past thirty-two years.

5. I have also been involved in the breeding of horses for over three decades.

6. With my horses and the horses I have trained and kept for clients, I have provided maintenance doses of various drugs, over the course of their lives, that keep them healthy.

7. I have reviewed the chart attached to this declaration. I am familiar with eighty per cent of the drugs listed on the chart, in connection with their use on horses both by myself and by others who I have observed over the course of the last three decades.

8. Over the course of the time I have owned horses, my veterinarians, other owners and/or I have given nearly seventy percent of the drugs on the chart to the horses I have owned, cared for, and trained.

9. Almost every item on the attached list is either commonly found in barns housing horses, and is used on those horses, or is found in catalogues and supply stores, for sale to private horse owners in America or available with a veterinarian's prescription. I am personally familiar

DECLARATION OF MICHELLE CONNER

I, Michelle Conner, declare as follows:

1. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection. If called, I could and would testify to these facts in a court of law.

2. I have owned horses for twenty-three years, and have been training horses professionally for the last eleven years. I currently run a training and boarding facility. Through that experience, I have come to learn about the drugs, medications and treatments that the owners of American horses give to their horses.

3. From 2002 through 2007 I worked closely with the Bureau of Land Management, working with foals who were between six and eighteen months of age, and trying to prepare them to make them more adoptable. In the course of that work, each of the foals was injected with a number of vaccines and dewormed with products that are found on the list attached to this declaration.

4. I have also been regularly involved with local horse shows and with 4-H Clubs using horses and so I am very familiar with the drugs and medications given to companion and show horses.

5. I have reviewed the chart attached to this declaration. I am familiar with most of the drugs listed on the chart, in connection with their use on horses both by myself and by others who I have observed over the course of the last three decades.

6. Over the course of the time I have owned horses, my veterinarians, other owners and/or I have given more than eighty percent of the drugs on the chart to the horses I have owned, cared for, and trained.

7. Almost every item on the attached list is either commonly found in barns housing horses, and is used on those horses, or is found in catalogues and supply stores, for sale to private horse owners in America or available with a veterinarian's prescription. I am personally familiar

with and use or have used at least eighty percent of the substances on that list, and am informed and believe that all of those substances are used regularly on American horses.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 15 day of January, 2013, in Calhan, CO.

Michelle Conner

DECLARATION OF RONALD T. FITCH

I, Ronald T. Fitch, declare as follows:

1. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection. If called, I could and would testify to these facts in a court of law.

2. I am a Health Environment and Safety Engineer for Chevron, where I ensure the safety and proper conditions for thousands of workers.

3. I have been involved with the rescue and rehabilitation of horses in need for approximately two decades. I am the author of the book Straight From the Horse's Heart, and I also provide a daily web-based educational forum that thousands of people rely on daily, disseminating information about issues related to the welfare and preservation of American horses. In that blog I address wild horses, domestic horses, horse racing, and horse slaughter.

4. I have been a foster or adoptive parent for horses for nearly two decades. In those roles, I consult with veterinarians who help me decide what medications the horses under my care should and do receive.

5. As part of my work with the horses I have rescued, fostered and adopted, I have become a student of horse nutrition and medication, and have learned much about these issues from a local veterinarian.

6. I have reviewed the chart attached to this declaration. I am familiar with most of the drugs listed on the chart, in connection with their use on horses both by myself and by others who I have observed over the course of the last three decades.

7. Over the course of the time I have owned horses, my veterinarians, other owners and/or I have given more than eighty percent of the drugs on the chart to the horses I have owned, cared for, and trained.

8. Almost every item on the attached list is either commonly found in barns housing horses, and is used on those horses, or is found in catalogues and supply stores, for sale to private

horse owners in America or available with a veterinarian's prescription. I am personally familiar with and use or have used at least sixty percent of the substances on that list, and am informed and believe that all of those substances are used regularly on American horses.

9. Every item on the attached list is either commonly found in barns housing horses, and is used on those horses, or is found in catalogues and supply stores, for sale to private horse owners in America or available with a veterinarian's prescription. I am personally familiar with and use or have used at least sixty percent of the substances on that list, and am informed and believe that all of those substances are used regularly on companion, pleasure and recreation, and competition/show horses.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 16th day of January, 2013, in Wylie, Tx.

Ronald T. Fitch

DECLARATION OF DIRK MURPHY

I, Dirk Murphy, declare as follows:

1. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection. If called, I could and might testify to these facts in a court of law.

2. I am 49 years old and was raised around horses, and have raised and trained horses from my youth till present. I have observed horses in all stages of development, from birth to breeding to old age. I have worked with horses as labor animals in my cattle-raising capacity, ridden horses in the rodeo, and had them as companions.

3. I have either trained or owned an estimated 100 horses over the course of my life.

4. For the most part, I use an all natural program of medical care on my horses, and so do not use many of the drugs and medications that others may use on their horses.

5. My horses do periodically receive phenylbutazone. They also get, from time to time, banamine, furizalidone, bronco fly spray, and aspirin.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 28 day of January, 2013, in Kuna ID.

Dirk Murphy

EXHIBIT 8

United States Department of Agriculture | Food Safety and Inspection Service | Washington, D.C. 20250

DECISION MEMORANDUM FOR THE UNDER SECRETARY

FROM: Alfred V. Almanza
Administrator

SUBJECT: Development of an Equine Slaughter and Further Processing Inspection Regime

ISSUE: The Under Secretary has asked for a proposed way forward on equine slaughter and further processing of equine meat for human consumption. This memorandum discusses the relevant technical issues and suggests how FSIS should proceed in light of a petition from the Humane Society of the United States (HSUS) to ban the slaughter and further processing of equines.

BACKGROUND: The Federal Meat Inspection Act (FMIA) provides for inspection of amenable livestock species intended for human consumption, including equine. Meat from amenable species that has not been inspected and passed cannot be shipped or sold for human consumption.

In 2006, Congress prohibited FSIS from spending any appropriated funds for ante-mortem inspection of equines. Because no equines can be slaughtered under the FMIA without ante mortem inspection, this action effectively shut down equine slaughter in the United States. In 2012, however, Congress did not include this prohibition in the appropriation law, and as a result, two establishments – one in Missouri and the other in New Mexico – have applied for a grant of inspection exclusively for equine slaughter. FSIS has yet to act on these applications. In addition, FSIS recently received an inquiry from an individual in Missouri who was looking into the feasibility of purchasing an existing further processing establishment and then further processing imported equine meat for human consumption for distribution through a mail-order catalog.

Additionally, FSIS received a petition from HSUS to ban equine slaughter. The petition's primary assertion is that drug use in horses is so widespread in the United States that it will be virtually impossible for FSIS to establish a residue testing program that will ensure the safety of equine meat.

DISCUSSION: Given that FSIS last conducted equine inspection 6 years ago, the Agency has determined that it needs to spend a significant amount of time reestablishing the processes needed for appropriate inspection of equines. In particular, a number of technical issues need to be addressed before the infrastructure for any equine inspection system is ready, and any establishment can receive a grant of inspection to slaughter or further process equines. These issues include:

- Slaughter and Further Processing Inspection Processes

- Inspector Training
- Environmental Impacts
- Residue Testing
- Petition Issues

Inspection Processes: Just as FSIS does for all amenable livestock species, the Agency would ensure industry compliance with all relevant statutes and regulations, including the FMIA, Hazard Analysis and Critical Control Point (HACCP) regulations, Sanitation Standard Operating Procedures (SOPs), other sanitation regulations, and the Humane Methods of Livestock Slaughter Act.

The principal difference between equine establishments and other livestock slaughter and further processing establishments is that the Agency's regulations require equine slaughter to be done in establishments separate from any establishment in which cattle, sheep, swine, or goats are slaughtered (9 CFR 305.2(b)). FSIS has denied three requests for a waiver of this regulation from domestic establishments. FSIS regulations provide authority for waivers for purposes of permitting experimentation so that new procedures, equipment, or processing techniques may be tested to facilitate specific and definite improvements (9 CFR 303.1(h)). FSIS denied the requests for waivers because FSIS concluded that simply permitting a practice that is prohibited under our current regulations would not be consistent with the purpose of the regulation that provides authority for such waivers.

> **Next Steps**: FSIS will continue to work closely and consistently with the establishments that have applied for a grant of inspection to ensure that all FSIS requirements are fully understood. When appropriate, the Agency will update its notices and directives for equine inspection.

Inspector Training: Although hiring and training new inspectors typically takes up to 3 months, if an existing cattle slaughter establishment decides to convert to equine slaughter establishment, then inspectors at that facility would only need to receive a few days of on-the-job training. FSIS is not aware of any reason why it could not use the inspection procedures it used for equine slaughter before 2006. Moreover, FSIS will likely be able to use the training materials it used at that time. In fact, one of the Agency's trainers formerly worked in an equine slaughter plant.

> **Next Steps**: Once FSIS fully incorporates equine slaughter into PHIS, FSIS will need to update the training materials to incorporate the reporting of inspection results into PHIS.

Environmental Impacts: HSUS has asserted that the National Environmental Policy Act (NEPA) requires FSIS to prepare an environmental assessment (EA) or an environmental impact statement (EIS) prior to approving a Grant of Inspection to an equine slaughter facility.

Actions of FSIS have been categorically excluded from the preparation of an EA or EIS unless the Administrator determines that an action may have a significant environmental effect (7 CFR 1b.4). The Department has long determined that FSIS' programs and activities would have no individual or cumulative effect on the human environment.

The inspection laws mandate that FSIS provide inspection as long as the establishment complies with the statutes' requirements and the Agency's regulations. A Grant of Inspection from FSIS differs from licenses, such as the nuclear reactor licenses issued by the U.S. Nuclear Regulatory Commission (NRC), because the FMIA does not give FSIS permitting authority over the construction of facilities like the Atomic Energy Act (42 U.S.C. 2133 and 2235) and the Federal Power Act (16 U.S.C. 797(e)) give the NRC.

HSUS relies on the case of *The Humane Society of the United States v. Johanns,* 520 F. Supp. 2d 8 (D.D.C. 2007). The Agency believes that case is not applicable to this situation. The *Johanns* case arose after Congress prohibited FSIS, as discussed above, from spending appropriated funds to carry out ante mortem inspection of equines. While the congressional prohibition cited inspection conducted under the FMIA, FSIS subsequently issued a regulation under the Agricultural Marketing Act (AMA) of 1946 that set up a voluntary user fee or fee-for-service program in which FSIS would provide ante-mortem inspection, just as it had done before under the FMIA, for a fee. The District Court ruled that because the regulation did not perpetuate the regulatory status quo, the effects of the horse slaughter operations should have been assessed pursuant to NEPA prior to promulgation of that rule. However, the Agency's view is that FSIS' current activities to potentially resume equine slaughter inspection are occurring under the FMIA, not the AMA, and therefore the situation in the HSUS case is not applicable.

> **Next Steps**: FSIS has evaluated the potential decision to provide equine slaughter inspection and has documented its tentative conclusion in an internal memo. The memo tentatively concludes that FSIS can invoke its categorical exclusion because no unique or potentially significant environmental effects exist compared to the thousands of existing Grants of Inspections for other species.

Residue Testing: As for all amenable species, FSIS will need to verify that any equines slaughtered do not contain an illegal drug residue that would render the meat unfit for human consumption. However, because the Food and Drug Administration (FDA) does not consider equine muscle to be "food," it has not set acceptable daily intake or tolerance levels for residues in equine meat as it has for the other amenable species. Thus, if FSIS finds a drug residue in any equine meat sample, it would not be able to find that the product is not adulterated, and thus the Agency would not be able to apply its mark of inspection to the meat. Importantly, unlike most other livestock, some equines are not raised for human food purposes. Some equines are used for racing and pleasure riding and, consequently, are administered drugs that never were intended for use in food animals (e.g., steroid treatments). Thus, drug residue profiles in equine tissue may be markedly different than for other livestock.

> **Next Steps**: To test equine meat for the presence of drug residues, the Agency intends to validate the methods that it uses to test other amenable species for use on equine meat. The equine residue testing data that the Agency developed from 1983 through 2007 (see attachment 1) suggests that many of the compounds likely to be used in equines fit for use as human food mirror to a large extent those for other amenable species. These data

from that period show that the majority of violations involved antibiotics such as Streptomycin (59 violations in 2000, 35 in 1999); Penicillin (9 violations in 2000, 8 in 1999); and Chlortetracycline, Gentamicin, and Oxytretatratcycline, among others. The remaining violations included various sulfa compounds, pesticides, and antiparasitic drugs.

FSIS has started to validate several new methods for equine tissue. A comprehensive residue testing program could be implemented by the end of the current calendar year. However, implementing validated lab methods for hormones and tranquilizers in equine tissue will not occur until 2014.

Petition Issues: While resolving these technical issues is critical to the development of any inspection system, the decision on how to respond to the HSUS petition will likely determine what type of inspection system FSIS would seek to implement and when. HSUS has petitioned FSIS to ban equine slaughter because, the petition asserts, drug use is so widespread in the United States that it will be virtually impossible for FSIS to establish a residue testing program that will ensure the safety of equine meat. Specifically, the petition requests that FSIS engage in rulemaking to prevent the risk that consumers of equine meat will have painful or prolonged adverse reactions or drug side effects or contract diseases after they have eaten the meat from these equines; and to ensure that proper controls are in place to prevent these equines from being slaughtered for food. HSUS highlights 42 compounds administered to equines that it believes pose food safety risks. FSIS has developed a plan for implementing testing for the majority of these compounds (see attachment 2).

HSUS argues that the only way to ensure the safety of equine meat is to establish a system that captures the history of drug use on each animal, similar to that employed by the European Union. Canada also has an equine slaughter system that may provide a model.

The EU System: The EU recently introduced the following requirements for equines intended for human food:

- The creation of a system of identity verification for equines intended for human food;
- A prohibition of anabolic steroids, or a system of segregating equines that have been treated with steroids;
- A system providing that all equines have lifetime treatment records documenting all substances used for treatments;
- Compliance with required 6-month withdrawal periods for veterinary medical products administered to equines; and
- The creation of a risk-based program to control the use of veterinary medical products and substances banned for use in the EU

The Canadian System: The Canadian Food Inspection Agency (CFIA) maintains a domestic equine slaughter inspection program that includes traceability and chemical residue testing. This program meets the EU requirements discussed above.

All Canadian equine slaughter establishments must keep complete identity and medical records of all animals presented for slaughter, either by an Equine Information Document (EID) or the Equine Lot Program (ELP), which is similar to the U.S. EV program. EID contains the animal description, 6-month drug history, picture ID/or other means of identification of the animal, and medical history. This document must accompany the animal at time of ownership transfer. In the ELP, an owner of a group or groups of animals may present a group declaration instead of individual EIDs. CFIA audits the ELP annually. According to CFIA, the advantage of ELP is that the owner is not required to provide a full narrative description of each individual animal, paperwork is reduced, and CFIA deems these animals under this program to be of lesser food safety risk.

CFIA has provided a list of drugs that food-producing animals should not receive throughout life and a list of drugs that should be not given during last 6 months of life. FSIS has not identified a mechanism used by CFIA to determine whether the prohibited drugs were ever given during an animal's life, as CFIA only reviews records from the last 6 months. However, CFIA has informed FSIS that Canada is working to develop a lifetime identity and traceability system for equine slaughter.

CFIA operates a residue testing program for equines based on EU requirements (EU Directive 96/23), and equines are also tested for Trichinae using a digestion method.

The question thus becomes whether, assuming that FSIS validates the methods that it intends to use on equine meat, and assuming that none of the questions discussed above present an insurmountable obstacle, FSIS could appropriately apply its mark of inspection to equine meat without requiring the type of documented drug use history required by the EU or Canada, or should it institute rulemaking to require such a history? There are two factors that bear on this question. First, once validated, will the tests that FSIS intends to employ be broad enough so that FSIS can confidently assert that a negative result in this testing ensures that no drugs have been illegally used on the equine? There is some sentiment in the FSIS labs that the answer to this question is yes. There is a belief that the presence of a residue of any drug likely to be illegally used in equines would be discovered by one of the tests that the Agency is validating for equine meat. FSIS would likely need to confirm this view with FDA should there be tentative acceptance of it.

The second factor is largely political. FSIS is already seen in some quarters in Congress as dragging its feet on the equine slaughter issue. To require a passport-type approach like that of the EU, FSIS would have to engage in rulemaking. Such rulemaking would likely take at least 2 years. Some are sure to argue that such a passport is unnecessary because FSIS operated the equine slaughter program prior to 2006, and prior to the EU's new requirements adopted in 2009, without requiring such information. Another factor to be considered is the possibility of punitive congressional action if FSIS fails to institute an equine slaughter program.

Finally, the Agency needs to consider the argument that equines are an amenable species under the FMIA, and therefore FSIS has no choice but to institute an equine slaughter and further

processing program. Under this argument, the fact that drug use is widespread in equines is essentially irrelevant. FSIS needs to have an inspection program for equines even if every equine presented for slaughter is condemned for a drug residue. It is up to the producers and the slaughter plant whether they wish to risk the investment that they have in the equines. It is FSIS's obligation to provide the slaughter program and take appropriate steps to ensure food safety.

RECOMMENDED OPTIONS:

FSIS expects to make recommendations on how to respond to the HSUS petition by late October. Assuming the technical issues discussed above (inspection processes, inspector training, environmental impacts, and residue methods) are satisfactorily resolved, FSIS could:

Option 1: Accept the petition and initiate rulemaking to require lifetime medical history for horses slaughtered for human consumptions on the grounds that equines, especially since 2006, have not been raised as food animals and have thus been administered a wide variety of drugs unfit for human consumption. To give the Agency time to develop rulemaking and formulate a process to implement a system that is EU-equivalent, as the petition recommends, FSIS would delay moving forward with implementing a system for equines that is based on lab methods for other amenable species. FSIS would need to initiate rulemaking to establish a system that captures the history of drug use on each animal, including lifetime treatment records, or simply request public input on the issue.

> *Pro*: This approach could both ensure that equine meat is safe, and work toward meeting new requirements implemented in 2009 by the EU.
>
> *Con*: First, developing and implementing such a system would require substantially more time, planning, and resources. Rulemaking would require at least 2 years. Second, this approach would be contrary to the one applied to all other livestock, for which the existing drug surveillance testing program is sufficient. Third, implementing validated lab methods for hormones and tranquilizers in equine tissue will not occur until 2014. Finally, establishing such an animal identification system, as required by the EU for export of equine meat, should come as a broader government-wide decision, not simply for one species.

Option 2: Deny the HSUS petition on grounds that it is not compelling as to why equine slaughter and processing are unique versus other livestock, and because the FSIS surveillance program for drug residues in horses should be sufficient to protect public health. When all lab methods relevant to equine tissue are validated, FSIS would proceed with implementing a residue program that parallels the one used for other amenable species. Establishments seeking to export to the EU would still need to separately meet EU requirements, and FSIS could work with the Agricultural Marketing Service to develop a voluntary, fee-for-service Export Verification (EV)-style program to verify that those requirements were met before export. AMS would be responsible for reviewing and approving companies as eligible suppliers of equine

meat and for maintaining approved supplier and products lists.

Pro: Implementing a system based on that used for other amenable species is logically consistent with FSIS' overall approach to residue testing. Once lab methods are fully developed, FSIS labs will be capable of testing for the compounds of concern in the petition. An EV program would allow establishments to export to the EU, and potentially other foreign markets.

Con: Many stakeholders, including the general public, may perceive that using a system based on other amenable species is not sufficient to protect the public health, potentially leading to further stakeholder and congressional action. Developing and implementing an EV program would require substantial time and resources.

Option 3: Postpone ruling on the merits of the petition or implementing inspection of horse slaughter or processing on the grounds that the petition has raised sufficient concern about the safety of equine meat that FSIS must further evaluate residue testing for equine tissue. FSIS would need to determine first, whether or not residues are present, and second, if the residues that are present have a lasting, harmful effect. While implementing validated testing methods for equine tissue would determine residue presence, FSIS would consult with FDA to determine whether or not FDA would find that certain drugs administered to equines have a lasting, harmful effect on the muscle tissue.

Pro: Further evaluating residue presence in equine tissue would provide evidence to substantiate or refute stakeholder claims that there is a public health risk associated with consumption of equine meat.

Con: FSIS could be seen as not following congressional direction and again delaying the process of developing a system for equine slaughter and further processing. FSIS would likely need to deflect persistent efforts from all interested stakeholders to change the Agency's course in the meantime. Industry would be indefinitely prevented from proceeding with equine slaughter. Acknowledging the uncertainty of the concerns raised in the petition would also likely open FSIS' existing residue testing program for all other species to similar scrutiny.

DECISION BY THE UNDER SECRETARY:

Option 1 _____

Option 2 _____

Option 3 _____

Discuss with me _____

Reviewed by _____

Date _____

Appendix 1

Updated - 8/8/2012 PB

FSIS National Residue Program - Historical Data on Equine Residue Testing

YEAR	Monitoring Program				Surveillance Samples		
1983	Compounds	# Analyzed	NV Positive	Violations	# tested	NV Positive	Violations
	Sulfadimethoxine	96	0	0	8	0	0
	Sulfamethazine	96	3	4	8	2	0
	Sulfathizole	96	1	0	8	0	0
	Sulfabromomethazine	96	0	0	8	0	0
	Penicillin	94	0	1	8	0	0
	Streptomycin	94	0	0	8	0	1
	Tetracycline	94	0	0	8	0	0
	Erythromycin	94	0	0	8	0	0
	Neomycin	94	0	0	8	0	0
	Oxytetracycline	94	0	0	8	0	0
	Chlortetracycline	94	0	0	8	0	0
	Chloramphenicol	11	0	0			

YEAR	Monitoring Program				Surveillance Samples		
1984	Compounds	# Analyzed	NV Positive	Violations	# tested	NV Positive	Violations
	Aldrin	343	0	0	30	0	0
	Benzene Hydrochloride	343	62	1	30	0	0
	Chlordane	343	4	1	30	1	0
	Dieldrin	343	25	1	30	5	0
	DDT and metabolities	343	69	0	30	5	0
	Endrin	343	2	0	30	1	0
	Heptachlor	343	32	0	30	13	0
	Lindane	343	3	0	30	0	0
	Methoxychlor	343	1	0	30	0	0
	Toxaphene	343	1	0	30	0	0
	PCB	343	0	0	30	0	0
	Hexachrolobenzene	343	53	0	30	0	0
	Mirex	343	0	0	30	0	0
	Strobane	343	0	0	30	0	0
	Nonachlor	343	0	0	30	0	0
	Penicillin	281	0	1	6	0	0
	Streptomycin	281	0	1	6	0	0
	Tetracycline	281	0	0	6	0	0
	Erythromycin	281	0	0	6	0	0
	Neomycin	281	0	0	6	0	0
	Oxytetracycline	281	0	0	6	0	0
	Chlortetracycline	281	0	0	6	0	0
	Gentamicin	281	0	0			
	Sulfathoxypyridazine	24	0	0			
	Sulfachloropyridazine	76	0	0			
	Sulfadimethoxine	102	0	0	1	0	0
	Sulfamethazine	102	0	3	1	1	0
	Sulfamethoxypyridazine	24	0	0			
	Sulfathiazole	102	0	1	1	0	0
	Sulfaquinoxaline	102	0	0			
	Sulfabromomethazine	102	0	0	1	0	0
	Sulfapyridine	102	0	0	1	0	0
	Chloraphenicol	115	0	0			
	Fenbendazole	109	0	1			

YEAR	Monitoring Program				Surveillance Samples		
1985	Compounds	# Analyzed	NV Positive	Violations	# tested	NV Positive	Violations
	Aldrin	313	0	0	10	0	0
	Benzene Hydrochloride	313	3	0	10	0	0
	Chlordane	313	3	0	10	0	0
	Dieldrin	313	2	0	10	0	0
	DDT and metabolities	313	35	1	10	0	0
	Endrin	343	0	0	10	0	0
	Heptachlor	313	5	0	10	0	0
	Lindane	313	1	0	10	0	0
	PCB				10	1	0
	Mirex	313	1	0	10	0	0
	Penicillin	339	0	1	5	0	0
	Streptomycin	339	0	1	5	0	0
	Tetracycline	339	0	0	5	0	0
	Tylosin	339	0	0	5	0	0
	Erythromycin	339	0	0	5	0	0
	Neomycin	339	0	0	5	0	0
	Oxytetracycline	339	0	0	5	0	0
	Chlortetracycline	339	0	0	5	0	0
	Gentamicin	339	0	0	5	0	0
	Licomycin	339	0	0	5	0	0
	Novobiocin	339	0	0	5	0	0
	Virginiamycin	339	0	0	5	0	0
	Sulfathoxypyridazine	105	0	0			
	Sulfachloropyridazine	105	0	0			
	Sulfadimethoxine	105	0	0			
	Sulfamethazine	105	0	1			
	Sulfamethoxypyridazine	105	0	0			
	Sulfathiazole	105	0	0			
	Sulfaquinoxaline	105	0	0			
	Sulfabromomethazine	105	0	0			
	Sulfapyridine	105	0	0			
	OPs (Screen) /Parathion				1	1	0

OP Screen: Coumaphos, Dichlrvos, Diazinon, Ethion, Malathion, Parathion, Ronnel, Cruomate, Trichlorfon, Methyl Parathion, Dioathion

YEAR	Monitoring Program				Surveillance Samples		
1986	Compounds	# Analyzed	NV Positive	Violations	# tested	NV Positive	Violations
	Aldrin	108	0	0			
	Benzene Hydrochloride	108	5	0			
	Chlordane	108	0	0			
	Dieldrin	108	9	1			
	DDT and metabolities	108	39	0			
	Endrin	108	0	0			
	Heptachlor	108	16	0			
	Lindane	108	1	0			
	Methoxychlor	108	0	0			
	Toxaphene	108	0	0			
	PCB	108	0	0			
	HCB	108	5	0			
	Mirex	108	0	0			
	Strobane	108	0	0			
	Nonachlor	108	0	0			
	Penicillin	111	0	3	20	0	0
	Streptomycin	111	0	2	20	0	3
	Tetracycline	111	0	0	20	0	0
	Tylosin	111	0	0	20	0	0
	Erythromycin	111	0	0	20	0	0
	Neomycin	111	0	0	20	0	1
	Oxytetracycline	111	0	0	20	0	0
	Chlortetracycline	111	0	0	20	0	0
	Gentamicin	111	0	0	20	0	0
	Licomycin	111	0	0	20	0	0
	Novobiocin	111	0	0	20	0	0
	Virginiamycin	111	0	0	20	0	0
	Sulfathoxypyridazine	111	0	0			
	Sulfachloropyridazine	111	0	0			
	Sulfadimethoxine	111	0	0			
	Sulfamethazine	111	0	0			
	Sulfamethoxypyridazine	111	0	0			
	Sulfathiazole	111	0	0			
	Sulfaquinoxaline	111	0	0			
	Sulfabromomethazine	111	0	0			
	Sulfadiazine	111	0	1			
	Sulfapyridine	111	0	0			
	OP (Screen)	106	0	0			

YEAR	Monitoring Program				Surveillance Samples		
1987	Compounds	# Analyzed	NV Positive	Violations	# tested	NV Positive	Violations
	Aldrin	337	0	0			
	Benzene Hydrochloride	337	15	0			
	Chlordane	337	4	3			
	Dieldrin	337	17	0			
	DDT and metabolities	337	68	0			
	Endrin	337	0	0			
	Heptachlor	337	30	1			
	Lindane	337	4	0			
	Methoxychlor	337	1	0			
	Toxaphene	337	0	0			
	PCB	337	0	0			
	HCB	337	44	0			
	Mirex	337	0	0			
	Strobane	337	0	0			
	Nonachlor	337	0	0			
	Penicillin	338	0	3	25	0	4
	Streptomycin	338	0	6	25	0	4
	Tetracycline	338	0	0	25	0	0
	Tylosin	338	0	0	25	0	0
	Erythromycin	338	0	0	25	0	0
	Neomycin	338	0	0	25	0	0
	Oxytetracycline	338	0	0	25	0	0
	Chlortetracycline	338	0	0	25	0	1
	Gentamicin	338	0	0	25	0	0
	Licomycin	338	0	0	25	0	0
	Novobiocin	338	0	0	25	0	0
	Virginiamycin	338	0	0	25	0	0
	Sulfathoxypyridazine	134	0	0			
	Sulfachloropyridazine	134	0	0			
	Sulfadimethoxine	134	0	0			
	Sulfamethazine	134	0	0			
	Sulfamethoxypyridazine	134	0	0			
	Sulfathiazole	134	0	0			
	Sulfaquinoxaline	134	0	0			
	Sulfabromomethazine	134	0	0			
	Sulfadiazine	134	0	0			
	Sulfapyridine	134	0	0			
	Arsenic	341	27	0			

YEAR	Monitoring Program				Surveillance Samples		
1988-89	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC screen	300		0			
	Chlorinated OPs	299		0			
	Ivermectin	305		1			
	Penicillin	305		0	552		5
	Streptomycin	305		3	552		1
	Tetracycline	305		0	552		1
	Tylosin	305		0			
	Erythromycin	305		0	552		0
	Neomycin	305		0	552		0
	Oxytetracycline	305		0	552		1
	Chlortetracycline	305		0	552		0
	Gentamicin	305		0	552		0
	Sulfathoxypyridazine	306		0			
	Sulfachloropyridazine	306		0			
	Sulfadimethoxine	306		0			
	Sulfamethazine	306		2			
	Sulfamethoxypyridazine	306		0			
	Sulfathiazole	306		0			
	Sulfaquinoxaline	306		0			
	Sulfabromomethazine	306		0			
	Sulfadiazine	306		0			
	Sulfapyridine	306		0			
	Arsenic	304		1			

YEAR	Monitoring Program				Surveillance Samples		
1990	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC screen	298		0			
	Chlorinated OPs	298		0			
	Ivermectin	310		0			
	Penicillin	313		1	512		14
	Streptomycin	313		17	512		8
	Tetracycline	313		0	512		
	Tylosin	313		0			
	Erythromycin	313		0	512		
	Neomycin	313		0	512		
	Oxytetracycline	313		0	512		
	Chlortetracycline	313		0	512		
	Gentamicin	313		0	512		1
	Sulfathoxypyridazine	313		o			
	Sulfachloropyridazine	313		0			
	Sulfadimethoxine	313		0			
	Sulfamethazine	313		0			
	Sulfamethoxypyridazine	313		0			
	Sulfathiazole	313		0			
	Sulfaquinoxaline	313		0			
	Sulfabromomethazine	313		0			
	Sulfadiazine	313		0			
	Sulfapyridine	313		0			
	Arsenic	310		0			

YEAR	Monitoring Program				Surveillance Samples			
1991	Compounds	# Analyzed		Violations	# STOP			Violations
	CHC screen	106		0				
	Chlorinated OPs	106		0				
	Ivermectin	101		3				
	Penicillin	100		0	708			17
	Streptomycin	100		2	708			17
	Tetracycline	100		0	708			
	Tylosin	100		0				
	Erythromycin	100		0	708			
	Neomycin	100		0	708			
	Oxytetracycline	100		0	708			
	Chlortetracycline	100		0	708			
	Gentamicin	100		0	708			3
	Sulachloropyrazine	106		0				
	Sulfachloropyridazine	106		0				
	Sulfadimethoxine	106		0				
	Sulfamethazine	106		0				
	Sulfamethoxypyridazine	106		0				
	Sulfathiazole	106		0				
	Arsenic	101		0				

YEAR	Monitoring Program				Surveillance Samples		
1992	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC/COP screen	98		1 (coumaphos)			
	Ivermectin	94		2			
	Penicillin	101		0	1008		25
	Streptomycin	101		0	1008		19
	Tetracycline	101		0	1008		0
	Tylosin	101		0			
	Erythromycin	101		0	1008		0
	Neomycin	101		0	1008		0
	Oxytetracycline	101		0	1008		1
	Chlortetracycline	101		0	1008		0
	Gentamicin	101		0	1008		0
	Sulachloropyrazine	103		0			
	Sulfachloropyridazine	103		0			
	Sulfadimethoxine	103		0	1008		1
	Sulfamethazine	103		0	1008		1
	Sulfamethoxypyridazine	103		0			
	Sulfathiazole	103		0			
	Arsenic	94		0			
	Benzimidazoles	99		0			

YEAR	Monitoring Program				Surveillance Samples		
1993	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC/COP screen	425		1 coumaphos 1 dieldrin 1 PCB	Enforcement		11 coumaphos
	Ivermectin	405		0			
	Penicillin	309		2	725		19
	Streptomycin	309		10			8
	Tetracycline	309		0			0
	Tylosin	309		0			0
	Erythromycin	309		0			0
	Neomycin	309		0			0
	Oxytetracycline	309		0			4
	Chlortetracycline	309		0			0
	Gentamicin	309		0			2
	Sulachloropyrazine	306		0			0
	Sulfachloropyridazine	306		0			0
	Sulfadimethoxine	306		1			6
	Sulfamethazine	306		2			0
	Sulfamethoxypyridazine	306		0			0
	Sulfathiazole	306		0			0
	Arsenic	0					

YEAR	Monitoring Program				Surveillance Samples		
1994	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC/COP screen	217		0			
	Ivermectin						
	Penicillin	0			421		8
	Streptomycin	0			421		4
	Tetracycline	0					0
	Tylosin	0					0
	Erythromycin	0					0
	Neomycin	0					0
	Oxytetracycline	0					0
	Chlortetracycline	0					0
	Gentamicin	0			421		1
	Sulachloropyrazine	0					
	Sulfachloropyridazine	0					
	Sulfadimethoxine	0					
	Sulfamethazine	0					
	Sulfamethoxypyridazine	0					
	Sulfathiazole	0					
	Arsenic	0					

YEAR	Monitoring Program				Surveillance Samples		
1995	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC/COPs screen	507		4 coumaphos	Enforcement		
				1 heptachlor	180 samples		0
	Ivermectin						
	Penicillin	0			318		8
	Streptomycin	0					
	Tetracycline	0					
	Tylosin	0					
	Erythromycin	0					
	Neomycin	0					
	Oxytetracycline	0					
	Chlortetracycline	0					
	Gentamicin	0					
	Sulfonamides	0					

FSIS National Residue Program - Historical Data on Equine Residue Testing

YEAR	Program				Surveillance Samples		
1996	Compounds	Monitoring	Enforcement	Violative	# STOP	# FAST	Violative
		Analyzed/V	Analyzed/V	Compound	Test/V		Componds
	Antibiotics -			**0**	**306/11**		
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						**1**
	Penicillin						**8**
	Streptomycin						**2**
	Tetracycline						
	Tylosin						
	Sufonamides -						
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	503/1	53/18	Dieldrin-1			
				Coumaphos-18			
	Trace metals	503	53	none			

Total Horse Slaughter in 1997: 82,025 heads

YEAR	Monitoring Program				Surveillance Samples		
1997	Compounds	Monitoring	Enforcement	Violative	# STOP	# FAST	Violations
		Analyzed/V	Analyzed/V	Compounds	Tests/Viol.	Tests/Viol.	Compounds
	Antibiotics -	386/20	0		59/1		
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						1
	Penicillin			5			
	Streptomycin			17			
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	234/1					
	Sulfacloropyridazine						
	Sulfadimethoxine			1			
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	457/5		Dieldrin - 1 Heptachlor - 1 PCB - 2 Phenybutazone - 1			
	Arsenic	87/0					
	Ivermectin	256/1					
	Clenbuterol		1,420				

Total Horse Slaughter in 1998: 68,783 heads

YEAR	Monitoring Program				Surveillance Samples		
1998	Compounds	Monitoring	Enforcement	Violative	# STOP	# FAST	Violations
		Analyzed/V	Analyzed/V	Compounds	Tests/Viol.	Tests/Viol.	Compounds
	Antibiotics -	442/20	10-0		70/0		
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin			6			
	Streptomycin			15			
	Tetracycline						
	Tylosin						
	Sufonamides -	226/0					
	Sulfaclopyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	467/0					
	Arsenic	91/0					
	Ivermectin	292/0					

Total Horse Slaughter in 1999: 64,036 heads

YEAR	Monitoring Program				Surveillance Samples		
1999	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	**446**			222		
	Bacitracin						
	Chlortetracycline			**2**			
	Erythromycin						
	Flavomycin						
	Gentamicin			**1**			
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline			**1**			
	Penicillin			**8**			**1**
	Streptomycin			**35**			
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	**285**					
	Sulfacloropyridazine						
	Sulfadimethoxine			**1**			
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	**301**		**Phenybutazone**			
				1			

YEAR	Monitoring Program				Surveillance Samples		
2000	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	434			552		
	Bacitracin						
	Chlortetracycline			1			
	Erythromycin						
	Flavomycin						
	Gentamicin			1			1
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline			1			
	Penicillin			9			3
	Streptomycin			59			2
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -						
	21 Sulfa compounds			Sulfadimethoxine			
				1			
	CHC/COPs screen	285		**Phenybutazone**			
	21 compound			1			
	Avermectin	285		2			
	Moxidectin	285					

Total Horse Slaughter in 2003: 50,062 heads

YEAR	Monitoring Program				Surveillance Samples		
2003	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	**193**		**0**	**108**	**9**	**0**
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin						
	Streptomycin						
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	**199**		**0**			
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	**157**		**0**			
	Avermectin	**149**		**0**			
	Moxidectin	**149**		**0**			

Total Horse Slaughter in 2004: 65,200 heads

YEAR	EXPLORATORY Program				Surveillance Samples		
2004	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	15					
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin			2			
	Streptomycin						
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	17					
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	15		**Phenybutazone**			
				1			
	Avermectin	17					
	Moxidectin						

Total Horse Slaughter in 2005: 93,768 heads

YEAR	EXPLORATORY Program				Surveillance Samples		
2005	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	8			85	30	0
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin			2			
	Streptomycin						
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	10					
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	9		Phenybutazone			
				1			
	Avermectin	7					
	Moxidectin						

Total Horse Slaughter in 2006: 104,433 heads

YEAR	Monitoring Program				Surveillance Samples		
2006	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	**112**		**0**	**75**	**4**	**0**
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin						
	Streptomycin						
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	**0**					
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	281		PBDE - 1			
	Avermectin	**113**		**0**			
	Moxidectin	**113**		**0**			

Total Horse Slaughter in 2007: 29,707 heads

YEAR	Monitoring Program				Surveillance Samples		
2007	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	0			7	6	0
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin						
	Streptomycin						
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -						
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	50		0			
	Avermectin	54		0			
	Moxidectin	54		0			

YEAR	Monitoring Program				Surveillance Samples		
2008	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	0			0	0	
	Sufonamides -	0					
	CHC/COPs screen	0					
	Avermectin	0					
	Moxidectin	0					

Appendix 2

COMPOUNDS	IMPLEMENTATION						
	2012	2013	2014				
	Current	Next	Hormones	Tranquilizers	Not - Relevant	Other	Comment
1. Acepromazine		X					Add to MRM
2. Acetazolamide		X					Sulfonamide
3. Acriflavin					X		Topical application
4. Glycosaminoglycan						X	Joint medication
5. Altrenogest			X				Hormonal effect
6. Amikacin	X						
7. Antibiotics	X						
8. Antiseptic					X		Topical application
9. Avermectin	X						
10. Boldenone			X				Hormonal effects
11. Butorphanol				X			Pain med
12. Carbadox	X						
13. Ceftiofur	X						
14. Chloramphenicol	X						
15. Copper					X		Topical application
16. Cupric sulfate					X		Topical application
17. Kerosene					X		Topical application
18. Deslorelin			X				Hormonal effect
19. Dexamethasone	X						
20. Diclofenac sodium				X			Pain med
21. Dormosedan				X			Sedative / analgesic
22. Doxycycline		X					Add to MRM
23. Enrofloxacin	X						
24. Eucalyptus oil					X		Topical application
25. Flunixin	X						
26. Furaltadone	X						
27. Furazolidone	X						
28. Gentamicin	X						
29. Hyaluronate						X	Joint disease
30. Isoflurane					X		Gas anesthetic
31. Levothyroxine			X				Thyroid replacement hormone
32. Luprostiol			X				Hormonal effect
33. Methylandrostenediol			X				Hormonal effect
34. Methylprednisolone	X						Prednisone but not

Appendix 2

COMPOUNDS	IMPLEMENTATION						
	2012	2013	2014				
	Current	Next	Hormones	Tranquilizers	Not - Relevant	Other	Comment
and Prednisone							methylprednisolone at this time
35. Moxidectin	X						
36. 3-dicarboximide		X					Dicarboximides are a class of fungicides including vinclozolin and iprodione, which are in the AMS PDP method on GC. These fungicides rapidly turn into 3,5-dichloroaniline in soil. Need to determine the correct analyte of interest.
37. Neomycin	X						
38. Omeprazole						X	Stomach ulcers
39. Phenylbutazone	X						
40. Prallethrin		X					Pyrethroid insecticide in the AMS PDP method on GC
41. Thyrostats	X						
42. Triamcinolone acetonide					X		Topical application
TOTAL	17	5	6	3	8	3	

NRP 2012	17
During NRP 2013	5
During NRP 2014	9
Not applicable	11

EXHIBIT 9

United States Department of Agriculture | Food Safety and Inspection Service | Washington, D.C. 20250

Bruce A Wagman, Esq.
Schiff Harden LLP
One Market, Spear Tower, 32nd Floor
San Francisco, CA 94105

JUN 28 2013

Dear Mr. Wagman:

The Food Safety and Inspection Service (FSIS) has completed its review of the petition you submitted on behalf of Front Range Equine Rescue and the Humane Society of the United States dated April 6, 2012. The petition asserts that meat and meat food products from horses without a proven lifetime history of all drugs, treatments, and substances administered to the animal are adulterated under the Federal Meat Inspection Act (FMIA) and as such must be prohibited for human food. To prevent these products from entering the human food supply, the petition requests that FSIS initiate rulemaking to require that any horse offered for slaughter for human food be identified as "U.S. Condemned" unless the slaughter establishment receiving or buying the horse obtains: 1) an accurate record of all of the horse's prior owners; 2) a record of all drugs, treatments, and substances administered to the horse since birth; and 3) verification that the horse has at no time been exposed to any substances prohibited for use in animals intended for human food. The petition also requests that FSIS issue regulations to require that any horse or horsemeat that meets the criteria described above be tested for the presence of all potentially dangerous substances in a manner that ensures detection of any residue or any potentially dangerous substance. The petition states that if any potentially dangerous substance is found, or if testing is not available to determine the presence of any prohibited substances, the regulations must require that the horse or horsemeat be identified as "U.S. Condemned."

FSIS has also reviewed the supplemental statement that you submitted on February 19, 2013, which contains declarations from several veterinarians and horse owners attesting that horses are routinely treated with a variety of veterinary drugs.

After carefully considering the issues raised in the petition and the supplemental statement, the Agency finds no merit in the assertion that all meat and meat food products from a horse without a proven lifetime history of all substances administered to it are adulterated under the FMIA. FSIS has concluded that its existing authority under the FMIA and implementing regulations, which include requirements for the disposition of livestock suspected of having biological residues, along with the Agency's National Residue Program (NRP), will allow the Agency to ensure that carcasses and horsemeat products that bear the mark of inspection are safe for human food. FSIS is able to fully carry out the purposes and achieve the ends of the FMIA to make certain that meat and meat food products from horses do not contain violative residues or other substances that would adulterate these products. Thus, for the reasons discussed below, the Agency is denying the petition.

As noted in your petition, under the FMIA, a meat or meat food product is adulterated if, among other circumstances: 1) it contains any added poisonous or deleterious substance that may render it injurious to health (21 U.S.C. 601(m)(1)); 2) it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or deleterious substance that would make such article unfit for human food (21 U.S.C. 601(m)(2)); 3) it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 601(m)(2)); or 4) it is "otherwise unfit for human food" (21 U.S.C. 601(m)(3)).

The petition and the supplemental statement assert that the variety of drugs administered to American horses makes their meat unfit for human food and thus adulterated under the FMIA because these drugs cannot legally be administered to food animals in any amount. To support this assertion, the petition includes an illustrative list of substances that bear the labeling statement: "Do not use in horses intended for human consumption" but that are routinely given to American horses. The petitioner claims that if a horse is treated with a substance that bears this labeling statement – at any point in its lifetime – any meat from the animal is unfit for human food and must be condemned. The petition also asserts that many substances administered to American horses are unsafe food additives, result in drug residues prohibited in meat in any amount, or render horsemeat "injurious to health."

FSIS disagrees with this interpretation and finds no basis in the statute or in science to support the petitioner's conclusion that meat from every horse treated with a substance listed in the petition is adulterated under the FMIA. The fact that a drug or other chemical was administered to an animal does not by itself mean that the meat and meat food products from the animal will be adulterated because administration of a substance does not necessarily affect the meat or meat food products derived from the animal. Residues do not remain in animals forever; they are eliminated from the body over time. After a substance has been administered to a horse, the drug would be excreted from the animal's system and would eventually leave no detectable residue. If no detectable drug or chemical residue remains in the animal at the time of slaughter, then the meat from that animal is not adulterated because there is no reason to believe that the meat will cause harm to human consumers, or that the meat is otherwise unfit for human food. Thus, the fact that a substance labeled "Do not use in horse intended for human food" was administered to a horse does not mean that the meat from the horse will be adulterated if the horse is eventually slaughtered for human food. The meat from that horse would be considered adulterated only if it contained residue of the substance.

Furthermore, FSIS fully protects consumers from harm by enforcing a zero tolerance (*i.e.*, no detectable levels permitted) policy for substances in horsemeat. FSIS enforces tolerance and action levels set by the Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) to ensure that meat and meat food products do not contain levels of animal drugs, pesticides, or other chemicals above the level that is considered safe. If there is no established tolerance for a substance, FSIS condemns the entire carcass of an animal that tests positive for that substance and prohibits its use for human food.

Because there are no tolerance levels for substances administered to horses, if a residue test reveals any amount of the substance in a horse, FSIS will condemn all meat from that horse. In addition, FSIS will conduct intensified residue testing at establishments that slaughter horses. FSIS has no reason to believe that it cannot use its existing authority to effectively target and enforce its zero tolerance policy for substances in horsemeat.

The petition asserts that the NRP and FSIS's sampling programs – the Scheduled Sampling Program and the Inspector Generated Sampling Program – would not be able to prevent the entry of adulterated horsemeat into the food supply. To support this assertion, the petitioner cites the Office of Inspector General's 2010 Report on the NRP for cattle (Audit Report 24601-08-KC). The petition asserts that the only way to ensure the safety of horsemeat is to establish a system that captures the history of drug use on each animal, similar to that employed by the European Union (E.U.). We disagree.

Food safety problems may arise at many points along the farm-to-table continuum for all amenable species, not just for horses. FSIS finds no merit in the petitioner's argument that the Agency's use of the NRP and the residue sampling program would not be effective in preventing adulterated horsemeat from entering the human food supply. FSIS has addressed the recommendations made by the OIG in 2010 and has made several improvements to strengthen the NRP and its inspection and sampling programs in the past three years. For example, FSIS has implemented several multi-residue methods for analyzing samples of meat and meat food products for animal drug residues, pesticides, and environmental contaminants. FSIS has validated the multi-residue methods for horsemeat. These methods allow the Agency to screen for chemical compounds that include several types of legal and illegal drugs, such as antibiotics, anti-inflammatories, and growth hormones. The petitioner was especially concerned about the use of phenylbutazone in horses. FSIS's methods can detect phenylbutazone as well as nine classes of antimicrobials from sulfas to penicillin; anti-inflammatory drugs like flunixin; anti-parasitic drugs like avermectins; several heavy metal and environmental contaminants; over 50 types of pesticides; and performance altering drugs such as the beta-agonists, clenbuterol and ractopamine. In the past, FSIS would have had to collect samples from horses and look for just one chemical at a time. However, under FSIS's new system, one sample can be screened for over 130 different compounds.

FSIS's NRP includes sampling from show animals and other livestock that, similar to horses, are not specifically raised for human food. Like all livestock that are offered for slaughter, these animals do not arrive at slaughter with a full history of drug use. To ensure that meat from show animals does not contain residues that would adulterate the meat under the FMIA, FSIS inspectors collect residue samples from these animals at a higher rate than they do for other livestock. FSIS will collect residue samples from horses in a manner similar to its residue sampling for show animals. Inspection program personnel will tag horses that appear unhealthy, that have visible needle puncture marks, or exhibit signs or symptoms associated with the effects of a particular substance as "U.S. Suspect" and perform inspector-generated testing. In addition, as they do for show animals, FSIS inspection program personnel will randomly select and sample a number of carcasses from every lot of horses that pass ante-mortem inspection.

Thus, the rate at which we will collect samples for horses will be be higher than the rate at which we collect samples from other livestock. The Agency will evaluate the results of residue testing from horses to determine the need to adjust its sampling rate as it gains experience with horse slaughter.

As noted in the petition, the Hazard Analysis and Critical Control Points (HACCP) inspection system regulations (9 CFR 417.2(a)(3)) make clear that violative residues present a food safety hazard that may be reasonably likely to occur, and, therefore, slaughter establishments must consider the likelihood of their occurrence in developing HACCP plans. The HACCP regulations provide that a "...hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed" (9 CFR 417.2(a)). Because of concerns about residues in horses, FSIS expects that an establishment that slaughters horses will incorporate controls for residues in its HACCP system. These controls could include independent sampling and testing for residues or requesting suppliers to certify that the horses are residue-free. The Agency will verify that an establishment that slaughters horses has addressed violative residues in its hazard analysis and will verify that the establishment's HACCP system is effective in preventing horsemeat containing residues that would adulterated the meat under the FMIA from entering the human food supply. FSIS will take action against an establishment that does not have an adequate chemical residue control program in place (see FSIS Directives 5,000.1 and 10,800.1). For example, if the Agency determines that an establishment's residue controls are ineffective, the Agency is authorized to take action and retain products because the products would have been produced under conditions that preclude the Agency from determining product is not adulterated (9 CFR 500.2(a)(2)).

In addition, FSIS maintains a list of animal producers that are repeat residue violators. The Residue Repeat Violators List includes producers associated with more than one violation on a rolling 12-month basis. The list will provide helpful information to horse processors and producers, serve to deter violators, and enable FSIS to make better use of its resources.

Furthermore, FSIS has recently issued a compliance guide to help livestock slaughter establishments avoid purchasing animals with illegal drug or other violative chemical residues. The compliance guide is available on FSIS's Web site at http://www.fsis.usda.gov/PDF/Residue_Prevention_Compliance_Guide_042512.pdf. The compliance guide focuses on establishments that slaughter cull dairy cows and bob veal because these animals account for 90 percent of the residues found in animals presented for slaughter; however, the compliance guide would be applicable to establishments that slaughter horses because applying the five basic measures suggested in the guidance would reduce or prevent the occurrence of residues that violate the FMIA.

The guide recommends that establishments: 1) confirm producer history; 2) buy animals from producers who have a history of providing residue-free animals and have effective residue prevention programs; 3) ensure that animals are adequately identified to enable traceback; 4) demonstrate that animals in a lot presented for ante-mortem inspection did not come from producers identified as repeat violators; and 5) notify producers in writing if their animals are found to have either residues that would adulterate the meat or residues at detectable levels that do not exceed established tolerance levels.

The petition also claims that allowing establishments to slaughter horses would pose a danger to the environment. To support this claim, the petitioner states that one slaughter facility in Texas was cited for wastewater violations and other nuisance violations. The petition asserts that the National Environmental Policy Act (NEPA) requires FSIS to prepare an environmental assessment (EA) or an environmental impact statement (EIS) before approving a grant of inspection to a horse slaughter facility.

Each USDA agency must comply with 7 CFR part 1b of the Departmental regulations, which supplements the NEPA regulations published by the Council on Environmental Quality. Under these regulations, actions of certain USDA agencies and agency units are categorically excluded from the preparation of an EA or an EIS unless the agency head determines that an action may have a significant environmental effect (7 CFR 1b.4(b)). FSIS is among the agencies categorically excluded from the preparation of an EA or EIS (7 CFR 1b.4(b)(6)). FSIS will decide on a plant-by-plant basis whether the categorical exclusion properly applies to issuing a grant of inspection to a horse slaughter establishment, or whether it is necessary for FSIS to prepare an EA or EIS.

Finally, the petition asserts that it is not possible to slaughter horses in a humane manner. In support of this assertion, the petition cites four FSIS noncompliance records (NRs), issued from 2005-2007, that document inhumane handling of horses. According to the petition, ill, diseased, and injured horses are unfit for food under the FMIA and should not be slaughtered for human consumption.

FSIS finds no merit in the petition's conclusion that it is not possible to slaughter horses in a humane manner. In FSIS's experience, inhumane handling incidents are rare and do not accurately depict behavior throughout the industry. From 2005 to 2007, FSIS issued only 12 NRs for humane handling violations in horse slaughter establishments. The NRs demonstrate that FSIS will take appropriate action to detect and prevent inhumane handling incidents.
In addition, FSIS has made significant changes to its inspection program in the years since these NRs were issued. FSIS has put more emphasis on animal handling inspection and has provided clarification and training on humane handling verification and enforcement activities to inspectors (see FSIS's Livestock Slaughter Inspection Training available at http://www.fsis.usda.gov/PDF/LSIT_HumaneHandling.pdf). Inspectors in establishments that slaughter horses will be required to complete such training.

As noted in the petition, the Humane Methods of Slaughter Act of 1978 (HMSA) requires livestock, including horses, to be humanely handled in connection with slaughter.

FSIS will take action against an establishment that does not comply with the HMSA and the regulations that implement it.
The petition also asserts that horses cannot be humanely transported to slaughter. USDA's Animal and Plant Health Inspection Service (APHIS) has authority over the commercial transportation of horses to slaughter and has enacted regulatory requirements for such transport (9 CFR Part 88). FSIS cooperates with APHIS in enforcing APHIS's humane transport requirements and will continue to cooperate with APHIS to enforce APHIS's requirements for the commercial transportation of horses. For example, FSIS inspectors will monitor the off-loading of horses at slaughter establishments, and if a horse arriving at a slaughter facility on a transport vehicle is not capable of standing on all four legs, FSIS inspectors will contact the APHIS Area Veterinarian-in-Charge. APHIS will send follow-up veterinary personnel to the facility to conduct an investigation.

For these reasons, FSIS is denying the petition requesting that the Agency amend its regulations governing the processing of horses and horsemeat intended for human consumption. FSIS has concluded that its existing regulations and the NRP would be effective in ensuring that adulterated horsemeat does not enter the human food supply.

In accordance with FSIS regulations, the petition was posted on the FSIS website in April 2012, and the Agency intends to post this response as well.

Sincerely,

Charles E. Williams
for

Rachel A. Edelstein
Assistant Administrator
Office of Policy and Program Development

EXHIBIT 10

Decision Memo–National Environmental Policy Act Categorical Exclusion

Application of Valley Meat Company, LLC, for a Grant of Federal Meat Inspection Services

Decision

It is my decision to grant federal meat inspection services to Valley Meat Company, LLC.

Description

Valley Meat Company, LLC (Valley Meat) is a small (7,290 square-foot) cattle slaughter and processing facility with a street address of 3845 Cedarvale Rd., Roswell, Chaves County, New Mexico. Valley Meat's zoning permit indicates that its facility is located on a 22-acre site about 12 miles east of Roswell and within an extraterritorial industrial zone that has been set aside in Chaves County for light industrial use. Its nearest neighbors are located approximately one mile to the east and one mile to the west of its facility. Valley Meat has existed as slaughter facility since 1982. Its current owner, Mr. Ricardo de los Santos, has conducted federally inspected commercial slaughter of cattle, veal calves, goats, sheep, lambs, and swine at this facility more or less continuously since January, 1991.[1] On March 2, 2012, Valley Meat filed an application with the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS), to modify its grant of inspection to receive inspection services for the commercial slaughter of horses, mules, and other equines.

Proposed Action

The proposed action is to grant federal meat inspection services for commercial horse slaughter operations at Valley Meat. The Federal Meat Inspection Act (FMIA) requires government inspectors to conduct an ante-mortem inspection of all amenable species, including cattle, sheep, swine, goats, horses, mules and other equines (21 U.S.C. § 603); a post-mortem inspection of the carcasses and parts of all amenable species (21 U.S.C. § 604); and an inspection of meat food products during processing operations (21 U.S.C. § 605) in establishments that sell or distribute in commerce meat that is intended for human consumption. Horses, mules, and other equines have been among the livestock species that are amenable to the FMIA since it was amended by the Wholesome Meat Act in 1967.[2] [3] The FMIA and its implementing regulations in 9 C.F.R.

[1]Valley Meat has operated as a slaughter establishment under several previous grants of federal inspection. It received its first grant in 1982 when it was known as Pecos Valley Meat Company (Pecos) and was under different ownership. Mr. de los Santos took over ownership of Pecos and obtained his first grant of inspection on January 8, 1991. He obtained his second (and still current) grant on September 1, 2010, after adding Mr. Jose Hernandez as a second owner and partner and changing the name of the slaughter plant to Valley Meat. Valley Meat has not operated under its current grant since April 13, 2012.

[2]FSIS regulations require that establishments that slaughter horses, mules, and other equines must be completely separate from any establishment that slaughters cattle, sheep, swine, or goats.

[3]FSIS temporarily suspended inspection of horse slaughter facilities from 2006 to 2012 because Congress prohibited FSIS from expending funds to pay for ante-mortem inspection of equines in each of those years, but the underlying statute requiring federal inspection of horse slaughter has never been amended or repealed. In 2012 Congress restored federal funding of ante-mortem inspection of horses at commercial horse slaughter plants. Therefore, issuing a grant of inspection for commercial horse slaughter is not precedent setting, but rather, a return to the status quo ante.

parts 302, 304, 307, 416, and 417 require facilities that wish to engage in the commercial slaughter of amenable species to produce meat intended for human consumption and sale or distribution in interstate commerce to apply to FSIS for a grant of federal inspection services and they establish criteria for determining the eligibility of the applicant to receive inspection services.

FSIS is also required to conduct an examination and inspection of the method by which amenable species, including horses, are slaughtered and handled in connection with slaughter in order to ensure that the establishment is in compliance with the Humane Methods of Slaughter Act (21 U.S.C. § 603) (HMSA). The HMSA was enacted to prevent the needless suffering of livestock, to improve products and economies in slaughter operations, and to produce other benefits for producers, processors, and consumers which tend to expedite an orderly flow of livestock and livestock products in interstate and foreign commerce. FSIS has implemented and enforces regulations under the HMSA (9 C.F.R. part 313).[4]

The National Environmental Policy Act and FSIS' Categorical Exclusion

The National Environmental Policy Act (42 U.S.C. § 4321 *et seq.*) (NEPA) and the Counsel of Environmental Quality implementing regulations (40 C.F.R. Parts 1501-1508) require all federal agencies to prepare an assessment of the environmental impact of a proposed agency action (called an environmental assessment, or EA) (40 C.F.R. §§ 1501.3 and 1501.4(b)). Based on the EA, NEPA further requires federal agencies to prepare an environmental impact statement (EIS) for major federal actions significantly affecting the quality of the human environment (42 U.S.C. § 4332(2)(c) and 40 C.F.R. § 1504.1(c)). However, federal agencies may identify classes of actions that normally do not require the preparation of either an EA or an EIS because such actions do not have a significant effect on the human environment, either individually or cumulatively (40 C.F.R. § 1507.3(b)(2)). Classes of actions that have no significant environmental effect, either individually or cumulatively, are said to be categorically excluded from NEPA requirements (40 C.F.R. § 1508.4). Despite allowing federal agencies to identify classes of action that are categorically excluded from NEPA requirements, NEPA still requires an agency to determine and inform the agency decision maker on whether or not there are any potential environmental impacts that may result from a proposed action of that agency.

[4]The Commercial Transportation of Equine for Slaughter Act (7 U.S.C. § 1901 note) is an animal welfare statute governing the commercial transportation of equine for slaughter by persons regularly engaged in that activity within the United States. In 1998, the Secretary issued regulations (9 C.F.R. part 88) that establish safety standards for conveyances being used to transport equines to slaughter; define the duties and responsibilities of owner/shippers prior to loading equines onto the conveyance, during the actual commercial transportation of said equines to the slaughter plant, and upon their arrival at a slaughter plant; and set forth paperwork and back tagging requirements for equines being commercially transported to slaughter. This program is administered by USDA's Animal and Plant Health Inspection Service, whose personnel historically have conducted their inspections of slaughter horses and the conveyances in which they are transported to slaughter upon the horses' arrival at a slaughter facility.

USDA's NEPA implementing regulations are found in 7 C.F.R. § 1b. These regulations list FSIS as an agency that conducts programs and activities that have been found to have no individual or cumulative effect on the human environment, such that FSIS is categorically excluded from the requirements of preparing procedures to implement NEPA and its actions are categorically excluded from the preparation of an EA or an EIS unless the FSIS Administrator determines that an action may have a significant environmental effect (7 C.F.R. § 1b.4).

When a federal agency's action is merely ministerial as opposed to discretionary and the agency lacks discretion to affect the outcome of its action, there is no major federal action that triggers NEPA requirements. A grant of federal inspection under the FMIA is purely ministerial because, if a commercial horse slaughter plant meets all of the statutory and regulatory requirements for receiving a grant of federal inspection services, FSIS has no discretion or authority under the FMIA to deny the grant on other grounds or to consider and choose among alternative ways to achieve the agency's statutory objectives. Therefore, a grant of federal inspection services under the FMIA is not a major federal action that is subject to NEPA requirements.

A grant of federal inspection likewise does not and will not allow FSIS to exercise sufficient control over the commercial horse slaughter activities at Valley Meat such that the grant will constitute a major federal action that triggers NEPA requirements. The sole purpose of federal meat inspection is to protect public health and welfare by ensuring that any meat produced for human consumption and sale or distribution in commerce is wholesome, not adulterated, properly packaged, and properly labeled as to species, quantity, and point of origin, and the FMIA does not authorize FSIS to regulate a commercial horse slaughter facility's slaughter activities beyond that which is necessary to achieve this purpose. Accordingly, the FMIA authorizes FSIS inspectors to conduct ante-mortem inspection of horses to ensure that they are not dead or dying, diseased, or non-ambulatory, and that they are not inhumanely handled or slaughtered. It likewise authorizes FSIS inspectors to conduct post-mortem inspection of the carcasses and meat food products resulting therefrom to ensure that the carcasses and meat are wholesome, unadulterated, and fit for use as human food. In addition, the FMIA authorizes FSIS to require commercial slaughter plants to maintain sanitary conditions with respect to the conduct of commercial slaughter, meat preparation, and meat packaging operations, the proper storage of carcasses and the meat products derived therefrom, and the storage and proper disposal of condemned or inedible materials. The FMIA further authorizes FSIS to require commercial slaughter plants to develop hazard analysis and critical control point plans that identify and prevent or control for potential food safety hazards at each step of the slaughter process. All FSIS inspectors assigned to conduct federal meat inspection at Valley Meat's facility will perform these duties in accordance with the policies and procedures set forth in several FSIS directives and notices, including but not limited to FSIS Directive 6900.2 Rev. 2, *Humane Handling and Slaughter of Livestock*; FSIS Directive 6100.1 *Ante-Mortem Livestock Inspection*; FSIS Directive 6100.2, *Post-mortem Livestock Inspection*; and FSIS Directive 6130.1, *Ante-mortem, Post-mortem Inspection of Equines and Documentation of Inspection Tasks*. However, FSIS inspectors will not have any authority or control over the day-to-day operations of the slaughter plant save to the degree necessary to achieve the agency's mission to protect public health by ensuring that horse meat intended for use as human food is safe to eat and properly labeled.

Even if FSIS did have sufficient authority and control over commercial slaughter activities at a horse slaughter establishment such that a grant of federal inspection to such an establishment could constitute a major federal action, federal ante-mortem and post-mortem inspection of horses at Valley Meat would not be the legally relevant cause of the establishment's commercial horse slaughter activities or the impacts, if any, that such slaughter activities might have on the environment. As noted above, federal inspection under the FMIA is required for any meat that is produced for human consumption and for sale or distribution in interstate commerce, and Valley Meat has operated for about 20 years under a grant of inspection for the commercial slaughter of amenable species other than horses that has not been revoked or otherwise terminated. Valley Meat could resume the slaughter of other amenable species under its existing grant of inspection, so a decision not to grant Valley Meat's current application for federal inspection of commercial horse slaughter would not result in the shuttering of the slaughter plant or relieve its alleged environmental impacts. Furthermore, a modification of the existing grant of inspection so that it applies exclusively to the commercial slaughter of horses would not be a substantial change to the agency's actions pursuant to the grant but would preserve the status quo because FSIS inspectors would continue to follow the policies and procedures set forth in the directives cited above, regardless of the amenable species being slaughtered. It also would not be a substantial change to Valley Meat's commercial slaughter activities but would preserve the status quo because the environmental impacts resulting from the commercial slaughter of horses, if any, would not be significantly different from those resulting from the commercial slaughter of other amenable species. Finally, if the meat produced at a commercial horse slaughter plant is not intended for human consumption, or if it is intended for human consumption but for sale or distribution only in intrastate commerce rather than in interstate commerce, then the commercial horse slaughter and the effects thereof may proceed independently of a grant of federal ante-mortem and post-mortem inspection, and FSIS would have no ability to prevent them. In the present instance, Mr. de los Santos has indicated that he intends to prepare horse meat for human consumption and that his intended market is Mexico, so he may operate only subject to a grant of federal inspection.[5] However, nothing in the FMIA precludes him from expanding his operation to include the preparation and sale of horse meat to pet food companies and zoos for non-human consumption. It thus is possible for Valley Meat to operate as a horse slaughter establishment, and possibly have an effect on the environment, without a grant of federal inspection. Accordingly, a grant of federal inspection services is not and cannot be the legally relevant cause of either the commercial slaughter activity or its environmental impact, if any.

Based on the foregoing, a decision to grant federal inspection services to Valley Meat does not constitute major federal action that will significantly affect the quality of the human environment and thus does not trigger any requirements under NEPA. Nevertheless, given the high level of public interest in this particular issue, FSIS has examined several aspects of granting federal inspection services to Valley Meat to determine if the categorical exclusion applies to this action

[5]It is not possible for Mr. de los Santos to prepare horse meat for human consumption by consumers located only in the State of New Mexico without a grant of federal meat inspection services because New Mexico has been designated by the Secretary of Agriculture as a state in which the FMIA applies to all transactions involving meat intended for human consumption, even if the meat is sold and distributed only in intrastate commerce. *See* 9 C.F.R. part 331.

or if any unique conditions or extraordinary circumstances exist that would cause this action to have a significant environmental effect and trigger NEPA requirements. These aspects are the following:

–**Impacts on Public Health and Safety**. As explained above, federal inspection under the FMIA is intended solely to protect public health and safety by ensuring that meat and meat food products intended for use as human food are not adulterated or misbranded. However, the agency recognizes that the potential impacts of commercial horse slaughter on public health may cause concern with segments of the public. One such concern is the potential public health risks that could arise from the presence in horse meat of trace amounts of certain classes of drugs that have not been approved for use in animals that will or could be slaughtered to produce food for human consumption. The Humane Society of the United States and other horse protection groups contend that horses' status as companion animals that usually are not slaughtered in this country to produce human food means that most horses in the United States have been treated with antibiotics, anti-inflammatory drugs, growth hormones, and other substances that typically are not used on other food animals and for which the Federal Drug Administration has established no tolerances. These groups further contend that residues of these substances remain in horse tissues indefinitely, thus rendering any meat produced from U.S. horses unsafe for human consumption and constituting a threat to public health. FSIS has addressed this risk by implementing a new drug residue testing program that will screen the meat of slaughtered horses for drug residues before the meat is allowed to enter the food supply chain (*see* FSIS Directive 6130.1, *Ante-mortem, Post-mortem Inspection of Equines and Documentation of Inspection Tasks*). Horse meat that tests positive for drug residues will be marked U.S. condemned and will not be allowed to enter the stream of commerce. Instead, the meat will be disposed of by sending it to a rendering facility, thereby ensuring that it endangers neither public health and safety nor the local environment. Additionally, as described below, an overlapping scheme of federal, state, and local environmental laws and ordinances will further ensure that the waste products generated by Valley Meat's commercial horse slaughter activities are properly disposed of and will not enter the human food supply chain or the local environment. Therefore, a decision to grant federal inspection to Valley Meat will safeguard public health and safety by ensuring that commercial horse slaughter at Valley Meat has no more potential to have a significant impact on public health and safety than did the commercial slaughter of cattle, pigs, sheep, and goats that preceded it.

--**Wildlife Hazards**. FSIS has determined that commercial horse slaughter activities at Valley Meat and/or federal inspection thereof will not create a wildlife hazard.

–**Impacts on Wild and Scenic Rivers and U.S. Waters and Wetlands**. FSIS has determined that commercial horse slaughter activities at Valley Meat and/or federal inspection thereof will not affect a river segment that is listed in the Wild and Scenic River System or National Rivers Inventory. FSIS also has determined that commercial horse slaughter activities at Valley Meat and/or federal inspection thereof will not impact federal or state regulated or non-jurisdictional wetlands.

–**Impacts on Energy and Natural Resources**. FSIS has determined that commercial horse

slaughter activities at Valley Meat and/or federal inspection thereof will not have a significant impact on energy and other natural resource consumption.

--**Impacts on Public Parks, Recreation Areas, Wildlife/Waterfowl Refuges, Historical Sites, and Other Publicly Owned Lands**. FSIS has determined that commercial horse slaughter activities at Valley Meat and/or federal inspection thereof will not have any impacts on any publicly owned land from a public park, recreation area, wildlife or waterfowl refuge, or historical site of national, state, or local significance.

In its June 2011 report on the unintended consequences of the cessation of commercial horse slaughter in the United States, the General Accounting Office (GAO) found that there has been an increase in horse abandonment on private or state park land since 2007. It likewise found an increase in horse abandonment on federal lands, including national parks and Indian reservations. The abandonment of horses on these lands results in over-grazing that degrades the land and puts environmental stress on other species that compete with horses for the same food sources. Horse abandonment on these and other federal lands that maintain populations of wild horses increases the chance that the abandoned horses will introduce equine diseases to the wild herds. The increasing numbers of unwanted horses also complicate the Bureau of Land Management's efforts to manage herds of wild horses and burros on federal lands by making it more difficult for the agency to adopt out the horses and burros that it removes from federal lands. Based on the foregoing, commercial horse slaughter at Valley Meat and other horse slaughter plants has the potential to reduce the horse overpopulation in the United States while providing owners of unwanted horses with an economically viable and an environmentally sustainable alternative to horse abandonment as a method of disposing of their unwanted horses.

FSIS has also made the following findings required by other laws:

--**Clean Air Act.** Section 176(c)(1) of the Clean Air Act (42 U.S.C. § 7401) requires federal agencies to assure that their actions conform to applicable implementation plans for achieving and maintaining the National Ambient Air Quality Standards that the Environmental Protection Agency (EPA) has set for certain criteria pollutants, such as sulfur dioxide, nitrogen dioxide, carbon monoxide, ozone, lead, and particulate matter. *See* 40 C.F.R. part 50. FSIS has determined that commercial horse slaughter activities at Valley Meat and/or federal inspection thereof will not increase the frequency or severity of any existing violations of standards for ambient air quality, result in any new violations of said standards, or prevent or delay the timely attainment of said standards in the area of concern.

--**Clean Water Act**. Following section 401(a) of the Clean Water Act (33 U.S.C. § 1341) (CWA), 9 C.F.R. § 304.2(c)(1) requires any applicant for federal meat inspection at an establishment where the operations thereof may result in any discharge into navigable waters as defined by the CWA to provide the Administrator, FSIS, with certification, obtained from the State in which the discharge will originate, that there is reasonable assurance that said operations will be conducted in a manner that will not violate the applicable water quality standards. On June 14, 2103, Mr. de los Santos provided the Administrator, FSIS, with an attestation that horse slaughter operations at Valley Meat will not result in any discharge into any navigable waters as

defined by the CWA. Mr. de los Santos also provided the Administrator, FSIS, with a copy of a National Pollution Discharge Elimination System (NPDES) Form 3510-11, No Exposure Certification for Exclusion from NPDES Storm Water Permitting, dated May 10, 2013, which he also submitted to EPA pursuant to section 402 of the Clean Water Act (33 U.S.C. § 1342) and its accompanying regulations (*see* 40 C.F.R. § 122.26(g)). This form notifies that EPA that Valley Meat does not require permit authorization for its storm water discharges associated with industrial activity.

--**Endangered Species Act**. FSIS has determined that commercial horse slaughter activities at Valley Meat and/or federal inspection thereof will not have any impact, either directly or indirectly, on any federally or state-listed or proposed endangered species of flora and fauna or impact critical habitat. According to the U.S. Fish and Wildlife Service (FWS), there are no known threatened or endangered species or designated critical habitat in the immediate vicinity of Valley Meat's slaughter facility. FSIS also has determined that commercial horse slaughter activities at Valley Meat and/or federal inspection thereof will not have any impact affect other biotic communities or habitat not protected by the Endangered Species Act.

It should be noted that any grant of federal inspection for commercial horse slaughter at Valley Meat will not be the issuance of a new grant, but instead will be a modification of an existing grant of inspection for the commercial slaughter of other amenable species under the FMIA (*e.g.*, cattle, sheep, goats, and pigs) at the same facility. Consistent with the response of FWS, the commercial slaughter of other amenable species occurred more or less continuously at Valley Meat's facility for more than 20 years with no discernible effects on listed endangered species or their designated critical habitat. Furthermore, there will no significant difference between the methods that Valley Meat will use to conduct commercial horse slaughter at its facility and the methods that it previously used to conduct the slaughter of other amenable species. Therefore, there is no reason to believe that the conversion of Valley Meat's facility to a dedicated commercial horse slaughter plant will have any more impact on endangered species and their critical habitat than did the prior commercial slaughter of other amenable species.

--**Migratory Bird Treaty Act**. FSIS has determined that commercial horse slaughter activities at Valley Meat and/or federal inspection thereof will not affect species protected under the Migratory Bird Treaty Act.

--**National Historic Preservation Act**. The National Register of Historic Places lists 19 sites located inside the Roswell, New Mexico, multiple resource area (MRA). Of these, only two, the Patrick Floyd Garret House and the South Spring Ranch, are located within the extraterritorial industrial zone, but both are located slightly more than three (3) miles from Valley Meat's facility. Therefore, FSIS has determined that commercial horse slaughter activities at Valley Meat and/or federal inspection thereof will not impact any historic or cultural property or resources protected by the National Historic Preservation Act.

In 2009, a coalition of northwest Indian tribes reported to the General Accounting Office that the increase in horse abandonments on tribal lands, combined with the sizable populations of wild horses that already existed on their lands, both increased the degradation of the land caused by

over-grazing and complicated efforts to restore native and religiously-significant plant species on tribal lands. Commercial horse slaughter at Valley Meat and other commercial horse slaughter plants thus has the potential to have a beneficial effect on the cultural resources of American Indian tribes whose tribal lands are being degraded by a combination of an overpopulation of wild horses and large scale abandonment of unwanted horses on their lands.

--**Federal Farmland Protection Policy Act.** FSIS has determined that commercial horse slaughter activities at Valley Meat and/or federal inspection thereof will not involve the acquisition or use of farmland protected by the Federal Farmland Protection Policy Act that would be converted to non-agricultural use.

--**Humane Methods of Slaughter Act.** As previously noted, Valley Meat's commercial horse slaughter operations will be subject to the humane handling requirements found in section 603(b) of the FMIA (21 U.S.C. § 603(b)) and the regulations promulgated thereunder (9 C.F.R. part 313). On February 24, 2012, FSIS suspended Valley Meat's grant of federal inspection for inhumane handling of cattle, but the suspension was put into abeyance with a letter dated February, 29, 2012. The firm ceased all slaughter operations in March 2012 and has not resumed slaughter under federal inspection. FSIS subsequently terminated its administrative enforcement action against Valley Meat with a Letter of Warning dated September 28, 2012.

--**State and Local Laws.** As previously noted, Valley Meat's facility is located inside an extraterritorial industrial zone in Chaves County. The county requires slaughter facilities to be built in an industrial area away from residential areas in order to prevent nuisances such as noise and odors (Chaves County, NM, Extraterritorial Zoning Ordinance art. 14 (2005)). FSIS has no information to believe that the location of this industrial area or the facilities operating therein has ever been questioned or challenged on the ground that it impinges on any natural resources, ecologically critical areas, or historical, archaeological, or cultural sites located in and around this area.

The property where Valley Meat's facility is located was re-zoned in 1982 from agricultural land to an industrial area for food processing and wholesale distribution. Valley Meat's facility initially was approved by the Zoning Commission as a packing facility for cattle, sheep, and hogs. Before allowing the property to be re-zoned, the Zoning Commission considered the impact of the slaughter facility upon the public health, safety and welfare of the community; the existing and anticipated traffic flows; parking conditions, setbacks, and height; landscaping and screening; open spaces; signage; lighting; and other items. The transition of Valley Meat's operations from the slaughter of cattle to the slaughter of horses will not change the impacts that already have been considered by the zoning commission.

Valley Meat's waste disposal is governed by New Mexico's Solid Waste Act (N.M. Stat. Ann. 74-9-1 *et seq.*) (SWA) and its accompanying regulations (N.M. Code R. 20.9.2 through 20.9.10). It is a violation of the SWA to store, process, or dispose of solid waste in an unapproved manner and to dispose of any solid waste in a place other than a solid waste facility that meets the requirements of the SWA and its accompanying regulations (N.M. Stat. Ann. 74-9-38; N.N. Code R. 20.9.2.10A(1), (3)), and disposing of solid waste in a manner that harms the

environment or endangers public health or safety can result in a fine of up to $5000 per day for each day in which the violation occurs (N.M. Stat. Ann. 74-9-38 and 74-8-31(3) and (5)). On January 22, 2010, FSIS asked the New Mexico Environmental Department's (NMED's) Solid Waste Bureau to investigate a large compost pile of cattle offal and other inedible parts that the plant was maintaining just off the slaughter plant's official premises. On August 2, 2012, NMED initiated an administrative action against Valley Meat seeking an Administrative Compliance Order directing it to clean up the compost pile. On November 16, 2012, NMED and Valley Meat settled the administrative action with a Final Stipulated Order that required Valley Meat to develop a plan for removing the compost pile and taking it to a landfill or other approved site within 45 days and imposed a civil penalty. Valley Meat paid its civil penalty in full on January 8, 2013, and NMED terminated the enforcement action. Valley Meat currently does not have a composting permit from NMED, as required by N.M. Code R. 20.9.3.27, and thus is not authorized under the SWA to compost any waste materials generated by its slaughter and processing activities. It has contracted with an inedible rendering company to pick up and dispose of inedible and condemned materials produced by commercial horse slaughter activities. Additionally, if FSIS issues Valley Meat a grant of federal inspection for commercial horse slaughter, FSIS will post a notice on the inspection office bulletin board alerting agency inspectors that composting solid waste at Valley Meat is prohibited and that the inspectors should notify NMED immediately if they observe composting on Valley Meat's premises.

Valley Meat's disposal of wastewater and effluent, including blood, is governed by New Mexico's Water Quality Act (N.M. Stat. Ann. 74-6-1 *et seq.*) (WQA) and its Water Quality Control Commission (WQCC) regulations (N.M. Code R. 20.6.2). Failure to comply with the WQA and its regulations may result in a fine of up to $15,000 per day for each day in which the violation occurs (N.M. Stat. Ann. 74-6-10). The WQCC regulations require establishments that propose to construct or modify any sewerage system to file plans and specifications of the construction or modification with the Ground Water Quality Bureau for discharges that may affect ground water, and to file the same with the Surface Water Quality Bureau for discharges that may affect surface water (N.M. Code R. 20.6.2.1202). The regulations also require establishments that discharge wastewater or effluent into ground water to apply for a discharge permit, DP-236 (N.M. Code R. 20.6.2.3104). If the holder of a discharge permit wishes to modify its permit, it must apply for said modification at least 120 days before the permit expires (N.M. Code R. 20.6.2.3106). In November, 1982, Valley Meat was issued a DP-236 for the discharge of up to 8,000 gallons of agricultural wastewater per day to a treatment and disposal system, and this permit was renewed or modified several times before expiring on May 19, 2009. On June 3, 2010, Mr. de los Santos applied for a renewal of his DP-236, and on May 31, 2013, the Ground Water Quality Bureau published a draft DP-236 for Valley Meat on NMED's website. The website stated that NMED would allow thirty (30) days from the date of publication of the draft discharge permit for interested parties to submit comments on the permit. It further stated that NMED will conduct a hearing on the renewal request if NMED determines that there is sufficient public interest in convening a hearing. Because the DP-236 is required by state rather than federal law, neither the notice and comment period nor a public hearing, if any, precludes FSIS from granting federal inspection services to Valley Meat if the agency determines that Valley Meat has met all other applicable federal requirements.

If NMED renews Valley Meat's DP-236, most of the water used by Valley Meat will become wastewater that ultimately will be discharged into the establishment's treatment and disposal system. Some of the blood produced by its slaughter operations likewise will drain into the establishment's treatment and disposal system.[6] Valley Meat uses a septic tank and lagoons to treat and dispose of its wastewater and effluent. The soil conditions found in and around Chavez County are conducive to the use of septic systems because the soil is moderately permeable, which allows for effluent absorption without over-saturation. The soil also has thick, impermeable layers of clay that protect the area's shallow aquifers. Therefore, the wastewater used in and blood generated by Valley Meat's commercial horse slaughter operations should not impact the local ground and surface water.

Conclusion.

Based on the foregoing, FSIS finds no unique conditions or extraordinary circumstances of the proposed action to grant federal meat inspection services to Valley Meat that would cause this action to have a significant environmental effect. Therefore, in accordance with 7 C.F.R. § 1b.4, the proposed action is categorically excluded from the preparation of an EA or an EIS.

[6]Some opponents of commercial horse slaughter have claimed that horses have, pound-for-pound, twice as much blood volume as cows, and that the blood produced by commercial horse slaughter will overwhelm any waste water disposal system. According to FSIS veterinarians, the blood volume of the average horse ranges from 6.14% to 8.63% of live animal weight, as opposed to 6.75% of live animal weight for the average cow, and thus is not appreciably different from that of cows. Furthermore, the volume of horse blood that commercial horse slaughter at Valley Meat is likely to produce will be a function of the sizes and breeds of the horses that are slaughtered there and the volume of horse slaughter and thus is highly speculative. As noted above, Valley Meat is located 12 miles from the nearest municipality and relies on septic tanks and lagoons for waste water disposal, rather than Roswell's waste water disposal system. Given the speculative nature of the horse slaughter opponents' claims about horse blood volumes, Valley Meat's distance from Roswell, and the nature of Valley Meat's waste water and disposal system, there is no reason to believe that Valley Meat's waste water and disposal system is inadequate to handle the volume of horse blood that is likely to be produced by commercial horse slaughter operations at its facility.

EXHIBIT 11

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE HUMANE SOCIETY OF THE UNITED STATES, ET AL. Plaintiffs, v. **MIKE JOHANNS, ET AL.** Defendants.	Civ. No. 1:06CV00265 (CKK)

DECLARATION OF ROBERT ELDRIDGE

I, ROBERT ELDRIDGE, declare as follows:

1. I am a plaintiff in the above-entitled action.

2. I am a resident of Kaufman, Texas and have lived there for fifty-three years. My home is located at 107 Booker Street, approximately one-half block from the Dallas Crown horse slaughter plant.

3. The plant has been slaughtering horses for over fifteen years, and since that time I have endured, and continue to endure, the sickening, noxious odor that spews from the plant. I continue to endure the severe stench on a daily basis.

4. During the summer, the stench is especially unbearable, and I am unable to use my yard for outdoor activities, such as barbequing, sports, or spending time with my family and friends.

5. There are blood spills and animal parts left outside to rot on Dallas Crown's property. This attracts many vermin and insects to the neighborhood and to my properties.

6. I also own a small real-estate holding company and have purchased several parcels of land in and around the Kaufman neighborhood of Boggy Bottom.

7. Adjacent to Dallas Crown, I own a 3.5 acre lot that I would like to develop into a small apartment complex for the elderly. I am unable to secure a loan to develop this lot into a senior apartment community. When the loan officer came to see the property, he saw all of the negative impacts of the horse slaughter plant and denied my loan request. However, I continue to pay taxes on this piece of land.

8. I have long advocated for the closure of Dallas Crown. I have attended all public hearings before the Kaufman Zoning Board of Adjustments and offered testimony on the detrimental impacts that Dallas Crown has inflicted, and continues to inflict, on myself and my fellow neighbors. Although the city board recently determined that Dallas Crown constitutes a public nuisance, the plant remains in operation.

9. I desire to obtain advance notice from USDA concerning the fee-for-service horse inspection program, so I can use that advance notice to participate in and comment on any rulemaking process concerning the program. I also wish that my comments be considered by the USDA before the Final Rule is issued.

10. My aesthetic and economic interests have been injured by USDA's decision to provide for a voluntary fee-for-service program for establishments that slaughter horses, because this program will allow the Dallas Crown slaughterhouse to remain in operation. As a result of this program, Dallas Crown's operations will continue to adversely affect my ability to enjoy going outside of my home and my ability to develop the adjacent plot of land into an apartment community.

11. Because USDA has issued its fee-for-service program without complying with the notice and comment requirements of the Administrative Procedure Act or with the National Environmental Policy Act, the USDA has also deprived me of my right to the public comment

process, as well as the information that would be developed through the preparation of an adequate National Environmental Policy Act document concerning the environmental impacts and consequences of horse slaughter.

12. These harms would be redressed if the Court were to order the defendants to carry out the purpose of the 2006 Agriculture Appropriations Act, and to abandon their attempt to issue regulations to defeat the requirements and purpose of the 2006 Act.

Pursuant to 28 U.S.C. § 1746, I declare, under penalty of perjury, that the foregoing statements are true and correct to the best of my knowledge.

Robert Eldridge

Dated: February 20, 2006

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE HUMANE SOCIETY OF THE UNITED STATES, ET AL. Plaintiffs, v. **MIKE JOHANNS, ET AL.** Defendants.	Civ. No. 1:06CV00265 (CKK)

DECLARATION OF JUANITA SMITH

I, JUANITA SMITH, declare as follows:

1. I am a plaintiff in the above-entitled action.

2. I am a resident of Kaufman, Texas and have lived there for nearly fifty years. My home is located at 309 West Carver Street, located directly behind the Dallas Crown horse slaughter plant. My backyard abuts the plant's property.

3. For over a decade, I have endured the severe odor and stench of the plant. I continue to endure the severe stench on a daily basis.

4. The stench is especially intolerable in the morning and evening hours, and for this reason I am unable to go outside of my home.

5. Before the plant was in operation, my family had gatherings, such as outdoor barbecues. I have a large extended family, and I cannot have family gatherings at my home because of the odor from Dallas Crown.

6. Sometimes, there is blood in my bathtubs, sinks, and toilets. This is because the plant's blood spills clog up the local wastewater treatment plant and septic systems.

7. Dallas Crown often has blood and animal parts outside of the plant that attracts animals and insects. I spray my home every two weeks, but I never get rid of the rodents and insects that are attracted to the smell and animal flesh next door.

8. If Dallas Crown was not in operation, then my family could come to visit me at my home. My family does not visit my home because of the smell and other nuisances coming from the horse slaughter plant. I no longer drive because of my illness, so my family must come, pick me up, and take me to their homes for a visit. This takes away from precious time with my family.

9. All of these harms to my aesthetic interests have been injured by USDA's decision to provide for a voluntary fee-for-service program for establishments that slaughter horses, because this program will allow the Dallas Crown slaughterhouse to remain in operation. As a result of this program, Dallas Crown's operations will continue to adversely affect my ability to enjoy going outside of my home.

10. These harms would be redressed if the Court were to enjoin the government from inspecting horses at the facility.

Pursuant to 28 U.S.C. § 1746, I declare, under penalty of perjury, that the foregoing statements are true and correct to the best of my knowledge.

Juanita Smith

Dated: February 20, 2006

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE HUMANE SOCIETY OF THE UNITED STATES, ET AL. Plaintiffs, v. **MIKE JOHANNS, ET AL.** Defendants.	Civ. No. 1:06CV00265 (CKK)

DECLARATION OF MARGARITA GARCIA

I, MARGARITA GARCIA, declare as follows:

1. I am a plaintiff in the above-entitled action.

2. I am a resident of 3800 North Terry Street, Fort Worth, Texas, and have lived there for four years. My home is located approximately one block from the Beltex Corporation horse slaughter plant, and I can view the plant from my home. I reside at my home with my husband and two children.

3. My family and I are constantly exposed to the severe stench of the plant. The odor is unbearable in the morning and early evening and when it is hot, which is often in Texas. The smell is so bad that we cannot open our windows to enjoy fresh air or cool breezes.

4. The noxious odor prevents my family and I from enjoying our yard and the property around our home. My kids are unable to play outside, and we cannot have friends or family over for barbequing.

5. I often see the slaughter trucks in our neighborhood. I am an animal lover, and it makes me upset to see the horses on their way to slaughter.

6. My personal well-being, and that of my family's, is being damaged by defendants' new rule allowing horse slaughter to continue, because this program will allow the Beltex slaughterhouse to remain in operation. Unless the court orders otherwise, Beltex's operations will continue to adversely affect me and my family's ability to enjoy our own home, yard, and neighborhood.

7. These harms would be redressed if the Court were to enjoin the government's fee-for-service horse inspection program.

Pursuant to 28 U.S.C. § 1746, I declare, under penalty of perjury, that the foregoing statements are true and correct to the best of my knowledge.

Margarita Garcia

Margarita Garcia

Dated: February 20, 2006

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE HUMANE SOCIETY OF THE UNITED STATES, ET AL. Plaintiffs, v. **MIKE JOHANNS, ET AL.** Defendants.	Civ. No. 1:06CV00265 (CKK)

DECLARATION OF MARY FARLEY

I, MARY FARLEY, declare as follows:

1. I am a member of The Humane Society of The United States, which is a plaintiff in the above-entitled action. I have been a member for approximately two years. I joined The HSUS, so that it would represent my interests on animal protection issues, such as the slaughtering of horses at the Cavel International plant.

2. I am a resident of DeKalb, Illinois. My home is located at 145 Buena Vista Drive, approximately 4.5 miles from the Cavel horse slaughter plant.

3. The quickest way to get home from work is driving past the Cavel International horse slaughter plant. I used to drive by every weekday. I used to see the transport trucks parked in front of Cavel and would think about how the horses suffered while in transport. I also continue to think about how the horses suffer at the plant, and it greatly upsets me to know that healthy, majestic horses are being slaughtered in my community.

4. When driving by the Cavel horse slaughter plant, the smell was so bad, and it would linger in my head for the rest of the day. Additionally, I would arrive home after work

upset and stressed out about the horses. It got so bad that I had to change routes. Now, my commute takes me fifteen minutes longer each way to get to and from work, and it costs more in gas. I used to be able to take the most direct route—using the Expressway—but now I cut around back roads to avoid having to see and smell the plant. I still think about what these horses go through daily, and on my new route to work, I see old horses in pastures and fear that they too will end up being slaughtered at the plant.

5. People in and around my community have come to associate DeKalb with the horse slaughtering plant. When I tell people where I live, they say, "Oh, that's where the horse slaughter plant is." Cavel is certainly a "black eye" in many people's minds that live in DeKalb, which is basically a farm town. Sadly, it has turned into a community where in one way there is a peaceful existence and on the other, brutal horse slaughter.

6. I, along with my fellow DeKalb citizens, have endured the unpleasantness and stigma of the horse slaughter plant for too long. The slaughterhouse's operations should be suspended as Congress required.

7. I would have liked the opportunity to give comments to the USDA on the fee-for-service horse inspection program. I know many other people from the community that would have liked to comment, too.

8. All of these harms to my aesthetic and economic interests would be eliminated if USDA's unlawful decision to create a new program for horse slaughter plants were overturned by the court. The USDA's decision will allow Cavel International to continue its operations. In turn, I will have to continue spending more time and money on my commute.

Pursuant to 28 U.S.C. § 1746, I declare, under the penalty of perjury, that the foregoing statements are true and correct to the best of my knowledge.

Mary Farley

Dated: February 20, 2006

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE HUMANE SOCIETY OF THE UNITED STATES, ET AL. Plaintiffs, v. **MIKE JOHANNS** and **BARBARA J. MASTERS,** U.S. Department of Agriculture Defendants, **BELTEX CORPORATION, CAVEL INTERNATIONAL, INC.,** and **DALLAS CROWN, INC.** Defendant-Intervenors.	Civ. No. 06-0265 (CKK)

DECLARATION OF ELIZABETH KERSHISNIK

I, Elizabeth Kershisnik, declare as follows:

1. I am a member of The Humane Society of The United States ("The HSUS"). I joined The HSUS so that it would represent my interests in preventing the slaughter of horses at the Cavel International, Inc. ("Cavel") plant in DeKalb, Illinois.

2. My family has lived in DeKalb, Illinois for nearly nine years. Our current address of five years is 135 Devonshire Drive. Our home is located less than one mile from the Cavel facility.

3. For the past several years, my family and I have had to endure the stench of Cavel. It is especially bad during the summer months, and the odor is evident several times a week.

4. From reading articles in the local newspapers, I am aware that Cavel has had ongoing water pollution violations since 2004 and has been fined heavily by the local sanitary district. I recently learned that Cavel's wastewater ends up in the Kishwaukee River. I am greatly concerned about this, because my home and subdivision is located only one block from the river, and I used to allow my children to play in the river during the summer. Because I am worried that the river may be polluted, I will no longer let my kids play in the river. As a result, my family's aesthetic and recreational enjoyment of the river has been lessened by Cavel's excess wastewater pollutant discharges.

5. I also drive by the Cavel slaughterhouse once or twice a month while running errands, and I have seen the polluted, green foam oozing from the plant's wastewater treatment tank. I am worried that the tank's polluted wastewater is seeping into the river and our groundwater.

6. I am very relieved that the recent court order has vacated the federal agency rule allowing Cavel to pay for required federal inspections, thus resulting in shut-down of the plant. However, if the court's decision is stayed, and Cavel is permitted to reopen and resume its horse slaughtering operations, the water pollution violations, odor, and other problems will occur again, and my and my family's ability to enjoy our home and the nearby river will again be harmed.

7. Cavel has given DeKalb a bad reputation, and due to the proximity of our home and subdivision to the plant, I am concerned about declining property value, as the smell of the plant, along with its water pollution problems, may drive away potential buyers. If the plant is allowed to reopen, I believe the value of my home may decrease.

8. I was also deprived of the right to participate in any environmental review process before the federal agency issued its rule allowing the horse slaughter plants to pay the salaries and expenses of federal meat inspectors. Because this rule allowed the plants to operate despite Congress's decision to de-fund horse slaughter, the rule also enabled Cavel's water pollution violations and stench to continue. I believe that, had I been given a chance to comment on Cavel's environmental, community, and neighborhood impacts, the agency might have made a different decision. I believe that the federal agency should carefully consider the environmental impacts of Cavel's water pollution. If Cavel reopens before there is any environmental review, my right to comment on the operation's impacts to my home and family will be rendered meaningless. As a result, my ability to fully participate in a meaningful environmental review process will be irreparably harmed.

9. Pursuant to 28 U.S.C. § 1746, I declare, under the penalty of perjury, that the foregoing statements are true and correct to the best of my knowledge.

Elizabeth Kershisnik

Dated: April 3, 2007

EXHIBIT 12

WHEN HORSE SLAUGHTER COMES TO TOWN

An Int'l Fund for Horses

SPECIAL REPORT

Written and Researched by Jane Allin

Edited by Vivian J Grant

March 2011

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I. Environmental Impact

Historically, the negative environmental impact of horse slaughter plants has been well documented.

In 2007, all three of the foreign owned horse slaughter plants in the United States were shut down under Texas and Illinois state laws. The two Texas based plants, Beltex in Dallas and Dallas Crown in Kaufman, were closed in February when the 5th District court ruled that a 1949 law against selling horse meat was valid and in force. The remaining plant, Cavel International in DeKalb, Illinois, closed in mid-September of the same year under a new state law making horse slaughter illegal.[1]

It was community administrators and local residents who actively petitioned to have horse slaughter plants shut, citing the extreme disregard for the welfare of the people and locales where they existed as well as the merciless suffering of the horses sent to them.

Numerous Violations Plague Communities

All three horse slaughter plants amassed numerous environmental violations and overwhelmed the waste water infrastructures due to dumping of blood, entrails, urine, feces, heads and hooves.

The Dallas Crown horse slaughter facility had been in operation in Kaufman since the late 70's and from the beginning had caused problems both economically and environmentally. "The slaughterhouse constantly flooded the town's drinking water with blood and tissue – literally coming out of the taps – and had never complied with city water standards, or paid fines."[2]

Furthermore, in May 2002, the City noted that another public health hazard "was the vector attraction due to bones and horseflesh falling off your bone trailer" and that "dogs were carrying the bones into the community."[3]

In fact, in an open letter to state legislators considering pro-horse slaughter resolutions, the town's mayor at the time, Paula Bacon, referenced Public Works reports regarding effluent and waste water violations "decaying meat [which] provides a foul odor and is an attraction for vermin and carrion," containers conveyed "uncovered and leaking liquids," there are "significant foul odors during the daily monitoring of the area," and "Dallas Crown continually neglects to perform within the standards required of them."[4]

Beltex was a Texas Corporation with European shareholders that had been slaughtering horses for human consumption for 27 years.

As with Dallas Crown, Beltex had a non-unionized workforce. OSHA records revealed that since the plants' inception in 1977 until its last inspection in 1997, Beltex had committed 29 violations of which 28 were deemed serious. OSHA records show that an ammonia leak occurred in 1996, but no one (fortunately) died or was permanently disabled. In 2000 the facility "accidentally pumped blood into the creek" and "in 2001, they were notified that waste water was flowing into adjacent properties and into the creek."[5]

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1 Holland, John; Horse Slaughter Trends 2006-2010; Equine Welfare Alliance; http://www.equinewelfarealliance.org/uploads/Horse_Slaughter_Trends_2006-2009.pdf ; February 2010.
2 Testimony of Congressman John E. Sweeney; H.R. 503 – American Horse Slaughter Protection Act; http://republicans.energycommerce.house.gov/108/hearings/07252006Hearing1992/Sweeney.pdf ; Jul. 25, 2006.
3 Sorg, Lisa; Violations Dog Beltex, Dallas Crown; http://tiny.cc/ag62l ; Jun. 19, 2003.
4 Bacon, Paula; Open letter to state legislatures considering pro-horse slaughter resolutions; Animal Law Coalition; http://tiny.cc/2wrx6 ; Feb. 13, 2009.
5 Sorg, Lisa (http://tiny.cc/ag62l).

Of particular note, the Sanitation Group of DeKalb, Illinois, where Cavel International was located, identified the incomparable hazard associated with the discharge from horse slaughter facilities.

"This hazard is uniquely acute for horse slaughter because of the wide range of drugs given to horses that are clearly labeled NOT FOR USE IN HORSES INTENDED FOR HUMAN CONSUMPTION."[6]

These noxious drugs are not only present in the meat intended for human consumption overseas but also in the waste water and sludge produced during processing. This runoff has the potential to contaminate down-stream water intakes, including groundwater used for human consumption, and can enter the food chain via sludge distribution on crops.

Unlike the aforementioned, decades old horse slaughter plants in Texas, Cavel International in Illinois was a sparkling new, purpose built facility that re-opened in June, 2004 with a state-of-the-art pre-treatment system.

Additionally, Cavel International had special Industrial Waste Permits that allowed much higher (8 times higher) contamination levels for waste water leaving the slaughter house. But Cavel was still out of compliance. And not just a few times. This facility was in significant non-compliance hundreds of times. In one report, a Cavel employee acknowledges "chunks" from slaughtered horses were oozing out of tanks. This does not include the numerous safety violations documented by the FSIS.[7]

As a final point, these practices and findings are not limited to the U.S. In Canada, Natural Valley Farms in Neudorf, Saskatchewan, was shut down by the Canadian Food Inspection Agency in 2009 for food safety concerns. NVF went into receivership on September 22, 2008, yet horses continued to be slaughtered at the facility by Velda Group, an international Belgian-based company. Velda was infamous in Illinois for numerous environmental charges and convictions at their Cavel International horse slaughter plant that closed business in September 2007.[8]

"Blood disposal appears to have been equally problematic for NVF as with other horse slaughter plants. Not only do horses have twice the quantity of blood as cows, but the blood is notoriously difficult to treat. The bacterial agents used in standard cattle digesters fail to provide acceptable discharge levels because of antibiotics often found in horse blood. As a result, pollution follows the horse slaughter industry where ever it goes."[9]

Former mayor of Kaufman, Paula Bacon, comments "In Canada they have apparently become even more blatant, dumping huge untreated piles of entrails onto open ground and even using a tanker truck to discharge blood and refuse into a local river."[10]

In any case, the negative environmental impacts and the chronic inability of the facilities to comply with local laws pertaining to waste management and air and water quality far outweigh any benefits.

This quote by Henry Skjerven, an investor and former director of NVF, sums it up: "Natural Valley Farms died the day the decision makers chose to kill horses . . . ."[11]

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6 DeKalb Sanitary District; DeKalb Sanitary District Board meeting Minutes; http://tiny.cc/31y3m ; Jan. 18, 2006.
7 Allen, Laura; Animal Law Coalition; "Sacia introduces new bill to support horse slaughter," ; http://tiny.cc/ufjo4 ; Jan. 14, 2010.
8 Holland, John; Canadian Horse Defense Coalition, Summary of Cavel International Violations – Non Compliance and Response; http://tiny.cc/sjwwj ; undated.
9 Holland, John; Horse Slaughter Dream a Financial Nightmare; Harnesslink Newsroom; http://tiny.cc/tq5o6 ; May 14, 2009.
10 Holland, John (http://tiny.cc/sjwwj).
11 Holland, John (http://tiny.cc/tq5o6).

Environmental issues continue to plague the horse slaughter industry. On December 3, 2010, the Bouvry Exports horse slaughter plant in Fort MacLeod, Alberta closed operations to complete renovations related to sanitation.[12]

II. Economic Growth, Employment and Community Welfare

Contrary to what some pro-horse slaughter proponents say, horse slaughter facilities trigger negative economic growth for the communities in which they are situated. This is far-reaching and insidious. The USDA states that profits from horse slaughter are negligible. "It is entirely foreign owned, and pays no corporate taxes or export tariffs. The horse slaughter industry is economically insignificant."[13]

Comments from Paula Bacon, former Mayor of Kaufman, Texas, home of Dallas Crown, elucidate the issues. Bacon was vigilant in underscoring the operation's copious environmental violations and subsequent negative impact upon the community. Persistent and tireless lobbying against the plant in support of the health and welfare of the community as well as the horses finally lead to the unanimous decision by the City's judicial board to close the plant.

> "Dallas Crown had a negative effect on the development of surrounding properties, and a horse slaughter plant is a stigma to the development of our city generally" . . . . "the corporations involved in this industry have consistently proven themselves to be the worst possible corporate citizens" . . . . "the industry caused significant and long term hardship to my community."
>
> "During this time, I learned that an estimated $5 million in Federal funding was being spent annually to support three foreign-owned horse slaughter plants! And when the Dallas Crown tax records were exposed in the city's legal struggle, we found that they had paid only $5 in federal taxes on a gross income of over $12,000,000!"
>
> "The more I learn about horse slaughter, the more certain I am: There is no justification for horse slaughter in this country. My city was little more than a doormat for a foreign-owned business that drained our resources, thwarted economic development and stigmatized our community. Americans don't eat horses, and we don't raise them for human consumption. There is no justification for spending American tax dollars to support this industry at the expense of Americans and our horses."[14]

Dallas Crown had numerous, repeated and unresolved violations to their industrial waste permit – denying the City access to their property for waste water testing despite requirement by city ordinance, city permit agreement, and court order as well as overloading the waste water treatment plant capacity among other serious infractions. Furthermore, in order to accommodate the water generated by the operation, city staff reported that a $6 million upgrade would be required even though it had been financed to last through to 2015.[15]

As with the Dallas Crown Corporation, foreign-owned slaughterhouses formerly in operation paid little to no taxes to the communities where they existed. Any profits were repatriated to European owners who garnered significant benefits through the inexpensive purchase of American horses by "killer buyers" at livestock auctions; horse meat sells for $20 /lb or more in most foreign countries.

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12 Press Release; Canadian Horse Defence Coalition; http://tiny.cc/n6nx7 ; Dec. 10, 2010.
13 Potter, Meg; Selling our soul; Expendable equines in the new recession; http://www.bridleandbit.com/artman/publish/article_25099.shtml ; Apr. 3, 2009.
14 Bacon, Paula; Open Letter to State Legislatures; http://tiny.cc/tnzg1 ; February 2009.
15 Ibid.

Furthermore, given that agricultural production represents 1.2% of the GDP and only 0.6% of employment nation-wide, building a horse slaughter facility has no significant impact on economic growth but simply serves to whet the palates of European and Asian epicureans.[16]

Many horse slaughter plants employ illegal immigrants and ex-felons who have committed violent crimes. The farmed-animal industry, horse slaughter included, deliberately recruits immigrants because they will accept low wages and can be easily manipulated for fear of losing their jobs.[17] Their willingness to accept low wages has the potential to drive down wages in the communities that support them.

Furthermore, animal processing facilities are one of the most dangerous places in America to work. According to statistics from the U.S. Department of Labor, nearly one in three slaughterhouse workers suffers from illness or injury, compared to one in 10 workers in other manufacturing jobs.

That said, several studies show that "more than half of the country's estimated 12 million illegal immigrants are uninsured (out of a total of 47 million uninsured people in the U.S.) and thus likely to use public emergency rooms that treat everyone regardless of ability to pay."[18] This has the capacity to put a strenuous burden on local government budgets and potentially lead to significant compensation claims that could deplete state resources.

What's more, the social consequences endured by several towns in the mid-west that have supported such industries are appalling.

According to researcher Amy Fitzgerald, "current statistics on whether slaughterhouses make good neighbors are a fait accompli. The documented crime increases include a 130% increase in violent crimes in Finney County, Kansas (Broadway 2000) and a 63% increase in monthly police bookings in Lexington, Nebraska (Gouveia and Stull 1995). Increases in crime have also been observed in at least one Canadian town to date: the town of Brooks, Alberta witnessed a 70% increase in reported crime."[19]

Regardless of what pro-slaughter groups claim, the evidence is unmistakable. "Low paying wages, increased haphazard populations without stable economic anchors, split up families, and the uneducated unskilled labor force, are not the kinds of dividends any community needs. Cranking up horse slaughter plants in times of economic necessity shows about as much ingenuity as legalizing bordellos. The cure is worse than the disease."[20]

When compared to other dirty, low paying jobs experts portray the industry as uniquely different in terms of spawning societal chaos . . . . "Dis-confirming those theories and finding unique effects of slaughterhouse employment would point to the alternative hypothesis as a possible explanation: that the type of work undertaken in slaughterhouses contributes to the social disruption observed."[21]

Research by Anderson, Patterson and Spiegel corroborates this hypothesis.

Unlike other low-paying routinely dangerous industrial jobs, they advise that slaughterhouses are fundamentally atypical. That is, "the correlation between dismembering animals and victimization of

16 GDP: Percent GDP from agriculture; EarthTrends- The Environmental Information Portal, World Resources Institute; http://tiny.cc/tycrd ; 2007.
17 Exploiting immigrant labor; http://www.goveg.com/workerRights_immigrant.asp ; undated.
18 Rahman, Mizanur; Illegal immigrants: benefits and negatives, Immigration Chronicles; http://blogs.chron.com/immigration/archives/2008/08/post_151.html ; Aug. 16, 2008.
19 Potter, Meg (http://www.bridleandbit.com/artman/publish/article_25099.shtml)
20 Ibid.
21 Ibid.

less powerful human groups such as women and children is clear and bears itself out in increased domestic violence in communities surrounding slaughterhouses."[22]

III. Legal Implications

U.S. Legislation to End Horse Slaughter

Legislation banning the domestic slaughter and export for slaughter of American horses for human consumption has a long history. It continues to be pursued at both the State and Federal levels where it receives majority bipartisan support from lawmakers and constituents.

The first legislative action banning horse slaughter and the export for slaughter began at the State level in 1998 in California when Proposition 6 passed with nearly 5 million voters approving the measure.

The first legislative action at the Federal level was introduced on July 17, 2001, in the 107th Congress. Bills banning horse slaughter and export for slaughter for human consumption have been re-introduced in Congress for the past decade. None of these bills have been successful.[23]

Any type of legislation appearing to have any potential for ending horse slaughter for human consumption – at the State and Federal levels – is opposed and vigorously lobbied against by powerful factions of the animal agriculture industry, on each occasion overriding the will and intention of the people who just as vigorously come out in support.

Federal legislation is set to be introduced in the 112th Congress that will eliminate the export of horses for the purpose of slaughter for human consumption and prohibit the return of horse slaughtering operations to U.S. soil.

Other Legislative Strategies to End Horse Slaughter

During the 109th Congress, sponsors of the American Horse Slaughter Prevention Act (H.R. 503/S. 311) successfully sought enactment of a rider in USDA appropriations acts to deny federal funding for USDA inspections of horse slaughtering operations under the Federal Meat Inspection Act (21 U.S.C. §§ 601 et seq.). Such inspections are required for the marketing of meat considered fit for human consumption, including horses.

The funding prohibition was originally enacted in 2005 as part of the FY2006 Agriculture Appropriations Act. However, the USDA responded by adopting new rules that allowed the slaughterhouses to pay for the inspections themselves.

A 2007 court ruling ordered the USDA to stop these inspections, thereby ending horse slaughter across the country.[24]

Legislators introducing bills to return horse slaughter to U.S. soil in their States, are seeking ways to bypass the federal ban, including creating their own State horse meat inspection programs.

Federal agriculture officials call that presumption into question, stating that the restrictions that ban U.S. Department of Agriculture inspectors from overseeing the killing and processing of horses also apply to all State inspection programs.

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22 Ibid.

23 Int'l Fund for Horses; Horse Slaughter Legislative Timeline; http://tiny.cc/zajwo ; 1998-2011.

24 New York Bar Association, Committee on Legal Issues Pertaining to Animals; http://www.nycbar.org/pdf/report/Horse_Slaughter.pdf ; undated.

"There is no possibility under the current law for a state-inspected meat plant to ship any meat, interstate or internationally, for human consumption," said USDA spokesman Neil Gaffney.[25]

EU Quarantine of American Slaughter Horses Bound for Canada

Apart from the obvious legal ramifications in North America, there is yet another reason to avoid re-opening horse slaughtering facilities.

In 2009, the Int'l Fund for Horses began alerting the European Parliament of the fact that "horse meat exported from North America to EU member countries where it is eaten, is adulterated because of the presence of Bute[26] and other prohibited medications routinely given to horses in the United States and Canada."[27]

The Int'l Fund for Horses were proven justified in doing so.

Decades of USDA studies asserting U.S. and Canadian horse meat as chemically harmless have been branded as bogus by a new peer reviewed scientific study.

The paper, titled "Association of Phenylbutazone Usage With Horses Bought for Slaughter: A Public Health Risk" appeared in the journal *Food and Chemical Toxicology*.[28]

This study questions USDA and CFIA horse meat testing capabilities. USDA and CFIA programs have consistently given U.S. horse meat exported for the dinner tables of Europe and other destinations a clean bill of health despite containing residues of Bute and scores of other dangerous chemicals potentially toxic to humans.

The EU responded with a new directive that equines from North America must be quarantined for a period of six months prior to slaughter for human consumption. Equine owners would now be required to record medical conditions and treatment history if they intend to present their horses for slaughter for human consumption.

The required records are in the form of an Equine Information Document (EID) that must be presented for each equine processed for edible purposes in a CFIA inspected processing facility start on July 31, 2010 forward.[29]

This rigorous enforcement of food safety regulations closely follows the current regime in Europe wherein EU countries use a "passport system" for slaughter animals that serves to document what substances animals have received over their lifetimes with the purpose of banning meat tainted by drugs. In the instance of horses, this would include those commonly given to horses, such as antibiotics, wormers and Bute, among others.[30]

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25 Young, JoAnne; Federal law would not allow horse meat to be shipped out of state; *Lincoln Journal-Star*; http://tiny.cc/sj6wk ; Feb. 28, 2011.

26 Dr. Bob Wright - Veterinary Scientist, Equine and Alternative Livestock/OMAFRA; Phenylbutazone (Bute) Use in Horses; http://tiny.cc/37jmn ; Dec. 1, 2004.

27 Int'l Fund for Horses; Canadian Food Inspection Agency readies for new EU directive on slaughter horses; Tuesday's Horse, http://wp.me/p6VVi-2dV ; Jan. 31, 2010.

28 Nicholas Dodman, Nicolas Blondeau and Ann M. Marini; Association of phenylbutazone usage with horses bought for slaughter: A public health risk ; http://tiny.cc/duvc4 ; Feb. 17, 2010.

29 Horse Industry Association of Alberta; Proposed regulations for horses going into the food chain; http://www.albertahorseindustry.ca/eNews/foodchainregs.html ; 2010.

30 Vets for Equine Welfare Fact Sheet: Medications and US Horse Meat; http://www.vetsforequinewelfare.org/medications.php ; February 2007.

Any country that intends to export food animals to the EU must have proper documentation and procedures in place that parallel those in the EU.[31]

The Int'l Fund for Horses, unhappy with the CFIA's response to the EU directive states:

> "The CFIA have devised a system of merely reporting horse health histories, instead of *quarantining* them, as ordered by the European Union's recent directive regarding slaughter horses in North America." Moreover, in 2007, a Wisconsin woman "has been fined for selling horses without testing them for disease and forging documents claiming the tests had been done." Although this took place before before the EU mandate, this is an obvious warning that the CFIA cannot rely on the integrity of its Equine Information Document."[32]

An article "New EU rules may end slaughter of American Horses," written by Carrie Gobernatz of Examiner.com states:

> "The new rules will mean that horses coming from auctions and other sources in the U.S. will have to be kept drug free on a feedlot for half a year. Producers estimate that feeding horses that long will more than double their cost, making them less competitive with horses from other sources. And that is likely to be only half their problem."[33]

In an interview with Henry Skjerven, a former director of the Natural Valley Farms slaughter plant in Saskatchewan, Canada, the truth behind horse slaughter becomes apparent:

> "Unfortunately, North America, U.S. and Canada, were never geared for raising horses for food consumption. The system as it stood when we were killing horses was in no way, shape or form, safe, in my opinion."

Skjerven states further:

> "We did not know where those horses were coming from, what might be in them or what they were treated with. I was always in fear - I think that it was very valid - that we were going to send something across there [to the EU] and we were simply going to get our doors locked after we had some kind of issue with the product."[34]

Implementation and Enforcement

Since the execution of the new EU directive in Canada as of July 31, 2010, the enforcement of these new regulations appears to be comparatively lax.

The flow of horses across the border from U.S. livestock auctions and killer buyers to Canada has not waned, nor has anything been reported on refusal of loads at the slaughter plants. Seemingly then, the EU continues to import drug-tainted horse meat.

Over 50% of the horses slaughtered in Canada for human consumption come from the U.S. Most, if not all, have received many of the drugs banned from the food chain and will not be quarantined for the requisite time frame for these drugs to have been eliminated from their systems.

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31 Explanatory memorandum to the horse passport regulations 2009 No. 1611; Office of Public Sector Information, UK; http://www.opsi.gov.uk/si/si2009/em/uksiem_20091611_en.pdf ; Jun. 2, 2009.

32 Int'l Fund for Horses; CFIA reporting system for slaughter horses flawed and unenforceable; Tuesday's Horse; http://wp.me/p6VVi-2hy ; Feb. 9, 2010.

33 Gobernatz, Carrie; New EU rules may end slaughter of American Horse; Horse News Examiner; http://tiny.cc/4ekjq Aug.4, 2009.

34 Ibid.

In particular, Bute is administered on a regular basis to relieve pain, particularly in sport horses, and is inappropriately likened to the term "aspirin". In fact, any animal that receives Bute is banned from ever entering the food chain as it is a known carcinogen thereby completely eliminating them for human consumption.

Even more alarming, some U.S. kill buyers have indicated that they are unconcerned about the new regulations and will simply falsify the required Equine Information Document (EID) paperwork. This is a common occurrence for other test certificates (e.g. Coggins) which are routinely anecdotal. The question then remains. How will the CFIA and EU regulators verify compliance?

Just the Beginning

While the current system may be inadequately implemented, this initiative is only the first in a series of new regulations that by 2013 are expected to generate an electronic database with full medical histories wherein the EID is to be an implanted microchip in each and every horse destined for slaughter. Any horses flagged for banned substances will be considered ineligible.

How then will the current enforcement of these regulations develop to guarantee this happens? It is doubtful the U.S. will comply or adopt any formal procedures to provide sufficient information for the completion of a Canadian EID.

In any case, the market for North American horse meat may be on the verge of collapse.

Many European importers have promised customers that they will no longer purchase from the North American supply chain. This stems in part from the realization of the extreme cruelty of the slaughter pipeline in North America and Mexico, as exposed by GAIA, a respected animal welfare in Belgium, and Animals' Angels USA,[35] together with the growing awareness that horses in North America are not subject to the restrictions that apply to food animals and have been administered otherwise forbidden drugs.

The Int'l Fund for Horses reports that horse meat faces a ban in Italy:

> "When this proposal is successful and horse meat is banned, it will take a huge bite out of demand and save more than 200,000 innocent [horse's] lives in Italy alone, not counting the horses who are slaughtered for human consumption in other countries for export to Europe."[36]

On June 16, 2010, Canadian Parliament by MP Alex Atamanenko (NDP Agriculture Critic) tabled a Private Member's Bill, C-544[37], banning the slaughter of horses for human consumption. The underlying basis of the bill is directly related to food safety as horses in North America are not primarily raised for human consumption.[38]

Moreover, it is an explicit response to the current EU regulations given that the majority of slaughter-bound horses cannot be in compliance with the EU quarantine mandate due to enforcement failures.

The bill currently sits in the first reading in the House of Commons.

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35 Int'l Fund for Horses; Horse Slaughter Bombshell hits Belgium and Holland;Tuesday's Horse; http://wp.me/p6VVi-2xT ; Apr. 19, 2010.

36 Int'l Fund for Horses; Horsemeat faces ban in Italy; Tuesday's Horse via *The Telegraph* UK, written by Nick Pisa; http://wp.me/p6VVi-2gJ ; Feb.9, 2010

37 House of Commons Canada; Bill Text C-544; http://tiny.cc/8qwtn ; Jun. 16, 2010.

38 Int'l Fund for Horses; Atamanenko moves to ban horse meat for human consumption in Canada; Tuesday's Horse; http://wp.me/p6VVi-2P9 ; Jun. 17, 2010.

IV. Opposition to Horse Slaughter

Formal and Informal Polls

State and nationwide polls show that the greater part of the American population is strongly opposed to horse slaughter:

In 1995 - A national call in television poll resulted in 93% of callers demanding that "the killing of horses for meat be banned."

In 1997 - A state-wide poll taken in California revealed that 88% of those questioned were opposed to horse slaughter.

In 1999 - A poll conducted in New York State yielded the following results:

- 91% considered horses companions, recreational or sporting animals -
- 72% would never eat horse meat -
- 73% believed that the manner that horses are slaughtered is cruel and inhumane -
- 81% personally opposed the practice of horse slaughter.[39]

These numbers have not changed significantly.

> "Most of the people in this country want to see slaughter ended," notes Karen Pomroy of Equine Voices, an Arizona-based horse rescue organization for horses abused by the pharmaceutical industry and slated for slaughter. "The newest polls say 85 percent. For years we've been trying to get laws through, but too many pockets are being lined in Washington while foreign companies are making millions of dollars by killing our horses."[40]

Congressional Vote

A legislative vote in the U.S. House of Representatives further demonstrates the will of the people.

On September 7, 2006, Bill H.R. 503, a comprehensive proposal to ban the slaughter of horses for human consumption as well as the transport for slaughter elsewhere passed overwhelmingly in the House of Representatives by roll call vote. "The totals were 263 Ayes, 146 Nays, 23 Present/Not Voting."[41]

The bill died as it was held up by pro-slaughter Senator Conrad Burns and was not allowed to come before the Senate for a vote.[42]

No longer a Senator, Burns' Montana 2006 milestones include being selected by Time Magazine as one of America's Five Worst Senators,[43] and in September 2006 as one of The 20 Most Corrupt Members of Congress by the Citizens for Responsibility and Ethics in Washington.[44]

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39 Equine Advocates; Horse slaughter an American disgrace, an American shame; http://www.equineadvocates.com/hs/slaughterprintout.html ; 2000.
40 McNamee, Gregory; Horse slaughter in America; Encyclopedia Britannica Blog; http://tiny.cc/btzst ; Aug. 4, 2007
41 H.R. 503; 109th Congress; http://www.govtrack.us/congress/bill.xpd?bill=h109-503 ; 2005-2006.
42 HorseIncorp; http://www.horseincorp.org/Slaughter.html ; undated.
43 Conrad Burns: Shock Jock, America's Five Worst Senators; *Time Magazine*; http://tiny.cc/lhsea ; Apr. 14, 2006.
44 20 most corrupt members of Congress: Burns, Frist, Santorum et al; *The Huffington Post*; http://tiny.cc/3yxci ; Mar. 28, 2008.

Re-Opening of Horse Slaughter Plants Fought

Despite protests to end slaughter, some states in the U.S. have attempted to re-open horse slaughter facilities.

In May of 2009, a new Montana state law, HB 418, was passed that invites private investors to develop horse slaughtering facilities in that state. However, it faces many challenges, one of which is the opposition to horse slaughter by state residents and veterinarians, together with other issues such as legal, environmental and economical.

An excerpt from an *Equestrian Magazine* news release is a measure of the distaste among the citizens of Montana;

> "Tens of thousands of humanitarians across Montana are opposed to horse slaughter. Survey after survey has shown that more than 70 percent of all Americans oppose the practice, where living horses have their throats slit and are dismembered while hanging upside down as they bleed to death to feed Frenchmen hungry for their poisonous chemically tainted meat. A poll on a respected on-line paper in Montana on the day of the vote reflected 76% of readers against building a plant."[45]

Dr. Lisa Jacobson DVM states:

> "As a Montanan and practicing equine veterinarian, I strongly oppose HB 418. I am a member of both AVMA & AAEP; however, these organizations misrepresent the views of their members. Their pro-horse slaughter stance is not based on a member survey.
>
> "Equine slaughter plants are documented to be very inhumane. Documents recently released by the USDA regarding horse slaughter in the U.S. make clear the unmistakable brutality inherent to the commercial slaughter of horses. Contained in the 906 page document covering eleven months of 2005 are 800 photos, showing horses with their eyeballs dangling, their legs ripped off, and even newborn foals." (See FOIA documents at http://www.kaufmanzoning.net/)[46]

Dr. Caroline M. Betts, PhD, Associate Professor, Department of Economics at the University of Southern California stated:

> "We are currently being inundated with arguments that the reintroduction of equine slaughter on U.S. soil is 'necessary'. The only thing it is necessary for is to fill the pockets of the big breeders and their agricultural associates, and perhaps the pockets of a bought politician or two. Apparently the senators and representatives of Montana who just passed a bill to introduce a new horse slaughter plant there care more about fulfilling those needs, than the fact that 85 percent of their own state citizens strongly object to the proposal."[47]

Documented Cruelty

There are countless reasons to oppose horse slaughter taken from citations of information presented during hearings on anti-horse slaughter legislation. The following are two of the many accounts of the horse slaughter industry.

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45 *Equestrian Magazine* news release; Horse slaughter; The snow job in Montana will melt.
46 Ibid.
47 Betts, Caroline M., PhD; The true economics of horse slaughter; http://tiny.cc/ppq35 ; via *Horseback Magazine*; 2009.

Testimony

Liz Ross, federal policy adviser to the Animal Welfare Institute in Washington, D.C., testifying before a Congressional Subcommittee, states:

> "Dozens of horses were already in the kill-pens destined for slaughter. Of those horses that went through the auction ring I was able to purchase three, all of whom undoubtedly would have otherwise gone to slaughter. One was in such bad shape that she should have never been brought through the ring and we had her euthanized on the spot. The other two were placed at an equine rescue facility in New Jersey where they still live today. "The pure animal suffering and terror I witnessed that day at New Holland was . . . fundamentally disturbing as was everything I subsequently learned about the horse slaughter industry.
>
> "In slaughter, horses suffer long before they reach the slaughterhouse. Crammed onto double deck trailers designed for cattle and sheep, horses travel in a bent manner for more than twenty-four hours without food, water or rest. In fact, so paltry are current regulations and so brutal is the trade that heavily pregnant mares, blind horses and those with broken limbs are regularly sent to slaughter.
>
> "It is also noteworthy that in Mexico the captive-bolt gun is often passed over in preference to the 'puntilla' knife which is used to stab the horse in the spinal cord to the point of paralysis before the animal is strung up and quartered, often while still alive. In fact, one of the Mexican plants that was the subject of an undercover investigation exposing this horrific practice employs lobbyists who work the halls of Congress to defeat this bill. Mr. Chairman, this is pure animal cruelty, through and through, and it must end."[48]

Testifying before Congress, Dr. Nicholas Dodman, BVMS, MRCVS, Professor, Section Head and Program Director of the Animal Behavior Department of Clinical Sciences at Tufts' Cummings School of Veterinary Medicine in North Grafton, Massachusetts, states:

> "Horse slaughter has never been considered by veterinary professionals to be a form of euthanasia. Congress and the general public must hear from veterinarians that horse slaughter is not and should not be equated with humane euthanasia. Rather, the slaughtering of horses is a brutal and predatory business . . . . One need only observe horse slaughter to see that it is a far cry from genuine humane euthanasia."[49]

Video Documentation

Horrors of the carnage that takes place inside Canadian horse slaughter plants is well documented.

The Canadian Horse Defence Coalition (CHDC) released video footage in two horse slaughter facilities, Bouvry Exports (Fort MacLeod, ALTA) and Viandes Richelieu (Massueville, PQ), taken in February, 2010.

Both of these videos exposed practices that fail to meet humane slaughter standards used by the Canadian Food Inspection Agency (CFIA) to audit Canadian slaughterhouses. These plants are clearly mismanaged and even in the presence of CFIA inspectors, abuse prevails.

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48 Allen, Laura; Animal Law Coalition; Excerpts of information presented during hearings on the 2008 anti-horse slaughter bill; http://tiny.cc/y6r6b ; Jun. 24, 2009.

49 Testimony in Support of H.R. 6958, Prevention of Equine Cruelty Act of 2008; http://www.horsefund.org/resources/Dodman_Testimony_HR6598_080731.pdf ; Jul. 31, 2008.

A statement from the World Society for the Protection for Animals describes the tragic scenario.

> "It is clear that neither the facilities nor the behavior of the personnel shown are suited to the humane slaughter of horses, and that extreme suffering results for many individual animals. Problems include failure to restrain each animal's head properly before shooting, shooting from too great a distance, shooting in the wrong part of the head or body, failure to follow up with an immediate second shot in animals that were not killed by the first, hoisting apparently conscious animals, and - in the case of the Richelieu plant - cruel handling and treatment of the horses, including excessive whipping and overuse of an electric prod as well as an apparent callous disregard for the animals' suffering. An additional cause of very major concern is the presence of what appear to be either plant supervisors or inspectors who observe the employees' actions and yet do nothing."[50]

Dr. Nicholas Dodman, BVMS, MRCVS, states:

> "Noise, blood and suffering is what you get at the Bouvry equine slaughter plant: Horses kicking after they have been shot, sinking down and rising up; sometimes periods of struggling or paddling before a second or third shot has to be administered. This atrocity goes against all veterinary guidelines for humane euthanasia.
>
> Terror and suffering is the rule at this equine house of horrors … and all in the name of the gourmet meat market."[51]

This sweeping investigation stirred much controversy and outrage with the public especially after the CFIA when confronted with the violations of their own regulations, found no major deficiencies, or intent of abuse toward the horses. Even the Calgary RCMP who probed the allegations acquiesced to this ruling. Based on this video documentation, it seems surreal that the RCMP could find no evidence of cruelty.

The public in both Canada and the U.S. were appalled by the government's apathetic reaction to this situation given that this was the second time in two years that undercover footage of horse slaughter operations in Canada revealed horrific and inhumane treatment of slaughter horses.

The Grassroots Movement

There will always be animal welfare groups, advocates and horse loving citizens continually working to shut down any horse slaughter operations that may find a way to open.

These groups of individuals work tirelessly to recruit their friends, families and colleagues to the anti-horse slaughter movement, urging them to rise up against the brutal practice of horse slaughter.

> "I think the recent press about the wild horse roundups has shed light on our country's dirty little secret, horse slaughter", said Shelley Abrams, co-founder of Americans Against Horse Slaughter (AAHS). "The wild horse advocates and organizations that have worked for so many years to protect the wild horses have done a wonderful job of creating mass awareness to the general public through the media and that has inspired the lay person to learn more." Abrams added.[52]

Laura Allen of the Animal Law Coalition adds:

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50 Chambers of Carnage, CHDC; http://www.defendhorsescanada.org/ChambersofCarnage.html ; March 2010.
51 Canadian Horse Defence Coalition; Canadian Slaughterhouse Horrors; http://tiny.cc/clhtx ; May 7, 2010.
52 AAHS; Man's best friend campaigns to end horse slaughter; http://tiny.cc/sw1px ; Jan. 27, 2010.

> "Horse slaughter is nothing more than abuse and it is being inflicted upon an animal that has never historically been considered a food animal, but rather a working partner and friend to man. An animal used primarily for pleasure, work, recreation and sport. The lies of the horse slaughterers can't stand up to the graphic footage of the realities."[53]

Racing Opposition

Several major racetracks oppose horse slaughter.

Suffolk Downs, located in East Boston, became the first track in the country to implement an anti-slaughter policy in June 2008. Churchill Downs, Santa Anita Park, Gulfstream Park and a host of other venues have moved to adopt similar policies since then.

The New York Racing Association (NYRA) announced in December 2009 that they are introducing an official anti slaughter policy whereby offending horsemen would be harshly penalized. The penalties are stiff. Any owner or trainer who is caught selling either directly or indirectly a horse to slaughter will have their stalls permanently rescinded and prohibited from racing on all New York tracks.[54]

The guidelines also encourage horsemen to use and support horse rescue and retirement adoptive initiatives as a recourse to slaughter.

> "We are fully committed to protecting our sport's equine athletes" said NYRA president, Charles Hayward. "This policy sends the message that horse slaughter will not be tolerated and that those participating in this practice, either knowingly or for lack of due diligence, will not be welcome at Aqueduct, Belmont Park, or Saratoga."[55]

V. Alternatives to Horse Slaughter

With the devastated economy, its slow recovery and the closure of all horse slaughter facilities in the U.S., pro-slaughter groups want you to believe there is no alternative. A study examining horse slaughter trends in the United States, Canada and Mexico carried out by researchers in conjunction with Animal Law Coalition shows otherwise.

Backed by data from the United States Dept of Agriculture, the Canadian Food Inspection Agency, the Bureau of Labor Statistics and other government and private sources, the conclusion was that the demand for horse meat is controlled by foreign markets rather than a surplus of unwanted horses. Europeans and Asians regard horse meat as a delicacy.[56]

John Holland, senior analyst for AAHS (Americans Against Horse Slaughter) explains:

> "Slaughter is useless as a tool for controlling the unwanted horse population and instead simply creates a market that competes with potential buyers of horses and encourages a continuous supply.
>
> "The trends are irrefutable. We found that equine abuse levels are clearly linked to economic conditions but that slaughter trends were antithetical to them for most of the study period.

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53 Allen, Laura; Animal Law Coalition; Native Americans Proved Not to be Proponents of Horse Slaughter; http://tiny.cc/zw02m ; Jul. 26, 2009.
54 Thoroughbred Retirement Foundation; http://tiny.cc/nhqmw ;undated.
55 Silver, Dan; NYRA Announces Anti-Slaughter Policy; http://tiny.cc/0y7d2 ; Dec. 10, 2009.
56 Stern, Peter; What's new at the dinner table; Tuesday's Horse; http://wp.me/p6VYi-J ; May 21, 2007.

> "The demand for horse meat creates a market where horse slaughter "kill buyers" compete with other people who want to buy horses. This encourages owners to supply that market through over-breeding horses, for example."[57]

Essentially what this implies is that if horse slaughter for human consumption is illegal as well as the transport of horses across U.S. borders to Canadian or Mexican slaughterhouses, then there will be no incentive for these individuals and the markets will turn elsewhere to find their meat.

Holland goes on to say:

> "Those demanding horse meat would simply look to other countries for horses. The study also shows that the market has quickly adjusted to large decreases in slaughter in the past, indicating that there would be no significant or sustained increase in unwanted or abandoned horses."[58]

To further support this premise, the American Quarter Horse Association (AQHA), an organization that is pro-horse slaughter, accounts for more than half of all horses going to slaughter. Astoundingly, the AQHA encourages breeders to breed without consideration so the surplus continues. "Many are culls which breeders were unable to sell."

In a slanted survey undertaken by the pro-slaughter American Horse Council and Unwanted Horse Coalition, remarkably, only 30% of these "stakeholders" thought this was contributing to the over population and neglect.[59] It is important to note that no anti-slaughter groups or individuals were invited to participate in this survey.

R.T. Fitch, author of "Pro-Slaughter Group Issues Tainted Survey Results," comments:

> "Americans should be outraged that Congress allows needed legislation to languish and continually be blocked and stalled by special interest groups that perpetuate the over breeding of horses."[60]

Simply stated, if there is no easy way to dispose of unwanted horses, fewer horses will be bred.

Moreover, Dr. Patricia Hogan, DVM, ACVS, a veterinary surgeon and AAEP member states:

> "If we want to be "part of the solution," then we truly need to examine our role in the problem, and actually put our own house in order. Put some 'teeth' into our bite. But that commitment needs to come from within our own circle before we can expect our advice to be heeded by other factions within the racing industry. If we had been truly living by the mantra of "putting the horse first," many of the issues we are facing today would simply not exist. United we stand, divided we fall. That statement has never been more true for horse racing; and for the veterinary community supporting it."[61]

It is a given fact that the depressed economy is making it harder for some horse owners and breeders to adequately care for their animals. Yet this is no reason to re-introduce a practice morally and socially unacceptable that is rife with unspeakable abuse, adding nothing to the economy and overwhelming the environment around it. These so-called "unwanted horses" …"are a serious problem….and so broad it

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57 Allen, Laura; Study shows ban on horse slaughter would not result in numbers of unwanted horses; Animal Law Coalition; http://tiny.cc/gl7vr ; Jun. 17, 2008.

58 Ibid.

59 Allen, Laura; Animal Law Coalition; A study of equine slaughter/abuse patterns following closure of horse slaughter plants in US; http://tiny.cc/6hwkd ; Jun. 18, 2008.

60 Fitch, R.T.; Pro-slaughter group issues tainted survey results; http://tiny.cc/8r4ht ; Jul. 10, 2009.

61 Hogan, Patricia, DVM, ACVS; Putting the horse first? Equine Advocates via *Bloodhorse*; http://tiny.cc/s9hvq ; 2009.

impacts the entire United States, not just the horse racing industry. Perhaps it's time for a wake-up call." says Tom LaMarra in an article posted in 2008 by *Bloodhorse.com*. [62]

The pro-horse slaughter AQHA continue to encourage rampant over breeding of horses, complain about how many "unwanted horses" there are, then reportedly lobby to defeat federal legislation banning horse slaughter and pass state resolutions to bring back horse slaughter back to the U.S. Yet the ruse continues as shown in this statement by Tom Persechino, senior director of marketing; "it's not practical to force breeders to limit the number of horses they breed, but it is feasible to educate them. He said the Unwanted Horse Coalition "believes teaching people to own responsibly will help lower the number of unwanted horses."[63]

Even so, there are movements within the horse industry to address the surplus horse dilemma.

These strategies are aimed at reducing the number of unwanted horses on the front end through responsible breeding, and on the rear end through rescue/retirement facilities, retraining for alternative careers, and low-cost euthanasia options.

The main objective of these policies is to improve the quality of life of unwanted horses and to reduce their numbers. Or are they?

The horse industry has among them "do-gooder" organizations such as the American Quarter Horse Association (AQHA), the American Veterinarian Medical Association (AVMA), the American Association of Equine Practitioners (AAEP), the American Horse Council (AHC), and the Unwanted Horse Coalition (UHC) among others, and a new group called the Equine Health and Welfare Alliance (EHWA).

And what do all of these organizations have in common? They are all pro-horse slaughter.

Masked behind policies designed to have you believe that they are looking to "focus solely on issues and mechanisms that protect, promote and preserve adequate humane measures of basic needs for the horse" lurks the specter of their final solution, death in a slaughterhouse.

As Economics Professor Dr. Caroline Betts, PhD cleverly points out in her article, "The economic reality of scarce and toxic horses":

> "I was not surprised that Dr Tom Lenz, past president of the American Association of Equine Practitioners, readily credited the organization for coining the phrase 'Unwanted Horse' in his article 'The Unwanted Horse in the United States – International Implications.'[64]
>
> "It is a coup d'etat of language choice for those American equine practitioners lobbying hardest to maintain a U.S. export market for horse meat. Dr Lenz manages to equate 'unwanted' with 'slaughtered for human consumption' and with 'should be slaughtered for human consumption, but aren't, because we need additional slaughter plants on American soil.'
>
> "Horses slaughtered are neither privately nor socially 'unwanted,' for they command a positive price both at auction and at the slaughter plant gate - and I suspect that if they did not, we would not be having this debate at all. As any Economics 101 student can tell you, positive prices signal not 'unwanted-ness,' but scarcity."

Dr. Betts concludes:

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62 LaMarra, Tom; Unwanted horses: How serious a problem? Bloodhorse; http://tiny.cc/50k6w ; Jun. 19, 2008.
63 Hogan, Patricia, DVM, ACVS; Putting the Horse First? http://tiny.cc/s9hvq .
64 Lenz, Tom; The unwanted horse in the United States – international implications; http://tiny.cc/4dcag ; Feb. 5, 2010.

> "The flesh of 'unwanted horses' is acknowledged to be toxic when consumed by humans. And who among the politicians, equine practitioners, and veterinarians lobbying to prevent a ban on the slaughter of American horses - in the name of equine welfare - would wish to be responsible for the deleterious impact for human welfare associated with promoting the slaughter of toxic horses?"[65]

In a letter to the editor of *HorseBack Magazine*, Dr. Betts proposes some reforms:

> "Why, instead, aren't these states considering the establishment of temporary state funded horse rescues, with jobs in them that provide tax revenue, until the economy recovers and the horses can find homes? Why aren't they providing additional funding and jobs for Humane Societies and Animal Control agencies to cope with whatever is being claimed that they are having to deal with? Why not do something that BENEFITS HORSES as well as creating some jobs? And why not impose a state tax on horse breeders to help fund it all?"[66]

In an article entitled "Stop Horse Slaughter: Is There Another Solution?" the author suggests we should enforce laws or rules that govern the ownership of a horse or horses.

> "Maybe we should be required to obtain a license for breeding horses. Maybe we should put limits on how many horses may be bred a year. Maybe we should have to be licensed to own a horse just like we have to be licensed to drive a car or to go hunting. With horse ownership, and even breeding ability, open to just anyone, there are too many people who can't or don't know how to care for their animals and too many horses who aren't useful. We, not the slaughter houses, are our horses' worst enemy."[67]

Congressional Intervention

It appears that legislators in Washington may have some ideas of their own.

Stephanie Sellers, in an editorial letter to *The Pilot* observes:

> "The 112th Congress is looking for ways to raise revenue.
>
> There are approximately 9.2 million horses in America. Applying fair taxes to horse owners would create significant revenue and spur the economy. Taxing horses would also create a greater sense of responsibility for horse owners.
>
> Citizens take better care of things they have to pay for. Taxing horses would also deter horse overpopulation, as breeding would be minimized. Redeeming pride for America's much-admired companion animal would make passing bills to halt horse slaughter more favorable."[68]

Probably the most relevant advantage of the taxation scheme is related to the taxation of breeders, not the average horse owner. Currently breeders enjoy a breeding incentive by way of millions of tax dollar write offs. Ideally, these breeding incentives and prohibitive tax write offs should be abolished and taxes enforced.

Overactive breeders are the root of the surplus horse situation devaluing the market. This would return horse breeding to quality over quantity and benefit the industry as a whole.

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65 Betts, Caroline M. PhD; HorseTalk; http://tiny.cc/v1glw ; Feb. 17, 2010.
66 Betts, Caroline M. PhD; Letter to the editor, *HorseBack Magazine*; http://wp.me/p6VVi-3T6 ; Mar. 25, 2009.
67 RegardingHorses.com; Stop horse slaughter: Is there another solution?; http://tiny.cc/8m182 ; Jan. 11, 2008.
68 Sellers, Stephanie;They Tax Horses Don't They?; ThePilot.com; http://tiny.cc/og3bs ; Feb. 3, 2011.

Rescuers to the Rescue

The quest to resolve the current problem of the surplus horse population continues in earnest.

In December, 2010, a group of leading equine rescue and sanctuary operators from across the United States put together a paper proposing a six-point plan (outlined below) to eliminate the slaughter of American horses.

The premise is based on viable interim alternatives and stipulates the provision that the commercial equine industry and the horse rescue sanctuary community collaborate rather than disagree on the much debated subject of horse slaughter.

Six-Point Plan to Eliminate the Slaughter of America's Horses

1. The creation of state and regional managed reserves to hold large numbers of horses safely until they can be absorbed back into the system.

2. Selected expansion of existing sanctuary capacity for rescues that establish business plans allowing them to accommodate and care for additional horses in their operations if more facility space is provided.

3. Expand existing and develop new sponsored foster home networks in which rescued horses are placed and supported with private individuals who have the facility and desire to keep horses, but are financially unable to.

4. Expand the concept of in-place rescue to keep more horses with dedicated and committed owners in their current homes with temporary financial or feeding assistance.

5. The creation of state and regional training centers and networks, in which younger, healthier horses, which represent most of those going to slaughter today, can receive the training they need to lead productive lives and therefore be much more eligible for adoption to new homes.

6. A relatively new development in equine rescue, a growing network of sanctuary operators who work together to place horses they cannot accept themselves, has saved literally thousands of horses in the past two years.[69]

Racing to the Rescue

Together with over-breeding and the economic downturn in the U.S. the financial burden of owning a horse has become onerous for many individuals. Many racehorses no longer able to win have historically been sold to slaughter plants. Now more than ever this has become routine as it presents an easy way to dispose of an animal that no longer is turning a profit.

In response to the impact of these forces on all aspects of the Thoroughbred industry, The New York Thoroughbred Breeders, Inc. (NYTB) is proposing a task force that includes the New York Racing Association, the New York Thoroughbred Horsemen Association, Finger Lakes Gaming & Racetrack and the New York State Racing & Wagering Board for the purpose of broadening programs that assist thoroughbred owners forced with selling their horses while developing a policy that punishes any owner, breeder or trainer that either directly or indirectly contributes to an outcome where a horse is knowingly sent to slaughter.[70]

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69 Warren, Allen (in collaboration); Horse Rescue Alternatives to Horse Slaughter; http://wp.me/P6VVi-3DC ; December 2010.

70 NYTB Press Release; New York Thoroughbred Breeders Seek Task Force to Strengthen Horse Rescue Efforts; Tuesday's Horse; http://wp.me/p6VVi-3Ls ; Feb. 8, 2011.

More recently other organizations have stepped up to the plate in terms of supporting off-the-track Thoroughbreds. On February 17, 2011, Frank Stronach, chairman and CEO of MI Developments Inc., announced the formation of the Gulfstream Park Thoroughbred After-Care Program to help find suitable homes for retired Thoroughbreds.[71]

Additionally, The Oklahoma Horse Racing Commission has approved a rule that would designate about $100,000 a year out of a breeder's incentive fund to help care for retired racehorses. The proposal would use money from the Oklahoma Breeding Development Fund Special Account to help pay for the retraining and care of Oklahoma-bred thoroughbred racehorses.[72]

Although racehorses are only one sector of the horses at risk, perhaps with these developments others will follow suit and reduce the number of horses that find their way to the slaughter pipeline.

VI. CONCLUSION

The horse slaughter industry is an insidious, brutal and predatory business that exists for one reason and one reason only. Horse slaughter exists to supply the demand for horse meat and to profit from it. Horse slaughter is not a humane end to a horse's life. Horse slaughter is not euthanasia.

When horse slaughter comes to town, environmental hazards, economic woes, and the stigma associated with the cruelties inherent to killing horses for their meat, are only a part of the price they will pay.

Putting those considerations aside, relevant as they are, what about the horses?

Horse slaughter is a cruel betrayal of an animal who has made it possible for America to develop the richness it enjoys.

As Laura Hillenbrand, author of "Seabiscuit" says,

> "Here are these exquisite, immensely powerful creatures, who willingly give us their labor in return for our stewardship. They have attended us throughout history, bearing us across frontiers and into battle, pulling our plows, thrilling us in sport, warming us with their beauty. We owe them more than we can ever repay. To send these trusting creatures to slaughter is beneath their dignity and ours."[73]

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71 Welsch, Mike; Stronach Forming New Equine Retirement Program; DRF; http://tiny.cc/ev2pt ; Feb. 17, 2011.
72 Associated Press; OK Racing Officials OK Help for Retired Racehorses; via Tuesday's Horse; http://wp.me/p6VVi-3Ny ; Feb. 19, 2011.
73 Save the Horses; Quotes against horse slaughter; http://tiny.cc/6dldb ; 2009.

EXHIBIT 13

USDA
United States Department of Agriculture

June 28, 2013

Valley Meat Co LLC
3845 Cedarvale Rd.
Roswell, NM 88203

SENT VIA EMAIL
CERTIFIED - RETURN
RECEIPT REQUESTED
7012 3460 0001 7360 3414

A copy of your Application for Federal Meat Inspection, FSIS Form 5200-2, is enclosed. This application specifies the type of operation conducted at your establishment and contains your agreement and certification that you will conform strictly to applicable Federal law and regulations pertaining to meat inspection. Your Grant of Inspection, FSIS Form 5200-1, and your Hours of Operation Request/Approval, FSIS Form 5200-15, are also enclosed.

A survey of your establishment conducted on April 23, 2013, at the location listed above indicated compliance with the applicable requirements of the regulations under the Federal Meat Inspection Act. On June 14, 2013 you submitted a letter self-certifying compliance with the Clean Water Act and 9 C.F.R. § 304.2(c). Accordingly, inspection service is granted. The date of inauguration of inspection services at your establishment will be June 28, 2013, Please advise the Dallas District office as soon as possible concerning the date on which you intend to commence horse slaughter operations at your establishment so that we may schedule the assignment of one or more inspectors to your establishment.

In accordance with 9 C.F.R. § 304.3(b), this Conditional Grant of Inspection shall be issued for a period not to exceed 90 days from the date on which your establishment commences horse slaughter operations. During this 90 day period your establishment must validate its Hazard Analysis and Critical Control Point (HACCP) Plan and prepare and maintain written procedures for the recall of meat food products produced and shipped by the establishment (9 C.F.R. § 418.3). Upon successful validation, inspection will be granted in accordance with Part 304. This grant is valid only for the applicant listed above who is liable for any inspection overtime or holiday costs for the operation of the plant. Should the applicant decide to sell, rent, or lease this location, the applicant will continue to be liable for any changes until the District Manager receives written notification of the change.

In accordance with 9 C.F.R. § 305.2, slaughter of horses, mules, or other equines or preparation of products therefrom is required to be conducted under inspection in establishments separate from any establishment in which cattle, sheep, swine, or goats are slaughtered or processed. Therefore we have withdrawn your grant of inspection for 7299/P-7299 concurrently with the issuance of the grant of inspection for E-7299. Voluntary Suspension or Voluntary Withdrawal of Inspection Service, FSIS Form 5200-3 for 7299/P-7299 is enclosed.

Food Safety and Inspection Service
Office of Field Operations
Dallas District Office
1100 Commerce Street, Room 516
Dallas, TX 75242
Voice 214-767-9116 Fax 214-767-8230
An Equal Opportunity Provider and Employer

Your establishment is under the supervision of the Dallas District office. Please call this office if you need help in interpreting the provisions of the regulations. [redacted] is the Front Line Supervisor for your establishment. She can be reached at 303-396[redacted]

Sincerely,

Jennifer Beasley-McKean, DVM
District Manager

Enclosures

Print Form

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

GRANT OF INSPECTION

1. DATE	2. ESTABLISHMENT NO
06/28/2013	E-7299

3. DISTRICT/REGIONAL CODE
40-41

4. NAME AND MAILING ADDRESS OF APPLICANT (Use 9 Digit Zip Code If Known)
Valley Meat Co. LLC
3845 Cedarvale Road
Roswell, NM 88203

5. LOCATION OF ESTABLISHMENT (PHYSICAL STREET ADDRESS)
Telephone: 575-622-1214

Same as No. 4.

6. ADDRESS OF DISTRICT/REGIONAL OFFICE
1100 Commerce Street, Room 516
Dallas, TX 75242

7. TYPE OF INSPECTION (Check all that apply)
☑ MEAT * ☐ POULTRY ☐ EGG ☐ IMPORT

8. TYPE OF GRANT
☑ CONDITIONAL (VERIFY HACCP PLAN) ☐ FINAL

9. DATE OF INAUGURATION OF SERVICE
June 28, 2013

A survey of your establishment at the location shown above (Item 4 or 5) indicates compliance with the applicable requirements of the regulations under the Federal Meat Inspection Act or the Poultry Products Inspection Act, or both. Accordingly, inspection service is granted. * as specified under remarks *

A copy of your Application for Federal Meat, Poultry or Import Inspection, Form FSIS 5200-2, is enclosed. This application specifies the type of operation conducted at your establishment and contains your agreement and certification that you will conform strictly to applicable Federal law and regulations pertaining to meat inspection, poultry inspection, or the importation of meat and poultry products.

Your establishment is under the supervision of the District/Regional Office. Call the District/Regional Office if you need help in interpreting the provisions of the regulations.

*Catfish is included under the category "Meat", as per the 2008 Food Conservation and Energy Act

REMARKS:
In accordance with the Code of Federal Regulations (CFR) Title 9, Parts 304.3(b), this Grant of Inspection is issued with conditions for a period not to exceed ninety (90) days from the commencement of operations, during which time Establishment E-7299 must validate it's Hazard Analysis and Critical Control Point (HACCP) plan(s). Upon successful validation, the conditions of this Grant of inspection will be removed, and inspection will be granted in accordance with 9 CFR 304.2.

This grant is valid only for the applicant listed above who is liable for any inspection overtime or holiday costs for the operation of the plant. Should the applicant decide to sell, rent, or lease this location, the applicant will continue to be liable for any charges until the District Manager receives written notification of the change. Slaughter and processing operations are conducted at this establishment.

[redacted] is the Frontline Supervisor. She may be contacted through the District Office in Dallas, Texas.

DISTRICT/REGIONAL MANAGER/IIO-HQ SIGNATURE

PRINT NAME
Jennifer Beasley-McKean, DVM

FSIS FORM 5200-1 (04/28/2010) PREVIOUS EDITIONS OBSOLETE.

EXHIBIT 14

United States Department of Agriculture

Food Safety and Inspection Service

Office of Field Operations

Des Moines District Office

Neal Smith Federal Building
210 Walnut Street
Room 985
Des Moines, IA 50309-2123
515-727-8960
Fax: 515-727-8991

July 2, 2013

CERTIFIED - RETURN RECEIPT REQUESTED

Keaton Walker
President
Responsible Transportation LLC
Establishment 45099
22034 200th Street
Sigourney, IA 52591

Dear Mr. Keaton:

A copy of your approved Application for Federal Inspection, FSIS Form 5200-1, is enclosed. This application specifies the type of operation conducted at your establishment.

A survey of your establishment at the location above, conducted on July 1, 2013, indicated compliance with the applicable requirements of the regulations under the Federal Meat Inspection Act. This office received a signed analysis of your operations showing compliance with the National Environment Policy Act (NEPA) concerning responsible stewardship of the environment. You submitted a permit from the Iowa Department of Natural Resources Water Protection Program concerning compliance with the Clean Water Act and Title 9 of the Code of Federal Regulations (9 CFR) 304.2(c). Accordingly, inspection service is granted.

In accordance with 9 CFR 304.3(b), this Conditional Grant of Inspection shall be issued for a period not to exceed 90 days during which time your establishment must validate its Hazard Analysis and Critical Control Point (HACCP) Plan. Upon successful validation, inspection will be granted in accordance with 9 CFR 304. This Grant is valid only for the applicant listed above who is liable for any inspection overtime or holiday costs for the operation of the plant. Should the applicant decide to sell, rent, or lease this location, the applicant will continue to be liable for any charges until this office receives written notification of the change and a new Application for Federal Inspection is submitted.

Please call this office is you need help in interpreting the provisions of the regulations. Dr. [redacted] is the Frontline Supervisor for your establishment and his telephone number is 515-491[redacted].

Sincerely,

Dawn Sprouls, D.V.M.
District Manager

Enclosures

FSIS FORM 2630-12 (6/86) EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

GRANT OF INSPECTION

1. DATE: 07/02/2013

2. ESTABLISHMENT NO.: 45099

3. DISTRICT CODE: 25-05

4. NAME AND MAILING ADDRESS OF APPLICANT *(Use 9 Digit Zip Code if Known)*
Responsible Transportation LLC
22034 200th Street
Sigourney, IA 52591

5. LOCATION OF ESTABLISHMENT
Same

6. ADDRESS OF DISTRICT OFFICE
210 Walnut Street, Room 985
Des Moines, IA 50309-2123

7. TYPE OF INSPECTION
☑ MEAT ☐ POULTRY ☐ IMPORT

8. DATE OF INAUGURATION OF SERVICE
July 2, 2013

9. IS THIS A USDA HEADQUARTERS ESTABLISHMENT?
☑ YES ☐ NO ☐ UNKNOWN

A survey of your establishment at the location shown above *(Item 4 or 5)* indicates compliance with the applicable requirements of the regulations under the Federal Meat Inspection Act or the Poultry Products Inspection Act, or both. Accordingly, inspection service is granted.

A copy of your Application for Federal Meat, Poultry or Import Inspection, Form FSIS 5200-2, is enclosed. This application specifies the type of operation conducted at your establishment and contains your agreement and certification that you will conform strictly to applicable Federal law and regulations pertaining to meat inspection, poultry inspection, or the importation of meat and poultry products.

Your establishment is under the supervision of the District Office. Call the District Office if you need help in interpreting the provisions of the regulations.

REMARKS:

CONDITIONAL GRANT OF INSPECTION

In accordance with Title 9 of the Code of Federal Regulations (9 CFR) 304.3(b) this Conditional Grant of Inspection is issued not to exceed 90 days *(September 30, 2013)* during which time Establishment 45099 must validate its Hazard Analysis and Critical Control Point (HACCP) plan. Upon successful validation, inspection will be granted in accordance with 9 CFR 304.2.

DISTRICT MANAGER Rosen Turner DVM for Dawn Sprouls, D.V.M.

FSIS FORM 5200-1 (3/29/1999) REPLACES FSIS FORM 5200-1 (10/97), WHICH MAY BE USED UNTIL EXHAUSTED.

EXHIBIT 15

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW MEXICO

FRONT RANGE EQUINE RESCUE, *et al.*, Plaintiffs, v. TOM VILSACK, Secretary of the U.S. Department of Agriculture, *et al.*, Federal Defendants, VALLEY MEAT COMPANY, LLC, *et al.*, Defendant-Intervenors.	Civ. No. 1:13-cv-00639-MCA-RHS

FEDERAL DEFENDANTS' NOTICE REGARDING GRANT OF INSPECTION FOR RAINS NATURAL MEATS IN GALLATIN, MISSOURI

Federal Defendants hereby give notice that Defendant-Intervenor Rains Natural Meats has met all statutory and regulatory requirements for a grant of inspection for the slaughter of horses for human consumption in interstate commerce pursuant to the Federal Meat Inspection Act ("FMIA"), 21 U.S.C. §§ 601-625, at its facility in Gallatin, Missouri.

As Federal Defendants have previously informed the Court, the FMIA mandates that the U.S. Department of Agriculture ("USDA"), acting through the Food Safety and Inspection Service ("FSIS"), grant inspections of livestock slaughter operations at facilities such as Rains Natural Meats' Missouri facility that meet the requirements of the FMIA. *See* ECF No. 66 at 12-17. And, as a result of the agency's lack of discretion in issuing grants of inspection under the FMIA, the requirements of the National Environmental Policy Act ("NEPA"), 42 U.S.C. §§ 4321-4370h, do not apply. *Id.* Nonetheless, as it did for the Valley Meat and Responsible

Transportation operations that are the subject of this Court's temporary restraining order, ECF No. 125 (as amended), FSIS has completed an analysis of the proposed grant of inspection for the Rains Natural Meats facility in accordance with NEPA, determining that the grant falls under the USDA categorical exclusion for FSIS actions. Exhibit A. Because the facility has satisfied the statutory and regulatory requirements for inspection, and FSIS has completed its NEPA process, FSIS is presently in a position to issue the grant of inspection for Rains Natural Meats as required by the FMIA.

When this Court entered its temporary restraining order, Rains Natural Meats had not yet met the requirements for a grant of inspection, and thus the temporary restraining order expressly applies only to FSIS's inspection of the Valley Meat and Responsible Transportation facilities. *See* ECF No. 125 at 7. But circumstances have changed, and Rains Natural Meats is now eligible and requesting a grant of inspection. Without waiving any objections as to whether the underlying temporary restraining order is appropriate in these circumstances, Federal Defendants recognize that the Court may consider it appropriate to expand the *coverage* of the temporary restraining order to include Rains Natural Meats, as there is no substantial basis to distinguish the grant of inspection for that company from the grants for the other two facilities with regard to the Court's assessment of the factors for emergency injunctive relief. Should it choose to do so, the Court can accomplish this modification simply by adding "Rains Natural Meats" to the three operative paragraphs referencing the other two facilities, "Valley Meat and Responsible Transportation," as follows (additions in **bold underline**):

> IT IS FURTHER ORDERED that the Federal Defendants are enjoined from dispatching inspectors to the horse slaughterhouse facilities operated by Intervenor-Defendants **Rains Natural Meats,** Valley Meat and Responsible Transportation until further order of the Court.
>
> IT IS FURTHER ORDERED that the Federal Defendants are ordered to suspend

> or withhold the provision of horse meat inspection services to **Rains Natural Meats,** Valley Meat and Responsible Transportation until further order of the Court.
>
> IT IS FURTHER ORDERED that Defendants **Rains Natural Meats,** Valley Meat and Responsible Transportation are enjoined from commercial horse slaughter operations until further order of the Court.

See ECF No. 125 at 7.[1]

Rains Natural Meats has informed FSIS that it is ready to begin operations, and has requested inspectors at its facility in Gallatin, Missouri, no later than September 23, 2013. Because FSIS is required, as a matter of law, to provide inspectors for these operations, *see* 21 U.S.C. § 603(a), FSIS must do so, in the absence of an amendment to the Court's temporary restraining order, as specified above. Federal Defendants have advised Plaintiffs and Defendant-Intervenor Rains Natural Meats, through counsel of record, of Federal Defendants' positions on the issues discussed in this Notice and that Federal Defendants intended to file this Notice.

Respectfully submitted this 13th day of September, 2013.

ROBERT G. DREHER
Acting Assistant Attorney General
Environment & Natural Resources Division
United States Department of Justice

/s/ Andrew A. Smith .
ANDREW A. SMITH (NM Bar 8341)
Senior Trial Attorney
c/o United States Attorney's Office
201 Third Street, N.W., Suite 900
P.O. Box 607
Albuquerque, New Mexico 87103
Telephone: (505) 224-1468
Facsimile: (505) 346-7205
Andrew.Smith@usdoj.gov

[1] Plaintiffs have sought to have the last of these three provisions removed from the temporary restraining order, ECF No. 112, but the Court has not ruled on that motion.

ALISON D. GARNER (DC Bar 983858)
Trial Attorney
P.O. Box 7611
Washington, D.C. 20044-7611
Telephone: (202) 514-2855
Facsimile: (202) 305-0506
Alison.Garner@usdoj.gov

Attorneys for Federal Defendants

CERTIFICATE OF SERVICE

I hereby certify that on September 13, 2013, I filed through the United States District Court ECF System the foregoing document to be served by CM/ECF electronic filing on all counsel of record.

/s/Andrew A. Smith .
ANDREW A. SMITH
U.S. Department of Justice

EXHIBIT 16

Decision Memo—National Environmental Policy Act Categorical Exclusion

Application of Responsible Transportation, LLC, for a Grant of Federal Meat Inspection Services

Decision

It is my decision to grant federal meat inspection services to Responsible Transportation, LLC.

Description

Responsible Transportation, LLC (Responsible Transportation), is a 34,600 sq ft brick-walled masonry building that is located on an 80.64-acre site at 22034 200th Street, Sigourney, Keokuk County, Iowa. The facility, built in 1977, was previously used by West Liberty Foods, LLC, for processing beef products. The facility is one-half mile from the nearest occupied house. Responsible Transportation filed an application for a Grant of Inspection on December 13, 2012. Mr. Keaton Walker is President of Responsible Transportation.

Proposed Action

The proposed action is to grant federal meat inspection services for commercial horse slaughter operations at Responsible Transportation. The Federal Meat Inspection Act (FMIA) requires government inspectors to conduct an ante-mortem inspection of all amenable species, including cattle, sheep, swine, goats, horses, mules and other equines (21 U.S.C. § 603); a post-mortem inspection of the carcasses and parts of all amenable species (21 U.S.C. § 604); and an inspection of meat food products during processing operations (21 U.S.C. § 605) in establishments that sell or distribute in commerce meat that is intended for human consumption. Horses, mules, and other equines have been among the livestock species that are amenable to the FMIA since it was amended by the Wholesome Meat Act in 1967.[1] [2] The FMIA and its implementing regulations in 9 CFR parts 302, 304, 307, 416, and 417 require establishments that wish to engage in the commercial slaughter of amenable species to produce meat intended for human consumption and sale or distribution in interstate commerce to apply to FSIS for a grant of federal inspection services, and they establish criteria for determining the eligibility of the applicant to receive inspection services.

FSIS is also required to conduct an examination and inspection of the method by which amenable species, including horses, are slaughtered and handled in connection with slaughter in order to ensure that the establishment is in compliance with the Humane Methods of Slaughter Act (21

[1]FSIS regulations require that establishments that slaughter horses, mules, and other equines must be completely separate from any establishment that slaughters cattle, sheep, swine, or goats.

[2]FSIS temporarily suspended inspection of horse slaughter facilities from 2006 to 2012 because Congress prohibited FSIS from expending funds to pay for ante-mortem inspection of equines in each of those years, but the underlying statute requiring federal inspection of horse slaughter has never been amended or repealed. In 2012 Congress restored federal funding of ante-mortem inspection of horses at commercial horse slaughter plants. Therefore, issuing a grant of inspection for commercial horse slaughter is not precedent setting, but rather, a return to the status quo ante.

U.S.C. § 603) (HMSA). The HMSA was enacted to prevent the needless suffering of livestock, to improve products and economies in slaughter operations, and to produce other benefits for producers, processors, and consumers which tend to expedite an orderly flow of livestock and livestock products in interstate and foreign commerce. FSIS has implemented and enforces regulations under the HMSA (9 CFR part 313).[3]

The National Environmental Policy Act and FSIS's Categorical Exclusion

The National Environmental Policy Act (42 U.S.C. § 4321 *et seq.*) (NEPA) and the Counsel of Environmental Quality implementing regulations (40 CFR. parts 1501-1508) require all federal agencies to prepare an assessment of the environmental impact of a proposed agency action (called an environmental assessment, or EA) (40 CFR §§ 1501.3 and 1501.4(b)). Based on the EA, NEPA further requires federal agencies to prepare an environmental impact statement (EIS) for major federal actions significantly affecting the quality of the human environment (42 U.S.C. § 4332(2)(c) and 40 CFR § 1504.1(c)). However, federal agencies may identify classes of actions that normally do not require the preparation of either an EA or an EIS because such actions do not have a significant effect on the human environment, either individually or cumulatively (40 CFR § 1507.3(b)(2)). Classes of actions that have no significant environmental effect, either individually or cumulatively are said to be categorically excluded from NEPA requirements (40 CFR. § 1508.4). Despite allowing federal agencies to identify classes of action that are categorically excluded from NEPA requirements, NEPA still requires an agency to determine and inform the agency decision maker on whether or not there are any potential environmental impacts that may result from a proposed action of that agency.

USDA's NEPA implementing regulations are found in 7 CFR § 1b. These regulations list FSIS as an agency that conducts programs and activities that have been found to have no individual or cumulative effect on the human environment, such that FSIS is categorically excluded from the requirements of preparing procedures to implement NEPA, and its actions are categorically excluded from the preparation of an EA or an EIS unless the FSIS Administrator determines that an action may have a significant environmental effect (7 CFR § 1b.4).

When a federal agency's action is merely ministerial as opposed to discretionary and the agency lacks discretion to affect the outcome of its action, there is no major federal action that triggers NEPA requirements. A grant of federal inspection under the FMIA is purely ministerial because, if a commercial horse slaughter plant meets all of the statutory and regulatory requirements for receiving a grant of federal inspection services, FSIS has no discretion or authority under the

[3]The Commercial Transportation of Equine for Slaughter Act (7 U.S.C. § 1901 note) is an animal welfare statute governing the commercial transportation of equine for slaughter by persons regularly engaged in that activity within the United States. In 1998, the Secretary issued regulations (9 CFR part 88) that establish safety standards for conveyances being used to transport equines to slaughter; define the duties and responsibilities of owner/shippers prior to loading equines onto the conveyance, during the actual commercial transportation of said equines to the slaughter plant, and upon their arrival at a slaughter plant; and set forth paperwork and back tagging requirements for equines being commercially transported to slaughter. This program is administered by USDA's Animal and Plant Health Inspection Service, whose personnel historically have conducted their inspections of slaughter horses and the conveyances in which they are transported to slaughter upon the horses' arrival at a slaughter facility.

FMIA to deny the grant on other grounds or to consider and choose among alternative ways to achieve the agency's statutory objectives. Therefore, a grant of federal inspection services under the FMIA is not a major federal action that is subject to NEPA requirements.

A grant of federal inspection likewise does not and will not allow FSIS to exercise sufficient control over the commercial horse slaughter activities at Responsible Transportation such that the grant will constitute a major federal action that triggers NEPA requirements. The sole purpose of federal meat inspection is to protect public health and welfare by ensuring that any meat produced for human consumption and sale or distribution in commerce is wholesome, not adulterated, properly packaged, and properly labeled as to species, quantity, and point of origin, and the FMIA does not authorize FSIS to regulate a commercial horse slaughter facility's slaughter activities beyond that which is necessary to achieve this purpose. Accordingly, the FMIA authorizes FSIS inspectors to conduct ante-mortem inspection of horses to ensure that they are not dead or dying, diseased, or non-ambulatory, and that they are not inhumanely handled or slaughtered. It likewise authorizes FSIS inspectors to conduct post-mortem inspection of the carcasses and meat food products resulting therefrom to ensure that the carcasses and meat are wholesome, not adulterated, and fit for use as human food. In addition, the FMIA authorizes FSIS to require commercial slaughter plants to maintain certain sanitary conditions with respect to the conduct of commercial slaughter, meat preparation, and meat packaging operations, the proper storage of carcasses and the meat products derived therefrom, and the storage and proper disposal of condemned or inedible materials. The FMIA further authorizes FSIS to require commercial slaughter plants to develop hazard analysis and critical control point plans that identify and prevent or control for potential food safety hazards at each step of the slaughter process. All FSIS inspectors assigned to conduct federal meat inspection at Responsible Transportation's facility will perform these duties in accordance with the policies and procedures set forth in several FSIS directives and notices, including but not limited to FSIS Directive 6900.2 Rev. 2, *Humane Handling and Slaughter of Livestock*; FSIS Directive 6100.1, *Ante-Mortem Livestock Inspection;* FSIS Directive 6100.2, *Post-mortem Livestock Inspection;* and FSIS Directive 6130.1, *Ante-mortem, Post-mortem Inspection of Equines and Documentation of Inspection Tasks.* However, FSIS inspectors will not have any authority or control over the day-to-day operations of the slaughter plant save to the degree necessary to achieve only the agency's mission to protect public health by ensuring that horse meat intended for use as human food is safe to eat and properly labeled.

Even if FSIS did have sufficient authority and control over commercial slaughter activities at a horse slaughter establishment such that a grant of federal inspection to such an establishment could constitute a major federal action, federal ante-mortem and post-mortem inspection of horses at Responsible Transportation would not be the legally relevant cause of the establishment's commercial horse slaughter activities or the impacts, if any, that such slaughter activities might have on the environment. If the meat produced at a commercial horse slaughter plant is not intended for human consumption, or if it is intended for human consumption but for sale or distribution only in intrastate commerce rather than in interstate commerce, then the commercial horse slaughter and the effects thereof may proceed independently of a grant of federal ante-mortem and post-mortem inspection, and FSIS would have no ability to prevent them. In the present instance, Mr. Walker has indicated that he intends to prepare horse meat for human

consumption and that his intended market is outside the State of Iowa, so he may operate only subject to a grant of federal inspection.[4] However, nothing in the FMIA precludes him from expanding his operation to include the preparation and sale of horse meat to pet food companies and zoos for non-human consumption. It thus is possible for Responsible Transportation to operate as a horse slaughter establishment, and possibly have an effect on the environment, without having a grant of federal inspection. Accordingly, a grant of federal inspection services is not and cannot be the legally relevant cause of either the commercial slaughter activity or its environmental impact, if any.

Based on the foregoing, a decision to grant federal inspection services to Responsible Transportation does not constitute major federal action that will significantly affect the quality of the human environment and thus does not trigger any requirements under NEPA. Nevertheless, given the high level of public interest in this particular issue, FSIS has examined several aspects of granting federal inspection services to Responsible Transportation to determine if the categorical exclusion applies to this action or if any unique conditions or extraordinary circumstances exist that would cause this action to have a significant environmental effect and trigger NEPA requirements. These aspects are the following:

–**Impacts on Public Health and Safety**. As explained above, federal inspection under the FMIA is intended solely to protect public health and safety by ensuring that meat and meat food products intended for use as human food are not adulterated or misbranded. However, the agency recognizes that the potential impacts of commercial horse slaughter on public health may cause concern with segments of the public. One such concern is the potential public health risks that could arise from the presence in horse meat of trace amounts of certain classes of drugs that have not been approved for use in animals that will or could be slaughtered to produce food for human consumption. The Humane Society of the United States and other horse protection groups contend that horses' status as companion animals that usually are not slaughtered in this country to produce human food means that most horses in the United States have been treated with antibiotics, anti-inflammatory drugs, growth hormones, and other substances that typically are not used on other food animals and for which the Federal Drug Administration has established no tolerances. These groups further contend that residues of these substances remain in horse tissues indefinitely, thus rendering any meat produced from U.S. horses unsafe for human consumption and constituting a threat to public health. FSIS has addressed this risk by implementing a new drug residue testing program that will screen the meat of slaughtered horses for drug residues before the meat is allowed to enter the food supply chain (FSIS Directive 6130.1, *Ante-mortem, Post-mortem Inspection of Equines and Documentation of Inspection Tasks*).

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4 It would be possible for Mr. Walker to prepare horse meat products for human consumption and sale or distribution only in the State of Iowa in accordance with the terms of Iowa's meat inspection program, which is "at least equal to" the federal program. The products could be distributed solely within the State to consumers located within the State (9 CFR § 321.1).

Horse meat that tests positive for drug residues will be marked U.S. condemned and will not be allowed to enter the stream of commerce. Instead, the meat will be disposed of by sending it to a rendering facility, thereby ensuring that it endangers neither public health and safety nor the local environment. Additionally, as described below, an overlapping scheme of federal, state, and local environmental laws and ordinances will further ensure that the waste products generated by Responsible Transportation's commercial horse slaughter activities are properly disposed of and will not enter the human food supply chain or the local environment. Therefore, a decision to grant federal inspection to Responsible Transportation will safeguard public health and safety by ensuring that commercial horse slaughter at Responsible Transportation has no potential to have a significant impact on public health and safety.

--**Wildlife Hazards**. FSIS has determined that commercial horse slaughter activities at Responsible Transportation or federal inspection thereof will not create a wildlife hazard.

–**Impacts on Wild and Scenic Rivers and U.S. Waters and Wetlands**. FSIS has determined that commercial horse slaughter activities at Responsible Transportation or federal inspection thereof will not affect a river segment that is listed in the Wild and Scenic River System or National Rivers Inventory. FSIS also has determined that commercial horse slaughter activities at Responsible Transportation or federal inspection thereof will not impact federal or state regulated or non-jurisdictional wetlands.

–**Impacts on Energy and Natural Resources**. FSIS has determined that commercial horse slaughter activities at Responsible Transportation or federal inspection thereof will not have a significant impact on energy and other natural resource consumption.

--**Impacts on Public Parks, Recreation Areas, Wildlife/Waterfowl Refuges, Historical Sites, and Other Publicly Owned Lands**. FSIS has determined that commercial horse slaughter activities at Responsible Transportation or federal inspection thereof will not have any impacts on any publicly owned land from a public park, recreation area, wildlife or waterfowl refuge, or historical site of national, state, or local significance.

In its June 2011 report on the unintended consequences of the cessation of commercial horse slaughter in the United States, the General Accounting Office (GAO) found that there has been an increase in horse abandonment on private or state park land since 2007. It likewise found an increase in horse abandonment on federal lands, including national parks and Indian reservations. The abandonment of horses on these lands results in over-grazing that degrades the land and puts environmental stress on other species that compete with horses for the same food sources. Horse abandonment on these and other federal lands that maintain populations of wild horses increases the chance that the abandoned horses will introduce equine diseases to the wild herds. The increasing numbers of unwanted horses also complicate the Bureau of Land Management's efforts to manage herds of wild horses and burros on federal lands by making it more difficult for the agency to adopt out the horses and burros that it removes from federal lands. Based on the foregoing, commercial horse slaughter at Responsible Transportation and other horse slaughter plants has the potential to reduce the horse overpopulation in the United States while providing owners of unwanted horses with an economically viable and an environmentally sustainable

alternative to horse abandonment as a method of disposing of their unwanted horses.

FSIS also have made the following findings required by other laws:

--**Clean Air Act**. Section 176(c)(1) of the Clean Air Act (42 U.S.C. § 7401) requires federal agencies to assure that their actions conform to applicable implementation plans for achieving and maintaining the National Ambient Air Quality Standards that the Environmental Protection Agency (EPA) has set for certain criteria pollutants, such as sulfur dioxide, nitrogen dioxide, carbon monoxide, ozone, lead, and particulate matter. *See* 40 CFR part 50. FSIS has determined that commercial horse slaughter activities at Responsible Transportation and/or federal inspection thereof will not increase the frequency or severity of any existing violations of standards for ambient air quality, result in any new violations of said standards, or prevent or delay the timely attainment of said standards in the area of concern.

--**Clean Water Act**. Following section 401(a) of the Clean Water Act (33 U.S.C. § 1341) (CWA), 9 CFR § 304.2(c)(1) requires any applicant for federal meat inspection at an establishment where the operations thereof may result in any discharge into navigable waters as defined by the CWA to provide the Administrator, FSIS, with certification, obtained from the State in which the discharge will originate, that there is reasonable assurance that said operations will be conducted in a manner that will not violate the applicable water quality standards. On June 25, 2013, Mr. Walker provided the Administrator, FSIS, with an attestation that horse slaughter operations at Responsible Transportation will not result in any discharge into any navigable waters as defined by CWA. Mr. Walker also provided the Administrator, FSIS, with a copy of Responsible Transportation's National Pollutant Discharge Elimination System (NPDES) General Permit that was issued pursuant to the authority of section 402(b) of the CWA (U.S.C. 1342(b)), Iowa Code 455B.174, and subrule 567-64.4(2), Iowa Administrative Code. The permit allows Responsible Transportation to discharge storm water associated with industrial activity. The discharge is subject to the terms and conditions detailed in the permit.

--**Endangered Species Act**. FSIS has determined that commercial horse slaughter activities at Responsible Transportation or federal inspection thereof will not have any impact, either directly or indirectly, on any federally or state-listed or proposed endangered species of flora and fauna or impact critical habitat. The U.S. Fish and Wildlife Service (FWS) lists nine endangered or threatened animal species that occur in Iowa and five threatened plant species that occur in the State.[5] Three of these animal and plant species occur in Keokuk County.[6] However none of these species will be adversely affected by operations at Responsible Transportation or federal inspection thereof, nor will these operations affect other biotic communities or habitat not protected by the Endangered Species Act because there is no suitable habitat for these species near Responsible Transportation's facility.

[5] http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrenceIndividual.jsp?state=IA.
[6] http://www.fws.gov/midwest/endangered/lists/iowa_cty.html.

--**Migratory Bird Treaty Act**. FSIS has determined that commercial horse slaughter activities at Responsible Transportation or federal inspection thereof will not affect species protected under the Migratory Bird Treaty Act.

--**National Historic Preservation Act**. The National Register of Historic Places lists 12 sites located in the Sigourney, IA, area. According to information from the State Historical Society of Iowa and the National Register of Historic Places the property owned by Responsible Transportation is not on the list of historic places in Keokuk Country, IA, and the listed historic site closest to Responsible Transportation, the Sigourney Public Library, is over two miles away from the slaughter facility. Therefore, FSIS has determined that commercial horse slaughter activities at Responsible Transportation or federal inspection thereof will not impact any historic or cultural property or resources protected by the National Historic Preservation Act.

In 2009, a coalition of northwest Indian tribes reported to the GAO that the increase in horse abandonments on tribal lands, combined with the sizable populations of wild horses that already existed on their lands, both increased the degradation of the land caused by over-grazing and complicated efforts to restore native and religiously-significant plant species on tribal lands. Commercial horse slaughter at Responsible Transportation and other commercial horse slaughter plants thus has the potential to have a beneficial effect on the cultural resources of American Indian tribes whose tribal lands are being degraded by a combination of an overpopulation of wild horses and large scale abandonment of unwanted horses on their lands.

--**Federal Farmland Protection Policy Act**. FSIS has determined that federal inspection of the slaughter activities at Responsible Transportation will not involve the acquisition or use of farmland protected by the Federal Farmland Protection Policy Act that would be converted to non-agricultural use.

–**Humane Methods of Slaughter Act**. As previously noted, Responsible Transportation's commercial horse slaughter operations will be subject to the humane handling requirements found in section 603(b) of the FMIA (21 U.S.C. § 603(b)) and the regulations promulgated thereunder (9 CFR part 313).

--**State and Local Laws**. As previously noted, Responsible Transportation's facility is located in the City of Sigourney, Keokuk County, IA.

Under the terms of a water supply operation permit issued February 25, 2013, by the Iowa Department of Natural Resources (IDNR), Responsible Transportation is authorized to operate a public water system under the applicable sections of the Iowa Code, including Chapter 455B and part 567 of the Iowa Administrative Code. The system is subject to monitoring requirements and general conditions detailed in the permit.

Under the conditions of a water use permit that originally was issued to West Liberty Foods, effective on September 20, 2001, and renewed on April 16, 2013, by IDNR, Responsible Transportation is authorized to withdraw water from three existing wells, ranging from 103 to 123 feet deep, that are located on land in the Northwest quarter of Section 30, T76N, R11W, Keokuk

County, IA. The water use permit allows Responsible Transportation to withdraw a maximum quantity of 18.25 million gallons per year at a maximum rate of 55 gallons per minute throughout each year for use in the operation of a meat processing plant.

Responsible Transportation's waste disposal system operates in accordance with an IDNR permit for a land application system that was issued March 1, 2013, pursuant to the authority of Iowa Code section 455B.174 and rule 567-64.3 of the Iowa Administrative Code.

Wastewater from Responsible Transportation's processing facility is treated in a lagoon system consisting of anaerobic lagoon and two aerobic storage lagoon cells. The treated wastewater is disposed of by land application using a center-pivot irrigation system. The 40-acre land application area is in the Northwest quarter of Section 30, T76N, R11W, Keokuk County, IA. A key condition of the permit is that no discharge into the waters of the State from the storage lagoon or the land application area is allowed. Other conditions are listed in the permit document.

Conclusion.

Based on the foregoing, FSIS finds no unique conditions or extraordinary circumstances of the proposed action to grant federal meat inspection services to Responsible Transportation that would cause this action to have a significant environmental effect. Therefore, in accordance with 7 CFR § 1b.4, the proposed action is categorically excluded from the preparation of an EA or an EIS.

EXHIBIT 17

Wagner, Scott - FSIS

From: Sarah De Los Santos [[redacted]yahoo.com]
Sent: Wednesday, June 13, 2012 10:47 AM
To: Gallegos, Anna - FSIS
Cc: Wagner, Scott - FSIS
Subject: Fw: Request for third party review

Hello,

Anna this is the email that had the drug residue guidelines from Dr. Holterman and the Omaha, NE office that I told you I would send. It appears that you may already have this copy from them also.

Thanks again.

Sarah De Los Santos

--- On **Mon, 5/7/12, Arnold, Ilene - FSIS <*Ilene.Arnold@fsis.usda.gov*>** wrote:

From: Arnold, Ilene - FSIS <Ilene.Arnold@fsis.usda.gov>
Subject: Request for third party review
To: "[redacted]yahoo.com" <[redacted]yahoo.com>
Cc: "Holterman, James - FSIS" <James.Holterman@fsis.usda.gov>, "Hulsey, Laura - FSIS" <Laura.Hulsey@fsis.usda.gov>, "Seebohm, Scott - FSIS" <Scott.Seebohm@fsis.usda.gov>, "Edelstein, Rachel - FSIS" <Rachel.Edelstein@fsis.usda.gov>, "Gallegos, Anna - FSIS" <Anna.Gallegos@fsis.usda.gov>, "[redacted] - FSIS" <[redacted]fsis.usda.gov>
Date: Monday, May 7, 2012, 2:44 PM

As requested, Dr. Hulsey asked Dr. Holterman and Dr. Arnold to review the documents sent to OPPD PDD for review.

Dr. Hulsey requested that I send you our combined recommendation related to the Sanitation SOP, HACCP plan, and residue prevention.

In reviewing the Sanitation SOP for compliance with the regulation, the recommendations are as follows:

1) Identify what the abbreviation means the first time it is used. There is a definition section, but it is still not clear what KF or PR means on the first page of the plan.

2) Page 2 identify what these procedures are as they appear to be cleaning occurring at either the end of production or the beginning of production

3) Page identified as Pre-Operational Sanitation/Slaughter Floor reads more like monitoring than the cleaning

procedures which goes along with the above comment in 2).

4) Page 2 of the Pre-Operational Sanitation/Slaughter Floor appears to be in conflict with page one since that page indicates [redacted] Need to clarify the purpose of this random selection of days as monitoring needs to be daily to meet the regulatory requirement in 9 CFR 416.13(c). Additionally it mentions in the last sentence of Page 2 that the results will be initialed by the verifier but makes no mention of the requirement for a date on the daily record.

5) Page 1 of Operational Sanitation Procedures Slaughter Floor has a similar issue in that it appears monitoring will only take place once a month rather than daily as required by regulation. It is not clear if this activity in the second paragraph is a separate or additional to the daily monitoring or not.

6) This document has multiple sections and pages and it would be helpful to have some type of numbering system to keep all the pages in order and make them easy to reference.

Since I have no idea what the facilities look like, the OFO inspection team still will need to make a final determination as to the adequacy of the written Sanitation SOP.

In reviewing the HACCP plan for compliance with the regulation, the recommendations are as follows:

1) Signature Page – It is unclear why this page only mentions CCP document to be signed and dated as the regulation requires all entries on the HACCP records to be initialed or signed and dated, so we did not know if this document is the pre-shipment review or that the establishment only sign and date this document which would then not be in compliance.

2) Page 2 Process flow – this will need the OFO inspection team to verify that all the steps in the process are being addressed.

3) Pages 4-11 It is not clear if the 'Basis' mentioned has written procedures or programs that will be monitored on an ongoing basis to support their conclusion of the food safety hazard not being reasonably likely to occur. There are steps where 'No' is entered but no 'Basis' is provided. Written decision-making documents are not included. OFO EIAO will need to assess the documents and make the final compliance determinations as to the design and then execution of the plan.

4) Missing page numbers on several pages; all pages should be appropriately labeled to make it easier to follow the document. There also appears to be pages missing as the numbers jump.

5) Page 7 Splitting Saw step and Trim Station both mention antimicrobial spray but it is not clear if something is applied at this step or later in the process. The steps on this page need further clarification. Since there are no supporting documents, it is not possible to discern how the design is supported.

6) Page 11 *E. coli* O157:H7 is the proper way to express this pathogen in the first column when it is included in decisions associated with a pathogen of concern. Verification activities require recording verification activity performed, the results, initial, and date. For Corrective Actions a designation of the responsible employee is needed.

7) Page 13 Monitoring records require an initial or signature, date, and time to be in compliance. What does 'correct application' mean in terms of a procedure? For Corrective Actions the same comment as on Page 11 above.

8) Page 16 Critical limit states [redacted] unclear how this is supported in the design of the CL. For Corrective Actions the same comment as on Page 11 above.

Since there is no supporting documentation and pages appear to be missing, the OFO inspection team and/or EIAO will

still need to make the final determination as to the adequacy of the written hazard analysis and HACCP Plan design and execution.

Residue Prevention recommendation:

Since there are no medications, wormers, or fly treatments approved for use in the United States for horses intended for food and horses are frequently subjected to treatment with a variety of chemicals we recommend you implement a very robust residue prevention program. In addition to obtaining a signed affidavit from the owner we recommend you employ all 5 recommendations found in the Compliance Guide For Residue Prevention

1. Confirm producer history

2. Buy residue-free animals

3. Ensure animals are adequately identified

4. Supply the producer information to FSIS at ante-mortem

5. Notify Producers of Violative Animals

Detailed information on each of the recommendations can be found at this link: Compliance Guide For Residue Prevention

The final determination of the acceptability of your HACCP plan will be made by your District Office.

FSIS recently issued this information on equine slaughter in the Constituent Update

Equine Slaughter Restarts

Currently there are no facilities approved for horse slaughter in the United States.

Following a decision by Congress in November 2011 to lift the ban on horse slaughter, one establishment, located in New Mexico, recently applied for a grant of inspection exclusively for equine and USDA's Food Safety and Inspection Service is reviewing the application.

However, given that the agency last conducted a horse inspection six years ago, FSIS has determined that despite the congressional decision to lift the ban, the agency will require a significant amount of time to update its testing and inspection processes and methods before it is fully able to develop a future inspection regimen.

I noticed that currently do not appear to have an askFSIS account. The askFSIS application is used to address inspection related questions. You can access askFSIS at http://askFSIS.custhelp.com to search for answers to common questions. If you would like to set up an account and need assistance you are welcome to call me and I will walk you through the process of setting up an account and then how to search and submit questions.

I hope the information provided is helpful to you.

Ilene D. Arnold, MS, VMD *for* Dr. Laura Hulsey PDD Director

Senior Staff Officer

USDA, FSIS, OPPD Policy Development Division

Edward Zorinsky Federal Building

1616 Capitol Avenue Suite 260, Omaha, NE 68102-5908

Phone (402) 344-5000 Fax (402) 344-5007

Policy is my passion.

Have you searched askFSIS?

From: Hulsey, Laura - FSIS
Sent: Friday, May 04, 2012 4:02 PM
To: [redacted]yahoo.com
Cc: Seebohm, Scott - FSIS; Holterman, James - FSIS

Subject: RE: RE: FW: Update

Hello,

We are having a couple of staff officers review these and they will be in touch with you next week. The most scrutiny will be on the support for residues, which is Dr. Holterman's area of expertise. We can provide a review and comment of the material submitted, but it will still be up to the District Office to make the final determination of compliance.

I am also sharing these documents with the Small Plant Outreach group. We plan to have discussion with them on equine slaughter policies in the next couple of weeks.

Thanks for sending, and Dr. Holterman will be in touch with any follow-up questions.

Laura Hulsey, DVM

Director, Policy Development Division

USDA/FSIS/OPPD

Zorinsky Federal Building

1616 Capitol Ave. Suite 260

Omaha, NE. 68102

Office 402-344-5000

Fax 402-344-5007

From: Sarah De Los Santos [mailto:[redacted]yahoo.com]
Sent: Friday, May 04, 2012 3:22 PM
To: Hulsey, Laura - FSIS
Subject: Fw: RE: FW: Update

Ms Hulsey,

Please see attached the FSIS findings on the second FSIS walkthrough...I am sending my original HACCP and

SSOP for third party review and possible conclusions.

Email attachments will follow.

Thank You,

Ricardo De Los Santos

Valley Meat Co.

Roswell, NM 88203

575-622-1214

EXHIBIT 18

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

FRONT RANGE EQUINE RESCUE,,
et al.

Plaintiffs,

vs. No. 1:13-CV-00639-MCA-RHS

TOM VILSACK, Secretary U.S.
Department of Agriculture, *et al.*

Defendants.

ORDER

THIS MATTER is before the Court on Plaintiffs' *Notice of Motion and Motion for Temporary Restraining Order and Preliminary Injunction; Memorandum of Points and Authorities in Support Thereof* [Doc. 5]. Having considered the submissions, the relevant case law, the oral argument of the parties, and otherwise being fully advised in the premises, the Court grants Plaintiffs' motion in part, in that it grants Plaintiffs' motion for a temporary restraining order.

The decision to grant a temporary restraining order is within the Court's discretion. See Winnebago Tribe of Nebraska v. Stovall, 341 F.3d 1202, 1205 (10th Cir. 2003). To obtain a temporary restraining order "the moving party must demonstrate: (1) a likelihood of success on the merits; (2) a likelihood that the movant will suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in the movant's favor; and (4) that the injunction is in the public interest." Attorney Gen. of Oklahoma v.

Tyson Foods, Inc., 565 F.3d 769, 776 (10th Cir. 2009) (internal quotation marks and citation omitted).

The Court will first address the likelihood of success on the merits of Plaintiffs' APA and NEPA claims challenging the grants of inspection and FSIS Directive 6130.1. In this case, Plaintiffs' challenge agency action under the APA. Under the APA, the Court reviews final agency action to determine whether it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Although the Court's review must be thorough, the standard of review is very deferential to the agency. Hillsdale Envtl. Loss Prevention, Inc. v. U.S. Army Corps of Engineers, 702 F.3d 1156, 1165 (10th Cir. 2012)

Beginning with FSIS Directive 6130.1, the Court concludes that the Directive constitutes final agency action as defined by the APA. The Directive appears to be FSIS's final statement regarding drug residue testing in equines. Additionally, the Directive is agency action from which rights and obligation are determined and legal consequences flow, since FSIS relied on the Directive in issuing the grants of inspection to Valley Meat and Responsible Transportation. Moreover, violations of the residue testing standards may result in a regulatory enforcement action.

The Court also concludes that the Directive is a legally relevant cause of Plaintiffs' alleged environmental harm. FSIS adopted the Directive in response to concerns regarding the potential presence in slaughtered horses of chemical residues from drugs not previously approved for use in food animals. FSIS specifically incorporated the

Directive into each grant of inspection and the Court is not persuaded that the Directive played no role or that it plays an insignificant role in the agency's decision to issue the grants of inspection. FSIS issued the grants of inspection to Valley Meat and Responsible Transportation, in relevant part, because it concluded that the Directive was sufficient to protect the public health and safety from the dangers posed by these drugs. Therefore, the Court finds that the evidence of causation is sufficient.

The Court next addresses whether the Directive constitutes "major Federal actions significantly affecting the quality of the human environment" under NEPA. Under 40 C.F.R. § 1508(b)(2) "major federal action" includes the "[a]doption of formal plans . . . upon which future agency action will be based." See Norton v. Southern Utah Wilderness Alliance, 542 U.S. 55, 73 (2004) (holding that the approval of a land use plan promulgated by the Bureau of land management constitutes "major federal action" under NEPA). FSIS Directive 6130.1 appears to be a formal plan or policy regarding drug residue testing in equines. Additionally, future agency action will be and indeed was based on the Directive. As previously explained, the grants of inspection were based, in relevant part, on the existence of FSIS Directive 6130.1 and future drug residue testing of equines at Valley Meat and Responsible Transportation will be based on the standards set forth in the policy.

There is no evidence in the record that FSIS relied on the categorical exclusion in adopting FSIS Directive 6130.1. Our Tenth Circuit has held that "categorical exclusions cannot be summoned as *post-hoc* justifications for an agency's decision." Utah Envtl.

Congress v. Russell, 518 F.3d 817, 825 n.4 (10th Cir. 2008). Accordingly, the categorical exclusion is inapplicable to the Directive.

Based on the foregoing, the Court concludes that Plaintiffs have established a substantial likelihood of success on the merits of their APA and NEPA claim challenging Directive 6130.1.

Turning to the grants of inspection, as previously stated, the grants of inspection were based, in relevant part, on the existence of the FSIS Directive to protect the public health and safety. The Court is not persuaded that the grants of inspection would have been issued in the absence of this Directive, the express purpose of which was to protect the public health and safety from the unique chemical residues possibly present in equines. Although the Court must afford deference to the FSIS's actions, the Court does not find credible the Federal Defendants' assertions that the grants of inspection would have been issued in the absence of the Directive given the express purpose of the Directive to protect the public health and safety and given the fact that FSIS specifically incorporated the Directive into their grants of inspection. The Court therefore concludes that Plaintiffs have established a substantial likelihood of success on the merits of their NEPA and APA claims challenging the grants of inspection.

Having determined that Plaintiffs have established a substantial likelihood of success on the merits of their claims, the Court next addresses the issue of irreparable harm. The Court acknowledges the concerns expressed in the pleadings and oral argument as to the welfare of horses, but the Court nonetheless must emphasize that

NEPA is a statute that protects the physical environment and, therefore, the harm with which we are concerned is the risk of harm to the physical environment. Plaintiffs must establish that irreparable harm to the physical environment is *likely* in the absence of a temporary restraining order. See Winter v. Natural Resources Defense Council, Inc., 555 U.S. 7, 22 (2008). "Purely speculative harm will not suffice, but [a] plaintiff who can show a significant risk of irreparable harm has demonstrated that the harm is not speculative and will be held to have satisfied this burden." Crowe & Dunlevy, P.C. v. Stidham, 640 F.3d 1140, 1157 (10th Cir. 2011) (internal quotation marks and citation omitted).

Plaintiffs have submitted evidence of environmental harm at commercial horse slaughter facilities that operated in the United States prior to the defunding of inspectors in fiscal year 2006. [See. Doc. 13] This environmental harm included blood spills, improper disposal of animal parts and carcasses, noxious odors, and the leeching of horse effluent into the local water supply and waterways. [Id.] These harms are compounded by the presence of chemical residues in equines that are not otherwise present in other amenable species subject to slaughter. Evidence has been proffered that a majority of horses subject to slaughter are administered a variety of pharmaceutical drugs not approved for use in food animals, the effects of which could adversely effect the physical environment. The Court concludes that Plaintiffs have fulfilled their burden to prove that environmental harm is likely to occur in the absence of the issuance of a temporary restraining order.

Turning to the balance of the harms, the Court recognizes that Valley Meat and Responsible Transportation will suffer significant economic harm if they are prohibited from operating during the pendency of the present litigation. However, the Court concludes that the environmental harms posed by commercial horse slaughter without adequate NEPA review outweigh the legitimately incurred costs to defendants resulting from a temporary restraining order.

Finally, the Court concludes that the issuance of a temporary restraining order is not adverse to the public interest. "[T]he public has an undeniable interest in the [government's] compliance with NEPA's environmental review requirements and in the informed decision-making that NEPA is designed to promote." Colorado Wild Inc. v. U.S. Forest Service, 523 F.Supp.2d 1213, 1223 (D. Colo. 2007). The Court recognizes that the public also has an interest in the enforcement of the Federal Meat Inspection Act and its implementing regulations, but concludes that this interest is outweighed by the risk of environmental harms posed by the commencement of commercial horse slaughter in the absence of NEPA review.

For the foregoing reasons, the Court concludes that Plaintiffs are entitled to a temporary restraining order as follows:

IT IS THEREFORE ORDERED that Plaintiffs' *Notice of Motion and Motion for Temporary Restraining Order and Preliminary Injunction; Memorandum of Points and Authorities in Support Thereof* [Doc. 5] is **GRANTED IN PART**.

IT IS FURTHER ORDERED that the Federal Defendants are enjoined from

dispatching inspectors to the horse slaughterhouse facilities operated by Intervenor-Defendants Valley Meat and Responsible Transportation until further order of the Court.

IT IS FURTHER ORDERED that the Federal Defendants are ordered to suspend or withhold the provision of meat inspection services to Valley Meat and Responsible Transportation until further order of the Court.

IT IS FURTHER ORDERED that Defendants Valley Meat and Responsible Transportation are enjoined from commercial horse slaughter operations until further order of the Court.

IT IS FURTHER ORDERED that the Court will set a hearing on Plaintiffs' request for a preliminary injunction within thirty (30) days.

IT IS FURTHER ORDERED that the Court will direct the Federal Defendants to expedite the production of the full administrative record.

IT IS FURTHER ORDERED that the matter of a security bond under Fed. R. Civ. P. 65(c) is hereby referred to the Honorable Robert Hayes Scott, United States Magistrate Judge, and Judge Scott is requested to convene a hearing (telephonic or otherwise) with the parties on Monday, August 5, 2013, to address this matter.

SO ORDERED this 2nd day of August, 2013, in Albuquerque, New Mexico.

M. CHRISTINA ARMIJO
United States District Judge

EXHIBIT 19

NEW MEXICO
ENVIRONMENT DEPARTMENT

Ground Water Quality Bureau

Harold Runnels Building
1190 St. Francis Drive
PO Box 5469, Santa Fe, NM 87502-5469
Phone (505) 827-2900 Fax (505) 827-2965
www.nmenv.state.nm.us

BILL RICHARDSON
Governor
DIANE DENISH
Lieutenant Governor

RON CURRY
Secretary
SARAH COTTRELL
Deputy Secretary

NOTICE OF VIOLATION
Certified Mail - Return Receipt Requested

May 7, 2010

Richard De Los Santos, President
Dairyland Packing, Inc.
Pecos Valley Meat Packing Co.
3845 Cedarvale Road
Roswell, NM 88203

RE: Notice of Violation, Pecos Valley Meat Packing Company, DP-236

Dear Mr. De Los Santos:

The New Mexico Environment Department (NMED) has determined that the above referenced facility is operating in violation of the Water Quality Act (WQA) and Water Quality Control Commission (WQCC) Regulations (20.6.2 NMAC). Please be advised that immediate action is required as described herein. The facility is located at 3845 Cedarvale Road, approximately 12 miles east of Roswell in Section 17, T11S, R25E, Chavez County.

Pursuant to Section 20.6.2.3109 NMAC, NMED issued a Discharge Permit Renewal and Modification (Discharge Permit), DP-236, to Dairyland Packing, Inc., on May 19 2004. The Discharge Permit expired on May 19, 2009, and NMED has yet to receive an application for renewal of the Discharge Permit.

Section 20.6.2.3104 NMAC states that no person shall cause or allow wastewater or leachate to discharge so that it may move directly or indirectly into ground water unless discharging pursuant to a Discharge Permit. Additionally, Subsection F of 20.6.2.3106 NMAC requires a holder of a Discharge Permit to submit an application for renewal (or renewal and modification) at least 120 days prior to the expiration of the Discharge Permit.

Section 20.6.2.3104 NMAC has been violated because wastewater is being discharged from this facility without an effective Discharge Permit. Also, Subsection F of 20.6.2.3106 NMAC has been violated because the Discharge Permit expired and, to date, NMED has not received an application for renewal (or renewal and modification).

In order to correct these violations, **complete the application for a Discharge Permit (copy enclosed), and submit three completed copies and a $100 filing fee to NMED by June 7, 2010.**

Failure to comply with this Notice of Violation may result in NMED's issuance of a compliance order that assesses a civil penalty pursuant to WQA § 74-6-10. Civil penalties may also be assessed for up to $15,000 per day for each violation of the WQA § 74-6-5, any regulation promulgated pursuant to that section or any permit issued pursuant to that section. Civil penalties may be assessed for up to $10,000 per day for each violation of any other provision of the WQA, or any regulation, standard, or order adopted pursuant to such other provision. Alternatively to the remedies described above, NMED may commence an action in district court for appropriate relief, including injunctive relief.

Nothing in this letter shall be construed as relieving you of the obligation to comply with the WQA, the WQCC Regulations and other applicable federal, state, and local laws, regulations, permits or orders. This letter is intended to obtain voluntary compliance in addressing violations of the WQA and WQCC Regulations.

If you have any questions regarding this matter, please contact George Schuman, Program Manager of the Ground Water Pollution Prevention Section, at (505) 827-2945 or Kimberly Kirby at (505) 222-9523.

Sincerely,

George Schuman for W. Olson

William C. Olson, Chief
Ground Water Quality Bureau

WO:KK/kk

enc: Application for a Ground Water Discharge Permit

cc: Marcy Leavitt, Director, Water and Waste Management Division, NMED
Gary Beatty, District Manager, NMED District IV
Tracy Hughes, General Counsel, NMED

United States Department of Agriculture
Food Safety and Inspection Service

Denver District Office of Field Operations
Denver Federal Center, Building 45
PO Box 25387
Denver, Colorado 80225-0387
Telephone: (303) 236-9800
Fax: (303) 236-9794

1-22-2010

Director
New Mexico State Government
Health Department: Roswell Health Office
200 East Chisum Street
Roswell, New Mexico 88203-5412
575-624-6050

Dear Mr./ Ms. :

I am the District Manager for the Denver District of the Food Safety Inspection Service (FSIS). We regulate meat, poultry, and egg products for 10 States and 3 territories out of this office including New Mexico. This week I was in Roswell and made a plant review of Est. 7299, Pecos Valley Meats, located at 3845 Cedarvale Road, Roswell, N.M. 88203-9020. The plant is operated by Mr. Ricardo De Los Santos. Plant phone is 575-662-1214.

The establishment is a slaughter and processing operation primarily for Beef. At this time the firm does custom exempt slaughter and also slaughters and processes under federal inspection. My concern is with his disposal of dead animals. Approximately 200 yards behind the facility, Mr. De Los Santos drags dead cattle (mostly old dairy cows) and piles them on a concrete pad where he leaves them to rot. He calls it "composting", but by all appearances rotting would be more accurate. I am told that during fly season the pile literally moves due to maggots. At some point, he then moves the pile a little further back on his property where there are massive piles with hooves, legs, etc. sticking out. These piles are high-perhaps 15 feet. These piles seem extensive and run along his back property line.

The animals for the most part are dairy cows over 30 months of age. These animals are restricted by our Agency in commerce because of the possibility of Specified Risk Materials (SRMs) that can occur in all beef of any age in tonsils and the distal ileum, and occur in higher percentages in cows over 30 months in brain, skull, eyes, dorsal root ganglia, spinal cord, vertebral column, tonsils, and distal ileum. Inverted Prions in these SRMs may be the causative agent of Bovine Spongiform Encephalitis (BSE) ("Mad Cow Disease"). There are still many things not known for sure about BSE but current science causes us to restrict movement of SRMs. Just behind Mr. De Los Santos's property is an earthen berm and then immediately adjacent is a number of silage pits for a dairy. Science believes that SRMs are accumulated in certain feedstuffs (rendered animal tissue) and are extremely resistant to heat. As cattle ingest SRMs, their potential for developing BSE increases.

Our concern is SRMs leached through the soil into feedstuffs could be a problem. In addition, the potential for extensive fly problems is obvious. Rodents could also be a problem although we have not observed that.

There is also a settling pond regulated by the EPA on this property about 100-125 yards behind the facility. The liquid is red. I assume that is blood from the slaughter plant. Again the fly problem will be extensive and has been extensive in previous years according to reports I receive.

We control the flies immediately adjacent to and in the federal facility. If flies are present, the operation is stopped until the problem is eliminated.

We have discussed this issue with Mr. De Los Santos. He says he will get a front end loader to remove the first pile within 45 days of 1-20-2010. We are doubtful if this will occur. Since his dead pile is off the federal premise, our authority is lessened. We would appreciate your assessment of this problem and any regulation you can impose to get this health hazard eliminated.

Many States have extensive regulations concerning disposal of dead animals, particularly with the advent of Bovine Spongiform Encephalitis and possible human involvement (Creutzfeldt Jacobs Disease- CJD). Lined or limed pits are two alternatives.

In any case, I want to make you aware of the situation, hope you will evaluate it further, and let me know if there is anything you can do to regulate the situation. Thank you for your time.

Sincerely:

Dr. Ron Nelson
Denver District Manager
USDA, FSIS, FO

Ron.Nelson@FSIS.USDA.

NEW MEXICO
ENVIRONMENT DEPARTMENT

Environmental Protection Division
Solid Waste Bureau

SUSANA MARTINEZ
Governor
JOHN SANCHEZ
Lieutenant Governor

1190 St. Francis Drive, Room S2050
P.O. Box 5469
Santa Fe, New Mexico 87502-5469
Telephone (505) 827-0197
Fax (505) 827-2902
www.nmenv.state.nm.us

RAJ SOLOMON
Acting Secretary

Record Number: ENTS 6310

Certified Mail - Return Receipt Requested No. 7008 0500 0001 1245 8061

January 4, 2011

Ricardo De Los Santos, and
Sarah De Los Santos, Owners
Valley Meat Company, LLC
3845 Cedarvale Road
Roswell, New Mexico 88203-9020

Re: Notice of Violation – Valley Meat Company, LLC Composting Facility

Dear Mr. and Mrs. De Los Santos:

On December 9 and 10, 2010, Teri D. Monaghan, Enforcement Officer, Solid Waste Bureau (SWB), New Mexico Environment Department (NMED), inspected Valley Meat Company, LLC's composting facility and related operations (formerly operated as Pecos Valley Meat Company) to determine compliance with the New Mexico Solid Waste Rules (SWR), 20.9.2 – 20.9.10 NMAC. The following violations were observed:

1. **Failure to register a composting facility** – The inspection documented that the Valley Meat Company, LLC failed to register its composting operation. The composting operation utilizes a significant amount of offal (a special waste under the SWR) that is generated at the on-site slaughterhouse. The SWB learned of the facility's questionable composting operations on February 2, 2010, when a complaint was received from the USDA Food Safety & Inspection Service. The SWB first documented the composting operation on May 13, 2010, at which time the registration requirement was discussed and it was agreed that a completed registration would be submitted within two weeks. The SWB has not received a registration application for the facility. The SWR, 20.9.3.27.A(2) NMAC, requires the owner or operator of a composting facility that accepts only source separated compostable materials to file an application for a registration at least 30 days prior to operations and every five years thereafter. In addition, the SWR, 20.9.3.27.A NMAC, states that "[f]acilities covered by this section [20.9.2.27 NMAC] that do not timely file a complete application for registration are hereby deemed unpermitted solid waste facilities, and the owner or operator may be subject to penalties, permit requirements and nuisance abatement orders."

2. **Improper composting of special waste (offal)** – The inspection documented the presence of waste materials, including animal parts (offal), that were protruding or uncovered within the current

compost pile(s). Insufficient use of carbonaceous material, such as manure and/or wood chips, and excessively high piles of compostable material were documented. Such operation represents a potential public nuisance due to odors, increased potential for disease vector harborage, and the potential for insufficiently-composted offal to be improperly utilized or disposed in a manner other than as required for special waste. The SWR, 20.9.2.8.D NMAC, states that "[a]ny person who generates, stores, processes, transports or disposes of solid waste shall do so in a manner that does not create a public nuisance."

3. **Failure to properly dispose of solid waste (old previously-composted material)** – The inspection further documented the presence of abandoned piles of old "composted" material that had been permanently stored upon the ground for several years. This material was located along the southeast property boundary. The SWR, 20.9.2.10.A(1) NMAC, states that no person shall "store, process, or dispose of solid waste except by means approved by the secretary and in accordance with board regulations." The SWR, 20.9.2.10.A(3) NMAC, states that no person shall "dispose of any solid waste in a place other than a solid waste facility that meets the requirements of [the SWR]...".

***Please note that the SWR, 20.9.2.7.D(5) NMAC, defines "dispose or disposal" as "causing, allowing, or maintaining the *abandonment*, discharge, deposit, placement, injection, dumping, burning, spilling, or leaking of any solid waste into or on any land or water." [Emphasis added]

The NMED is seeking your voluntary cooperation in the immediate correction of these violations. Please respond in writing within ten (10) days of receipt of this notice as to what action you have taken, or plan to take, to correct the violations. Your response should include a completed composting facility registration application and a written plan for removal and use or disposal of the abandoned piles of old "composted" material. Send your response to me: c/o Manager, Enforcement Section, Solid Waste Bureau, 1190 St. Francis Drive, P.O. Box 5469, Santa Fe, New Mexico 87502-5469.

The failure to ensure timely corrective action, or evidence of continued non-compliance, will result in additional enforcement action that may include the assessment of a civil penalty of up to $5,000 per day, per violation.

If you have any questions regarding the inspection or the conditions of this letter, please call me at (505) 827-2924, or alternately, you may call Ms. Monaghan (505) 222-9511.

Sincerely,

George W. Akeley Jr. (Chuck)
Manager, Enforcement Section

GWA:tdm

Enclosure – Solid Waste Facility Inspection Report, Abatement Plan Help Sheet, Registration Form

cc: Auralie Ashley-Marx, Chief, Solid Waste Bureau
Terry Nelson, Manager, Permit Section, Solid Waste Bureau
Teri D. Monaghan, Enforcement Officer, EA-I, Solid Waste Bureau
Enforcement Officer, EA-IV, Solid Waste Bureau

EXHIBIT 20

SCHIFF HARDIN LLP
BRUCE A. WAGMAN, ESQ. (CSB #159987)
bwagman@schiffhardin.com
One Market, Spear Street Tower
Thirty-Second Floor
San Francisco, CA 94105
Telephone: (415) 901-8700
Facsimile: (415) 901-8701

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

FRONT RANGE EQUINE RESCUE, THE HUMANE SOCIETY OF THE UNITED STATES, MARIN HUMANE SOCIETY, HORSES FOR LIFE FOUNDATION, RETURN TO FREEDOM, RAMONA CORDOVA, KRYSTLE SMITH, CASSIE GROSS, DEBORAH TRAHAN, and BARBARA SINK,

Plaintiffs,

v.

TOM VILSACK, Secretary, U.S. Department of Agriculture; ELIZABETH A. HAGEN, Under Secretary for Food Safety, U.S. Department of Agriculture; and ALFRED A. ALMANZA, Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture,

Defendants.

Case No.

DECLARATION OF KRYSTLE SMITH

Via Fax

I, Krystle Smith, declare as follows:

1. I am over eighteen years of age and make this statement of my own free will. The statements here of my own personal knowledge or based on information and belief. The facts set forth are true to the best of my knowledge and recollection. If called, I could and would testify to these facts in a court of law.

2. I have lived in Roswell my entire life. My grandmother and mother have also lived in Roswell and southern New Mexico for their entire lives. I have been employed at the Roswell Humane Society for the past seven years.

3. I regularly spend time fishing and camping at Lake Van, which is downstream from Valley Meat, and which is connected to the waterways in proximity of Valley Meat by a series of underground channels that extend all the way to Carlsbad. I have been fishing and camping on Lake Van for years, and plan on continuing to do so, as long as the water and environment are not contaminated.

4. The Pecos River, which is in proximity to Valley Meat, runs all the way through Roswell and surrounding towns including Hagerman, Artesia, and Carlsbad. A series of natural underground streams connect many of the waterways in the area downstream and in the vicinity of Valley Meat.

5. I am informed and believe that Valley Meat has violated New Mexico's and federal requirements regarding the protection of the environment and waterways.

6. I am informed and believe that all horses who will be slaughtered at the Valley Meat facility have all been given multiple drugs and other substances that render their meat adulterated and dangerous, so that the byproducts of Valley Meat's horse slaughter will pollute the surrounding area, including the rivers and streams.

7. If Valley Meat begins horse slaughter, I will be extremely worried about the discharges it is allowing to enter the local waterways, and I will be certain that the water in which I fish is unsafe. I will not be able to eat fish from the river if Valley Meat is slaughtering horses.

8. I eat beef and am aware of the recent scandal in many countries in Europe regarding the cross-contamination of beef with horse meat. I am aware the the USDA has informed the public that cross-contamination of American beef with horse meat is not a problem, because horse meat is not produced in any American facilities.

9. Based on USDA's statement, it will be very reasonable to believe, and I will believe, that if horse slaughter begins in America, then the beef products I would like to buy are cross-contaminated with horse meat. I will experience a very real aesthetic injury if I believe I might be eating horse meat, and I will therefore be forced to stop eating beef, which will cause a significant injury to me. I will caution my family and friends about the chances of cross-contamination of their beef with horse meat, which will harm them as well.

10. My family does a significant amount of camping in the areas near Valley Meat. If Valley Meat begins slaughtering horses, I will stop camping in the area, because I would be able to smell the Valley Meat facility and would concerned that the water in the area was contaminated form the Valley Meat runoff.

11. I am informed and believe that horse slaughter is inherently inhumane and that any method of horse slaughter will cause extreme and unnecessary pain and suffering for the horses involved. If I see horses being taken to Valley Meat, or trucks returning from there with carcasses, I will have an immediate and long-lasting injury from viewing those trucks and animals.

12. As part of my job with the Roswell Humane Society, I travel to a nearby veterinary hospital no less than five times, and usually more times, each week. In order to get to that shelter I must drive right by where the Roswell Livestock Auction Barn is located. Any horses purchased by Valley Meat from the auction would be in plain view of the road I travel. If Valley Meat is slaughtering horses, I will be directly confronted with the view of the horses in holding pens and transport trucks waiting to be transported to Valley Meat for slaughter. These images will cause me intense aesthetic injury. I will be frightened to go past the facility, and will have to be sure that my family does not go past the facility.

13. If Valley Meat begins slaughtering horses, I will also surely be driving behind horses being carried to slaughter, which will be extremely jarring to my senses.

14. If Valley Meat begins slaughtering horses, the stench will carry into Roswell on a regular basis, especially with our intense summer heat, and will seriously affect my ability to enjoy my work, my life, and my ability to enjoy the surrounding parks and rivers and streams, which will all likely be affected by the contamination by Valley Meat from horse slaughter.

15. The local livestock auction is approximately two miles from my home. I see livestock trucks going past my work two to three times each day.

16. If livestock trucks carrying horses begin to drive past my work, I will be deeply affected because I will know that those horses are going to an inhumane death in the

slaughterhouse, and because the offal and remains of those horses will pollute the ground around the facility and wherever else they are dropped, which could affect the entire community.

17. Because of the possibility that runoff from Valley Meat will get into the local waterways and eventually into the Pecos River, if horse slaughter starts at Valley Meat I will end my longstanding practice of fishing in Lake Van. This will cause me great injury and distress.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 27 day of June 2013, in Roswell, New Mexico.

Krystle Smith

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

FRONT RANGE EQUINE RESCUE, THE HUMANE SOCIETY OF THE UNITED STATES, MARIN HUMANE SOCIETY, HORSES FOR LIFE FOUNDATION, RETURN TO FREEDOM, RAMONA CORDOVA, KRYSTLE SMITH, CASSIE GROSS, DEBORAH TRAHAN, and BARBARA SINK,

Plaintiffs,

v.

TOM VILSACK, Secretary, U.S. Department of Agriculture; ELIZABETH A. HAGEN, Under Secretary for Food Safety, U.S. Department of Agriculture; and ALFRED A. ALMANZA, Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture,

Defendants.

Case No.

DECLARATION OF DEBORAH TRAHAN

Via Fax

I, Deborah Trahan, declare as follows:

1. I am over eighteen years of age and make this statement of my own free will. The statements here of my own personal knowledge or based on information and belief. The facts set forth are true to the best of my knowledge and recollection. If called, I could and would testify to these facts in a court of law.

2. I have lived in Roswell more than ten years.

3. I am disabled, and suffer from both rheumatoid arthritis and osteoporosis and degenerative bone disease. It is my experience that my autoimmune diseases are exacerbated by increases in stress and even subtle changes in diet.

4. I live within ten miles of the Valley Meat facility.

5. The natural beauty and healthy waterways in the area of Valley Meat are a vital part of my appreciation of the area. I am informed and believe that Valley Meat has violated New Mexico's and federal requirements regarding the protection of the environment and waterways.

6. My family does a significant amount of camping in the areas near Valley Meat. If Valley Meat begins slaughtering horses, I will stop camping in the area, because I would be able to smell the Valley Meat facility and would be concerned that the water in the area was contaminated form the Valley Meat runoff.

7. I am informed and believe that all horses who will be slaughtered at the Valley Meat facility have been given multiple drugs and other substances that render their meat adulterated and dangerous, so that the byproducts of Valley Meat's horse slaughter will pollute the surrounding area, including the rivers and streams.

8. Fish is an important part of my diet, and I believe the incorporation of fresh fish into my diet is important as a dietary treatment for all of three of the diseases mentioned in Paragraph 3. If Valley Meat begins slaughtering horses and discarding the byproducts of that process, I will no longer be able to eat the fish from our local waterways, for fear of triggering an exacerbation of my disease.

9. A series of natural underground streams connect many of the waterways in the area downstream and in the vicinity of Valley Meat. If Valley Meat begins horse slaughter, I will be extremely worried about the discharges it is allowing to enter the local waterways.

10. I eat beef and am aware of the recent scandal in many countries in Europe regarding the cross-contamination of beef with horse meat. I am aware that the USDA has informed the public that cross-contamination of American beef with horse meat is not a problem, because horse meat is not produced in any American facilities.

11. Based on USDA's statement, it will be very reasonable to believe, and I will believe, that if horse slaughter begins in America, then the beef products I would like to buy are cross-contaminated with horse meat. I will experience a very real aesthetic injury if I believe I might be eating horse meat, and I will therefore be forced to stop eating beef, which will cause a significant injury to me. I will caution my family and friends about the chances of cross-contamination of their beef with horse meat, which will harm them as well.

12. I am informed and believe that horse slaughter is inherently inhumane and that any method of horse slaughter will cause extreme and unnecessary pain and suffering for the horses involved. If I see horses being taken to Valley Meat, or trucks returning from there with carcasses, I will have an immediate and long-lasting injury from viewing those trucks and animals.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 1st day of July 2013, in Roswell, New Mexico.

/s/ Deborah Trahan
Deborah Trahan

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

FRONT RANGE EQUINE RESCUE, THE HUMANE SOCIETY OF THE UNITED STATES, MARIN HUMANE SOCIETY, HORSES FOR LIFE FOUNDATION, RETURN TO FREEDOM, RAMONA CORDOVA, KRYSTLE SMITH, CASSIE GROSS, DEBORAH TRAHAN, and BARBARA SINK,

Plaintiffs,

v.

TOM VILSACK, Secretary, U.S. Department of Agriculture; ELIZABETH A. HAGEN, Under Secretary for Food Safety, U.S. Department of Agriculture; and ALFRED A. ALMANZA, Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture,

Defendants.

Case No.

DECLARATION OF CASSIE GROSS

Via Fax

I, Cassie Gross, declare as follows:

1. I am over eighteen years of age and make this statement of my own free will. The statements here of my own personal knowledge or based on information and belief. The facts set forth are true to the best of my knowledge and recollection. If called, I could and would testify to these facts in a court of law.

2. I have lived in Roswell for over thirty years, and have worked for the Roswell Humane Society for twenty years.

3. I currently live with my husband, two sons aged seven and twelve, and my father-in-law. My sons attend public school in Roswell.

4. I live within ten miles of the Valley Meat facility.

5. Roswell has an international fame based on the reported sighting of UFOs in Roswell in 1947. It is home to the International UFO Museum and Research Center, and an annual Roswell UFO Festival that brings substantial income to the city.

6. If people learn that Roswell is home to a horse slaughterhouse, I am informed and believe that tourism will be severely affected if Valley Meat is allowed to begin slaughtering horses in Roswell. Because of the negative sentiment about horse slaughter of a large majority of New Mexican citizens and all Americans, tourism will significantly drop this year and in future years, impacting many programs dependent on Roswell public funding.

7. If Valley Meat opens its slaughterhouse, funding for the public schools where my sons go, as well as other municipal privileges and benefits, will be reduced, injuring me and my family in a variety of ways.

8. If horse slaughter comes to Roswell, merchants will also lose significant income which comes in from tourists visiting Roswell all year long and especially for the Festival, and will need to raise prices. This will also cause me economic harm based on the increased prices merchants will need to charge.

9. I am an organic gardener, and I fish with friends and family at Lake Van and the Pecos River, which are close to Valley Meat. The natural beauty and healthy waterways in the area of Valley Meat are a vital part of my appreciation of the area, and I enjoy eating the fish I catch.

10. I am informed and believe that Valley Meat has violated New Mexico's and federal requirements regarding the protection of the environment and waterways.

11. I am informed and believe that all horses who will be slaughtered at the Valley Meat facility have been given multiple drugs and other substances that render their meat adulterated and dangerous, so that the byproducts of Valley Meat's horse slaughter will pollute the surrounding area, including the rivers and streams, as well as the air quality in our town.

12. A series of natural underground streams connect many of the waterways in the area downstream and in the vicinity of Valley Meat.

13. If Valley Meat begins horse slaughter, I will be extremely worried about the discharges it is allowing to enter the local waterways, and I will be certain that the water in which I fish is unsafe. I will not be able to eat fish from the river if Valley Meat is slaughtering horses.

14. I eat beef and am aware of the recent scandal in many countries in Europe regarding the cross-contamination of beef with horse meat. I am aware the the USDA has informed the public that cross-contamination of American beef with horse meat is not a problem, because horse meat is not produced in any American facilities.

15. Based on USDA's statement, it will be very reasonable to believe, and I will believe, that if horse slaughter begins in America, then the beef products I would like to buy are cross-contaminated with horse meat. I will experience a very real aesthetic injury if I believe I might be eating horse meat, and I will therefore be forced to stop eating beef, which will cause a significant injury to me. I will caution my family and friends about the chances of cross-contamination of their beef with horse meat, which will harm them as well.

16. My family does a significant amount of camping in the areas near Valley Meat. If Valley Meat begins slaughtering horses, I will stop camping in the area, because I would be able to smell the Valley Meat facility at various campsites in that area, as well as in town, and would concerned that the water in the area was contaminated form the Valley Meat runoff.

17. I am informed and believe that horse slaughter is inherently inhumane and that any method of horse slaughter will cause extreme and unnecessary pain and suffering for the horses involved. If I see horses being taken to Valley Meat, or trucks returning from there with carcasses, I will have an immediate and long-lasting injury from viewing those trucks and animals.

18. As part of my job with the Roswell Humane Society, I travel to a nearby veterinary hospital no less than three times, and usually more times, each week. In order to get to that clinic, I must drive right by the Roswell Livestock Auction Barn, where any horses sold to Valley Meat will be trucked and temporarily kept. If Valley Meat is slaughtering horses, I will be directly confronted with the horror of the horses in holding pens waiting to be sent to Valley Meat to be slaughtered. I

will be forced to see trucks loaded with horses, on their way to their death. These images will cause me intense aesthetic injury. I will be frightened to go past the facility, and will have to be sure that my children do not go past the facility.

19. If Valley Meat begins slaughtering horses, I will surely be driving behind horses being carried to slaughter, which will be extremely jarring to my senses.

20. If Valley Meat begins slaughtering horses, the stench from the plant will come over me on a daily basis, as winds from the South come into town consistently. The intense heat in the area, will make the odors much worse and will seriously affect my ability to enjoy my work and my activities of daily life, and it will also ruin my ability to enjoy the surrounding parks and rivers and streams, which will all likely be affected by the contamination by Valley Meat from horse slaughter.

21. If Valley Meat begins to slaughter horses, I may be forced to move away from Roswell and start over in another town. I enjoy living in Roswell, where I have lived for over thirty years, but with the significant turmoil this horse slaughter will cause me, it makes me think I may have to move my family elsewhere. I've worked hard to get where I am today, in the position I hold in my job, and my family's placement in my community, and I'm afraid I won't be able to handle living in a town that slaughters horses.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 27th day of June 2013, in Roswell, New Mexico.

Cassie Gross

Cassie Gross

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Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

FRONT RANGE EQUINE RESCUE, THE HUMANE SOCIETY OF THE UNITED STATES, MARIN HUMANE SOCIETY, HORSES FOR LIFE FOUNDATION, RETURN TO FREEDOM, RAMONA CORDOVA, KRYSTLE SMITH, CASSIE GROSS, DEBORAH TRAHAN, and BARBARA SINK,

Plaintiffs,

v.

TOM VILSACK, Secretary, U.S. Department of Agriculture; ELIZABETH A. HAGEN, Under Secretary for Food Safety, U.S. Department of Agriculture; and ALFRED A. ALMANZA, Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture,

Defendants.

Case No.

DECLARATION OF RAMONA (LISA) CORDOVA

Via Fax

I, Ramona (Lisa) Cordova, declare as follows:

1. I am over eighteen years of age and make this statement of my own free will. The statements here of my own personal knowledge or based on information and belief. The facts set forth are true to the best of my knowledge and recollection. If called, I could and would testify to these facts in a court of law.

2. I was born and raised in Roswell, New Mexico, and have lived here for almost all of my life. My parents, brother, aunts, uncles and cousins all live here, and we are all proud of Roswell's reputation and community.

3. I work in the Human Resources Department of Eastern New Mexico University's Roswell campus.

4. My family and I are integrally connected to Roswell and its surrounding areas. A vital part of our sense of community and family structure comes from our love of the surrounding parks and lakes and natural structures in proximity to Roswell, and our ability to appreciate the town and the natural environment.

5. I live less than ten miles from the Valley Meat facility.

6. I engage in gardening, walking around the Roswell community, and some hiking. My family goes to the parks in proximity to the Valley Meat facility, including Bottomless Lakes State park and others.

7. My family also engages in recreation and fishing on the Pecos River, which runs close to Valley Meat. We have been doing these activities for years and will continue to do them. A tributary of the Pecos River, the Spring River Canal, runs very close to Valley Meat and I am informed and believe that there are storm water runoff ditches that drain from Valley Meat into the Spring River Canal.

8. I am informed and believe that all horses who will be slaughtered at the Valley Meat facility have all been given multiple drugs and other substances that render their meat adulterated and dangerous, so that the byproducts of Valley Meat's horse slaughter will pollute the surrounding area, including the rivers and streams.

9. I am informed and believe that horse slaughter is inherently inhumane and that any method of horse slaughter will cause extreme and unnecessary pain and suffering for the horses involved. If I see horses being taken to Valley Meat, or trucks returning from there with carcasses, I will have an immediate and long-lasting injury from viewing those trucks and animals.

10. I regularly see the trucks carrying cows and other animals to the local livestock auction. If I see horses on their way to the auction and then to slaughter at Valley Meat, I my appreciation of my community and the proud nature of being a Roswell citizen will be immediately and permanently altered. If I see horses trucked to slaughter, I will be deeply affected and experience immediate harm.

11. Because the road out from Valley Meat will likely cross the paths I regularly take, if Valley Meat begins slaughtering horses, I will likely see the trucks bringing horse carcasses to market. This sight will affect me deeply and will likely cause me physical symptoms, as well as aesthetic injury from the sight of the trucks carrying dead horses.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 1st day of July 2013, in Roswell, New Mexico.

/s/ Ramona (Lisa) Cordova
RAMONA (LISA) CORDOVA

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Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

FRONT RANGE EQUINE RESCUE, THE HUMANE SOCIETY OF THE UNITED STATES, MARIN HUMANE SOCIETY, HORSES FOR LIFE FOUNDATION, RETURN TO FREEDOM, RAMONA CORDOVA, KRYSTLE SMITH, CASSIE GROSS, DEBORAH TRAHAN, and BARBARA SINK,

Plaintiffs,

v.

TOM VILSACK, Secretary U.S. Department of Agriculture; ELIZABETH A. HAGEN, Under Secretary for Food Safety, U.S. Department of Agriculture; and ALFRED A. ALMANZA, Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture,

Defendants.

Case No.

DECLARATION OF BARBARA ANN SINK

Via Fax

I, Barbara Ann Sink, declare as follows:

1. I am over eighteen years of age and make this statement of my own free will. The statements here of my own personal knowledge. The facts set forth are true to the best of my knowledge and recollection. If called, I could and would testify to these facts in a court of law.

2. I have a strong interest in the protection and welfare of horses. For approximately seventeen years, I lived at a residence that ran a boarding house and refuge for horses and other animals. When I was younger, I spent much of my free time on a horse ranch where learned to love and appreciate horses.

3. For two years, I was a civil engineer with a specialty in environmental support in the United States Air Force. In this position, I monitored water quality, water supply, wastewater, and water contaminants in the workplace, community, and surrounding environment. Water quality is a passion of mine, and I have continued to study and stay apprised of water quality and sewage issues near my home.

4. I have lived in the Gallatin, Missouri area for nearly thirteen years. My home is located at 502 West Van Buren Street in Gallatin, approximately three miles from the Rains Natural Meats facility.

5. I chose to move to Gallatin specifically because of its particular environmental qualities, including its natural beauty, clean air, and healthy waterways. Because of the dangerous nature of horsemeat and the inherent problems with horse slaughter, if Rains Natural Meats begins slaughtering horses in Gallatin, my appreciation of Gallatin's environmental aspects will be negatively impacted, and my quality of life will be significantly decreased. If slaughter operations begin, I will see it as a blight to my community and will want to seek out another place to live.

6. I am informed and believe that horse slaughter is inherently inhumane and that any method of horse slaughter causes extreme pain and suffering for the horses involved. If Rains Natural Meats begins slaughtering horses, I will be extremely upset and will be disturbed by the knowledge that this brutal activity is taking place so close to my home.

7. Fishing and gardening are my greatest enjoyments in life. I often spend time fishing in the Grand River, which flows downstream from Rains Natural Meats, approximately one mile away. The stream adjacent to Rains Natural Meats flows directly into the Grand River. I currently eat the fish I catch. If Rains Natural Meats begins slaughtering horses at its facility, I

will stop fishing locally and will stop eating locally caught fish, because I would be concerned that the water in the area was contaminated from the runoff from the slaughter facility.

8. I often take my children and grandchildren to nearby lakes, rivers, and streams to swim, hike, play, and fish. If Rains Natural Meats begins slaughtering horses, I will stop bringing my family to these areas, because I would be concerned that the water in the area was contaminated from the runoff from the slaughter facility.

9. I drive through Gallatin often. I also drive to Jamesport to shop at the Amish markets. The quickest route from home to Jamesport is to drive past the Rains Natural Meats facility. If Rains Natural Meats begins slaughtering horses, I will see the trucks with horses being carried to slaughter if I drive to Jamesport along this route. I will also be seeing vehicles that are trucking away the remains and parts of horses which are being carried to landfills as well as the horse flesh they wish to sell. In order to avoid seeing these vehicles and to avoid passing by the slaughter house, I would have to drive to Jamesport via Hamilton, which is twenty miles round trip out of my way. If I see horses being taken to Rains Natural Meats, or trucks returning from there with carcasses, I will have an immediate and long-lasting injury from viewing those trucks and animals. This sight will cause a real harm to my aesthetic interests.

10. Based on what I have been informed and understand about horse slaughter facilities that have previously existed in this country, I also know that they emit a strong noxious stench, which I will smell when I am in town, and which will seriously detrimentally impact my ability to enjoy my life and my community.

11. A livestock auction is located approximately four blocks from my home. I regularly see trucks carrying cows and other livestock to this auction. However, I view horses as distinct from other livestock, because horses are companion animals that are extensions of the human race. Therefore, if I see horses on their way to the auction and then to slaughter at Rains Natural Meats, I will suffer distress, and my appreciation of my community and the proud nature of being a Gallatin citizen will be immediately and permanently altered.

12. I am informed and believe that all horses who will be slaughtered at the Rains Natural Meats facility have been given multiple drugs and other substances that render their meat

adulterated and dangerous, so that the byproducts of Rains Natural Meats' horse slaughter will pollute the surrounding area, including the rivers and streams near our home.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 1st day of July 2013, in Gallatin, Missouri.

/s/ Barbara Ann Sink
BARBARA ANN SINK

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Plaintiffs,

v.

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Defendants.

Case No.

DECLARATION OF LAWRENCE STEVEN SEPER

Via Fax

I, Lawrence Steven Seper, declare as follows:

1. I am over eighteen years of age and make this statement of my own free will. The statements here of my own personal knowledge. The facts set forth are true to the best of my knowledge and recollection. If called, I could and would testify to these facts in a court of law.

2. I am a member of The Humane Society of the United States, which is a plaintiff in the above-titled action. I joined the HSUS so that it would represent my interests on animal protection issues, such as the slaughtering of horses at the Rains Natural Meats plant.

3. I have lived in the Gallatin, Missouri area for nearly three years. My home is located at 502 West Van Buren Street in Gallatin, approximately three miles from the Rains Natural Meats facility.

4. I was drawn to live in Gallatin in particular because of the area's natural beauty and its unpolluted air and waterways. Because of the toxicity of horsemeat and the environmental and animal welfare concerns inherent with horse slaughter, if Rains Natural Meats begins slaughter operations in Gallatin, my appreciation of the Gallatin area will be negatively affected, and my quality of life will be significantly reduced.

5. I am informed and believe that all horses who will be slaughtered at the Rains Natural Meats facility have been given multiple drugs and other substances that render their meat adulterated and dangerous, so that the byproducts of Rains Natural Meats' horse slaughter will pollute the surrounding area, including the rivers and streams near our home.

6. I usually eat the fish that my fiancé catches in the Grand River, which flows downstream from Rains Natural Meats. If Rains Natural Meats begins horse slaughter operations, I will stop eating locally caught fish, out of fear that the water has been contaminated from the Rains Natural Meats facility's runoff.

7. Based on what I have been informed and understand about horse slaughter facilities that previously operated in the U.S., I know that they emit a strong, noxious stench, which I will smell when I am in town, and which will seriously, detrimentally impact my ability to enjoy my life and my community.

8. I often drive through Gallatin and sometimes drive to the Amish markets in Jamesport. The fastest route from my home to Jamesport is to pass by Rains Natural Meats. The second best route to Jamesport is to drive through Hamilton, which adds twenty miles to the entire trip. If Rains Natural Meats begins slaughtering operations, I will see trucks with horses being carried to slaughter along the quickest route to Jamesport. On this route, I will also see

vehicles trucking away the remains and parts of horses being carried to landfills as well as the horse flesh that the slaughter plant wishes to sell. In order to avoid seeing these vehicles and to avoid passing by the slaughter house, I must take the longer route to Jamesport via Hamilton. Seeing horses being taken to Rains Natural Meats, or trucks returning from there with carcasses, will cause an immediate and long-lasting injury. This sight will cause a real harm to my aesthetic interests.

9. I am informed and believe that horse slaughter is inherently inhumane and that any method of horse slaughter causes extreme pain and suffering for the horses involved. If Rains Natural Meats begins slaughtering horses, I will be extremely upset and will be disturbed by the knowledge that this brutal activity is taking place so close to my home.

10. A livestock auction is located approximately four blocks from my home. I regularly see trucks carrying cows and other livestock to this auction. If Rains Natural Meats begins horse slaughter operations, I will see horses on their way to the auction and then to slaughter at Rains Natural Meats. Because I view horses as companion animals that are unique from any other livestock animal and that should not be slaughtered in any circumstance, I will suffer distress, and my appreciation of my community and the proud nature of being a Gallatin citizen will be immediately and permanently altered.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 1st day of July 2013, in Gallatin, Missouri.

/s/ Lawrence Steven Seper
LAWRENCE STEVEN SEPER

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