Exhibit 15

http://www.chow.com/food-news/53692/they-eat-horses-dont-they/

CHOW* : *TOP STORIES* : *FEATURE

They Eat Horses, Don't They?

Published on Friday, November 17, 2006 by **nicholassday**

65 Comments

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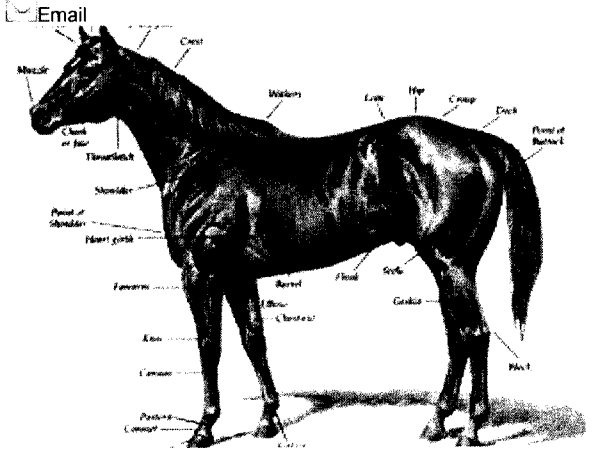


Ask a restaurant if it serves horsemeat, and you might as well be asking if the chef's sleeping with his sister.

"Oh, no, no, no," says the receptionist at Café des Bruxelles, a Belgian restaurant in New York City. "It's against the law in New York, isn't it?"

It isn't: Eating horsemeat in America is perfectly legal, according to Steven Cohen of the USDA's food safety and inspection service. If it seems wrong, that's not the law—that's, well, you. But bear in mind that the Japanese and many Europeans eat all kinds of horse: horse sashimi in Japan; horse tartare or steak in Belgium; *pastissada*, or horsemeat stew, in Italy's Veneto. Fears of mad cow disease in recent years prompted a spike in horsemeat prices in Germany and Italy.

If it seems wrong, that's not the law—that's, well, you.

Our taboo against horsemeat hasn't stopped the industry from responding to this fondness for it elsewhere. Horses aren't raised in the United States for domestic consumption, but upwards of 80,000 horses are slaughtered here each year for export. A bill passed by the U.S. House of Representatives (and pending in the Senate) would end that practice by banning all horse slaughtering, and transport for slaughtering, in America. The law says, in effect: Eating horsemeat is so repulsive that we'll stop other people from doing it.

What's behind such a visceral reaction?

Let's start with where these controversial horse cuts come from: No horse in America is raised for meat. Horses are treated as either pets or work animals. If they're working, it's likely at a racetrack. That's why the horse racing industry is the force behind the anti-slaughter legislation. "It's a big issue," says Ted McClelland, author of a book on the industry, *Horseplayers: Life at the Track* (Chicago Review Press, 2005). "It's considered something that would give the industry a bad name. There is a feeling that the horse worked hard to entertain the public and should get a nice retirement—it shouldn't be a piece of meat." The industry has littered Congress and the media with

polls finding that the vast majority of Americans oppose horse slaughtering. Their contention is that the affection Americans have for horses distinguishes those animals from meat animals like cows or pigs.

But does affection explain everything? After all, a lot of us have affection for bacon *and* Wilbur of *Charlotte's Web*. Eating horse is often likened to eating a companion animal—"dog" is the first word on the lips of most ban supporters. But although a taboo against eating cats and dogs is widely shared, horsemeat is far more common. It's true that the Anglophone countries of Britain, Australia, and the United States share a mysterious aversion to it. But in Canada, a country rarely considered exotic, you can get raw horse in Vancouver (at Yoshi's, a Japanese restaurant), horse steak in Toronto (at the bistro La Palette), and horse anything in Quebec—even a fast-food chain, the Belgian Frite Alors, sells horse tartare. (Horse is free of tuberculosis and tapeworms, and thus safer than beef to eat raw.)

If Americans make a sentimental exception for horses, that isn't more ethical, says Jay Weinstein, the author of *The Ethical Gourmet* (Broadway, 2006). "Horses are beautiful creatures, but there's beauty in so many animals and that's not really a just criteria," he says. "If you're going to eat meat, you can't pick and choose which animals you're going to eat and which ones you're not." For him, livestock for food and livestock repurposed for food are ethically one and the same.

Weinstein would argue that our get-out-of-dinner card for horses isn't moral or consistent. It's simply cultural. But why? "Eating it goes against the cowboy mythology," says Rob Walsh, the restaurant critic for the *Houston Press* and a self-described "culinary thrill seeker." Walsh is working on *The Texas Cowboy Cookbook*, and he suspects that cowboys and the role that horses played in the nation's history might be behind the taboo. Inversely, he also thinks that's why Europeans *do* eat horse: "The cowboy culture came from Spain in the 11th century. In Europe, the vast majority never rode horses." That's why, say, Slovenians are able to swallow foal carpaccio: horses didn't show up in their third-grade history textbooks. Walsh may have an explanation, but he doesn't really understand it himself. "It never ceases to amaze me that Texans love venison sausage but are appalled by horse sausage." (Yes, he's had horse before—in France. His verdict? "It was delicious.")

Roberto Passon, the Italian-born chef of the eponymous New York restaurant, also loves the taste. Passon emphasizes a key point: Since Americans have never had to eat horse, unlike the historically impoverished peasantry of Europe, the meat's never become normalized. "If we train Americans, they would eat it," he says. Asked if he would serve horsemeat to New Yorkers if they'd order it, Passon is enthusiastic: "Oh, definitely." Horse is typically compared to beef—although it is lighter and less fatty—and Passon, who loves its taste, likens its texture to that of skirt steak. "It's very sweet and it's very bloody," he adds. Traveling in Italy recently, he purchased a horse salami, or *salami di cavallo*. (Horsemeat was traditionally used for sausage in Italy's north.) "I compared it to

the pork one, and it was ten times better," he says. "I gave it to my partner, and he's like, this is the best sausage I've ever had. And I said, you're right. That's because it's horse."

No matter how tasty the salami di cavallo was, a lot of Americans would still consider that a nasty practical joke. I asked the butcher at Mitsuwa Market, a massive Japanese supermarket outside Chicago, if he ever had any he could sell. Although the Japanese have no aversion to eating horse, he seemed to suspect a prank. "Uh, what do you want it for?" he said. Well, to cook it, I said.

Pause.

"What sort of cook *are* you?"

Exhibit 16

http://www.foodsafetynews.com/2011/10/horse-slaughter-issue-wont-go-away/

Food Safety News

Horse Slaughter Issue Won't Go Away

by Dan Flynn | Oct 25, 2011

In the nearly five years since the last legal horse slaughterhouses in the United States shut down, strange events keep happening in Florida's C-9 Basin, north of Okeechobee Road and west of the Florida Turnpike.

This time, Miami-Dade police are investigating the illegal sale of horse meat, specifically a brown bay thoroughbred they found without legs and with its heart cut out.

Neighbors who heard noises and saw the carcass called police back to the isolated area where evidence of slaughtered horses has been found before, including last year.

In the most recent case, police are benefiting from a tattooed identification number on the upper lip of the six-year old racehorse. "This could have been the best race horse ever, Richard Couto of the Animal Recovery Mission, told the Miami Herald. "We just don't know who she was yet."

Couto's Animal Recovery Mission focuses exclusively on the horse meat trade in South Florida.

The C-9 Basis is a mix of small farms, wetlands, and trailer parks., where 21 horse carcasses were found in 2009, a year when joint task forces shut down 70 illegal horse slaughter operations.

Couto says horse meat can go for as much as $40 a pound in South Florida with some demand for its medicinal value and others who see it as a delicacy. He said the horse was still alive when its heart was removed and died from slowly bleeding to death.

While its been nearly five years since the last legal horse slaughterhouses in the U.S. shut down, the Animal Law Coalition estimates that somewhere between 60,000 and 100,000 horses a year are exported -- mostly to Mexico and Canada -- for slaughter for human consumption.

That's roughly the range that were previously slaughtered annually by the last three domestic slaughter operations, two in Texas and one In Illinois.

America's Cowboy Culture has long spared the horse from the menu, but in much of Europe and Asia "Mr. Ed" is seen as just another choice for dinner.

Congress, which helped bring about the closure of domestic slaughterhouses without exactly making it illegal, is now getting involved in the issue again.

Sen. Mary Landrieu, D-LA, and Sen. Lindsey Graham, R-SC, have introduced S.B. 1176, which would prohibit the sale or transport of horses or equine parts in interstate or foreign commerce with intent of processing for human consumption.

And earlier this year, an House amendment to the appropriations bill continues to de-fund inspections required for horses bound for slaughter for human consumption.

In rural America, however, states are moving in a different direction with Arkansas, Montana, Nebraska and North Dakota among those moving toward horse meat production under state regulation. Rural states are concerned about a crisis over horse populations, with expensive euthanasia and disposal the only option.

In Colorado, with more than 250,000 horses, a state group called the Colorado Unwanted Horse Alliance conducted a formal Environmental Assessment. It found the horse crisis is due both to closure of the U.S. plants processing horses and the worsening economic conditions.

The Unwanted Horse Alliance said the state's horse rescue facilities are full, sanctuaries are full, and euthanasia options are "limited and expensive."

Colorado's humane officers and sheriffs are reporting more horse surrender and abandonment, said the alliance's environmental assessment. It call for more options and resources for cost effective euthanasia and increased rescue capacity.

Just as it did five years ago, the horse slaughter issue largely pits animal rights groups against animal agriculture.

Wayne Pacelle, president and chief executive of the Human Society of the United States (HSUS), recently wrote: "Today's apologists for cruelty are most sophisticated and deceptive, now laying claim to the argument that they are best defenders of animals, and that when it comes to caring for them, they know best."

For its part, horse country did an online petition asking the Obama Administration to restore horse slaughter for human consumption in the U.S., an action they said would "improve horse welfare, stop needless and wasteful suffering of horses and even create jobs."

No incident of foodborne illnesses from horse meat can be found on the Foodborne Illness Outbreak Data Base.

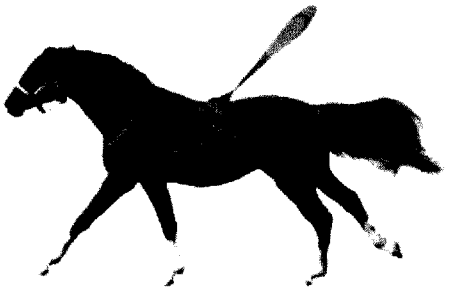
Exhibit 17

Slaughtering horses for meat is banned in the U.S. Why?

By Brian Palmer | Posted Monday, Oct. 24, 2011, at 7:04 PM ET
| Posted Monday, Oct. 24, 2011, at 7:04 PM ET

The Delicious Mr. Ed

Why don't Americans eat horse meat?



Americans have an aversion to eating horses, but the practice is common in Europe

Photo illustration by Holly Allen. Horse and fork images by Thinkstock.

Slaughtering horses for food has been prohibited in the United States since 2007, but animal rights advocates and ranchers continue to argue over the ban. A report (PDF) from the Government Accountability Office released in June says the prohibition merely shifted horse slaughter abroad, where consumers aren't so squeamish about equine dining. Why don't Americans eat horse?

Because we love our beasts of burden. As with many food taboos, there's no settled explanation for why most Americans are perfectly willing to eat cows, pigs, and chickens but turn their noses up at horse. Horse-eating, or hippophagy, became popular in Europe in the 19th century, when famines caused several governments to license horse butcheries. Today, horse meat is most widely available in France, Belgium, and Sweden, where it outsells mutton and lamb combined. While Americans have occasionally consumed their equine friends during times of scarcity, the practice just didn't catch on. It may be that so many Americans forged intimate relationships with horses during our founding and expansion that eating the creature seemed morally wrong by the time of the nation's major food shortages of the 20th century.

Hippophagy may have become somewhat popular in industrial Europe, but it had been taboo there for at least a millennium before. We know because Pope Gregory III wrote a letter to Boniface, an eighth-century bishop in Germany, instructing him to eliminate the practice among pagan converts. The pope described hippophagy as a "filthy and abominable custom." (Also, horses aren't kosher.) The popular view among historians is that banning horse-eating helped distinguish Christians from the pagans, but some think the pope's real motivation was to preserve horses for warfare. Around the same time, the Irish Collection of Canon law sought to end the Celtic and Teutonic habit of eating horse, forcing violators to subsist on bread and water for four years.

Americans looked on with curiosity as Europeans went back to horse meat in the 1800s. It had become so common by the end of the century that Scientific American published an article in 1892 remarking on the popularity of horse in France, the Netherlands, Germany, Sweden, Switzerland, and Milan. (Residents of Turin apparently hated the stuff.) While Americans wanted no part of hippophagy, they were perfectly willing to supply the raw materials. In 1899, the USDA engaged in a contentious exchange with a Norwegian paper that complained American inspectors rarely visited horse meat factories, because they didn't sell domestically.

U.S. hippophagy seems to have reached its high point during and shortly after World War II, because of domestic shortages of other, more conventional meats. Horse steak was even on the menu at the Harvard faculty club, although ordinary Americans never fully embraced it. After publishing an article about the growing popularity of horse meat in 1943, Life got a series of pithy letters to the editor. One reader wrote: "If your illustrated article on horse meat is followed by one showing how to make chicken chitterlings, the meat problem will be solved. We'll all be vegetarians." Another responded: "Not this side of starvation. Not while there are beans." (One hippophagy enthusiast suggested that the problem was horse doesn't have a dinner table euphemism like "beef" or "pork.")

Some horse-eaters say the meat tastes like beef, only slightly sweeter and more tender. (Other gourmets are less impressed.) During a meat shortage in 1946, American housewives reportedly tried to fool their husbands by swapping the cheaper and more widely available horse for beef.

Bonus Explainer: Is horse meat good for you? It's a little better than beef. A three-ounce serving of roast horse has 149 calories, 24 grams of protein, and five grams of fat. The same amount of beef tenderloin has 179 calories, 24 grams of protein, and nine grams of fat. Horse milk, which some Central Asians drink in fermented form, has one-third the fat of cow's milk.

Got a question about today's news? Ask the Explainer.

Explainer thanks Richard Bulliet of Columbia University and Adrienne Hall of Drexel University.*

Correction, Oct. 25, 2011: This article originally misspelled the first name of Adrienne Hall.

Exhibit 18

November 3, 2010

At Breeders' Cup, a Volatile Mix of Speed and Drugs

By JOE DRAPE

LOUISVILLE, Ky.

You cannot hold a Breeders' Cup, a series of championship races for the world's best horses, without the issue of medications and illegal drugs coming up. John Gosden is among many European trainers who are critical of how permissive and harmful American medication rules are for horses.

Yet one of his Breeders' Cup Turf contenders, Debussy, will run on the diuretic Lasix, which is banned just about everywhere outside the United States on race days. Of the more than 20 European horses, all but 4 will use the drug, including Goldikova, who is favored to win the Mile for a third consecutive time. It is rare for American horses not to use the drug in a race.

If they do not use Lasix, European trainers say, they are giving their American competitors a clear advantage. 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. The California-based trainer Doug O'Neill, for example, is saddling one of the entrants in the Juvenile Turf Sprint on Saturday.

Twice this year, his horses exceeded the threshold level for total carbon dioxide in a postrace test, which indicates a horse may have been given a concoction of baking soda, sugar and electrolytes known as a milkshake. It is administered by shoving a tube down a horse's throat and is intended to help the animal ward off fatigue. O'Neill was suspended and fined in one instance and is awaiting a hearing on the other.

But O'Neill is hardly a stranger to medication violations. He averages one per every 807 starts by his horses, according to records compiled from the Association of Racing Commissioners International and entered in a database.

O'Neill is not the worst offender among those saddling horses at Churchill Downs on Friday and Saturday for the 14 Cup races, which have purses worth a total of $26 million. Richard

Dutrow Jr., who has horses in six races, averaged a medication violation every 343 starts. John Sadler, who has horses in four races, including Tell a Kelly in the Juvenile Fillies, was cited for a medication violation every 478 starts, according to the data base.

In fact, of the top 20 trainers in the United States by purses won, only two — Christophe Clement and Graham Motion — have never been cited for a medication violation. The American thoroughbred industry knows it has a drug problem, and it is beginning to raise some standards to address it.

"While the development and enforcement of drug rules routinely and correctly fall under the purview of state racing commissions alone, the Jockey Club believes that there is no place in this sport for anyone who repeatedly violates drug rules," said James L. Gagliano, president and chief operating officer of the Jockey Club. "Bettors are the lifeblood of our sport. They expect and deserve an honest game."

Breeders' Cup organizers have been a catalyst for change in recent years. Out-of-competition testing for blood-doping agents and other prohibited substances was introduced in Kentucky this year for the first time to meet Breeders' Cup standards. Next year, trainers will be banned from the Breeders' Cup if they have violated a regulation prohibiting the possession or use of a Class I substance, like cobra venom, in any jurisdiction in the 12 months before the championships.

"This is a priority for us," the Breeders' Cup president, Greg Avioli, said. "To call our event a true world championship, we have to take all measures available to us to ensure a level playing field."

A Jockey Club study released last March determined that racehorses died at the rate of 2.04 per 1,000 starts in the United States and Canada, a rate twice as deadly as in any other country. The Jockey Club has pointed to multiple studies that show permissive drug rules are part of the cause of the high mortality rates. It has gotten the Association of Racing Commissioners International, or R.C.I., to lower the allowable level of phenylbutazone, which can be used to mask injuries to horses.

In addition, many veterinarians are calling for the elimination of corticosteroids, which can be injected into joints days before a race and help get sore horses to the starting gate.

While those efforts make their way through the bureaucracy of racing commissions in individual states, there is a simpler, quicker and, perhaps, more effective way to get horsemen to quit abusing medications and using illegal drugs. Make public a database of their violations and punishments.

Create a new statistic: Starts per medication violation.

"Transparency and accessibility to rulings would further ensure the integrity of our sport," the Jockey Club's Gagliano said. "The Jockey Club has built and maintained several databases and would be glad to collaborate with the R.C.I. to build and maintain a comprehensive and searchable database of already publicly disclosed rulings."

Exhibit 19

CHAPTER: Post-Approval Monitoring of Animal Drugs, Feeds and Devices

SUBJECT: **Illegal Residues In Meat, Poultry, Seafood, and Other Animal Derived Foods**	IMPLEMENTATION DATE 08/01/2005 COMPLETION DATE Continuous
DATA REPORTING	
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
Industry codes: 16, 17, 67-69	71006, 71S006 71004 71003A

FIELD REPORTING REQUIREMENTS

1. Hardcopy Reporting

For all Federal and State investigations/inspections submit, Field Accomplishments Compliance Tracking System (Facts) Coversheet with endorsement, completed Tissue Residue Evaluation Form(s) (Attachment C), Drug Inventory Survey Form (Attachment G), to the Compliance Information Management Team, HFV-235, Attention: Fran Pell.

2. FACTS Reporting

a. Report time for all Federal drug residue follow-ups against Program Assignment Code (PAC) 71006. For state inspections of residue violations conducted under contract report time against PAC 71S006. For state inspections of residue violations conducted under cooperative agreements report the time under PAC 71006 with a state position class to identify the work as state-performed. For all inspections include the FSIS sample number in the description field of FACTS.

b. Report time for follow-up at medicated feed mills against PAC 71004.

c. Report time for Contamination Response System (CRS) investigations of non-drug residues against PAC 71003A.

PART I – BACKGROUND

This Compliance Program was developed to provide a cohesive framework for the Field to use that would include inspectional priorities, helpful technical information, and resources to facilitate the investigation of residue violations routinely reported to the Food and Drug Administration (FDA) by the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS). To protect consumers from potentially harmful residues in the food that they eat it is important that inspections are conducted to determine the cause of the illegal drug residues and to develop data descriptive of on-farm practices of management and animal drug use for program decision support, identification of educational needs, and policy development. This program also provides guidance for enforcement measures.. The Federal Food, Drug, and Cosmetic Act (the Act)(21 U.S.C. 321(f)) defines food as "(1) articles used for food or drink for man or other animals...and (3) articles used for components of any such article." (Section 201(f)). Food-producing animals and fish, even though not in their final, edible form, have been held to be food under the statute United States v. Tomahara Enterprises Ltd., Food Drug Cosm. L. Rep. (CCH) 38,217 (N.D.N.Y. 1983) (live calves intended as veal are food) and United States v. Tuente Livestock, 888 F. Supp. 1416, 1423-26 (S.D. Ohio 1995) (live hogs are food). More generally, courts have long held that unprocessed or unfinished articles are or can be food. *See* Otis McAllister & Co. v. United States, 194 F.2d 386, 387 (5th Cir. 1952) and cases cited there (unroasted coffee beans are food). Thus, live animals raised for food are "food" under the Act.

Tissue residue investigations may reveal:

- the illegal sale of veterinary prescription drugs
- the illegal use of bulk drugs
- the extra-label use of drugs (which includes inadequate pre-slaughter withdrawal period)
- cross-contamination of animal feeds due to poor Good Manufacturing Practices (GMPs) (21 CFR Parts 225 or 226)
- failure to follow good animal husbandry practices
- the misuse of drugs in medicated animal feeds
- the marketing of treated/medicated animals intended for rendering purposes being diverted to slaughter for human consumption
- inadequate animal identification

Protection of the public by assuring a safe meat and poultry supply is a responsibility shared by the USDA Food Safety and Inspection Service (FSIS), the Grain Inspection, Packers and Stockyards Administration (GIPSA), the Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), The FSIS exercises supervision over the slaughter and processing of meat and poultry products in federally inspected

establishments and is responsible for the safety of these food products. FSIS reports violative residues of drugs, and both violative and non-violative reisidues of pesticides, and other contaminants in meat and poultry to FDA for follow-up.

The GIPSA works closely with FSIS in regulating animal marketing practices. GIPSA is an enforcement agency within USDA charged with enforcing the Packers and Stockyards Act of 1921 (7 U.S.C. §181) through economic regulation. GIPSA has also assisted FDA in securing producer identification when sales are through auction barns or dealers.

A final rule on swine identification became effective on November 14, 1988. All swine in interstate commerce must be identified and records concerning identification must be maintained. USDA (APHIS and FSIS) is responsible for enforcement. (53 FR 40378, October 14, 1988).

The EPA establishes the tolerances for pesticide residues in meat and poultry. FDA enforces these tolerances.

FDA is responsible for the approval of new animal drugs, including the establishment of tolerances for residues of those drugs in edible tissues. FDA conducts investigations of FSIS-reported residues to determine the party responsible for causing the tissue residue violation and the party responsible for introducing the adulterated food into interstate commerce. The results of FDA investigations have shown that, in most instances, the animal producer is primarily responsible for the illegal drug residues because of failure to comply with drug withdrawal times, other label warnings, use of contaminated animal feeds, use of drugs for unapproved purposes, and employing poor animal husbandry practices. Investigations may also lead to other individuals such as a hauler, buyer, dealer, auction barn, veterinarian, or slaughter house.

FDA has the responsibility to ensure the safety of the seafood supply. In 1995, FDA published the final HACCP (Hazard Analysis and Critical Control Points) regulations for seafood processors (53 FR 40378, December 18, 1995) (21 CFR Parts 123 and 124). The final rule became effective on December 18, 1997. Primary processors of aquaculture products are responsible for ensuring that their HACCP Plans address systems for drug residue control. The Center for Food Safety and Applied Nutrition (CFSAN) issued a Compliance Program Guidance Manual (7304.018), Chemotherapeutics in Seafood, in FY 2002 outlining procedures for sampling aquaculture products to be tested for drug residues. This compliance program addresses sampling of product from both domestic and imported sources.

In 1994, Congress passed legislation that would allow veterinarians to prescribe drugs in a manner inconsistent with the approved new animal or new human drug labeling. This act is called the Animal Medicinal Drug Use Clarification Act (AMDUCA)(21 U.S.C. §360b(a)) and the regulations that implement AMDUCA are published in Title 21 Code of Federal Regulations Part 530. These regulations describe the specific conditions under which extralabel use is permitted.

Expansion of the Tissue Residue program has paralleled the Agency's growing concern about consumer exposure to drug residues in the edible products of food animals. For example, in 2002, the Agency became aware of the use of drugs in the production of honey, to treat diseases of honey bees. This Compliance Program has been expanded to address this concern.

In an effort continually to improve the program, CVM develops new training courses for Federal and State investigators to address identified training needs. CVM also organizes national cooperative meetings with officials from FDA, FSIS, GIPSA, APHIS and individual states, writes educational articles, and conducts industry outreach programs in an effort to provide message-specific information to educate firms on sound drug use and residue prevention practices.

CVM encourages the District Offices to develop cooperative agreements (i.e., contracts, partnership agreements, memoranda of understanding, and informal arrangements) with their state agencies to conduct initial inspections. These inspections are predominantly educational in nature and are extremely important in the prevention of future residues.

For residues detected in seafood products the ultimate goal is to determine the cause of the residue and pursue regulatory action. The current CFSAN sampling program focuses on drugs that are not approved for use in aquaculture.

There are currently only two drugs approved for use in honey bees, oxytetracycline and fumagillin. If a residue is reported of a drug other than the two approved drugs, then the residue was caused by an extra-label use, and may be considered a violation of AMDUCA .

PART II – IMPLEMENTATION

A. INTRODUCTION

This program provides a framework from which each District can fashion its own drug residue control initiatives. CVM requests that Districts receiving reports of violative tissue residues from USDA/FSIS take steps to protect the consumer by either conducting Federal or assigning State onsite investigations at the farm level and other points of responsibility throughout the marketing chain, and to initiate actions commensurate with the findings.

CVM will issue FACTS assignments to request Federal investigation of repeat violators. CVM will also issue inspectional assignments via FACTS for violative residues detected in seafood and other animal derived human food. The Districts are encouraged to recommend enforcement action for such violations.

B. OBJECTIVES

- To conduct investigations/inspections to determine the cause of illegal drug residues and/or shipment of adulterated food.
- To develop data descriptive of on-farm practices of management and animal drug use for program decision support, identification of educational needs, and policy development.
- To obtain correction through voluntary and/or enforcement actions.

C. PROGRAM MANAGEMENT INSTRUCTIONS

1. Inspectional

FDA Districts conduct on-site inspections in the follow-up of violative tissue residue findings of public health concern reported to them by FSIS. In association with these assignments the Districts should investigate all those in the marketing chain who may have acted irresponsibly.

Districts are encouraged to watch for trends or patterns in types of residues or involved parties; for example, the same buyer/dealer involved in a number of residues or a sudden increase in residue reports involving the same drug. The Residue Violation Information System (RVIS) is an excellent source for this type of data on residues.

The Agency's approach to focusing on individual firms for case development will be to use a coordinated team approach when determining which case(s) to pursue. If the District believes that it should develop a case on a specific producer or someone in the marketing chain please contact the Compliance Information Management

Team, HFV-235, Randy Arbaugh or Deborah Cera to discuss investigational approach/priority.

Districts should request intensified sampling of egregious firms in an effort to obtain timely residues to facilitate case development. Please submit such requests via email to the Compliance Information Management Team, HFV-235, Deborah Cera, who will handle coordination with the FSIS Technical Services Center. In order to facilitate successful sample collection please be sure to provide as much relevant information as possible regarding the firm's marketing practices, e.g., what slaughter plant(s) they use, are animals delivered directly to slaughter, or through a middleman (provide name), and on what day of the week do the animals generally go to slaughter.

NOTE:
The current CFSAN Compliance Program, 7304.018, Chemotherapeutics in Seafood, is a sample collection program designed to test for drugs that that are not approved for use in aquaculture. If a domestic sample is found to be positive, CVM will issue an assignment for follow-up to document the violation. Case development should be considered for such residues with all questions directed to the Compliance Information Management Team, HFV-235, Fran Pell.

To discuss case development for drug residues in meat and poultry contact the Enforcement and Regulatory Policy Team, HFV-232, Reginald Walker. For all other residues detected in animal derived foods, contact Compliance Information Management Team, HFV-235, Fran Pell, to discuss case development.

Pesticide and industrial chemical residues, mycotoxin contamination, microbiological residues, and heavy metals reported to the Districts by FSIS under its Contamination Response System (CRS) will be covered under the Feed Contaminants Program (7371.003). Under unique conditions, certain violative drug residues may be reported through the CRS. Follow-up investigational time for CRS drug residues should be charged to this program (7371.006). Contact the Enforcement and Regulatory Policy Team, HFV-232, Sandra Washington before initiating a follow-up to a CRS report.

a. On-Site Inspections by FDA of Meat and Poultry Violations

1) **Repeat Violators:** This is the **top priority** for FDA inspections/investigations. Firms or individuals who repeatedly present adulterated animals for slaughter may represent a significant public health risk. Therefore, CVM will issue an assignment to the District in FACTS requesting an FDA on-site investigation for each repeat violator. A repeat violator is an individual who sells a slaughter animal whose carcass is found to contain a violative concentration of a drug, pesticide, or environmental contaminant within a 12-month period after the first violation and after receiving the FSIS Notification Letter.

2) **First-time Violators:** As resource allow, conduct an on-site inspection/investigation for first-time violators when FSIS reports violative tissue residues for the following situations:

- Drugs prohibited from extra-label use in food-animal use - chloramphenicol, diethylstilbestrol (DES), nitrofurans (furazolidone, nitrofurazone), or nitroimidazoles (e.g., dimetridazole, ipronidazole), clenbuterol, sulfonamides in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine and sulfaethoxypyridazine), fluoroquinolines, glycopeptides, and phenylbutazone in female dairy cattle 20 months of age or older.

- Drugs not approved for food animal use: beta agonists (e.g., fenoterol, salbutamol), tranquilizers, etc.

- Very high level residues, indicating intentional misuse of the drug and/or a complete disregard for the withdrawal period.

- Drug tissue residues reported under the CRS. These assignments will be issued from CVM.

NOTE:
If none of the above criteria is met on an initial residue violation then resource constraints do not allow for an FDA investigation. Cooperating State agencies should be assigned inspections of all other first-time violators to determine the cause of the residue and to attempt to prevent a repeat violation through education and/or any regulatory action deemed appropriate by the State.

b. On-Site Inspections by FDA of Seafood.

The drugs that are being tested for in Seafood are for unapproved drugs. All violations require an FDA follow-up and a FACTS assignments will be issued by CVM.

c. Investigation of Food Animal Marketing Firms

Focusing on firms/people responsible for the delivery for introduction or the introduction into interstate commerce of adulterated products is an important concept under this program. Experience has shown that investigations can lead to producers, haulers, dealers, auction barns, and buyers, any one of which may be held responsible for the violation. Parties throughout the chain of distribution may act irresponsibly by not determining if animals they handle are medicated or not forwarding this information to the next person or firm in the marketing chain. For example, a dealer or auction barn can take precautions by determining if animals are medicated and selling them as such. Dealers have been found to purchase medicated animals supposedly for dog food and then offer them for sale at a slaughterhouse for human food. Please relay these incidences to the local Grain Inspection Packers and Stockyards Administration. Any animal offered for sale at a USDA licensed slaughter facility is for human food. Implementation of the marketing chain strategy should be coordinated at the local and national levels between FDA, FSIS, APHIS, and GIPSA and State agencies. For example, we can request that FSIS increase sampling of a producer or dealer's animals. The goal is to use the expertise and the legal tools possessed by each group. FDA is the lead agency in collecting evidence and initiating regulatory action.

Districts should work closely with the Enforcement and Regulatory Policy Team, HFV-232, Reginald Walker at the onset of selecting a firm or individual for possible regulatory action.

d. Inspections at Aquaculture Farms

There are six drugs approved for use in aquaculture. They are: oxytetracycline, sulfadimethoxine/ormetoprim, formalin, chorionic gonadotropin, tricaine methanesulfonate and sulfamerazine. Sulfamerazine is not currently marketed. The brand names, species approved for and conditions of use can be found at:

http://www.fda.gov/cvm/aqualibtoc.htm#ApprovedDrugs

All of the drugs in the current CFSAN testing program are not approved for aquaculture use in the United States. The drugs may be labeled for non-food fish and later diverted to food fish producers. It is important to determine if the drug manufacturer or distributor is marketing these drugs for this use. If an FDA approved drug was used in an extra label manner determine if a veterinarian was involved. If so, follow-up with the veterinarian as appropriate. Determine why the producer used the drug and, if not prescribed by a veterinarian, what information was used by the producer to determine how to use the drug.

e. Inspection of other Animal-Derived Products

During inspections of other animal-derived product producers, the drug identified by the residue may have been used in an extra-label manner, so determine if there was a veterinarian involved with the use, and whether all of the conditions of AMDUCA were met.

f. Extra-label Use

The Animal Medicinal Drug Use Clarification Act became law in 1994 and the regulations implementing this law can be found in Title 21 Code of Federal Regulations Part 530 (21CFR 530). The regulations describe the conditions under which FDA approved drugs can be used in a manner inconsistent with the approved labeling as long as such use is by or on the lawful written or oral order of a licensed veterinarian within the context of a Veterinary-Client-Patient Relationship (VCPR). This regulation only applies to FDA approved drugs and the use must be therapeutic in that the animal must be sick or might die if not treated, and there needs to be a valid veterinarian client patient relationship. For more details refer to the 21CFR 530.

While AMDUCA does not permit the extra-label use of an FDA approved drug in or on feed, CVM recognizes that for some species of animals this is not always practical. FDA published a Compliance Policy Guide (CPG Sec. 615.115), 'Extra-Label Use of Medicated Feeds for Minor Species', which permits the extra-label use of medicated feed for minor species under specific circumstances. Briefly, this extra-label use can only be done upon the order of a veterinarian, the feed must be manufactured according to the approval and there is no reformulating of the feed. For aquaculture species there are two approved medicated feeds for food fish. More details can be found at:

http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg615-115.html

g. FSIS Special Programs

(1) FAST

FAST (Fast Antimicrobial Screen Test) is a microbial inhibition screening test. It was designed to be used by an FSIS veterinarian or a designated food inspector in a slaughter plant, for the detection of antibiotic and sulfonamide residues in livestock kidney tissue. The FAST test reacts with at least 56 different antimicrobials.

The FAST test is based on the principle that if animal tissue contains a residue of previously administered antimicrobial, fluid from the tissue will inhibit the growth of a sensitive organism on a bacterial culture plate. The plates are examined for zones of inhibition around the sample, which constitutes a positive test. The significance of the FAST test is its high degree of sensitivity over the old CAST (Calf Antibiotic Sulfa Test) test and the fact that test results can be obtained after a minimum of **6 hours** incubation to a maximum of 24 hours from the time the plate is incubated.

If the result is negative the carcass is released. If the result is positive, tissue samples (muscle, kidney, and liver) are sent to the laboratory for bioassay testing and the carcass is retained pending laboratory results.

(2) STOP

STOP (Swab Test on Premises) is an in-plant test currently being used by FSIS plant inspectors on suspect animals to test for antibiotic microbial inhibitors. STOP-positive carcasses are retained pending the receipt of results of confirmatory tests, which are automatically conducted in FSIS laboratories.

h. FSIS Condemnation Practices

Where FDA has established a tolerance for a marker residue in a target tissue FSIS will condemn the entire carcass when a violative residue is confirmed in the target tissue. For other drugs, if the liver or kidney is found to contain violative residues, they alone are condemned. In all cases if the muscle contains a violative residue then the entire carcass is condemned.

An exception to the above is the routine condemnation of the entire carcass of any non-ruminating veal calf found to contain a hormonal implant.

2. District Monitor Responsibilities

Each District should assign an individual to serve as a monitor for this compliance program. The monitor's duties should include the following:

- Review Weekly Residue Report. CVM, in consultation with the District Program Monitor, will issue assignments to the District in FACTS for FDA Investigations and enter the appropriate assignment activity code in RVIS. The Monitor should enter all activity codes for assignments and follow-ups.

- Once an investigation is completed. The Program Monitor should, review the EIR for newly identified sources, name/address, firm-type corrections, and additional middleman information. This information should then be entered into RVIS.

- The Monitor should promptly enter appropriate activity codes covering Repeat Violator Status, Completed Investigations, Regulatory Reserve Samples, and Regulatory Actions taken. Every violation followed up by an FDA or State investigator should have the FDA Responsibility Flag entered into RVIS as responsible, not responsible, or involved. This information is needed before FSIS can post a firm to its Web Report of Repeat Violators.

- Periodically review RVIS for violator/violation trends, e.g., specific middleman involvement in a number of violations or an increase in the number of residues for a specific drug. Notify the Compliance Information Management Team, Deborah Cera, Fran Pell, or Randy Arbaugh if you believe that an investigation is warranted. Keep abreast of RVIS enhancements.

- Assign State investigations per guidance contained in Part II.C.1.a. of this program. Provide the state with computer-generated Attachment C forms for TRIMS data collection and remind them to complete the Drug Inventory Survey Form (Attachment G).

- Review completed EIRs/Attachment C forms and Drug Inventory Survey forms to determine if required fields have been completed. Discuss any incomplete reports with the appropriate parties to improve the quality of future data reported.

- For all Federal and State investigations/inspections submit a copy of the Field Accomplishments Compliance Tracking System (Facts) Coversheet with endorsement, completed Tissue Residue Evaluation Form(s) (Attachment C), Drug Inventory Survey Form (Attachment G), to the Compliance Information Management Team, HFV-235, Attention: Fran Pell

- Request that the inspectors/investigators contact the District Program Monitor before the start of an on-farm follow-up so that they can get an updated violator history to ensure that additional residues have not occurred since the assignment date.

- Request the Regulatory Reserve Portion of samples for all firms that might become the subject of an enforcement action. Requests should be timely to ease FSIS's burden of sample retention. All samples not requested will be destroyed after 12 months. All requests should be directed to Don Gordon, Donald.Gordon@FSIS.USDA.Gov, Tel. No. 314-263-2680 ext. 341.

- Monitors should maintain a list of samples that they have requested to be stored in an FDA laboratory. Periodically review this list and request a Sample Destruction Notices (SDNs) be prepared through the appropriate channels in your Districts once it becomes clear that the District will not be initiating enforcement action against a firm.

- Provide the District Director, and Directors of Compliance and Investigations, where appropriate, with a list of local Repeat Violators and associated District activities, at least twice annually.

- Serve as a clearinghouse for distribution of information to cooperating State officials.

- Inform District management of all CVM/ORA-sponsored training initiatives. Recommend training of all Federal/State personnel conducting residue investigations.

- Maintain routine communications with local representatives from FSIS, APHIS, GIPSA, and the States.

- Work with CVM to distribute Industry outreach materials appropriate to address local residue concerns.

3. Analytical

Ordinarily FSIS will analyze tissues and conduct confirmatory analyses. FDA confirmatory analyses of tissue samples collected, analyzed, and confirmed by FSIS are not necessary to support regulatory action. Other tissue samples **should not** routinely be sent to the Denver District Laboratory. FSIS has agreed to run confirmatory tests on those samples that the FDA District needs to support casework. For example, if during an investigation of a neomycin residue it is revealed that a sulfa was used in combination with neomycin, a portion of the reserve sample can be sent back to FSIS for analysis for sulfas.

One exception to the above would be when FSIS reports finding a hormone implant in a veal calf submitted by a "Repeat Violator". The District should request that the reserve sample of the actual implant be shipped to the Denver District Laboratory where hormones present in the implant will be identified.

Please contact the Compliance Information Management Team, HFV-235, Deborah Cera, to facilitate requests for additional analyzes.

4. Program Interaction

When the investigation implicates a medicated feed produced by either a commercial feed mill or an on-farm mixer/feeder, conduct a comprehensive GMP inspection. For example, carbadox residues in swine generally result from feed and not dosage form drugs. Charge all time expended for GMP inspections to the Feed Manufacturing Program PAC 71004, regardless of whether done at the feed mill or the mixer-feeder. Remember, the regulations in 21 CFR Part 225 sections 225.10 to 225.115 apply to facilities manufacturing one or more medicated feeds for which an approved medicated feed mill license is required. The regulations in 21 CFR Part 225 sections 225.120 to 225.202 apply to facilities solely manufacturing medicated feeds for which an approved medicated feed mill license is not required.

When the tissue residue results from a non-drug chemical contaminant, such as pesticides, metals, mycotoxins, or microbiological contaminants, charge the time expended for follow-up investigations to PAC 71003A - Feed Contaminants Program.

The success of the Agency's program to support the prevention of the introduction and amplification of BSE in the United States is dependent on the ability of investigators to identify violative firms and operations. While initial efforts by Federal and State investigators have identified and inspected most renderers and commercial feed mills, continued efforts are needed to identify and continue to inspect all firms subject to the regulation. Ruminant feeders are an important obligation that should receive additional attention. Unless another BSE inspection has recently been conducted, add-on BSE inspections should be conducted for each ruminant feeder visited during a tissue residue follow-up. Charge time expended for such inspections to PAC 71009 – BSE/Ruminant Feed Ban Inspections.

Tissue residue monitors should maintain close contact with their Regional Milk Specialists and State milk authorities. RVIS reports of dairy animal violations are supplied to these individuals on a quarterly basis. One long-term goal is for involved agencies to share all available information related to drug residues (milk and meat) in dairy animals. This effort can maximize resource utilization in targeting enforcement actions and promoting effective residue controls.

5. Inter-Agency Agreements

See MOU 225-85-8400 - MOU between FDA, FSIS, and EPA regarding regulatory activities concerning residues of drugs, pesticides and environmental contaminants in foods, which went into effect on February 1, 1985.

6. Federal/State Relations

States participate in this program under agreements (contract, MOU, partnership, and informal) to conduct inspections. The emphasis of the State programs is to determine the cause of the residue and to provide producer education in an effort to prevent future violations.

Regions/Districts are urged to develop cooperative work sharing agreements with **each of their** states. General guidance for the development of work-sharing agreements is found in RPM Chapter 3-20. Maintain a high level of communication with cooperating States and share with them the periodic RVIS reports of State findings and results of program evaluations.

For information on the formation of agreements with States, contact the Division of Federal-State Relations, HFC-150.

PART III - INSPECTIONAL

A. Inspectional Operations

The three elements of a case for which evidence should be collected by the investigator are: jurisdiction, violation(s), and responsibility. The order in which the evidence is gathered is at the District's discretion. Because of the public health significance, the District should be attentive to steps that can be taken to prevent adulterated animals from going to market. For example, if an on-farm investigation reveals that veal calves, due to go immediately to market, are still being fed a neomycin-containing milk replacer, steps should be taken to prevent their marketing by requesting State assistance (quarantine power or other enforcement tools) and by alerting the FSIS Regional Office of the potential offering of these animals at USDA licensed slaughter facilities.

1. Jurisdiction

Establish and document interstate (IS) commerce.

Obtain affidavits from the involved auction/sales barn or slaughter facility or processing plant attesting to the fact that it routinely deals in interstate commerce and include the approximate percentage of IS business. Examples of recent records of IS sales may also be appropriate as part of the documentation with slaughter facilities or the processing plant, a current affidavit (desirably no older than 6 months for injunction or prosecution cases) is acceptable for establishing IS commerce. Call the Enforcement and Regulatory Policy Team, HFV-232, Reginald Walker for assistance/advice.

Notify the producer or other implicated person that animals or meat from animals he/she offers for sale may move in interstate commerce, even if the animals are not delivered directly into interstate commerce. In those cases in which extra-label use or other drug adulteration or misbranding charges may be appropriate, interstate jurisdiction over the drug(s) should be documented.

2. Violation

a. Meat and Poultry Residues

FSIS reports violative residues to FDA on a single-animal basis for FDA to follow-up. FSIS sample results show the amount and type of the drug detected. FSIS analysis may be limited to the identification of one drug. If investigational evidence supports the presence of another drug, call the Compliance Information Management Team (HFV-235), Deborah Cera or Fran Pell so that she can request analysis of the tissue sample for the additional compound. Animal identity problems should be worked out with the FSIS Technical Services Center, Dr. Julie Cornett, 402-221-7400, or local APHIS

Animal Identification Specialist. ID Specialists can be reached by contacting the local Veterinary Services Office. (See Attachment D) The identification of the responsible party given by FSIS **should** be positively confirmed by the FDA investigation. Use ear tag numbers, lot numbers, or other means to adequately link the animal to the producer/party responsible for the violation. FSIS, APHIS, and GIPSA can assist in responsible party identity.

NOTE: When doing a follow-up of a repeat violator that has received FDA prior warning, an affidavit should be obtained from all FSIS in-plant inspectors associated with each residue. Please notify the FSIS Technical Services Center, Dr. Julie Cornett, 402-221-7400 to arrange for and authorize a time for you to meet with the appropriate inspector(s) to obtain necessary documentation. (See Attachment F for an example of the kind of affidavit needed.)

Medication/treatment resulting in illegal residues may be performed by the grower/feedlot, veterinarian, or in rare cases, by the dealer, hauler, auction barn, buyer, or slaughterhouse. Because of the number of people involved in the marketing chain, it is essential that time factors and animal identity is well-documented. For example, if an animal is slaughtered within 24 hours of leaving the farm, it is unlikely that a middleman treated the animal. Collect affidavits from middlemen affirming that whether or not drugs were used on the animal.

Many residues are caused by conditions conducive to potential tissue residue violations at the farm, i.e., "poor husbandry practices." When doing an investigation at the producer, determine and describe the conditions you observe. That should include <u>at least</u> the following:

(1) Inventory all drugs on the premises (See Attachment G).

(2) Determine and list other drug-containing products, such as medicated feeds, or other drug sources, that could have been, or are being used in food-producing animals. Although most violative residues result from direct misuse of drugs in the animals, tissue residue investigations have revealed residues resulting from cross-contamination of withdrawal feeds with medicated feeds in feeding bins, or from feeding calves milk from treated cows. If possible, physical or documentary samples of drugs or feeds should be collected if implicated in the residue.

(3) Describe where the drugs are stored, how they are stored, and who has access to the drugs.

(4) Determine who administers medication and try to interview those individuals about their medication practices (who determines what animals are to be medicated, how are the medications selected, how are dosages determined, etc.).

(5) Determine identification systems and segregation/quarantine practices, if any, for medicated animals.

(6) Determine if medication records are maintained. Describe the record system. Do they include the date of medication, the drug used, the dosage administered, milk withholding and slaughter withdrawal times, etc.

(7) Determine how the producer has assured that **withdrawal times** are met prior to marketing.

Look for and document fraudulent buying or selling practices (violations of Packers and Stockyards Act and regulations) and the giving of false certificates or guarantees. GIPSA has been successful in levying substantial administrative fines for such violations. All swine in interstate commerce must be identified and records concerning identification must be maintained (9 CFR Part 71). This rule was published by USDA **(APHIS and FSIS) and they will** be responsible for its enforcement. If FDA Field offices encounter problems with identification of swine, these should be reported to, and worked out with your APHIS Animal ID Coordinator. We are also requesting that you alert CVM to these problems by reporting them to the Compliance Information Management Team, HFV-235, Deborah Cera.

We recommend objectionable conditions be listed on a FDA 483, and discussed with management at the conclusion of the inspection. Record the applicable information on Attachment C.

b. Seafood and Aquaculture Residues

All drugs that the Agency is currently testing for in seafood are not approved for use in aquaculture. The list of approved drugs can be found at:

http://www.fda.gov/cvm/aqualibtoc.htm#ApprovedDrugs

Some compounds are not traditional drugs but based on their intended use, 'to treat or mitigate a disease' they can be considered drugs. One example of a compound that falls into this category is malachite green. When doing an investigation at the producer, determine and describe the conditions that you observe. That should include at least the following:

(1) Inventory all drugs on the premises.

(2) Determine and list other drug-containing products, such as medicated feeds, or other drug sources, that could have been, or are being used in fish. Although most violative residues result from direct misuse of drugs in the fish, tissue residue investigations have revealed residues resulting from cross-contamination of withdrawal feeds with medicated feeds in feed storage bins. If possible, physical or documentary samples of drugs or feeds should be collected if implicated in the residue.

(3) Describe where the drugs are stored, how they are stored, and who has access to the drugs.

(4) Determine who administers medication and try to interview those individuals about their medication practices (who determines what fish are to be medicated, how are the medications selected, how are dosages determined, etc.).

(5) Determine identification systems and segregation/quarantine practices, if any, for medicated fish. Keep in mind fish are normally medicated in their pond/raceway/net pen. They would medicate all the fish in that group. Brood fish may be individually medicated.

(6) Determine if medication records are maintained. Describe the record system. Do they include the date of medication, the drug used, the dosage administered, and slaughter withdrawal times, etc.

(7) Determine how the producer has assured that **withdrawal times** have been met prior to marketing.

3. Responsibility

Determine and document who committed the violation, i.e., who did what, and when. This would include: misuse of approved drugs, use of illegal and unapproved drugs, GMP violations, and poor animal husbandry practices that could contribute to causing the violative drug residue, and the issuance of false certificates, guarantees, or any other statement on the medication status of the animal offered for sale. Keep in mind that more than one firm/individual in the marketing chain may be held responsible for tissue residue violations.

a. Dealer Involvement

Persons involved in handling, transporting, holding, and marketing food-producing animals should be encouraged to establish systems to ensure that if **they administer** drugs to animals in their control or care, those drugs are used properly, and to establish systems to prevent potentially hazardous drug residues in edible animal products.

Persons who do not administer medications but who acquire animals for sale for slaughter (such as livestock dealers) should also establish and implement a recordkeeping system. This system should include information on the source of the animal and whether the animal has been medicated (when, with what drug, and the withdrawal period) to preclude marketing of adulterated edible animal tissues.

Specifically, describe the system the dealer has for the following:

(1) Their system to identify the animals they purchase or acquire with records to establish traceability to the source of the animal;

(2) Their system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and,

(3) If the animal has been medicated, their system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissues. If they do not hold the medicated animal, then describe how they assure that the animal is clearly identified and sold as a medicated animal.

Such persons may be subject to regulatory action if they market animals containing illegal residues and have failed to take reasonable precautions to prevent the sale of adulterated food [21 U.S.C. 331(a)].

Seafood does not have dealers like the terrestrial animals. Fish haulers are sometimes either associated with the producer or the processor. Determine if any drugs or chemicals are put into the fish haul truck tanks to reduce stress to fish.

b. Veterinarian Involvement

If the investigation reveals that the drug involved in causing the residue was prescribed, administered, or dispensed by a veterinarian include the following:

(a) Describe the veterinarian/client/patient relationship that existed at the time the animals in question were treated. Refer to 21 CFR Part 530.

- Does the veterinarian regularly visit the farm premises and examine the animals?

- Is the veterinarian aware of the husbandry practices utilized by this firm?

- Did the veterinarian examine, prescribe, or administer the drug to the animal in question?

- If the veterinarian administered the drug, report the dosage and describe what kind of instructions he/she left for milk withholding and/or pre-slaughter withdrawal times. (Did the producer follow those instructions?)

- If the veterinarian did not administer the drug, with whom and what kind of instructions did he/she provide for drug administration and milk withholding and/or pre-slaughter withdrawal times? (Did the producer follow those instructions?)

(b) Describe how the veterinarian established the recommended withdrawal time and how he/she attempted to assure that the producer adhered to that time.

(c) Describe how the dispensed product was labeled.

(d) If the drug was one that the veterinarian prepared (by combining 2 or more products, or other manufacturing methods), list the products or ingredients, describe who prepares them, and how they are prepared. Use CPG Sec.608.400 - Compounding of Drugs for Use in Animals and 21 CFR Part 530.13 for additional guidance.

B. GMP Inspections

Conduct GMP inspections at the feed mill or mixer/feeder when either is implicated as causing the residue violation. Use CP 7371.004 for guidance and be sure to use Form 2481 when conducting an inspection. See 21 CFR Part 225 sections 225.120 to 225.202 for GMP requirements for feed mills that do not require a license. The GMP regulations at 21 CFR Part 226 are for the manufacturers of Type A medicated articles.

C. Sampling

Collect samples (including both documentary samples and/or physical samples) to document violative conditions. See IOM Sampling Schedule Chart 16 for both potency and drug carryover in feeds.

If illegal or unapproved drugs, such as chloramphenicol or nitrofurans, are found on a food-producing animal farm, collect documentary samples of seizable-sized lots.

1. Sample Submission

Ship all medicated feed and animal drug samples for drug or microbiological analyses to the Denver Laboratory. Before shipping samples contact the Laboratory Director, Karen Kreuzer, HFR-SW260, at 303-236-3060, to discuss inspectional findings and required sample analyses.

2. Collection Report (CR)

Prepare a CR for the FSIS-collected sample only when regulatory action is being considered. CRs need to be prepared for each drug being used in an extra-label manner and for any other sample collected during the investigation

D. Reporting

Submit, Field Accomplishments Compliance Tracking System (Facts) Coversheet with endorsement, completed Tissue Residue Evaluation Form(s) (Attachment C), Drug Inventory Survey Form (Attachment G) to the Compliance Information Management Team, HFV-235, Attention: Fran Pell. Photocopy necessary forms for District use. The completion of Attachments C and G are essential for the success of the automated database, TRIMS (Tissue Residue Information Management System). Upon request CVM will provide information for comprehensive District reports. TRIMS is extremely useful in identifying trends in causes of tissue residues, e.g., illegal use of bulk drugs, extra-label use of dosage form drugs, medicated feeds, etc.

A copy of the fully completed FACTS coversheet, along with pertinent parts of the memo of investigation or EIR should be forwarded to the FSIS Technical Services Center. Please Fax or email any source information changes to FSIS immediately so they can issue a corrected notification letter to the appropriate individual and update RVIS. It is FDA's responsibility to provide FSIS with updated violator information for RVIS. Do not complete an Attachment C for violations in Seafood or Honey. Send the EIR with attachments to the Compliance Information Management Team, HFV-235, Attention: Fran Pell.

E. Criminal Activity Investigations

When illegal residue investigations uncover activities of a criminal nature, such as using false names, knowingly purchasing medicated animals for slaughter, purchasing animals with the understanding that they will be sold for rendering or other non-human food use and then offering the animals for slaughter for human food, you should consider referring the case to FDA's Office of Criminal Investigations (OCI). This Office has skills, contacts, and expertise that may be invaluable in conducting the investigation and pursuing the appropriate enforcement action. The formal procedure for referral is described in the Investigations Operations Manual (IOM) Chapter 9, Subchapter 980. **If OCI is unable to pursue a specific case, the District should still conduct follow-up inspections in accordance with this program.** OCI may be able to assist in certain areas or FDA investigators may work jointly with OCI agents in the investigation.

PART IV - ANALYTICAL

A. Responsibilities

1. Sample Preparation

Prepare feed samples for drug analysis as described in the AOAC 16th Ed.

2. Tissue Sample Storage

The analyzing FSIS laboratory will retain all FSIS-collected violative samples for up to 12 months. Once the FDA District Office decides that a firm may warrant regulatory action they should immediately request that the pertinent sample(s) be shipped to an FDA laboratory. Please note that unless a sample shipment request is received, all samples will be destroyed by FSIS after 12 months. Samples should be retained by FDA until a compliance action is completed or the firm sufficiently demonstrates its sustained ability to market animals free of violative residues.

Districts should devise a sample accountability system for the FSIS-collected tissue samples. A suggested system would be to prepare a sample accountability card for each sample received using the FSIS laboratory form number as the sample number. By using the form number, a CR would not be prepared, thereby eliminating the problem of how to report time for preparing the CR. A CR would, however, need to be prepared before a case is forwarded for regulatory consideration.

Tissue samples using this system are handled in the same manner as any FDA sample.

An FSIS Directive establishes a formal system to guarantee sample integrity. An intact FSIS official seal should be affixed to the sample container. Contact Compliance Information Management Team, Deborah Cera, if you find this not to be the case routinely. Although FDA would prefer all samples from FSIS to be sealed, the lack of a seal should not deter you from appropriate follow-up.

3. Problem Area Flags (PAF) for PACs

PAC 71003A - PAF (PES, NAR)
PAC 71004 - PAF (NAR, KIT, DRT, ANT, DRA)
PAC 71006 - PAF (NAR, DRT, ANT, DRA, KIT)

Note: This only applies to Meat and Poultry samples reported to FDA by USDA, FSIS. Follow C.P. 7304.018, Chemotherapeutics in Seafood, for information on seafood samples for drug residues.

PART V - REGULATORY/ADMINISTRATIVE

A. GENERAL

Enforcement follow-up activity is prioritized by the degree of human health risk potential involved in the residue violation(s). Additionally, enforcement action may be against individual(s) responsible for multiple residue violations involving drugs presenting a lesser human health risk. The following information covers most violative residue situations. Occasionally, however, unique situations are encountered which require new or special investigational or enforcement procedures. Discuss these new or special situations with CVM, Division of Compliance, Enforcement and Regulatory Policy Team, Reginald Walker as they occur so that an acceptable investigational or enforcement strategy can be developed. Also notify and discuss with the Compliance Information Management Team, Deborah Cera proposed joint interagency (FDA//FSIS/GIPSA) enforcement actions against individuals/firms (other than the producer) at the initial stage of development. CVM will contact FSIS, and GIPSA headquarters units and the District will contact FSIS, and GIPSA field units to implement interagency enforcement actions.

For aquaculture questions contact the Compliance Information Management Team, Fran Pell. For other animal derived human foods contact Deborah Cera, or Fran Pell.

Animals are considered food under the Act when offered or intended for slaughter for human food at slaughter facilities that ship their products into interstate commerce.

The Federal Food, Drug, and Cosmetic Act (the Act)(21 U.S.C. 321(f), defines food as "(1) articles used for food or drink for man or other animals...and (3) articles used for components of any such article." (Section 201(f)). Food-producing animals and fish, even though not in their final, edible form, have been held to be food under the statute United States v. Tomahara Enterprises Ltd., Food Drug Cosm. L. Rep. (CCH) 38,217 (N.D.N.Y. 1983) (live calves intended as veal are food) and United States v. Tuente Livestock, 888 F. Supp. 1416, 1423-26 (S.D. Ohio 1995) (live hogs are food). More generally, courts have long held that unprocessed or unfinished articles are or can be food. *See* Otis McAllister & Co. v. United States, 194 F.2d 386, 387 (5th Cir. 1952) and cases cited there (unroasted coffee beans are food). Thus, live animals raised for food are "food" under the Act.

Regulatory action can be taken against a producer or other responsible persons when it has been documented that the animals offered for slaughter in interstate commerce resulted in illegal residue(s) in edible tissue. [21 U.S.C. 331(a)] For example, regulatory action can be taken against a producer who sells animals containing illegal drug residues to an intermediate party, which in turn sells them at

an auction, where they are purchased by a buyer who in turn sells them to a slaughter plant doing an interstate business. In such circumstances the producer can be charged with causing the delivery for introduction into interstate commerce of adulterated food, even if the producer has no specific knowledge of the ultimate destination of the animals.

The other parties involved in the scenario may also be charged with causing the delivery for introduction into interstate commerce of adulterated food, or they may be charged with offering for introduction into interstate commerce. Additionally, "caused to be introduced" charges may be brought against veterinarians, animal dealers, buyers, vendors, auction barns, or other persons who are responsible for having caused the residue or having introduced animals into interstate commerce without first assuring that the animals were free of illegal residues [21 U.S.C. 331(a)]

When treated animals remain on the premises, initiate action to prevent further processing of the animals, such as requesting that USDA/FSIS sample and hold future shipments made by the producer and/or requesting State detention/quarantine of the animals. Provide complete information (e.g., suspected shipment date, destination, drugs involved, etc.) to cooperating agencies and officials.

B. INITIAL VIOLATION

The FSIS Violation Notification Letter includes appropriate language to serve as FDA prior warning to the producer shipping animals with violative residues. Under the following circumstances it is appropriate to issue a Warning Letter to an initial violator (when the investigation confirms his culpability):

- Involvement of drugs considered of **high risk to human** health/safety whether approved or unapproved.
- Involvement of apparent extra-label use. Refer to 21 CFR Part 530.
- The occurrence of residue levels so high as to indicate intentional misuse of the drug
- Involvement of drugs where no tolerance has been established.

Seafood violations: All drugs for which seafood is currently tested are not approved for any food fish use in the United States. If the violation, jurisdiction, and responsibility can be documented, CVM would consider a Warning Letter for the initial violation.

C. REPEAT/MULTIPLE VIOLATIONS

Firms or individuals who repeatedly present adulterated animals for slaughter may represent a significant public health risk.

1. Warning Letter

A Warning Letter should be considered as a follow-up to a repeat violation. See Attachment B for model Warning Letters. Warning Letters for tissue residue violations may be issued directly by the District Director except those concerning tissue residue violations where no tolerance has been established, extra-label use is documented, and/or those which involve the use of compounded drugs or other drug adulteration. Warning Letters for aquaculture and other animal-derived products also require CVM concurrence prior to issuance. The exceptions listed above require CVM concurrence prior to issuance.

Warning Letters must be submitted to CVM no later than 8-10 weeks from the date of **last evidence collection** to meet Agency timeframes. In the past the regulatory time clock has routinely started on the date of investigation/inspection of the animal producer. However, since residue investigations frequently require additional time-consuming visits to fully document the violation, it is important to include dates of visits made to the veterinarian, auction barn, dealer, slaughter house, etc. in your recommendation to CVM. Include language in the Warning Letter that clearly specifies the beginning and end dates of the investigation.

Title 18 violations may also be included in the Warning Letter to inform the recipient that GIPSA or FSIS may take actions against these violations. (See Attachment E). These are circumstances where false certificates or guarantees are knowingly provided or when provided without any knowledge of the animal's medication status. Do not issue Warning Letters containing only Title 18 violations.

If the state inspection documents residue violation, responsibility, and jurisdiction, CVM will consider Warning Letter recommendations based on the state inspectional data.

2. Injunction

If a tissue residue violation(s) **occurs after the** issuance of a Warning Letter then injunction should be considered against a producer and/or other parties that are responsible for introducing animals into interstate commerce that result in illegal residues. As with most injunctive actions, we need a history of violations and a good description of scope and size of the violator's operation to help explain the need for court action to achieve compliance. Contact FSIS to initiate intensive sampling of the producer's animals. The injunction will be reviewed concurrently with the effort to obtain any additional documented violations. In order to proceed with a preliminary injunction a documented violative residue or, if it involves a

producer, an FDA inspection, no older than 60 days is required. If the 60-day time frame cannot be met, consider proceeding with a permanent injunction. If another residue violation occurs after a consent decree has been signed, and the inspection documents a violation, responsibility, and jurisdiction, the District should contact the Office of General Counsel (OGC) attorney who handled the original consent decree to discuss enforcement options. In the absence of the original attorney please contact Eric Blumberg, GCF-1 for further advice.

3. Prosecution

Prosecution may be considered when the residue violations involve one or more of the following elements and the individuals knowingly do or use:

- Drugs not permitted for extra-label use in food animals, banned or unapproved drugs that present significant human health safety concerns.
- Blatant misuse of toxicologically significant drugs resulting in residues substantially above tolerance.
- Issuing false guarantees that animals with violative residues were drug-free or had been properly withdrawn from the drug(s).
- Multiple misdemeanor counts and/or one or more felony counts.

The Office of Criminal Investigations (OCI) is responsible for reviewing all matters in FDA for which a criminal investigation is recommended, and is the focal point for all criminal matters.

FDA personnel must refer all criminal matters, regardless of their complexity or breadth, to OCI. This includes criminal search warrants, misdemeanor prosecutions, felony prosecutions, referrals for criminal investigation, and Section 305 meetings.

District management must communicate with its local OCI office before pursuing any criminal matter. This communication is absolutely essential to preclude potential interference with other on-going criminal investigations and to prevent confusion among the components of the Office of Chief Counsel and the Department of Justice that are responsible for handling FDA's criminal cases. During this communication, OCI is to be provided with all of the facts of the potential case and any additional information that is relevant to, or could impact, the case in any way. OCI will decide promptly whether or not it is interested in pursuing the case and will communicate its decision back to the District Office.

If OCI chooses not to pursue a criminal matter, the District Office is at liberty to proceed with the case in accordance with the procedures in Chapter 6 of the Regulatory Procedures Manual.

PART VI - CONTACTS, ATTACHMENTS, AND REFERENCES

A. PROGRAM CONTACTS

1. CVM

a. Program Inquiries

Deborah Cera, Program Manager
240-276-9209
Compliance Information Management Team, HFV-235
CVM/Division of Compliance
Deborah.cera@fda.hhs.gov

b. Technical Guidance

Frances Pell, 240-276-9211 or Deborah Cera, 240-276-9209
Compliance Information Management Team, HFV-235
CVM/Division of Compliance, HFV-235
Deborah.cera@fda.hhs.gov
Frances.pell@fda.hhs.gov

c. Regulatory Inquiries

Reginald Walker
240-276-9234
Enforcement and Regulatory Policy Team, HFV-232
CVM/Division of Compliance
Reginald.walker@fda.hhs.gov

d. Policy Questions

Gloria Dunnavan, Director
240-276-9200
CVM/Division of Compliance, HFV-230
Gloria.dunnavan@fda.hhs.gov

2. ORA

a. Inspectional Inquiries

Division of Field Investigations, HFC-132,
Telephone: Jim Dunnie, 301-827-5652

b. Analytical Inquiries

Division of Field Science, HFC-141,
Telephone: George Salem, 301-827-1031

c. Federal/State Relations Inquiries

Division of Federal-State Relations, HFC-152
Telephone: Glenn Johnson, 301-827-2907

B. LIST OF ATTACHMENTS

1. Attachment A - FSIS Laboratory Reporting Codes
2. Attachment B- Model Letters
3. Attachment C- Tissue Residue Evaluation Form
4. Attachment D - USDA Contacts
5. Attachment E - GIPSA/Title 18 Memo
6. Attachment F - Example of Slaughter Plant Affidavits
7. Attachment G - Drug Inventory Survey
8. Attachment H – Program Monitor Checklist

C. APPLICABLE REFERENCES OR AIDS

1. INVESTIGATIONS OPERATIONS MANUAL (IOM): Chapters 4 & 5 Sampling and Inspection.

2. 21 CFR Parts 500-599, Animal Drugs, Feeds, and Related Products.

3. Compliance Policy Guides:

   Sec. 608.400 - Compounding of Drugs for Use in Animals. (CPG 7125.40)

   Sec. 615.300 - Responsibility for Illegal Drug Residues in Meat, Milk and Eggs. (CPG 7125.05)

   Sec. 608.100 - Human-Labeled Drugs Distributed and Used in Animal Medicine. (CPG 7125.35)

   Sec. 615.200 - Proper Drug Use and Residue Avoidance by Non-Veterinarians. (CPG 7125.37)

   Sec. 615.115 - Extra-label Use of Medicated Feeds for Minor Species

4. Compliance Programs

   7303.039 National Drug Residue Milk Monitoring Program
   7371.002 Illegal Sales of Veterinary Prescription Drugs
   7371.003 Feed Contaminants
   7371.004 Feed Manufacturing
   7304.018 Chemotherapeutics in Seafood Compliance Program

5. Regulatory Procedures Manual.

6. AOAC Official Methods of Analysis, 16th Edition.

7. Memorandum of Understanding - MOU 225-85-8400 - Memorandum of Understanding between FDA, FSIS and EPA.

PART VII - CVM RESPONSIBILITIES

A. Program Evaluation

Information extracted from Attachment C Evaluation Forms will be entered into TRIMS (Tissue Residue Information Management System). This database will facilitate the management and analysis of information related to tissue residue violations.

The Compliance Information Management Team will periodically prepare reports of program findings.

B. Inter-Center Action

The Compliance Information Management Team will coordinate CVM efforts to exchange residue data with the Center for Food Safety and Applied Nutrition, especially when the data may indicate a potential for residues in seafood, milk, and/or eggs.

C. Compliance Information Management Team

The Compliance Information Management Team has the primary responsibility for managing/coordinating FDA-related tissue residue activities.

Significant functions include the following:

- To serve as the primary contact between the FDA District Tissue Residue Monitors and CVM; the objective is to exchange information and provide guidance on residue-related issues and to respond to any problems/needs the Field identifies.
- To identify, recommend, develop, and implement preventive measures to reduce the number violative residues.
- To prioritize work efforts for program-related resources.
- To identify specific residue/violator trends through the Residue Violation Information System (RVIS) and the Tissue Residue Information Management System (TRIMS).
- To provide CVM's Division of Compliance and the Field with relevant residue information to support enforcement actions.
- To coordinate all FDA efforts concerning the RVIS.
- To serve as the primary contact point between FDA and FSIS in an effort to provide meaningful input into the development and implementation of the National Residue Program for meat and poultry.

- To serve as the primary contact point between FDA's CVM and CFSAN to provide input into the development and implementation of drug residue testing programs.

D. Enforcement and Regulatory Policy Team

CVM's Enforcement and Regulatory Policy Team is responsible for the review of all CVM-related enforcement actions and can frequently help in determining the responsible parties. It can also provide guidance on the proper collection of the analytical, investigational, and other evidence needed to support a case. For questions involving case development, please contact the Enforcement and Regulatory Policy Team, HFV-232, Reginald Walker for assistance.

ATTACHMENT A – USDA REPORTING CODES
FSIS/USDA Laboratory Reporting Codes

USDA Residue	USDA Residue Name
0	CAST GENERAL
1	RESIDUE-ACTUAL SPIKED AMOUNT
30	AFLATOXIN
50	NITROSAMINES
51	N-NITROSADIMETHYLAMINE
52	N-NITROSADIETHYLAMINE
53	N-NITROSODIPROPYLAMINE
54	N-NITROSODIBUTYLAMINE
55	N-NITROSOPIPERDINE
56	N-NITROSOPYRROLIDINE
57	N-NITROSOMORPHOLINE
59	RECOVERY
60	CYANIDE
61	STYRENE
80	SYNTHETIC PYRETHRINS
81	CYPERMETHRIN
82	DELTAMETHRIN
83	FENVALERATE
84	FLUCYTHRINATE
85	PERMETHRIN
86	NATURAL PYRETHRINS
87	PYRETHRIN I
88	PYRETHRIN II
89	CINERIN I
90	CINERIN II
92	PIPERONYL BUTOXIDE
99	OTHER
100	HALOCARBON PESTICIDES
101	ALDRIN
102	BENZENE HEXACHLORIDE

USDA Residue	USDA Residue Name
103	CHLORDANE
104	DIELDRIN
105	DDT AND METABOLITES
106	ENDRIN
107	HEPTACHLOR AND METABOLITES
108	LINDANE
109	METHOXYCHLOR
110	TOXAPHENE
111	PCB'S
112	HEXACHLOROBENZENE
113	MIREX
114	STROBANE
115	NONACHLOR
116	OCTACHLORO DIBENZODIOXIN
117	HEPTACHLORO DIBENZODIOXIN
118	HEXACHLORO DIBENZODIOXON
119	TETRACHLORO DIBENZODIOXIN
120	DICHLOROPHENOL
121	TRICHLOROPHENOL
122	TETRACHLOROPHENOL
123	PENTACHLOROPHENOL
124	P,P-DDT
125	O,P-DDT
126	P,P-DDE
127	O,P-DDE
128	P,P-TDE
129	O,P-TDE
130	UNIDENTIFIED RET REL TO 101
131	UNIDENT PEAK 1 RETN REL TO 101
132	UNIDENT PEAK 2 RETN REL TO 101
133	UNIDENT PEAK 3 RETN REL TO 101
134	UNIDENT PEAK 4 RETN REL TO 101
135	UNIDENT PEAK 5 RETN REL TO 101
136	UNIDENT PEAK 6 RETN REL TO 101

USDA Residue	USDA Residue Name
137	UNIDENT PEAK 7 RETN REL TO 101
138	UNIDENT PEAK 8 RETN REL TO 101
139	UNIDENT PEAK 9 RETN REL TO 101
140	UNIDENTIFIED RET AMT TO 101
141	UNIDENT PEAK 1 AMT REL TO 101
142	UNIDENT PEAK 2 AMT REL TO 101
143	UNIDENT PEAK 3 AMT REL TO 101
144	UNIDENT PEAK 4 AMT REL TO 101
145	UNIDNET PEAK 5 AMT REL TO 101
146	UNIDENT PEAK 6 AMT REL TO 101
147	UNIDENT PEAK 7 AMT REL TO 101
148	UNIDENT PEAK 8 AMT REL TO 101
149	UNIDENT PEAK 9 AMT REL TO 101
150	KEPONE
161	PARA-DICHLORO-BENZENE
162	TETRACHLOROETHYLENE
163	HEPTACHLOR - CHECK SAMPLE REPORTING
164	HEPTACHLOR EPOXIDE - CHECK SAMPLE REP.
181	HALOWAX
191	PBB
192	ETHYLENEDIBROMIDE
193	METHYLBROMIDE
200	ANTIBIOTICS
201	PENICILLIN
202	STREPTOMYCIN

USDA Residue	USDA Residue Name
203	CHLORAMPHENICOL
204	TETRACYCLINE
205	TYLOSIN
206	ERYTHROMYCIN
207	NEOMYCIN
208	OXYTETRACYCLINE
209	CHLORTETRACYCLINE
210	UNIDENTIFIED MICROBIAL INHIBITOR
211	GENTAMICIN
212	LINCOMYCIN
213	CLOXACILLIN
214	APRAMYCIN
215	AMOXICILLIN
216	NOVOBIOCIN
217	SPECTINOMYCIN
218	VIRGINIAMYCIN
298	TETRACYCLINES (INJECTION SITE)
299	SWAB POSITIVE-BIOASSAY NEGATIVE
300	ORGANIC PHOSPHORUS PESTICIDES
301	COUMAPHOS AND OXYGEN ANALOG
302	DICHLORVOS
303	DIAZINON
304	ETHION AND OXYGEN ANALOG
305	MALATHION
306	PARATHION
307	RONNEL
308	CRUFOMATE
309	TRICHLORFON
310	METHYL PARATHION
311	DIOXATHION
312	DISULFOTON
313	FENETHROTHION
314	STIROFOS (OR TETRACHLORINPHOS)
315	CHLOPYRIFOS
316	FENTHION

USDA Residue	USDA Residue Name
318	CARBOPHENTHION (TRITHION R)
319	AZINPHOS-METHYL (GUTHION R)
320	CHLORFENVINPHOS
330	UNIDENTIFIED RET REL TO 306
331	UNIDENT PEAK 1 RETN REL TO 306
332	UNIDENT PEAK 2 RETN REL TO 306
333	UNIDENT PEAK 3 RETN REL TO 306
334	UNIDENT PEAK 4 RETN REL TO 306
335	UNIDENT PEAK 5 RETN REL TO 306
336	UNIDENT PEAK 6 RETN REL TO 306
337	UNIDENT PEAK RENT REL TO 306
340	UNIDENTIFIED RET AMT TO 306
341	UNIDENT PEAK 1 AMT REL TO 306
342	UNIDENT PEAK 2 AMT REL TO 306
343	UNIDENT PEAK 3 AMT REL TO 306
344	UNIDENT PEAK 4 AMT REL TO 306
345	UNIDENT PEAK 5 AMT REL TO 306
346	UNIDENT PEAK 6 AMT REL TO 306
347	UNDIENT PEAK 7 AMT REL TO 306
360	CHLORINATED ORGANIC PHOSPHORUS
361	ETHION METABOLITE
362	COUMAPHOS METABOLITE
363	CHLORPYRIFOS METABOLITE
370	ORGANIC PHOSPHORUS COMPOUNDS
371	2-ETHYLHEXYLDIPHENYL PHOSPHATE
400	ARSENIC
401	ARSENIC
402	MERCURY
403	COPPER
404	LEAD
405	ZINC
406	CADMIUM
407	ANTIMONY
408	SELENIUM
409	ALUMINUM

USDA Residue	USDA Residue Name
410	TITANIUM
411	IRON
412	NICKLE
413	COBALT
414	MANGANESE
415	CHROMIUM
416	TIN
417	SODIUM
418	PHOSPHORUS
419	CALCIUM
420	POTASSIUM
421	MAGNESIUM
500	HORMONES
501	DIETHYLSTILBESTROL
502	DIENESTROL DIACETATE
503	ESTRADIOL BENZOATE
504	MELENGESTROL ACETATE
505	PROGESTERONE
506	TESTOSTERONE
508	MEDROXYPROGESTERONE ACETATE
509	CHLOMADINONE ACETATE
510	ZEARALANOL (ZERANOL)
511	ESTRADIOL MONOPALMITATE
512	HEXESTROL
513	ZEARALENONE
514	TALERANOL
600	CARBAMATES
601	CARBARYL
602	ALDICARB & METABOLITES SULFOXIDE & SULFO
604	PROPOXUR
605	CARBOFURAN AND 3 HYDROXYCARBOFURAN
606	METHIOCARB AND ITS METABOLITE SULFOXIDE
607	BUFENCARB

USDA Residue	USDA Residue Name
608	METHOMYL
615	THIRAM
620	LARVICIDE
621	CYROMAZINE
622	MELAMINE
650	NITROGEN PESTICIDES
651	CARBOXIN
652	AMITRAZ
700	HERBICIDES
701	2,4,-D
702	2,4,5-T
703	METHNEARSONIC ACID
710	TRIAZINE
711	PROMETON
712	PROPAZINE
713	TERBUTYLAZINE
714	ATRAZINE
715	PROMETRYN
716	TERBUTRYN
717	SIMAZINE
718	AMETRYN
800	SULFAS
801	SULFAETHOXYPYRIDAZINE
802	SULFACHLORPYRIDAZINE
803	SULFADIMETHOXINE
804	SULFANITRAN
805	SULFAMETHAZINE
806	SULFACHLOROPYRAZINE
807	SULFAMETHOXYPYRIDAZINE
808	SULFAMERAZINE
809	SULFATHIAZOLE
810	SULFAQUINOXALINE
811	SULFABROMOMETHAZINE
812	SULFAMETHIZOLE
813	SULFANILAMIDE

USDA Residue	USDA Residue Name
814	SULFAPYRIDINE
815	SULFADIAZINE
816	SULFADOXENE
830	UNIDENTIFIED RET REL TO 814
831	UNIDENT PEAK 1 RETN REL TO 814
832	UNIDENT PEAK 2 RETN REL TO 814
840	UNIDENTIFIED RET AMT TO 814
841	UNIDENT PEAK 1 AMT REL TO 814
842	UNIDENT PEAK 2 AMT REL TO 814
900	DRUGS, GENERAL
901	CLOPIDOL
902	FURAZOLIDONE
903	NITROFURAZONE
904	DECOQUINATE
905	MONENSIN
906	IPRONIDAZOLE
907	CARBADOX
908	ROBENIDINE
910	LEVAMISOLE
911	DIMETRIDAZOLE
912	GENTIAN VIOLET
913	DIBUTYLTINDILAURATE
914	LYSERGIC ACID DIETHYLAMIDE
915	PHENCYCLIDINE
916	XYLAZINE
917	LASALOCID
918	NARASIN
921	MORANTEL TARTRATE
922	PYRANTEL TARTRATE
923	IVERMECTIN
924	ARSENIC (DRUGS)
926	HALOFUGINONE
927	CLORSULON
931	UNIDENT PEAK 1 RETN REL TO 2
932	UNIDENT PEAK 2 RETN REL TO 2

USDA Residue	USDA Residue Name
941	UNIDENT PEAK 1 AMT REL TO 29
942	UNIDENT PEAK 2 AMT REL TO 29
950	BENZIMIDAZOLES
951	ALBENDAZOLE
952	FENBENDAZOLE
953	THIABENDAZOLE & METABOLITE
954	MEBENDAZOLE
955	OXFENDAZOLE

USDA TISSUE LOOK-UP TABLE

Code	Name	Code	Name
01	Fat		
02	Liver		
03	Muscle	37	Cheeks
04	Kidney	38	Cloaca
06	Other	39	Colon
07	Lung	40	Comminuted Meat
08	Lymph Node	41	Corpus Luteum
09	Heart	42	Crop
10	Skin	43	Ductus Deferens
11	Spleen	44	Duodenum
12	Brain	45	Ears
13	Eye or Eye Lesion	46	Epididymis
14	Peritoneum	47	Esophagus
15	Nerve	48	Feather
16	Bursa Fabricius	49	Feather Follicle
17	Adrenal Gland	50	Fur
18	Abdomen	51	Gall Bladder
19	Abomasum	52	Ganglion
20	Air Sacs	53	Gizzard
21	Alveolar Duct	54	Gray Matter
22	Alveolar Sac	55	Hair
23	Alveoli	56	Hemal Node
24	Aorta	57	Hock
25	Artery	58	Hoof
26	Blood Vessel	59	Horn
27	Bone	60	Intestinal Glands
28	Bronchi	61	Joint
29	Bronchioles	62	Large Intestine
30	Cardiac Tissue	63	Larynx
31	Cartilage	64	Leg
32	Cecum	65	Lips
33	Cerebellum	66	Lymphatic
34	Cerebrum	67	Lymph Vessel
35	Ceruminous Glands	68	Mammary Gland
36	Cervix	69	Mesentery

USDA TISSUE LOOK-UP TABLE

Code	Name	Code	Name
70	Mouth	98	Thigh
71	Neck	99	Thorax
72	Nose	A1	Thymus
73	Omasum	A2	Thyroid Gland
74	Omentum	A3	Tongue
75	Ovary	A4	Tooth
76	Palate	A5	Trachea
77	Pancreas	A6	Tumor Mass
78	Parathyroid	A7	Ureter
79	Penis	A8	Urinary Bladder
80	Peripheral Nerve	A9	Uterine Horn
81	Phalanges	B1	Uterus
82	Pineal Gland	B2	Vagina
83	Pituitary Gland	B3	Vein
84	Placenta	B4	Ventriculus
85	Prostate Gland	B5	Villi
86	Proventriculus	B6	Vulva
87	Reticulum	B7	White Matter
88	Rectum	B8	Intestine
89	Rumen	B9	Blood Smears
90	Salivary Gland	C1	Oviduct
91	Sebaceous Gland	C2	Keel Bursa
92	Seminal Vesicle	C3	Blood
93	Small Intestine	C4	Serum
94	Spinal Cord	C5	Diaphragm
95	Stomach	C6	Parasite
96	Testis	C7	Multiple Specimens
97	Tissue Mass	C8	Plant Mat. - Soya

USDA TISSUE LOOK-UP TABLE

Code	Name	Code	Name
D1	Secretory Glands		
D2	Plant Fiber		
D3	Urine		
D4	Kidney B		
D5	Serum A		
D6	Serum B		
D7	Bile		
D8	Tailhead Fat		
D9	Brisket Fat		
E1	Hard Bone		
E2	Soft Bone		
E3	Eggs		
E4	Milk		
E5	Colostrum		
E6	Fatty Tissue		
E7	Saliva		
E8	Condensate		
E9	Feed		
F1	Edible Proc. Product		
U3	Urine		

MARCIS SPECIES CODES ON USDA RECORDS

Code	Name	Code	Name
00	Non-Species	51	Market Hog
01	Horse	52	Boar or Stag
10	Bovine	53	Sow
11	Bull	59	Other Red Meat
12	Steer	60	Chicken
13	Beef Cow	61	Young Chicken
14	Heifer	63	Mature Chicken
15	Dairy Cow	70	Turkey
20	Calf	71	Fry Roast Turkey
21	Bob Veal	72	Young Turkey
22	Formula Fed Veal	73	Mature Turkey
23	Non-formula Fed Veal	81	Duck
24	Heavy Calves >400 lbs.	82	Geese
30	Sheep	91	Rabbit
31	Mature Sheep	92	Deer
32	Lamb	97	Blank
40	Goat	98	Blank
50	Porcine	99	Other

SPECIES/ANIMAL LOOK-UP TABLE USED BY USDA

Species #	Species Name	Animal #	Animal Name
1	EQUINE	1	HORSE
10	CATTLE	10	COWS
		11	BULLS/STAGS
		12	STEERS
		13	COWS - BEEF
		14	HEIFERS
		15	COWS - DAIRY
20	CALVES	20	CALVES
		21	BOB - VEAL
		22	FORMULA FED VEAL
		23	NON FORMULA FED VEAL
		24	HEAVY CALVES
30	SHEEP	30	SHEEP
		31	MATURE SHEEP
		32	LAMBS & YEARLINGS
40	GOATS	40	GOATS
50	SWINE	50	SWINE
		51	BARROWS & GILTS / MARKET HOGS
		52	BOARS / STAGS
		53	SOWS
		54	ROASTER PIGS
59	OTHER	58	WATER BUFFALO
		59	OTHER (BUFFALO, ETC.)
		99	OTHER ANIMAL
60	CHICKENS	60	CHICKENS
		61	YOUNG CHICKENS
		63	MATURE CHICKENS
70	TURKEYS	70	TURKEYS
		71	FRYER ROASTER
		72	YOUNG TURKEY
		73	MATURE TURKEY
80	DUCKS	81	DUCKS
		82	GEESE
		84	QUAIL
90	RATITE	83	OSTRICH
		85	EMU
		86	RHEA
91	RABBITS	91	RABBITS
92	DEER	92	DEER

ATTACHMENT B-1
SAMPLE PRODUCER WARNING LETTER
(or for other individual administering medication)

[date]

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

OR Federal Express

RESPONSIBLE INDIVIDUAL(S), TITLE (S)

FIRM NAME

RESPONSIBLE INDIVIDUAL'S COMPLETE MAILING ADDRESS

WARNING LETTER

(#)

Dear [Name]:

An investigation of your [dairy, swine raising, etc.] operation located at [inspected facility's physical address (if different from mailing address)], conducted by a representative of the U.S. Food and Drug Administration (FDA) on [inspection dates (including the last date of evidence collection)], confirmed that you offered (an) animal(s) for sale for slaughter as food that was adulterated under sections 402(a)(2)(C)(ii) [21 U.S.C. 342 (a)(2)(C)(ii)] and 402(a)(4) [21 U.S.C. 342 (a)(4)] of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed that you caused the [new animal drug(s)] [medicated feed(s)] [trade name or generic name of drug(s) or feed(s)] to become adulterated within the meaning of section [501(a)(5)][21 U.S.C. 351(a)(5)] [501(a)(6)][21 U.S.C. 351(a)(6)] and unsafe under section 512 of the Act [21 U.S.C 360b]. You can find the Act and its associated regulations on the Internet through links on the FDA's web page at www.fda.gov.

On or about [date], you [sold] [consigned] a [identify animal/species], identified with [provide some form of man made identification to appropriately identify the animal] for slaughter as food at [name of slaughterhouse]. On or about [date] this animal was slaughtered at [name of slaughterhouse]. United States Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) analysis of tissue samples collected from that animal identified the presence of [level and name of drug(s) for each tissue(s) in which (an) illegal residue(s) (was)/(were) reported]. [No tolerance] [A tolerance of (level)] has been established for residues of [name of drug(s)] in the edible tissues of [type of animal][.] as codified in Title 21, Code of Federal Regulations, Part 556.# (21

C.F.R. 556.#). The presence of [this]/[these] drug(s) in edible tissue(s) from this animal causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) [(21 U.S.C. § 342(a)(2)(C)(ii)].

[For three or more residues you may want to develop a table for clarification]

Our investigation also found that you hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. You lack an adequate system to ensure that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. For example, [you failed to maintain treatment records] [you failed to maintain complete treatment records] [you failed to segregate treated animals] [you lack an adequate inventory system for determining the quantities of drugs used to medicate your animal(s)] **[etc.]**. Food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) of the Act [21 U.S.C. 342 (a)(4)].

In addition, you adulterated [name of drug(s)] within the meaning of section 501(a)(5) [21 U.S.C. 351 (a)(5)] of the Act when you failed to use the drug in conformance with its approved labeling. "Extralabel use," i.e., the actual or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling, is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship. The extralabel use of approved veterinary or human drugs must comply with sections 512(a)(4) and 512(a)(5) of the Act and 21 C.F.R. Part 530. Our investigation found that your extralabel use of [name of drug(s)] failed to comply with these requirements.

For example, you administered the [name of drug(s)] without following the [dosage level] [duration of treatment] [frequency of treatment] [withdrawal period] [in the approved animal class or species] **[other appropriate items]** set forth in the approved labeling and you did so without the supervision of a licensed veterinarian, in violation of 21 C.F.R. 530.11(a). Furthermore, your extralabel use resulted in an illegal drug residue, in violation of 21 C.F.R. 530.11(c). Because your extralabel use of this drug was not in compliance with 21 CFR Part 530, the drug was unsafe under section 512(a) of the Act [21 U.S.C. 360b(a)] and your use caused it to be adulterated within the meaning of section 501(a)(5) of the Act [21 U.S.C. 351(a)(5)].

In addition, you adulterated [name of medicated feed(s)] within the meaning of section 501(a)(6) of the Act [21 U.S.C. 351(a)(6)] when you failed to use the drug in conformance with its approved labeling. Your use of this [medicated feed(s)] without following the [dosage level] [duration of treatment] [frequency of treatment] [withdrawal period] [in the approved animal class or species] **[other appropriate items]** set forth in the approved labeling causes this drug to be unsafe within the meaning of section 512 of the Act [21 U.S.C. 360b]. Section 512 does not permit the extralabel use of medicated feeds.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the food you distribute is in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to [name], Compliance Officer, U.S. Food and Drug Administration, [mailing address]. If you have any questions about this letter, please contact Compliance Officer [name] at [phone, fax, Email, mailing address].

Sincerely yours,

[name]
District Director
[name] District

cc: Additional Responsible Individual(s)
State Regulatory Authority
Producer's Servicing Veterinarian

bcc: HFA-224
HFC-210
HFC-230
HFV-230
HFV-235
HFV-2__ (Center CSO reviewer)
HFI-35 (purged)

ATTACHMENT B-2

SAMPLE WARNING LETTER
EXTRA-LABEL DRUG USE by VETERINARIAN

[Date]

WARNING LETTER
Ref:

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Responsible Individual, Title
Firm Name
Firm's Complete Address

Dear Dr. ____;

On (dates), an investigator from the U.S. Food and Drug Administration (FDA) conducted an investigation involving the use of drugs in your veterinary practice. That investigation revealed that you caused animal drugs to be unsafe under Section 512(a) of the Federal Food, Drug, and Cosmetic Act (the Act) and adulterated within the meaning of Section 501(a)(5) of the Act because the drugs were used in a manner that did not conform with their approved uses or the regulations for Extralabel Drug Use in Animals, Title 21, Code of Federal Regulations (21 CFR), Part 530.

The extralabel use of approved veterinary or human drugs in animals is permitted only if it complies with Sections 512(a)(4) and 512(a)(5) of the Act and 21 CFR Part 530. Our investigation found that you failed to comply with 21 CFR Part 530 in that:

1. You used the drug (trade name) brand of (generic name) in an extralabel manner by administering the drug intravenously to (type of animal). The extralabel use of this drug in this animal is prohibited by 21 CFR Part 530.41(a)(9). Approved uses of such drugs are listed in 21 CFR Part 520.2220a, copy enclosed.

2. You used the drug (trade name) brand of (generic name) in an extralabel manner by administering the drug to (type of animal) without meeting the requirements of 21 CFR Part 530. For example, in the treatment of this animal, milk discard and meat withdrawal periods were not established as required by 21 CFR Part 530.20(a)(2)(ii).

3. You prescribed the intravenous administration of the injection form of the drug (trade name) brand of (generic name) to treat pneumonia in lactating dairy cattle. This is an extralabel use. Approved uses of (generic name) injection are listed in 21 CFR Part 520, copy enclosed. Your prescription

for the extralabel use of this drug did not meet the requirements of 21 CFR Part 530(a)(2)(i)–(iv), which require that you:

(i) Make a careful diagnosis and evaluation of the conditions for which the drug is to be used;

(ii) Establish a substantially extended withdrawal period prior to marketing of milk, meat, eggs, or other edible products supported by appropriate scientific information, if applicable;

(iii) Institute procedures to assure that the identity of the treated animal or animals is carefully maintained; and

(iv) Take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subjected to extralabel treatment.

You caused the aforementioned animal drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act because the drugs were prescribed and used in a manner that did not conform with their approved uses or the regulations for Extralabel Drug Use in Animals, 21 CFR Part 530.

The above is not intended to be an all-inclusive list of violations. As licensed veterinarians, you are responsible for complying with the requirements of the Act, including the extralabel use regulations promulgated under the Act. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

We have enclosed a copy of 21 CFR Part 530 for your reference. We strongly suggest that you review 21 CFR Part 530 and become familiar with all of its requirements so that you can prevent future violations of the Act.

You should notify this office in writing within 15 working days of receiving this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also, include copies of any available documentation demonstrating that your corrections have been made.

Your reply should be directed to Compliance Officer (name) at the address indicated on the letterhead.

Sincerely,

District Director

cc: State Board of Veterinary Medicine, FSIS TSC, State, HFV-232, etc.

ATTACHMENT B-3
SAMPLE WARNING LETTER
ILLEGAL DRUG SALE

[Date]

WARNING LETTER
Ref:

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

FIRM NAME
RESPONSIBLE INDIVIDUAL, TITLE
FIRM'S COMPLETE ADDRESS

Dear ____,

Recently an inspection was made of your veterinary drug distribution facility located at (address). This inspection was conducted on (dates), by a Food and Drug Administration (FDA) investigator from this office, who documented the sales of prescription veterinary drugs, such as (name of drug(s)), without requiring a written prescription or oral order from a licensed veterinarian. Under Section 503(f)(1)(C) of the Federal Food, Drug and Cosmetic Act, the dispensing of a prescription drug other than by or upon the lawful written or oral order of a licensed veterinarian results in the drug being misbranded.

In addition, the prescription drugs dispensed by your firm are misbranded within the meaning of section 502(f)(1) because they lack adequate directions for use. Pursuant to Title 21, Code of Federal Regulations, section 201.5, "adequate directions for use" means adequate directions under which the layman can use a drug safely and for the purposes for which it was intended. Such adequate directions for use by laypersons cannot be written for prescription drugs because the drugs can only be used safely at the direction of, and under the supervision of, a licensed veterinarian.

The corrective action of posting a sign with a list of prescription veterinary drugs that require a veterinarian's prescription does not appear to be adequate. During the inspection of your firm, the FDA Investigator observed your employee selling prescription animal drugs without requiring a written prescription or oral order from a licensed veterinarian. In addition, photographs of your firm's product inventory showed that prescription animal drugs where being held for sale that do not appear on the sign posted by your firm.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

The violations listed above are not intented to be an all-inclusive list. As a corporate official of this firm, you have a responsibility to ensure that all drugs sold by you or other employees of your firm comply with all state and federal laws.

It is necessary that you take action on this matter now. Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the steps you are taking to correct the problems and bring your firm into compliance with the law. Your response should include each step being taken, or that will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, please state the reason for delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demostrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration (Attention: Compliance Officer) at the above address. If you have any questions concerning the deficiencies noted, you may contact Compliance Officer (name).

Sincerely,

District Director

ATTACHMENT B-4
SAMPLE WARNING LETTER
BUYER/DEALER

[Date]

WARNING LETTER
Ref:

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear _____:

An inspection of your operation located in (City, State), by a Food and Drug Administration investigator on (dates), confirmed a (cow/calf/hog) purchased and sold by you on or about (date), for slaughter for human food to (slaughter house), was in violation of Section 402 (a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act.

USDA/FSIS analyses of tissues collected from that animal disclosed the presence of the drug (level and name of drug for each tissue in which illegal residue was reported). A tolerance of ( ) level ppm has been established for residues of (name of drug) in the edible tissues of (type of animal) Title 21 Code of Federal Regulations Section 556. The presence of this drug in edible tissue from this animal causes the food to be adulterated under Section 402(a)(2)(C)(ii) of the Act.

- If appropriate, include the following:

In addition, USDA has reported the finding of illegal residues in (number) other (type of animals) sold by you and offered for slaughter for human food (list animal. drug, date). Copies of letters from USDA/FSIS notifying you of these residues are attached.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.
The violations listed above are not intended to be an all-inclusive list. It is your responsibility to assure that your operations are in compliance with the law. As a dealer of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce, the adulterated animal. As such, you share the responsibility for violating the Federal Food, Drug and Cosmetic Act. To avoid future illegal residue violations you should take precautions such as:

1. Implementing a system to identify the animals you purchase with records to establish traceability to the source of the animal;

2. Implementing a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and

3. If the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

If appropriate, include the following:

You should be aware that it is not necessary for you to have personally shipped an animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an animal for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration Attention Compliance Officer.

Sincerely,

District Director

cc: FSIS TSC, State, HFV-232, etc.

Attachment C - 7371.006

Complete one attachment C for each sample investigated.

The information on each Attachment C is a source and sample combination. This means that all the information on the Attachment has to be related to the source identified in the section "Name and Address of Owner of Animal from FSIS Warning Letter." If you determine during your inspection that 1) the owner wasn't correctly identified, or 2) the residue can't be properly traced back or 3) the investigated source ownership changed, then terminate the inspection per Question #2. You should complete a new Attachment C for each new source investigated.

When completing Attachment C, Question #2, select only one answer for either an FDA investigation (A) or a State Investigation (B). If B is selected, fill in the appropriate 2-letter state code.

Complete questions 9-14 for each residue reported for each sample.

Make sure you properly relate the source to the sample in RVIS.

Send to HFV-235, ATT: Deb Cera

- A complete Attachment C for each source/sample investigated.
- A summary of findings for each investigation.
- If the Attachment C (at least the first two pages) is not printed from the system, please write the source Id on the front page of the Attachment.

EVALUATION FORM FOR ILLEGAL RESIDUES
IN MEAT AND POULTRY

Complete this form only when a tissue residue violation is investigated by an on-site inspection. Complete a separate form for each violation except when there are multiple violations per source. See Section 3 for further details. Submit the completed form and ALL the following:

i. A completed summary of the investigation (FDA Form 481 parts A to E; or equivalent)

ii. A legible copy of USDA-FSIS letter to owner

iii. A legible copy of the USDA-FSIS laboratory report

iv. Any other relevant documents, e.g., FDA 483

The information gathered via this form is crucial to the Residue Reduction Program. To reduce errors, PLEASE TYPE OR PRINT using black ink.

Section 1
BACKGROUND INFORMATION

FSIS Sample Number Initiating Investigation	FSIS Sample Collection Date of Report	FSIS Warning Letter Date	FSIS Case Number

CONCENTRATIONS OF RESIDUES(S) IN TISSUES AS REPORTED BY FSIS:

Residue	Tissue	Concentration

NAME AND ADDRESS OF FIRM FROM FSIS WARNING LETTER IDENTIFIED AS OWNING ANIMAL:

OTHER INFORMATION ABOUT THIS FIRM:

Firm Type: (Circle all that apply.)

DAIRY FARM	PRODUCER/INDEP GROWER
INTEGRATED OPERATIONS	OWNER
CALF RAISER	BEEF RANCH
SWINE OPERATION	FEEDLOT
CONTRACT GROWER	PACKER
HOBBY HERD/FLOCK	TRUCKER
DEALER/JOBBER/TRADER	BUYING STATION
AUCTION MARKET	VETERINARIAN
BROKER	VETERINARY SUPPLY HOUSE
FEEDMILL	UNDETERMINED

FIRMS IDENTIFIED AS BEING RELATED TO THIS SOURCE:

Name:
Address:

1. **WERE THE NAME AND ADDRESS OF THE ANIMAL OWNER IDENTIFIED ABOVE BY USDA SPELLED AND LISTED CORRECTLY? ..... YES/NO**
YES (go to #2), NO (ask District Program Monitor to make corrections in RVIS and to notify appropriate FSIS personnel.)

Section 2
THE INVESTIGATION
(Questions 2 - 8)

2. **TYPE OF INVESTIGATION CONDUCTED IN RESPONSE TO CURRENT FSIS RESIDUE REPORT (circle one letter):**

A. FDA INVESTIGATION (complete 1 or 2 below)

B. STATE _____ (enter 2-letter state code)

(circle one number for either A or B):

1. On-site Inspection (Complete Remainder of Report).

2. Inspection Terminated Due to:
   a. Unable to locate source or traceback
   b. Investigated source's ownership changed
   c. Incorrect source identified by USDA
   d. Other _____

3. **DATE INVESTIGATION/INSPECTION STARTED: __/__/__ (mm/dd/yy)**

4. **DID THE OWNER IDENTIFIED AT SLAUGHTER ADMIT TO TREATING OR AUTHORIZING THE TREATMENT OF THIS ANIMAL/HERD/FLOCK.....? YES/NO**

5. LIST THE FOLLOWING INFORMATION FOR ALL INDIVIDUALS/ORGANIZATIONS WHO HANDLED THE ANIMAL/HERD/FLOCK...WITHIN THREE MONTHS PRIOR TO THE SLAUGHTER DATE.

	Name	Address	Date Animal Acquired	Date Animal Disposed of
A.	_____	_____	_____ mm/dd/yy	_____ mm/dd/yy

Firm type (i.e. dealer, hauler) _____

Reason for Acquisition _____

Reason for Disposition _____

B.	_____	_____	_____ mm/dd/yy	_____ mm/dd/yy

Firm type (i.e. dealer, hauler) _____

Reason for Acquisition _____

Reason for Disposition _____

C.	_____	_____	_____ mm/dd/yy	_____ mm/dd/yy

Firm type (i.e. dealer, hauler) _____

Reason for Acquisition _____

Reason for Disposition _____

D.	_____	_____	_____ mm/dd/yy	_____ mm/dd/yy

Firm type (i.e. dealer, hauler) _____

Reason for Acquisition _____

Reason for Disposition _____

E. None of these

Which source in #5 is responsible for the residue? (Write the letter A-E)___

6. IS THE SLAUGHTER CLASS OF REPRESENTATIVE OF THE PRODUCER'S BUSINESS?

IF YES (go to #7) / NO (circle one below)

The general description of this production unit is (circle one):

A. Dairy Farm
B. Swine Operation
C. Feedlot(Beef)
D. Poultry Flock
E. Beef Ranch (other than Feedlot)
F. Veal Operation
G. Other(Select One)
   1. Sales/Auction Barn
   2. Buyer/Dealer
   3. Slaughter Facility
   4. Hobby herd/flock
   5. Multi-species unit
   6. Other _____

7. APPROXIMATE SIZE OF BUSINESS (circle one):

Number of Animals (On the premises at the date of inspection/investigation)

A. 1-20
B. 21-100
C. 101-500
D. 501-2000
E. Over 2000

Note: For dairies use total animals on contiguous production unit, do not include calves/replacements reared by a contractor at remote locations

8. GENERAL ANIMAL HUSBANDRY PRACTICES OF BUSINESS (Answer each letter):

A. One individual or multiple individuals are authorized to treat animals
(1)One/(M)Multiple..... 1 / M

B. Utilizes services of veterinarian..... YES/NO
(If yes please circle one)
1. On as-needed basis (not routine)
2. For herd health programs only, including pregnancy check
3. For all veterinary medical needs (herd health and as needed)
4. As a member of staff

C. Mixes own feed..... YES/NO
(If yes please circle all that apply)
1. Grinder/mixer/mill routinely cleaned/flushed after processing of medicated feeds
2. Uses sequencing to control unsafe contamination
3. Conforms to cGMPs for mills
4. Mixes non-medicated feed only

D. Buys commercial feed (a complete feed)..... YES/NO

E. Uses medicated milk replacer..... YES/NO

F. Feeds, or allows the young to suckle milk from treated dams..... YES/NO

G. Observes the directions of products used during the dry cow period.... YES/NO

H. Water for animals comes from a private water source (wells, etc.)..... YES/NO

I. Has system for separating treated and non-treated animals..... YES/NO

J. Keeps medical records..... YES/NO

Circle all numbers below that are included in medical recordkeeping:

1-Animal Id
2-Treatment date
3-Drug(s)/medicated feed used
4-Dosage(s) given
5-Route of administration
6-Withdrawal time for meat and milk
7-Individual who administered drug
8-If treatment recommended by veterinarian
9-Date animal can be slaughtered and/or milk can be used

K. Keeps records on the sale and purchase of animals..... YES/NO

L. Keeps records on inventory & accountability of drugs & medicated feeds YES/NO

Section 3
THE COMPOUND
(Questions 9 - 14)

SAMPLEID ID:

The following questions are about the drug(s) whose use resulted in the current tissue residue violation. If multiple animals are involved and uses/causes/treatments vary among animals please complete a set of the following questions (9-14) for each animal. (Also if multiple residues are reported for a single sample complete questions 9-14 for each residue reported.)

9. NAME OF DRUG USED ON THE ANIMAL WHICH CAUSED THE RESIDUE

(Obtain from the product label if available; if unknown write "UNKNOWN")

DRUG NAME _____
(Trade/Proprietary name preferred)

NADA# _____ or NDC# _____

IS THE PRESCRIPTION LABEL PRESENT?..... YES/NO

(i.e. "Caution Federal Law restricts this drug to use by or on the order of a licensed veterinarian.)

10. DRUG(S) WERE ADMINISTERED AS FOLLOWS:

DOSE (i.e. #cc's/#sites) _____ **ROUTE** _____ **FREQUENCY** _____

FOR ROUTE WRITE IN LETTER USING LIST BELOW:

A. Intravenous	D. Intramammary	G. Drinking Water
B. Intramuscular	E. Oral Bolus, Liquid, Tablet	H. Milk Replaces
C. Subcutaneous	F. Feed	I. Intra-Uterine
		J. Topical

FOR FREQUENCY, WRITE IN LETTER USING LIST BELOW):

A. Once	D. TID (Three times daily)	G. PRN (As Needed)
B. SID (Once a day)	E. QID (Four times daily)	H. Other _____
C. BID (Twice a day)	F. EOD (Every other day)	

DATE OF LAST TREATMENT: _____

11. REASON THE DRUG WAS ADMINISTERED TO THE ANIMAL/HERD/FLOCK.
(circle one letter):

A. If used because of illness; specify ailment(s) treated:

_____

_____

B. If used as a preventive measure (circle all numbers that apply):

1. Prior to transportation

2. Prior to addition to an established herd/flock

3. Prior to or during introduction to a farm, ranch, or region with endemic disease

4. To aid animal or flock's adjustment to changes in weather conditions

5. Other: _____

C. If used as a growth promotant/production aid

D. Other: _____

_____

12. Is DRUG LABELED FOR THE USE INDICATED IN QUESTION 11: Y/ N/ CANNOT BE DETERMINED

A. PRODUCT WAS PURCHASED FROM? INDICATE NAME, ADDRESS, AND FIRM TYPE:

NAME: _____

ADDRESS: _____

_____

(circle one number)

1. Feed/Supply Store
2. Mail Order
3. Feed From A Commercial Feed Mill
4. Mobile Peddler/Salesperson
5. Veterinarian
6. Other: _____

B. Did veterinarian, through a valid veterinarian-client-patient relationship (VCPR), prescribe the use of the drug in #9? ..... YES/NO

(If yes, verify and answer 12C and 12D)

Is there a veterinarian's label on the product?..... YES/NO

Does the veterinarian's label on the product specify the following:

1. Indication for Use?..... YES/NO
2. Dosage?..... YES/NO
3. Duration of Therapy?..... YES/NO
4. Expiration Date?..... YES/NO
5. Name and address of practitioner? ..... YES/NO
6. Contraindications?..... YES/NO
7. Route of Administration?..... YES/NO
8. Withdrawal Period?..... YES/NO
9. Active Ingredients?..... YES/NO

COMPLETE C AND D BELOW IF A FOLLOW-UP AT THE VETERINIARIAN IS CONDUCTED
(CP 7371.006, Part III, pp. 4-5)

C. Do the veterinarian's records substantiate a valid VPCR?
..... YES/ NO/ CANNOT BE DETERMINED

D. Was the prescribed use:

1. Consistent with an approved product's label?..... YES/NO

2. Modification of indications, dose, precautions of an approved product? YES/NO

3. Compounded from one or more (approved or unapproved) ingredients?..... YES/NO

(If #3 is yes, circle one answer for each letter):

a. For a (T)Therapeutic or (P)Production use..... T/P

b. Based on (C)Clinical needs or (A)Anticipation of sale..... C/A

c. Product (I)Is or is (N)Not promoted for sale..... I/N

If compounded by a veterinarian, list all the components of the product:

Product 1	Product 2
Name: _____	Name: _____
Components:	Components:
A. _____	A. _____
B. _____	B. _____
C. _____	C. _____
D. _____	D. _____
E. _____	E. _____
F. _____	F. _____
Prescribed withdrawal time_____days	Prescribed withdrawal time_____days

13. What was the PRIMARY factor causing this violation?

(circle one letter):

A. Production Management Causes
(If production management is the cause, circle one number):

1. Animal(s) fed colostrum or milk containing drug residue
2. Animal(s) fed medicated feed by mistake
3. Drug administered to animal(s) by mistake
4. Failure to keep proper animal identity and treatment records
5. Inadequate segregation of treated animal(s)
6. Failure to follow labeled/prescribed withdrawal time
7. Feed manufacturing cGMP deviations

B. Extra-Label Use
(If extra label use is the cause, circle one number):

1. Veterinarian's prescribed withdrawal period not observed
2. Withdrawal period verbally recommended by veterinarian not observed
3. Animal treated with higher than the recommended dosage of drug
4. Labeled route of administration not observed
5. No withdrawal period prescribed
6. Drug not approved for species
7. Frequency of treatment different than on label
8. Duration of treatment longer than on label

C. Unable to Determine.

D. Interviewee stated drug used was not the same as residue reported by FSIS.

E. Interviewee told purchaser/hauler animal was medicated - animal later diverted for human food.

F. All label/prescription directions followed and documented, residue still occurred.

G. Other _____

14. What are ADDITIONAL factors contributing to this violation?

(circle one letter):

A. Production Management Causes
(If production management is the cause, circle one number):

1. Animal(s) fed colostrum or milk containing drug residue
2. Animal(s) fed medicated feed by mistake
3. Drug administered to animal(s) by mistake
4. Failure to keep proper animal identity and treatment records
5. Inadequate segregation of treated animal(s)
6. Failure to follow labeled/prescribed withdrawal time
7. Feed manufacturing cGMP deviations

B. Extra-Label Use
(If extra label use is the cause, circle one number):

1. Veterinarian's prescribed withdrawal period not observed
2. Withdrawal period verbally recommended by veterinarian not observed
3. Animal treated with higher than the recommended dosage of drug
4. Labeled route of administration not observed
5. No withdrawal period prescribed
6. Drug not approved for species
7. Frequency of treatment different than on label
8. Duration of treatment longer than on label

C. Unable to Determine.

D. Interviewee stated drug used was not the same as residue reported by FSIS.

E. Interviewee told purchaser/hauler animal was medicated - animal later diverted for human food.

F. All label/prescription directions followed and documented, residue still occurred.

G. Other _____

15. ACTION(S) TAKEN TO EDUCATE INDIVIDUAL/ORGANIZATION(S) RESPONSIBLE PARTY FOR CURRENT VIOLATION ON HOW TO PREVENT THE OCCURRENCE OF TISSUE RESIDUE VIOLATIONS IN THE FUTURE (circle all that apply):

A. Discussed the need to adhere to drug-label instructions with special emphasis on dosage, withdrawal time, route of administration, and approved species

B. Discussed the need to properly identify animals

C. Discussed the need to keep good medical and sales/purchase records on treated animals

D. Discussed the need to maintain a cull pen for treated/sick animals, especially the need to separate treated dams (or their products) from sucklings

E. Discussed availability of husbandry information and consultation services provided by Federal/State/County Extension Service

F. Discussed inventory and accountability of all drugs and medicated feeds

G. Other: _____

i.e. Consult vets, QA programs, train people involved w/ drugs, control access to drugs, etc.

ATTACHMENT D – USDA CONTACTS

FSIS Technical Service Center (TSC) The TSC serves as the Agency's center for technical assistance, advice and guidance.Telephone (402) 221-7400 FAX (402) 221-7438

FSIS District Offices

Alameda, CA
District 05
State: California
Dr. Neal Westgerdes, District Manager
620 Central Avenue
Building 2c
Alameda, CA 94501
Phone: (510)337-5000
Ext. 1 for DM or DDM
FAX: (510)337-5081
Emergency 24-Hour: 1-866-729-9307

Albany, NY
District 65
States: Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, Vermont
Mr. Louis Leny, district Manager
230 Washington Ave. Extension
Albany, NY 12203-5369
Phone: (518)452-6870
FAX: (518)452-6870
Emergency 24-Hour: 518-452-6870, Ext. 250

Atlanta, GA
District 85
States: Florida, Georgia, Puerto Rico, Virgin Islands
Dr. Larry Smith, District Manager
100 Alabama St., SW; Bldg 1924
Suite 3R90
Atlanta, GA 30303
Phone: (404) 562-5900
FAX: (404) 562-5877
Emergency 24-Hour: 1-800-282-7005

Beltsville, MD
District 75
States: Delaware, District of Columbia, Maryland, Virginia, West Virginia
Dr. Mohamed Ibraheim, District Manager
5601 Sunnyside Ave.
Suite 1-2288 B
Beltsville, MD 20705-5200
Phone: (301) 504-2136
FAX: (301) 504-2140
Emergency 24-Hour: 1-800-289-4116

Boulder, CO
District 15
States: Alaska, American Samoa, Arizona, Colorado, Guam, Hawaii, Idaho, New Mexico, Nevada, Northern Mariana Islands, Oregon, Utah, Washington

Boulder Office
Dr. Ronald K. Jones, District Manager
Boulder Office
665 South Broadway
Suite B
Boulder, CO 80303
Phone: (303) 497-5411
FAX: (303) 497-7306
24-Hour Emergency: (303) 497-5411

Salem Office
530 Center Street, NE
Mezzanine
Salem, Oregon 97301
Phone: (503) 399-5831
FAX: (503) 399-5636
24-Hour Emergency: (303) 497-5411

Chicago, IL
District 50
States: Illinois, Indiana, Ohio
Mr. Richard Mackey, District Director

Chicago Office
1919 South Highland Avenue

Suite 115C
Lombard, IL 60148
Phone: (630) 620-7474
FAX: (630) 620-7599
24-Hour Emergency: 1-888-874-6503

Pickerington Office
155 East Columbus Street
Pickerington, OH 43147
Phone: (614) 833-1405
FAX: (614) 833-1067
24-Hour Emergency: 1-888-874-6503

Dallas, TX
District 40
State: Texas
Mr. Alfred Almanza, District Manager
1100 Commerce Street
Room 516
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Phone: (214) 767-9116
FAX: (214) 767-8230
24-Hour Emergency: (214) 767-9116, Ext. 250

Des Moines, IA
District 25
States: Iowa, Nebraska
Mr. Dennis Greening, District Manager
Room 985, Federal Building
210 Walnut Street
Des Moines, IA 50309
Phone: (515) 727-8960
or 1-800-990-9834
FAX: (515) 727-8991
24-Hour Emergency: (515) 710-1829 or (515) 240-0181

Jackson, MS
District 90
States: Alabama, Mississippi, Tennessee
Dr. Paul Resweber, District Manager
715 S. Pear Orchard Road, Suite 101
Ridgeland, MS 39157
Phone: (601) 965-4312
FAX: (601) 965-5901
24-Hour Emergency: (601) 662-3407

Lawrence, KS
District 30
States: Kansas, Missouri
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4920 Bob Billings Parkway
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Phone: (785) 841-5600
FAX: (785) 841-5623
24-Hour Emergency: (785) 840-0020

Madison, WI
District 45
States: Michigan, Wisconsin
Dr. Linda Madson, District Manager
2810 Crossroads Dr.
Suite 3500
Madison, WI 53718-7969
Phone: (608) 240-4080
FAX: (608) 240-4092
24-Hour Emergency: 1-888-724-3212 Pin #300267

Minneapolis, MN
District 20
States: Minnesota, Montana, North Dakota, South Dakota, Wyoming
Dr. Nathaniel Clark, District Manager
Butler Square West, Suite 989-C
100 N. 6th Street
Minneapolis, MN 55403
Phone: (612) 370-2400
FAX: (612) 370-2411
24-Hour Emergency: 1-800-923-9535

Philadelphia, PA
District 60
States: New Jersey, Pennsylvania
Mr. Jan T. Behney, District Manager
Mellon Independence Center
701 Market Street – Suite 4100-A
Philadelphia, PA 19106-1576
Phone: (215) 597-4219, Ext. 101
or 1-800-637-6681
FAX: (215) 597-4217
24-Hour Emergency: 1-800-637-6681, Ext. 101 or Ext. 113

Raleigh, NC
District 80
States: Kentucky, North Carolina, South Carolina

Dr. Lewis Burgman, District Manager
6020 Six Forks Road
Raleigh, NC 27609
Phone: (919) 844-8400
or 1-800-662-7608
FAX: (919) 844-8411
24-Hour Emergency: (919) 844-8400

Dr. Marcia Endersby, District Manager
Country Club Center
Bldg. B, Suite 201
4700 South Thompson
Springdale, AR 72764
Phone: (479) 751-8412
FAX: (479) 751-9049
24-Hour Emergency: (479) 751-8412

Springdale, AR
District 35
States: Arkansas, Louisiana, Oklahoma

Office of Program Planning, Evaluation, and Enforcement
Regional Offices

Western Region
States: Alaska, American Samoa, Arizona, California, Colorado, Guam, Hawaii, Idaho, Mariana Islands, Nevada, New Mexico, Oregon, Utah, Washington
Regional Manager
620 Central Avenue, Building 2B
Alameda, CA 94501
Phone: (510) 337-5000, Ext. 249
FAX: (510) 337-5080
Emergency: (202) 276-1610

Southwest Region
States: Arkansas, Louisiana, Oklahoma, Texas
Regional Manager
1100 Commerce Street, Room 516
Dallas, TX 75242
Phone: (214) 767-9116, Ext. 400
FAX: (214) 767-8230
Emergency: (214) 763-1853

Great Plains Region
States: Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, North Dakota, South Dakota, Wyoming
Regional Manager
4920 West 15th Street, Suite B
Lawrence, KS 66049
Phone: (785) 840-9026
FAX: (785) 843-0548
Emergency: (785) 423-5402

Midwest Region
States: Illinois, Indiana, Ohio, Michigan, Wisconsin
Regional Manager
1919 South Highland Avenue, Suite 120C
Lombard, IL 60148
Phone: (630) 916-6226, Ext. 264
FAX: (630) 620-7876
Emergency: (630) 768-8418 (Alert 1)

Southeast Region
States: Alabama, Delaware, District of Columbia, Florida, Georgia, Kentucky, Maryland, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virginia, Virgin Islands, West Virginia
Regional Manager
100 Alabama Street SW
1924 Building, Suite 3R90
Atlanta, GA 30303
Phone: (404) 562-5962
FAX: (404) 562-5935
Emergency: (404) 569-3060

APHIS Veterinary Services Offices

(Call Veterinary Services Office to contact current Animal ID Coordinator)

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GIPSA

Headquarters

GIPSA
1400 Independence Ave., SW
Room 1641
South Bldg
Washington, DC 20250
(202) 720-7051

Regional Offices	States Covered
P&SP 75 Spring Street Suite 230 Atlanta, GA 30303 (404) 562-5840	AL, AK, CT, DC, DE, FL, GA, LA, MA, MD, ME, MS, NC, NH, NJ, NY, PA, RI, SC, TN, VA, VT, WV
P&SP 1 Gateway Centre 3950 Lewiston Suite 200 Aurora, CO 80011 (303) 375-4240	AK, AZ, CA, CO, HI, ID, KS, MT, NE, NM, OK, OR, TX, VT, WA, WY
PS&P Federal Bldg Room 317 210 Walnut Street Des Moines, IA 50309 (515) 323-2590	IA, IL, IN, KY, OH, MI, MO, MN, ND, SD, WI

ATTACHMENT E – GIPSA / TITLE 18 MEMO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Date JUN 2 3 1987

From Acting Associate Director for
Surveillance and Compliance, HFV-200

Subject 403(a), Packers and Stockyards Act, and Title 18, Chapter 100 References in Regulatory Letters: Illegal Residues

All District offices

We have recently had occasion to review a number of issues regarding Regulatory Letters issued on illegal tissue residue violations in cases where false certificates were identified under the *USDA* Voluntary Veal Certification Program.

Our considerations in this memorandum are based on the presumption that you have other supportable Title 21 charges to include in your Regulatory Letter. We are not prepared to issue Regulatory Letters addressing Title 18 alone. In addition, *FDA* is not committing itself to take regulatory action under Title 18, or the PSA Act for false drug residue certificates, which are in fact, presented to another Federal agency, i.e. FSIS, as it would be their prerogative and responsibility to bring such action our intent in addressing Title 18, in these circumstances, is to inform the violator that another agency (PSA or FSIS) may be interested in taking action under their Acts (7 U.S.C. 181 et. seq, 15 U.S.C. 50) or under 18 U.S.C. 1001, for false information presented to that agency. This is the result of an agreement with those agencies that we will convey the message concerning Title 18 violations in letters we issue.

1. Title 18 (18 U.S.C. 1001)

(a) When an illegal tissue residue violation occurs and the offering of a false certificate is well documented, demonstrating a willful, intentional act, we recommend the District consider referral of the case to the Packers and Stockyards Administration (PSA) and the Food Safety Inspection Service (FSIS) (see attached lists for referral), since a felony prosecution may be appropriate. A Title 18 reference in a Regulatory Letter would not be appropriate in these circumstances.

(b) When evidence of false certificates exists, without a well documented, willful, intentional act, we recommend the following cautionary statement:

We caution you that it is a violation of United States Code, Title 18, Section 1001 (18 U.S.C. 1001) (copy enclosed) to make intentional or willful, false, fictitious or fraudulent statements or representations in any matter within the jurisdiction of any department or

agency of the United States, and that you may be subject to severe penalties under the criminal provisions of 18 U.S.C. 1001.

2. Likewise in all cases where evidence of false certificates exist, with documentation of an intentional act, *the* District should refer, in the information portion of the Regulatory Letter, to possible action by the Packers and Stockyards Administration, under the Packers and Stockyards Act (7 U.S.C. 181 et. seq. and 15 U.S.C. 50), in addition to referral of the case to the Packers and Stockyards Administration.

Example: We note that you have provided (a) false drug residue certificate(s) on the calf (calves) identified with Back Tag ___, which may subject you to possible action under the Packers mid Stockyards Act (7) U.S.C. 181 et. seq. and 15 U.S.C. 50 by the Packers and Stockyards Administration.

3. In addition, a copy of the Regulatory Letter should be sent to the local/regional office of the Packers and Stockyards Administration, in all cases where false certificates exist. A copy should also be sent to the local compliance office of the Food Safety and Inspection Service. (Use attached lists for mailing copies)

4. 403(a) Charge

A 403(a) charge has been proposed in at least one tissue residue case, for the offering of a false drug residue certificate, considering the certificate as labeling, and the "labeling" as false and misleading.

We currently are unable to support a 403(a) misbranding charge for the offering of a false certificate by the seller of an animal. We do not believe a 403(a) charge is appropriate in such circumstances.

ATTACHMENT F-1
Example of Slaughter House Affidavit to Document Chain of Custody

AFFIDAVIT Sample No. (Doc. Sample No.)

STATE OF_____ COUNTY OF_____

Before me, _____, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803: Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. I of 1953, Secs.1-9, effective April 11. 1953; and P.L. 96-88, Sec. 509. 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths. Affirmations and affidavits, personally appeared _____ in the county and State aforesaid, who, being duly sworn, deposes and says:

I am the Accounts Payable Livestock employee at firm name, address, city, state, Zip, and I am responsible for all record keeping practices regarding the consignment, slaughter, identification, distribution, and compensation for dairy cows and other types of animals.

On 5/1/04, _____Dairy, located at _____, consigned three cows at this slaughter facility, as shown by Consignment Record dated ____. This record shows that the cows were identified by back tag #'s ___, ___, and ___. It also shows that insert dealer name and address picked up these cows, identified them, and transported them to us in his truck and trailer for slaughter into food for human consumption.

Kill Sheet dated ____ shows that we slaughtered the cow identified by back tag #___ as part of lot #___. It also shows that she was identified by several numbers, i.e., House Tag #___, and USDA Retain Tag #____ (last four digits).

While in our possession, we did not medicate this cow in any manner.

All records have been identified by me and supplied to Investigator _____.

_____
AFFIANT'S SIGNATURE AND TITLE

_____
FIRMS NAME AND ADDRESS (Include ZIP Code)

_____
Subscribed and sworn to before me at _____ (City /State) this day of _____

_____
(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925. Reorganization Plan IV effective June 30, 1940. Reorganization Plan No, I of 1953, effective April 11, 1953; and PL 96-88 effective May 4, 1980.

DATE OF ISSUANCE: August 1, 2005
MINOR CORRECTIONS: August 23, 2005
FORM FDA 2438

ATTACHMENT F-2
Example of Slaughter Plant Inspector Affidavit

AFFIDAVIT Sample No. _____

STATE OF_____ COUNTY OF_____

Before me, _____, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803: Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. I of 1953, Secs.1-9, effective April 11. 1953; and P.L. 96-88, Sec. 509. 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths. Affirmations and affidavits, personally appeared _____ in the county and State aforesaid, who, being duly sworn, deposes and says:

On September ___, 200_, a F.A.S.T. test that I ran yielded a positive result.

Whenever a tissue sample is collected for laboratory analysis an FSIS Form 10, Q-02-2 is prepared by filling in items one (1) through seventeen (17). The tissue and the forms are then sent directly to the USDA laboratory in _____ for identification and quantification of the drug residue. The samples are packed in specially constructed shipping ice boxes which contain bottles of frozen water to refrigerate the samples which are shipped by overnight delivery. I or my staff collected the sample and performed the F.A.S.T. screening test on the following animal:

Sample Form No. _____
Collection Location _____
Collection Date _____
Retain Tag Number_____
Animal ID Tag(s)_____

_____
AFFIANT'S SIGNATURE AND TITLE

_____
FIRMS NAME AND ADDRESS (Include ZIP Code)

_____
Subscribed and sworn to before me at _____ (City /State) this day of _____

_____
(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925. Reorganization Plan IV effective June 30, 1940. Reorganization Plan No, I of 1953, effective April 11, 1953; and PL 96-88 effective May 4, 1980.

ATTACHMENT G
DRUG INVENTORY

TISSUE RESIDUE INSPECTIONS

Drug inventory to be completed by all Federal and State investigators conducting tissue residue inspections.

FSIS Sample Number:_____

Fiscal Year:_____

State:_____

FDA District:_____

Type of Animal: _____

Please circle the drug tradename of **all** drugs found at the firm (drugs are listed alphabetically by active ingredient, and under each active ingredient by dosage form and trade name.) The information collected via this inventory will be used to develop future sampling strategies. While completing this document please look for and document the use of any illegally compounded products, Animal Medicinal Drug Use Clarification Act (AMDUCA)-prohibited drugs, or unapproved drugs (a further description of these products can be found at the end of this inventory). Space has been allotted at the end of the list for additional drugs you may find on the premises. Return this drug inventory survey to your local FDA district Tissue Residue Coordinator. If you have any questions on this inventory please contact Deborah Cera at (301)827-0181.

Acepromazine Maleate (tranquilizer)

- Injection

  PromAce® Injectable

  Acepromazine Maleate Injection

- Oral

  PromAce® Tablets

  Acepromazine Maleate Tablets

Albendazole: (antiparasitic, benzimidazole family)

- Oral: Valbazen®

Albuterol: (bronchodilator, Beta-agonist) Approved for use in horses only. Not approved in cattle or swine.

- Intranasal: Torpex ™

Amikacin (antimicrobial, aminoglycoside {AGS})

- Injection
  Amiglyde-V
  Amikacin Sulfate Injection

Amoxicillin Trihydrate (antimicrobial, penicillin family beta lactam)

- Oral:
  Amoxi-Doser
  Amoxi-Bol
  Amoxi-Sol
  Amoxi-Tabs
  Amoxi-Drop® Oral Suspension
  Clavamox® Tablets
  Clavamox® Drops
  Robamox®-V Tablets

- Injectable
  Amoxi-Inject 25 Grams
  Amoxi-Inject 3 Grams
  Robamox®-V

- Intramammary: Amoxi-Mast

Ampicillin Anhydrous: (antimicrobial, penicillin family beta lactam)

- Injectable: Omnipen 250 mg

Ampicillin Sodium: (antimicrobial, penicillin family beta lactam)

- Injectable: Amp-Equine

Ampicillin Trihydrate (antimicrobial, penicillin family beta lactam)

- Injectable:
  Polyflex®
  Princillin Injection
  Ampicillin Trihydrate
  Princillin Injection 200 mg
  Ampi-Ject

- Oral:
  Princillin Bolus
  Ampi-Bol
  Princillin Capsules 125 mg
  Princillin Capsules 250 mg
  Princillin Capsules 500 mg
  Princillin "125" For Oral Suspension

- Water: Princillin Soluble Powder

Amprolium: (anticoccidial)

- Water:
  Amprovine 9.6% Solution
  Amprovine 20% Soluble Powder
  Corid 20% Soluble Powder

- Medicated Feed:
  Broiler PMX No.1620,
  Amprol HI-E® Plus
  Amp Ethopabate CTC® Sodium Sulfate
  Erythro® (Low Lev) / Amp plus Etho

Swisher Super Broiler 300-108;
Swisher Super Broiler 400-112
Chick Grower-Developer Fortified
Amprol Plus / Lincomix® / Roxarsone
Lincomix® / Amprol Plus
Amprol HI-E® / Roxarsone
Amprol HI-E® / BMD® / Roxarsone
Rainbrook Broiler Premix No.1
Rainbow Broiler Base Concentrate
Rainbow Broiler Base Concentrate
Amprol HI-E® & Bambermycins
Amprol HI-E® / Flavomycin®
3-Nitro® / Amprol HI-E® / Flavomycin®
3-Nitro® / Amprol / Flavomycin
3-Nitro® / Amprol / Flavomycin®
Zinc Bacitracin & Amprol HI-E®
Baciferm® / Amprol HI-E® Premix
Amprol / Carb-O-Sep®
Amprol HI-E® / Stafac®
Flavomycin® / Amprolium
3-Nitro® / Amprol® / BMD®
Amprol® / BMD®
Albac® / Amprol Hi-E®
3-Nitro® / Albac® / Amprol Hi-E®
3-Nitro® / Albac® / Amprol Hi-E®

- Oral: Purina® Liquid Amprol

Aspirin: (Non Steroidal Anti Inflammatory {NSAID})

- Oral: boluses

Boldenone Undecylenate (anabolic steroid) Controlled Drug (DEA)

- Injectable: Equipoise®

Bovine Somatotropin (growth hormone)

- Injectable: Sometribove Zinc)Posilac 1 Step®

Butorphanol (analgesic, opioid) Controlled Drug (DEA)

- Injectable:

  Torbutrol® Injection

  Torbugesic®

  Torbugesic-SA ®

  Dolorex®

- Oral: Torbutrol® Tablets

Carbadox (anticoccidial)

- Medicated Feed:

  Mecadox® Premix 10

  Banminth® / Mecadox®

Ceftiofur: (antimicrobial, cephalosporin family beta lactam)

- Injectables:

  Excenel®

  Naxcel®

Cephapirin (antimicrobial, cephalosporin family beta lactam)

- Intramammary:

  Cefa-Dry®

  Tomorrow® Infusion

  Cefa-Lak®

  Today® Intramammary Infusion

Chloramphenicol (antimicrobial) Extra label use prohibited in Food Animals
(chloramphenicol drugs below are small animal approvals)

- Injection: Mychel-Vet Injection
- Oral:
  - Chlorasol
  - Chloromycetin Tablets 100 mg
  - Chloromycetin Tablets 250 mg
  - Chloromycetin Tablets 500 mg
  - Chlora-Tabs 100
  - Tevcocin Tablets
  - Amphicol-V
  - Chloromycetin Ophthalmic Ointment
  - Chloramphenicol Capsules
  - Chloricol
  - Mychel-Vet Capsules (50 mg)
  - Chloramphenicol Capsules
  - Anacetin Tablets
  - Mychel-Vet Tabs
  - Medichol Tablets
- Topical chloramphenicol:
  - Chlorasone Ophthalmic Ointment
  - Chloramphenicol 1% Ophthalmic
  - Vetrocloricin Opthalmic Ointment

Chlortetracycline: (antimicrobial, tetracycline family)

- Medicated feed
  Aureomix S 700-A
  Aureomix S 700-E
  Aureomix S 700 Crumbles
  Aureomix S 700 g
  Chlorachel ™ 10
  Chlorachel ™ 20
  Chlorachel ™ 35
  ChlorMax ™ 10 Type A Medicated Article
  CLTC-10
  CLTC-20
  CLTC-30
  CLTC-50
  CLTC-50 MR
  Pennchlor ™ 64
- Milk replacer: Pfichlor 100S Milk Replacer Type A Medicated Article
- Oral
  Aureomycin® Tablets 25 mg
  Calf Scour Boluses,
- Water
  Soluble powder
  Aureomycin® Soluble Powder

Chlorothiazide: (diuretic)

- Oral: Diuril® bolus

Clenbuterol: (beta agonist) Extra label use prohibited in food animals

- Oral : Ventipulmin®

Clindamycin (antimicrobial, lincosamide family)

- Oral:
  Antirobe® Capsules,
  Antirobe® Aquadrops Liquid
  Clindamycin Hydrochloride Oral Liquid
  Clinsol®
  Clindamycin Hydrochloride Capsules
  Clintabs®

Cloxacillin (antimicrobial, penicillin family beta lactam)

- Intramammary
  Boviclox
  Dry-Clox®
  Dry-Clox® Intramammary Infusion
  Orbenin DC, Dariclox®

Danofloxacin (antimicrobial, fluoroquinolone family) Extra label use prohibited in food animals

- Injection: A180® (beef cattle)

Dihydrostreptomycin (antimicrobial, aminoglycoside family)

- Intramammary:
  Quartermaster® Dry Cow Treatment
  Dry-Mast
- Injection:
  Dihydrostreptomycin
  Pfizer-Strep
- Bulk drug[1]:
  Dihydrostreptomycin Sulfate

[1] Bulks drugs prohibited from use in compounded drugs for Animals, under AMDUCA!

Dexamethazone: (anti-inflammatory long acting glucocorticoid [steroid])

- Injectable

  Azium® Aqueous Suspension Veterinary

  Voren® Suspension, generics

- Oral

  Azium® Boluses

  Azium® Powder 10 mg

  Naquasone® Bolus,

Decoquinate (anticoccidial, quinolone)

- Medicated feed:

  Deccox® Type A Medicated Article

  Deccox® / Lincomycin

  Decoquinate & Lincomycin

  3-Nitro® / Deccox®

  Albac® / Deccox®; Broiler Finisher Medicated

  ChlorMax ™ / Deccox®

  Decoquinate & Chlortetracycline

  Lincomix® / Deccox®

  Deccox® / Lincomycin

  Decoquinate & Lincomycin

  3-Nitro® / Deccox® / Albac®

  Deccox® - M Medicated Powder for Whole Milk

  3-Nitro® / BMD® / Deccox®

  BMD® / Deccox®

  Chloromax® / Deccox®

  Decox ® / Rumensin ®

  Deccox® / Rumensin® / Tylan®

  Aureomycin® / Deccox®

  3-Nitro® / Albac® / Deccox®

  Albac® / Deccox®

Detomidine (sedative, nonopioid)

- Injectable: Dormosedan ™

Dimethyl sulfoxide (DMSO): (NSAID, solvent)

- Topical: Domoso® Solution, Domoso® Gel

Dinoprost Tromethamine: (hormone, synthetic prostaglandin analog)

- Injectable: Lutalyse® Sterile Solution

Dipyrone: (NSAID) Not approved in the US!

- injectable

Enrofloxacin: (antimicrobial-fluoroquinolone family) Extra label use prohibited in food animals

- Injection: Baytril® 100 Injectable Solution (beef cattle), Baytril® Antibacterial Injectable Solution (dogs)
- Oral: Baytril® Antibacterial Tablets (dogs); Baytril® Taste Tabs ™ Antibacterial Tablets (dogs); Baytril® 3.23% Concentrate Antimicrobial Solution (chickens)
- Topical: Baytril® Otic (dogs)

Eprinomectin (antiparasitic-ivermectin family)

- Topical Pour-On

  Ivomec® Eprinex ™ Pour-On for Beef and Dairy Cattle

  Ivomec® Eprinex ™ Pour-On for Cattle

Erythromycin (antimicrobial-macrolide family)

- Injectable: Erythro® - 100, 200; Gallimycin® Injectable, Erythro®-100 Injection
- Intramammary: Erythro®-36 Dry; Gallimycin®-36 Dry, Erythromast 36, Gallimycin®-36 Sterile
- Medicated feed: Gallimycin® 50

Estradiol (hormone, nonsynthetic)

- Implants:
  Compudose 200
  Compudose 400
  Revalor®-200
  Revalor®-H
  Revalor®-IH
  Synovex® Plus

Estradiol Benzoate (hormone, synthetic)

- Implant:
  Component® TE-G with Tylan®
  Component® TE-S with Tylan®
  Synovex®-C
  Synovex®-S
  Synovex®-H

Estradiol Cypionate (hormone, synthetic) Not approved in US

- Injection: Estradiol Cypionate

Fenbendazole: (antiparasitic, benzimidazole family)

- Oral:
  Panacur® Suspension 10% (Rx label)
  Panacur® Granules 22.2%
  Panacure®-C, Panacur® Paste
  Safeguard® (OTC label) –paste
  Safe-Guard® Suspension 10%
  Purina® Worm-A-Rest Litter Pack
- Medicated feed:
  Safeguard® Type A medicated article
  BMD® / Safe-Guard®
- Medicated feedblocks: Safe-Guard® Enproal Feedblocks

Florfenicol (antimicrobial, chloramphenicol family)

- Injection: Nuflor® Injection
- Oral: Nuflor® Concentrate Solution

Flunixin meglumine: (NSAID)

- Injection:
  Banamine® injectable Solution
  Flunixin Meglumine Injection
  Flunixin Meglumine Solution
- Oral:
  Banamine® paste
  Banamine granules

Furazolidone [see nitrofurazone]: (antimicrobial-nitrofuran family) Extra label use prohibited in food animals

- Topical:
  Furox® Aerosol Powder
  Topazone Aerosol Powder

Furosemide: (diuretic)

- Injection: Lasix®

Gentamicin: (antimicrobial, aminoglycoside)

- Dip (turkey eggs):
  - Garasol® Solution
  - Gentasol
- Injectables: ***No approvals in Cattle, very long preslaughter withdrawal***
  - Gentocin®
  - Garasin®
  - Garasol®
  - Gentamicin Sulfate Inj. Sol.
  - Gentamicin Sulfate Solution
  - Legacy Sterile Solution
  - Gentaglyde ™ Solution
  - Gentamex ™ 100
  - Gentamicin Sulfate Solution
- Intramammary: *none approved* (may dilute in saline, or reconstitute)
- Ophthalmic:
  - Gentocin® Durafilm Ophthalmic Solution
  - Gentocin® Ophthalmic Ointment
  - Gentocin® Pink Eye Spray
- Oral:
  - Garacin Oral Solution
  - Gentocin® Oral Solution
  - Gentocin® (Garacin) Pig Pump Oral Solution
  - Gentocin® (Garacin) Soluble Powder
  - Gentamicin Sulfate Pig Pump Oral Solution
  - Gentoral®

- Topical:

  Gentocin® Otic Solution

  Topagen® Ointment

  Gentocin® Topical Spray

  Otomax®

  Mometamax ™ Otic Suspension

  Betagen ™ Topical Spray

  Tri-Otic Ointment

  Gentavet® Otic Solution

- Water: Gen-Gard ™ Soluble Powder

Hetacillin (antimicrobial, penicillin family beta lactam)

- Intramammary:

  Hetacin® K

  Hetacin® K Intramammary Infusion

Isoflupredone: (anti-inflammatory, glucorticoid)

- Injectable: Predef® 2x Sterile Aqueous Suspension
- Topical: Neo Predef® Sterile Ointment

Ivermectin: (antiparasitic, ivermectin family)

- Injection:

  Eqvalan® Injection

  Ivomec® F Injection For Cattle

  Ivomec® Plus Injection For Cattle

  Ivomec® .27% Injection Grower And Feeder Pigs

  Ivomec® 1% Injection

  Ivomec® 1% Injection Cattle And Swine

  Ivomec® Injection

- Oral:

  Eqvalan® Oral Liquid For Horses

Eqvalan® Oral Liquid
Ivomec® Liquid
Eqvalan®; Eqvalan® Paste For Horses
Ivomec® Cattle Paste 0.153%
Ivomec® Sustained-Release Bolus for Cattle
Phoenectin ™ Injection for Cattle and Swine
Phoenectin ™ Paste 1.87%
Iversol Liquid for Horses
Equell ™
Primectin ™ Equine Oral Liquid
Primectin ™ Drench for Sheep
Ivercide ™ Liquid for Horses
Ivermectin Liquid for Horses
Phoenectin ™ Liquid for Horses

- Topical Pour On:
  Ivomec® Pour-On For Cattle
  Ivomec® Premix for Swine
  Ivomec® Premix for Swine and Lincomix® Premix
  BMD® / Ivomec® Premix for Swine
  Ivermectin Pour-On for Cattle
  Phoenectin ™
  Phoenectin ™ Pour-On for Cattle
  Iver-On ™
  Virbamec ™ Pour-On
  Privermectin ™
  Ecomectin

- Medicated Feed: Ivomec® Premix plus BMD®

Kanamycin: (antimicrobial)

- Injectable: Kantrim® 200

- Oral: Amforol® Suspension

Ketamine: (anesthetic) Controlled Drug (DEA). Should not be on the farm unless in the Vet's truck

- Injectable: Ketaset®

Ketoprofen: (NSAID)

- Injectable: Ketofen®

Lasalocid: (anticoccidial-ionophore family)

- Medicated feeds:

  Avatec® Premix

  Bovatec® Premix

  Bovatec® Type A Medicated Article)

  Moorman's® Cattle Minerals BT

Levamisol: (antiparasitic, imidiathiazole family)

- Oral:

  Ripercol L Bolus

  Tramisol® Cattle Wormer Bolus

  Ripercol L Soluble Drench Powder

  Ripercol L Wormer Oblets

  Tramisol® Sheep Wormer Oblets

  Levasole® Soluble Drench Powder

  Tramisol® Soluble Drench Powder

Lincomycin: (antimicrobial, lincosamide family)

- Injectable:

  Lincomix® Injectable – 25

  Lincomix® Injectable – 50

  Lincomix® Injectable – 100

  Lincomix® Injectable – 300

  Lincocin® Sterile Solution (Rx)

  Lincomycin Injectable 30%

- Topical: Lincocin® Aquadrops
- Oral: Lincocin® Tablets
- Medicated feed:
  Lincomix® Feed Medication Types A, B
  Lincomix® / Amprol Plus / Roxarsone
  Lincomix® & Amprol Plus
  Lincomix®, Lincomix® / Deccox®
  Coyden® / Lincomix®
  Lincomix® / Bonaid
  Lincomycin & Buquinolate,
  Deccox® / Lincomycin
  Decoquinate & Lincomycin,
  Lincomix® / Zoamix®, Coban® / Lincomix®
  Coban® / Lincomix®
  Coban® / Lincomix® / Roxarsone, Nicarbazin Lincomycin Premix
  3-Nitro® / Avatec® / Lincomycin
  Banminth® / Lincomix®
  Purina® Check-R-Ton Li
  Linco-8
  Linco-20
  Cadco Li-8
  Cadco Li-20
  Link-8
  Link-20
  Swine L-4
  Swine L-8
  Swine L-20
  Linco 8
  Linco 20
  Lincomycin 4 Antibiotic Premix

Lincomycin 5 Antibiotic Premix

Lincomycin 10 Antibiotic Premix

Lincomycin 20 Antibiotic Premix

Linco 8

Linco 20

Nutra-Mix Linco 4

Master Mix Linco Option 5

Master Mix Linco Option 10

Micro-Pak LX

Linco 4

Linco 20

Bio-Cox® / Lincomix®

Banminth® / Lincomix®

Banminth® / Lincomix® 20

Lincomix® / Stenorol®

3-Nitro® / Bio-Cox® / Lincomix®

Lincomix® / Maxiban®

Lincomix® Type A Medicated Article/ Safe-Guard® Type A Medicated Article

Ivomec® Premix for Swine and Lincomix® Premix

3-Nitro® / Lincomix® / Sacox®

Sacox® / Lincomix®

3-Nitro® / Lincomix® / Nicarmix 25®

Lincomix® / Nicarmix 25®

- Water:

  Lincomix® Soluble Powder

  L-S 50 Water Soluble® Powder

  Lincomycin Hydrochloride Soluble Powder

  Lincomycin Soluble

  Linco Soluble

  Lincosol Soluble Powder

Melengestrol Acetate (MGA): (hormone, synthetic)

- Medicated Feed Ingredient:

  MGA® 100 / Rumensin® / Tylan®

  MGA® 200 / Rumensin® / Tylan®, MGA® 100 Premix

  MGA® 200 Premix

  MGA® 500 Liquid Premix

Metronidazole: (antiprotozoal, nitroimidazole family) Extra label use prohibited in food animals

- Oral: Flagyl® (human approval only, no animal approval)

Monensin: (anticoccidial-ionophore family)

- Medicated Feed:

  Rumensin®

  Rumensin® 80

  Coban® - 45

  Coban® - 60

  Coban® - 110

  Elancoban-100

Neomycin sulfate: (antimicrobial, aminoglycoside family)

- Oral:

  Biosol® Sterile Solution

  Biosol® Sterile Solution 50 mg

  Neo-Sol 50®

  NEORAL Oral Solution

- Water:

  Neomix® 325 Soluble Powder

  Neomix® AG 325 Soluble Powder

  Neomycin 325 Soluble Powder

Nitrofurazone: (antimicrobial, nitrofuran family) Extra label use prohibited in food animals

- Topical:

  Furacin®

  NFZ® Puffer

  Nitrofurazone Solution

  Furacin Dusting Powder

  Furacin Ear Solution

  Furacin Solution Veterinary

  Furacin-Microfur

  Sulfamylon-N

  Fura Ointment

  Furaderm

  Fura-Solution

  Fura-Septin Soluble Dressing

  Nitrofurazone Dressing

  Fura-Vet

  Nitrofurazone Anesthetic Dress.

  Furacol Solution

  Nitrozone Solution

  Fura-Zone

  Fura-Zone Solution

  NFZ® Wound Dressing

  Nitrofurazone Soluble Dressing

- Water: Furacin Soluble Powder

Novobiocin: (antimicrobial)

- Intrammary: Albamast® Suspension

Orbifloxacin: (antimicrobial-fluoroquinolone family) Extra label use prohibited in food animals

- Oral: Orbax ™ Tablets

Oxytetracycline: (antimicrobial, tetracycline family)

- Injectable:
  LA 200®
  Liquamycin® Injectable
  Terramycin® Injectable
- Oral
  Terramycin® Animal Formula
  Terramycin® Soluble Powder
  Terramycin® Scour Tablets
  MGA® (liquid) / Terramycin®

Penicillin: (antimicrobial-penicillin family beta lactam)

- Penicillin benzathine injectable:
  Combicillin® AG
  Dura-biotic
  Longicil Fortified
  Benza-Pen
  Pen BP-48
  Bicillin Fortified
- Procaine Penicillin G Injectable
  Flo-cillin®
  Agricillin Pen Aqueous
  Aqua-Cillin; Penicillin G Co-op
  Crystalline Pro Penicillin G
  Crysticillin
  Penicillin G Procaine
- Intrammammary:
  Albadry Plus® Suspension
  Quartermaster® Dry Cow Treatment

Aqua-Mast
Hanfords Four-Pen
Formula A-34
Uni Biotic 4 Dose
Dry-Mast

Phenylbutazone: (NSAID) Prohibited in female dairy cows over 20 months of age

- Injection:
  Butazolidin Injectable 20%
  EquiBute Injection
  Robizone-V Injection
- Oral:
  Butazolidin Bolus
  Butazolidin Tablets
  Tevcodyne tablets
  Bizolin®-100 tablets
  Bizolin®-200 tablets
  Robizone-V tablets

Pirlimycin: (antimicrobial, lincosamide family)

- Intramammary:
  Pirsue® Aqueous Gel
  Pirsue® Sterile Solution

Progesterone: (hormone, nonsynthetic)

- Implants:
  Synovex®-C
  Synovex®-S
  Component® E-C with Tylan®
  Component® E-S with Tylan®

- Intravaginal: EAZI-Breed™ CIDR® Cattle Insert

Ractopamine: (growth promotant, beta agonist) Approved for use in growing swine only. Not approved in cattle.

- Medicated Feed:
  Paylean®; Paylean® 45
  Paylean® / Tylan®

Salicylic Acid: (NSAID, aspirin)

- Bougie[2]: Shurjets
- Oral: None approved at this time

Spectinomycin: (antimicrobial, aminoglycoside family)

- Injectable:
  Adspec® Sterile Solution
  Spectam® Injectable
  PROSPEC® Injectable
  Spectinomycin Injectable
  Spectinomycin Injection

- Oral:
  Spectinomycin Tablet
  Spectam® Scour Halt
  Spectinomycin Oral Liquid
  Spectam® Tablets

- Water
  Spectam® Water Soluble Concentrate
  L-S 50 Water Soluble® Powder

Streptomycin: (antimicrobial, aminoglycoside family)

- Bulk Drug: *Under AMDUCA, compounded drugs made from bulk illegal for use in Animal Drugs*

[2] Device for delivery of the drug-stays in teat canal till next milking

Dihydrostreptomycin Sulfate
Streptomycin Sulfate Bulk (Veterinary)

- Medicated Feed:
  Rainbrook Broiler Premix No.1

- Oral:
  Entromycin Powder
  Entromycin Tablets No.1
  Entromycin Tablets No.2
  Streptomycin Oral Solution
  Strep-Sol

Sulfadimethoxine: (antimicrobial, Sulfonamide)

- Injectable:
  Albon®
  Agribon Injection 40%

- Oral:
  Albon®
  Agribon Boluses - 2.5
  Agribon Boluses - 5.0
  Agribon Boluses - 15.0
  Albon® S.R. (Sustained Release)

- Water:
  Agribon 12.5% Drinking Water Solution
  Di-Methox Antibacterial Soluble Powder
  Sulfasol® Soluble Powder

Sulfabromomethazine: (antimicrobial, Sulfonamide)

- Oral: Sulfabrom 2.5 g

Sulfaethoxypyridazine: (antimicrobial, Sulfonamide)

- Injectable: S.E.Z. Intravenous Solution
- Oral: S.E.Z. Oblets 15 G
- Water: S.E.Z. Drinking Water Solution

Sulfamethazine: (antimicrobial, Sulfonamide) Extra label use prohibited in lactating dairy cows

- Injectable:
  Sulmet® Solution Injectable
- Oral:
  Tylocine Sulfa Tablets 50
  HavaSpan Prolonged Release Bolus;
  SulfaSpan Prolonged Release Bolus
  Sulka-S ™ Bolus
  Sulfa Sustained Release Bolus
  Calfspan ™
  Purina® Sulfa
  Sulfamethazine Spanbolet II
  Sustain III® Bolus
  Sulmet® Oblets
  Veta-Meth ™
- Medicated Feed
  Aureo SP-250; Aureomix 500
  Aureomix S 700 Crumbles; Aureomix S 700 g
  Tylan® 10 Sulfa-G Premix; Tylan® 40 Sulfa-G Premix
  Aureomix S 700-A
  Aureomix S 700-D
  Aureomix S 700-G
  Aureomix S 700-E
  Aureomix S 700-F
  Aureomix S 700-C-2

Aureomix S 700-B

Aureomix S 700-H

Purina® Pork-Plus Medicated

Chlorachel ™ 250 Swine / Pficlor SP 250

ChlorMax ™-SP 250; ChlorMax ™-SP 500

ChlorMax ™-SP 1000

CO-OP Tylosin 40 Plus Sulfamethazine

Tylan® 40 Plus Sulfa-G

Hubbard Tylan® Plus Sulfa Premix

Swine Med-A-Mix TS 8000 Premix

Tylan® 40 Sulfa-G

Tylan® 20 Sulfa-G

Tylan® 10 Sulfa-G

Tylan® 5 Sulfa-G

Quali-Tech Tylan®-Sulfa Premix 10 -10

Tylan® 5 Sulfa-G; Tylan® 10 Sulfa-G

Tylan® 20 Sulfa-G; Tylan® 40 Sulfa-G

Medi-Flex T:S

Tylan® Sulfa 10-10 Premix

Tylan® 5 Sulfa-G

Tylan® 10 Sulfa-G

Tylan® 20 Sulfa-G

Tylan® 40 Sulfa-G

Tylan® Sulfa 5 G

Tylan® Sulfa 10 G

Tylan® Sulfa 20 G

Tylan® Sulfa 40 G

Purina® Tylan® 40 Plus Sulfamethazine

Mill Co Medicator TS-40 Premix

Seeco Tylan®-Sulfa 10 Premix Med.

Tylan® 20 Sulfa-G

Tylan® 40 Sulfa-G

HFA Tylosin-10 Plus Sulfa

Tylan® 5 Sulfa-G

Tylan® 10 Sulfa-G

Tylan® 20 Sulfa-G

Tylan® 40 Sulfa-G

Tylan® 5 Sulfa-G

Tylan® 10 Sulfa-G

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Tylan® 40 Sulfa-G

Tylan® 5 Sulfa-G

Tylan® 10 Sulfa-G

Tylan® 20 Sulfa-G

Tylan® 40 Sulfa-G

Nutra-Mix Tylan®-Sulfa Premixes

Heinold Tylan® 5 Sulfa Premix

Tylan® 5 Sulfa-G

Tylan® 10 Sulfa-G

Tylan® 20 Sulfa-G

Tylan® 40 Sulfa-G

Tylan® 5 Sulfa-G

Tylan® 10 Sulfa-G

Tylan® 20 Sulfa-G

Tylan® 40 Sulfa-G

Tylan® Sulfa

Tylan® 5 Sulfa Premix

Tylan® 10 Sulfa Premix

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- Water

  Sulmet® Drinking Water Solution

  Aureomycin® Sulmet Soluble Powder

  Aureo Sulfa Soluble Powder

  Sulmet® Soluble Powder

Sulfachlorpyridazine: (antimicrobial, sulfonamide) Extra label use prohibited in lactating dairy cows

- Oral:

  Prinzone Bolus

  Pyradan Bolus

  Vetisulid® Bolus

  Vetisulid® Tablets

  Prinzone Oral Suspension

  Pyradan Oral Suspension

  Vetisulid® Oral Suspension

- Injection:

  Prinzone Injection

  Pyradan Injection

  Vetisulid® Injection

- Water:

  Prinzone Powder

  Pyradan Powder

  Vetisulid® Powder

Sulfamethoxazole: (antimicrobial, sulfonamide-no current approvals) Extra label use prohibited in lactating dairy cows

Sulfadiazine/trimethoprim: (antimicrobial, potentiated sulfonamide) Extra label use prohibited in lactating dairy cows

- Injectable: Tribrissen® 48% Injection
- Oral:

  Tribrissen® 30 Tablets

  Tribrissen® 120 Tablets

  Tribrissen® 480 Tablets

  Tribrissen® 960 Tablets

  Tribrissen® 400 Oral Paste

  Tucoprim® Powder

  Sulfa Di-Trim® Tablets

Testosterone Propionate: (hormone)

- Implant: Synovex®-H

Tetracycline: (antimicrobial, tetracycline family)

- Oral

  Panmycin® 500 Bolus

  Polyotic® Oblets®

  Tet-Sol 10

  Tet-Sol 324 ™

Tilmicosin: (antimicrobial, macrolide family)

- Injectable: Micotil® 300
- Medicated Feed: Pulmotil®

Trenbolone Acetate: (hormone, synthetic "androgenic" anabolic steroid)

- Implant: Finaplix®-HFinaplix®-SRevalor®-G
  Revalor®-S
  Revalor®-200
  Revalor®-H
  Revalor®-IH, Synovex® Plus
  Component® TE-G with Tylan®
  Component® TE-S with Tylan

Trichlormethiazide: (diuretic)

- Oral: Naquasone® Bolus (also contains dexamethasone)

Tripelennamine Hydrochloride (antihistamine) Human approved drug is called PBZ®

- Injectable: Recovr® Injectable

Tylosin: (antimicrobial, macrolide family)

- Injectable: Tylan®, Tylosin® Injection
- Medicated Feed: ***See Sulfamethazine under Feeds***
  Tylan® 40 CAL Type A Medicated Article
  Tylan® 100 CAL Type A Medicated Article
  Tylan® Soluble, Tylan® 100 Premix
  CO-OP Tylan® 10 Mix
  Tylosin® 5 Type A Medicated Article
  Tylosin® 10 Type A Medicated Article
  Tylosin® 20 Type A Medicated Article
  Tylosin® 40 Type A
  Quali-Tech Tylan®-10 Premix
  Tylan® 5 Sulfa-G
  Tylan® 10 Sulfa-G
  Tylan® 20 Sulfa-G

Tylan® 40 Sulfa-G

Xylazine (sedative, nonopioid)

- Injectable:
  Rompun® Injectable (20 mg)
  Rompun® Injectable (100 mg)
  Anased®; Anased® Injectable
  Xylazine HCl Injection
  Sedazine ™
  Chanazine®
  Chanazine®

Zeranol (hormone, synthetic "estrogenic" anabolic steroid)

- Implants:
  Ralgro® Implants
  Ralgro® Magnum

Additional Drugs:

Explanation of terms used in entries and footnotes:

Example:

Gentamicin: (antimicrobial)

- Dip (turkey eggs): Garasol® Solution, Gentasol

Antimicrobial is a broad term that includes drugs that kill or inhibit bacteria. Gentamicin is "cidal", i.e. kills bacteria susceptible to it.

Garasol® is the drug "**trade name**" : designated by the "®". **An approved new animal drug always has an NADA (new animal drug application) number on the labeling!** Note that the approved use should also be on the labeling.

Gentamicin is the "**established name**" for this drug. Sometimes "established name" is used interchangeably with the term "generic", and they are not necessarily the same thing.

Generic: This term is used 2 ways-

1. used interchangeably with term "established name" for a drug.

2. a "**Generic Drug**": an FDA approved generic drug . Requirements for approval of an ANADA (abbreviated new animal drug application) include: the "pioneer" drug has to be off patent and still considered safe and effective; generic has to be an *exact* copy of the "pioneer" including its manufacturing, claims, etc. Generic copies generally do not have "®" after the name, and sometimes the drug established name is the only name given on the bottle, i.e. gentamicin sulfate. **An approved Generic Drug always has an ANADA number on the labeling!**

Pioneer Drug: These drugs are from the sponsor's original approval, often the first trade name to come on the market for a particular drug entity. The "pioneer", or first, drug approved for a particular drug entity has patents and other protections so that "generic copies" cannot be made for several years following the original approval. **In the case of gentamicin,** Schering-Plough has the original approvals-the "pioneer products" with tradenames **Garasol®, Garacin®, Gentocin®.**

AMDUCA Prohibited Drugs List http://www.fda.gov/cvm/Documents/530_41.txt

The following drugs (both animal and human), families of drugs, and substances are prohibited for extra-label uses in all food-producing animals:

- **Chloramphenicol;**
- **Clenbuterol;**
- **Diethylstilbestrol (DES);**
- **Dimetridazole;**
- **Ipronidazole;**
- **Other nitroimidazoles (i.e. metronidazole);**
- **Furazolidone, Nitrofurazone, other nitrofurans;**
- **Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine);**
- **Fluoroquinolones (enrofloxacin, danofloxacin, orbifloxacin)**
- **Glycopeptides (vancomycin, teicoplanin, oritavancin)**
- **Phenylbutazone (in female dairy cattle 20 months of age or older)**

Compounded Drugs:

- FDA defines compounding as the manipulation of drugs to obtain products that differ from the starting materials in an approved dosage form drug. **Under AMDUCA, compounding is considered to be extra-label drug use, and must be done from approved finished dosage form drugs only.**
- It is illegal for veterinarians, or pharmacists, to compound unapproved finished new animal drug products from *bulk* drugs.
- **Non-commercial labels may serve as a cue for identifying compounded products.**

ATTACHMENT H - District Monitor Checklist

RVIS Activities

Review Weekly Report for assignment

Check RVIS for addl. residues prior to insp.

Provide State with computer-generated Attachment C forms prior to inspection

Enter appropriate follow-up activity codes

Each Fed/State inspec. must have an FDA responsibility code entered (R, I, N)

Enter activity codes for Enforcement Actions

Periodically run reports to identify specific violation/violator trends/patterns

Twice per year provide District mgmt. with list of Repeat Violators

Review the "Not Investigated Repeat Violator Report" to make sure none of your DO's firms are on the report.

Review the "Investigated w/No Responsibility Code Entered Report" to make sure none of your DO's firms are on the report.

Administrative Activities

Promptly issue assignments for Fed/State inspections per CP guidelines

Remind all to complete the Drug Inventory Survey

Review completed EIR's for changes to firm info.

Enter firm change information into RVIS.

Review Attachment C's for compleeteness (IF not complete, contact FDA investigator or State Coordinator and explain what should have been completed in effort to improve quality of future rpts.

Request Regulatory Reserve Samples for firms possibly subject of an enforcement action.

Monitors should maintain a list of samples that they have requested to be stored in an FDA laboratory. Periodically review this list and request a Sample Destruction Notices (SDNs) be prepared through the appropriate channels in your District once it becomes clear that the District will not be initiating enforcement action against a firm.

For all Federal and State investigations/inspections submit to HFV-235 a copy of the FACTS coversheet w/ endorsement, and Attachments C & G.

Work with CVM to distribute industry outreach materials to address local residue concerns.

Serve as a clearinghouse for distribution of pertinent information to cooperating State Officials and District Mgmt.

Recommend training of al Fed/State personnel conducting residue investigations.

Maintain routine communications with local reps. Form FSIS, APHIS, GIPSA and the States.

Exhibit 20

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Association of phenylbutazone usage with horses bought for slaughter: A public health risk

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ABSTRACT

Sixty-seven million pounds of horsemeat derived from American horses were sent abroad for human consumption last year. Horses are not raised as food animals in the United States and, mechanisms to ensure the removal of horses treated with banned substances from the food chain are inadequate at best. Phenylbutazone (PBZ) is the most commonly used non-steroidal anti-inflammatory drug (NSAID) in equine practice. Thoroughbred (TB) race horses like other horse breeds are slaughtered for human consumption. Phenylbutazone is banned for use in any animal intended for human consumption because it causes serious and lethal idiosyncratic adverse effects in humans. The number of horses that have received phenylbutazone prior to being sent to slaughter for human consumption is unknown but its presence in some is highly likely. We identified eighteen TB race horses that were given PBZ on race day and sent for intended slaughter by matching their registered name to their race track drug record over a five year period. Sixteen rescued TB race horses were given PBZ on race day. Thus, PBZ residues may be present in some horsemeat derived from American horses. The permissive allowance of such horsemeat used for human consumption poses a serious public health risk.

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1. Introduction

Phenylbutazone (PBZ) was marketed in the United States for the treatment of rheumatoid arthritis and gout in 1952. Serious and often fatal adverse effects such as aplastic anemia and agranulocytosis appeared in the literature within three years of its use (Benjamin et al., 1981; Böttiger and Westerhom, 1973; Cameron et al., 1966; Chaplin, 1986; Deaths due to butazolidin, 1952; Dunn, 1972; Etess and Jacobson, 1953; Hale and DeGruchy, 1960; Leonard, 1953; Mauer, 1995; McCombs, 1958; Nelson et al., 1995; Ramsey and Golde, 1976; Risks of agranulocytosis and aplastic anemia, 1986; Steinberg et al., 1953). The serious adverse effects of PBZ culminated in its unavailability for human use in the United States.

Because of the bone marrow toxicity caused by PBZ in humans, the Food and Drug Administration (FDA) has set no safe levels of PBZ in animals intended for food and bans the administration of this drug in any horse sent to slaughter for human consumption (http://www.fda.gov/cvm/CVM_Updates/buteup.htm).

By 1990, over a dozen foreign-owned slaughter houses in the United States were slaughtering approximately 350,000 horses per year (weekly United States Department of Agriculture statistics up to 2007 when all of the slaughter plants were closed by state statutes: http://www.ams.usda.gov/mnreports/SJ_LS711.txt), and the United States was exporting another 70,000 live horses per year for slaughter to Canada (monthly United States Department of Agriculture statistics: http://www.fas.usda.gov/ustrade/USTExFatus.asp?QI=).

Veterinary records from American horses sent to slaughter for human consumption are not available to the public. Moreover, horses are not raised as food animals in the United States and there appears to be inadequate testing to ensure that horses given banned substances such as PBZ do not enter the slaughter pipeline.

Thoroughbred race horses may have a higher rate of PBZ exposure because of their intense training and racing schedule. Thoroughbred race horses frequently develop training- or race-related musculoskeletal injuries that require treatment with a non-steroidal anti-inflammatory drug (NSAID). Phenylbutazone is the most widely used NSAID in horses because of its availability and cost (Hopes, 1972; Goodrich and Nixon, 2006).

The method of identifying TB race horses by lip tattoo and PBZ administration from race track records makes it possible to determine PBZ exposure in horses that have raced at certain tracks that permit race day PBZ and record its administration.

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In our study, the objective is to show that TB race horses are given PBZ prior to being bought for intended slaughter for human consumption. We present data which shows that some TB race horses sent to intended slaughter for human consumption were given PBZ on race day. The data show that the FDA ban on PBZ usage in horses intended for human consumption is ignored by some members of the race track community and that this ignorance in addition to the fact that approximately one-half of all TBs that are born are slaughtered for human consumption abroad portends a potentially serious health hazard.

2. Methods

We contacted individuals who rescued TB race horses from the slaughter pipeline over a five year study period. Through these individuals, we identified 50 TB horses rescued from slaughter and an additional 18 TB horses that were sent for intended slaughter. Each of the 68 horses could be identified by a lip tattoo registered with the Jockey Club of America and all of the 68 horses have Lifetime Past Performance records that are available on the public database.

The lip tattoo allowed us to find the registered name of each TB horse by submitting the horse's tattoo into the Jockey Club of America database and thus to obtain the race track drug records.

The race track drug record was acquired from two national sources: (1) the Lifetime Past Performance record and (2) individual race track records. Both sources are available to the public. The Lifetime Past Performance record is obtained by entering the registered name of the TB horse into the Equibase database at the following web site: http://www.equibase.com/premium/eqpHorseLookup.cfm?SAP=HLN&PID=50214.

These records reveal a great deal of information about an individual TB horse including all race tracks at which the TB horse raced over its lifetime. TB race horses that raced at one or more race tracks where PBZ given on race day is allowed were documented in the Lifetime Past Performance record. At least three individual race track drug racing records were obtained from eight out of the thirty-four TB race horses that were randomly selected from the study population to ensure that the drug record from the specific race track matched the drug record from the same race track listed in the Lifetime Past Performance record. Individual race track records from a TB race horse that was given race day PBZ were obtained by entering the registered name of the TB horse at the following Equibase web site: http://www.equibase.com/premium/eqpVchartSearch.cfm.

We were able to obtain records (track records and Lifetime Past Performance record) to determine whether PBZ was administered on race day or given within 24 h of a race on 32 horses: all 18 of the non-rescued TB horses and 16 of the 50 rescued horses. National databases were used to determine the number of TB race horses sent to slaughter for human consumption during the five year study window.

The thirty-four TB race horses described in this study came from the West coast, the Midwest and the Northeast of the United States.

3. Results

All eighteen horses sent to intended slaughter for human consumption and 16/16 of the 50 identified rescued TB horses had a positive history of PBZ administration (Table 1). One of the 18 non-rescued horses was not given PBZ on race day but was documented to have been given the drug by a licensed veterinarian prior to being sent to slaughter for human consumption. Another TB race horse that was sent to slaughter for human consumption had documented PBZ in its blood. This horse won at a race track in the United States where all winners must be tested for PBZ blood levels by law. Approximately 91,000 TB race horses were sent to slaughter over the five years that we examined the data.

Table 1
TB horses given PBZ and sent to slaughter or rescue.

TB race horse category	*N*	Positive PBZ track record review (*N*)	Other positive information (*N*)	Positive (%)
Not rescued	18	16	2	100
Rescued	50	–	–	–
Records examined	16	16	–	100
Records not examined	34	–	–	–

The PBZ profile of TB horses bought for intended slaughter is presented in Table 2. The time interval from the last known PBZ administration to intended slaughter ranged from 0.25 to 48 months. It should be emphasized that it is unknown whether additional PBZ was given to any of the horses from the time they left they left the race track to the time the horse was bought for slaughter. It is common for old race track injuries to require additional NSAID treatment after their racing career is over.

4. Discussion

In February 2007, a federal appeals court ruled that the two slaughter houses in Texas were in violation of a 1949 law against selling horsemeat for human consumption (Empacadora de Carnes de Fresnillo vs Tim Curry, 2007), and by March the Texas plants were closed. By September of 2007, a new state law in Illinois (Illinois HB 1711) resulted in the closure of the third and final horse slaughter facility in the United States.

The foreign owners of the three slaughter plants relocated their operations to Canada and Mexico. By the first quarter of 2008, the increased export of American horses to slaughter in Canada and Mexico had replaced the reductions in slaughter within the United States and the total slaughter of American horses had recovered to its 2006 level (Fig. 1). It is normally the case that once a horse ends

Table 2
Data on PBZ administration and slaughter date.

Thoroughbred horse	Date of last known PBZ administration	Date horse sent to slaughter	Approximate time interval (months)
1	6/17/2006	4/18/2008	10
2	6/28/2007	4/18/2008	10
3	9/2004[a]	9/2004	1
4	2/09/2008	4/21/2008	2
5	3/2/2003	3/2003	1
6	12/13/2006	4/18/2008	16
7	6/03/2008	10/17/2008	4
8	9/17/2007	9/2007	0.5
9	–[b]	6/20/2008	0.25
10	10/14/2007	4/11/2008	6
11	03/01/2007	4/18/2008	13
12	10/07/2004	7/2008	45
13	10/30/2004	1/2005	3
14	5/07/2008	10/17/2008	5
15	9/06/2003	4/22/2004	7
16	3/24/1993	3/1993	0.25
17	10/29/2004	11/2004	0.25
18	11/17/2004	2008	48

[a] This thoroughbred race horse was not given PBZ as indicated in the Past Performance Record. A licensed veterinarian provided documentation of PBZ administration prior to being sent to slaughter.

[b] This thoroughbred race horse was not given PBZ according to its Past Performance Record. PBZ was documented in blood via drug testing after winning a race. All winning horses are required by law to have drug testing.

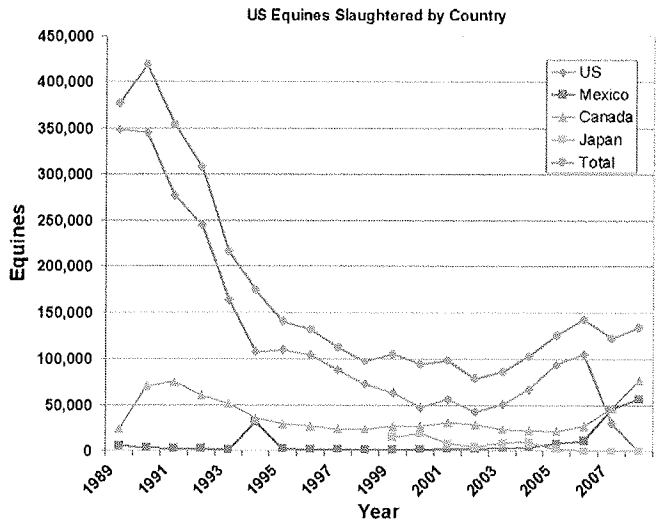

Fig. 1. Equines slaughtered by country and year. The number of equines (horses, ponies, donkeys and mules) slaughtered is plotted against the year slaughtered. The data were obtained from the USDA (http://www.nass.usda.gov:8080/QuickStats/Index2.jsp).

up on a slaughter truck, the next stop is a feed lot associated with a slaughter plant.

Currently, three Mexican horse slaughter facilities are known to export horsemeat to the European market while a large number of small provincial plants provide meat for local consumption. In the wake of the closing of plants in the United States, Canadian horsemeat production has approximately doubled (http://www.atssea.agr.gc.ca/stats/5034x-eng.pdf). There is a limited market for horsemeat in French speaking areas of Canada, with the bulk of the meat produced being exported to Europe.

This is the first report to show that many TB race horses bought for human consumption may have residual PBZ; over 30% of the TB horses were given PBZ within six months of being sent to slaughter for human consumption. Winning TB horses have PBZ blood levels determined to ensure they are within the range and allowed by law (<5 $\mu g\ ml^{-1}$). According to Dr. Lawrence Soma, the racing commissioner's equine research director at the New Bolton Center of the University of Pennsylvania School of Veterinary Medicine, the mean PBZ concentration in the blood of a horse that tests "negative" (horses that have a legally permissible level of PBZ) is about 2 $\mu g\ ml^{-1}$ (personal communication). One of the slaughter bound horses listed in Table 1 had a documented PBZ level after winning a race at a race track in the United States. The total number of winning TB race horses with documented PBZ blood levels bought for slaughter for human consumption is unknown. This is an important point because this horse's Lifetime Performance Record did not indicate race day PBZ administration. A second TB race horse presented in this study had PBZ administration documented by a licensed veterinarian. Again, the Lifetime Performance Record of this horse did not indicate race day PBZ administration. These results support the view that TB race horses can and do receive PBZ at times other than on race day.

It is disturbing to note that a documented 9000 lb of horsemeat (500 lb of dressed horsemeat per horse × 18 contaminated horses) taken from horses with known exposure to PBZ was sent abroad for human consumption over the five year study period. This estimate of the amount of contaminated horsemeat may be at the low end because our sample size is small and the records indicate a high likelihood of exposure in this cohort.

The scope of the amount of horsemeat that may be contaminated with PBZ can be inferred from the number of rescued horses given race day PBZ. All sixteen of the rescued TB horses on which we obtained Lifetime Past Performance records were given PBZ on race day or within 24 h of a race. If rescue organizations did not outbid horse dealers that buy for the slaughterhouses, more horsemeat would be expected to be contaminated with PBZ.

The data presented in Table 2 shows that the time interval from the last known dose of PBZ to the animal being bought for slaughter varies from about one week to four years. In our study, four years may be a safe withdrawal time since a horse was given PBZ prior to being sent to slaughter. However, the FDA does not allow any use of PBZ in horses destined for human consumption and neither does the United Kingdom (UK) or the European Union (EU) regardless of withdrawal time. In addition, we did not have access to veterinary records prior to, during racing or after retirement from racing. Therefore, we do not know whether any of the horses sent to slaughter for human consumption were given PBZ during the interval between the last known PBZ dose and the time they were bought by horse dealers that buy horses for the slaughterhouses. Thus, it is possible that horses given race day PBZ four years ago could have been given more of this drug at times other than racing and prior to being sent to slaughter.

In 2008, three TB horses whose records we examined were bought for slaughter and given PBZ on the same day. These TB horses were rescued from slaughter (http://tuesdayshorse.wordpress.com/2008/11/11/five-banned-in-suffolk-downs-no-slaughter-policy-mass/). A fourth TB horse, given race day PBZ six weeks prior to being taken off a slaughter truck, was also rescued (http://www.horsetalk.co.nz/news/2008/09/019.shtml). This information underscores the fact that recent administration of PBZ given to horses destined for slaughter for human consumption is a current and immediate problem.

In horses, phenylbutazone is metabolized in the liver where it is converted to oxyphenbutazone, γ-hydroxyphenylbutazone and probably γ-hydroxy-phenbutazone and follows a bi-exponential model of decay. The plasma half-life of PBZ is 5.46 h in young horses but is longer in horses older than ten years and those with impaired liver function. In addition, PBZ uptake into the bloodstream is delayed by food in the stomach (Lees et al., 1985, 1986, 1987, Maitho et al., 1986, McConnico et al., 2008). Oxyphenbutazone is a major metabolite of PBZ and remains elevated up to at least 72 h (Lees et al., 1985, 1986, 1987, McConnico et al., 2008). Tissue levels of phenylbutazone and oxyphenbutazone were highest in kidney. In one study, high levels were also found in liver, lung and heart whereas the lowest levels were found in muscle (gluteus and biceps) and tendon (Lees et al., 1987). Since the elimination of PBZ follows exponential decay, traces of PBZ will remain as a contaminant of horsemeat in previously treated horses for a very long and as yet undetermined period of time.

Oxyphenbutazone has NSAID properties and at one time was thought to be less toxic that PBZ. However, oxyphenbutazone also has serious adverse effects in humans including those of producing aplastic anemia, agranulocytosis, thrombocytopenia, leucopenia, pancytopenia, and hemolytic anemia (Chaplin, 1986). The mortality rate of PBZ- and oxyphenbutazone-induced aplastic anemia was 94% and 71%, respectively (Benjamin et al., 1981; Böttiger and Westerhom, 1973; Cameron et al., 1966; Chaplin, 1986; Deaths due to butazolidin, 1952; Dunn, 1972; Etess and Jacobson, 1953; Hale and DeGruchy, 1960). Overall, the data suggest that the risk for the development of the lethal adverse effects in humans by PBZ and oxyphenbutazone are not always dose-dependent indicating an idiosyncratic effect. In addition to its well-known bone marrow suppression effects, PBZ is also associated with a hypersensitivity reaction in the liver which can cause death (Benjamin and Ishak, 1981). Taken together, it is clear why phenylbutazone is currently unavailable for human use in the United States and is banned in animals destined for human consumption.

In response to a letter under the Freedom of Information (FOIA) act, the United States Department of Agriculture (USDA) indicated that during an "exploratory project" they found two of twenty-four horse carcasses tested (8.3%) that were violative for PBZ in 2004–2005. The USDA also stated that they determined PBZ levels in equine fat samples in 2002 and 2003 and none was detected. Horse carcasses were not among those animal carcasses tested for PBZ during the year of 2006, the year that horses were under Federal Inspection by the Food Safety and Inspection Service (FSIS), the USDA's Public Health Regulatory Agency. This agency works with the Environmental Protection Agency (EPA) and FDA "to control veterinary drug, pesticide, and environmental contaminant residues in meat, poultry, and egg products. Residue control is a cooperative effort. EPA and FDA have statutory authority for establishing residue tolerances or action levels, and FSIS, through the National Residue Program (NRP), tests animal tissues and egg products to verify that tolerances or action levels are not violated" (http://www.fsis.usda.gov/science/2006_Red_Book/index.asp). The FDA has set no safe residue limits of PBZ in animal carcasses. If PBZ is found to be present in food animal tissue, it is considered a violation. Given that musculoskeletal injuries are frequent in horses and are treated commonly with PBZ to ameliorate the pain associated with these injuries, it is unclear why none of the horse carcasses were tested for PBZ in 2006 (http://www.fsis.usda.gov/science/2006_Red_Book/index.asp). Moreover, it is unclear why FSIS would analyze fat to determine PBZ levels because the volume of distribution indicates that almost the entire drug stays in the bloodstream. In fact, the FSIS directive requires that PBZ levels be determined in kidney. Kidney is the organ that exhibits the highest levels of PBZ (Lees et al., 1987).

PBZ is used in equines of all ages and while most of the horses sent to slaughter are young and sound, old equines are also sent to slaughter. Slaughter bound horses are either bought directly by dealers or purchased at auction houses. There is limited information on how the horses are handled at dealer feedlots and there are no laws of governance. Clearly, the longer horses are kept on dealer feedlots the lower the profit. Whether horses on dealer's feedlots are given any medications is unknown. Domestic horses may need medications to treat bacterial or viral infections. Moreover, domestic horses need drug treatment to control parasitic infections and certain vaccines are also required by law. Many of the drugs used to treat bacterial, parasitic and viral illnesses are also banned if the animal is sent to slaughter for human consumption. Banned drugs given to horses such as PBZ are not tracked for human consumption purposes.

As stated above, almost all of the PBZ remains in the bloodstream. The blood is drained from horses but its level of completeness is unknown. There are 100 ml of blood/kg of thoroughbred horse. Thus, there are fifty quarts or 12.5 gallons for a horse that weighs 1000 lb. This is confirmed at: http://www.thehorse.com/ViewArticle.aspx?ID=5491. So, a horse has about 1.25 gallons per 100 lbs of body weight. To provide a point of comparison, a 1400 lb cow has 60 ml/kg body weight or almost 10 gallons (http://www.milkproduction.com/Library/article_series/bovine_biology/14_Blood.htm) or 0.71 gallons per 100 lbs of cow. The ratio is 1.25/.71 = 1.76:1. Thus, a horse has 1.76 times as much blood per pound of body weight compared to a cow. The owner of a horse slaughter house in Canada that was shut down by the Canadian Food Inspection Agency for food safety issues stated publicly that they were slaughtering more than 100 horses a day. Thus, the blood may not be completely drained from muscle increasing the likelihood of contamination.

The FDA, like the EU and UK, specifically bans the use of PBZ in any horse destined for slaughter for human consumption. Yet, this ban is being circumvented because there is no pre-slaughter mechanism to determine and remove horses that receive PBZ during their lifetime. This is because horses are not regarded as or treated as food-producing animals in the United States and there are no USDA regulations to prevent them from being given banned substances like PBZ.

The lack of oversight to prevent horses given PBZ from being sent to slaughter for human consumption as ordered by the FDA indicates a serious gap in food safety and constitutes a significant public health risk, a fact that has been recently highlighted by the Department of Animal and Food Science at the University of Delaware (http://copland.udel.edu/~kniel/VirtualFarm/Templates/horses.htm). We recommend that the FDA and USDA join forces to track the administration of PBZ to horses and stop the slaughter or exportation for slaughter of horses with a positive history of PBZ treatment. If such a process cannot be put in place expeditiously, both agencies should ensure that horse carcasses only be used for non-human purposes.

Conflict of interest statement

The authors declare that there are no conflicts of interest.

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Exhibit 21

FDA Order Prohibits Extralabel Use of Phenylbutazone in Certain Dairy Cattle

February 28, 2003

The Food and Drug Administration (FDA) is issuing an order prohibiting the extralabel use of phenylbutazone animal and human drugs in female dairy cattle 20 months of age or older. FDA is issuing this order based on evidence that extralabel use of phenylbutazone in these dairy cattle will likely cause an adverse event in humans. The Agency finds that such extralabel use presents a risk to the public health for the purposes of the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA).

AMDUCA amended the Federal Food, Drug, and Cosmetic Act to allow licensed veterinarians to prescribe extralabel uses of approved animal drugs and human drugs in animals. Section 2(a)(4)(D) of the AMDUCA provides that the Agency may prohibit an extralabel drug use in animals if, after affording an opportunity for public comment, the Agency finds that such use presents a risk to the public health.

Phenylbutazone became available for use in humans for the treatment of rheumatoid arthritis and gout in 1949. However, it is no longer approved, and thus not marketed, for any human use in the United States. This is because some patients treated with phenylbutazone have experienced severe toxic reactions, and other effective, less toxic drugs are available to treat the same conditions

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.

For animals, phenylbutazone is currently approved only for oral and injectable use in dogs and horses. Use in horses is limited to use in horses not intended for food. There are currently no approved uses of phenylbutazone in food-producing animals.

Investigation by FDA and State regulatory counterparts has found phenylbutazone on farms and identified tissue residues in culled dairy cattle. In addition, USDA's Food Safety Inspection Service has reported phenylbutazone residues in culled dairy cattle presented for slaughter for human food throughout the U.S. in the past two calendar years. This evidence indicates that the extralabel use of phenylbutazone in female dairy cattle 20 months of age or older will likely result in the presence, at slaughter, of residues that are toxic to humans, including being carcinogenic, at levels that have not been shown to be safe.

FDA will consider all comments on this order that the Agency receives by April 29, 2003. Written comments should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. All comments should include Docket number 03N-0024. The order will become effective May 29, 2003, unless FDA revokes or modifies the order or extends the comment period.

Additional information on this prohibition is contained in the February 28, 2003, Federal Register. Questions about this prohibition may be directed to: Gloria J. Dunnavan, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-1168, e-mail: gdunnava@cvm.fda.gov.

Additional Information

- Final Rule: New Animal Drugs; Phenylbutazone; Extralabel Animal Drug Use; Order of Prohibition [1]

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1. http://edocket.access.gpo.gov/2003/03-4741.htm