EXHIBIT 54

U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

CPG Sec. 565.100 FDA Jurisdiction Over Meat and Poultry Products

BACKGROUND:

Recently USDA contacted FDA concerning two meat products, each of whose package contained dried components requiring them to be mixed, rehydrated and cooked before serving. One of the envelopes in each of the products cartons contained material labeled "Cooked, Ground, Freeze-Dried Beef." The envelope label had received USDA approval. The preparation instructions indicated the foods, when ready for serving, would have the properties of "Beef Stew" and "Beef with Gravy with Rice". Articles of food identified as "Beef Stew" and "Beef with Gravy with Rice", when in commerce, are subject to the Federal Meat Inspection Act and the Federal Food, Drug, and Cosmetic Act.

USDA reported that review of the preparation instructions for the two products using the amount of freeze-dried beef contained in the envelopes revealed neither of the resultant products would contain the required 25% minimum of beef, computed on the raw meat basis in relation to the total ingredients, as required by USDA regulation. USDA concluded the two products appeared to be misrepresented through improper labeling, and referred the matter to FDA for follow-up. The articles were not in a USDA-inspected establishment when encountered.

FDA's General Counsel furnished the following opinion concerning FDA's jurisdiction over meat food products in general, and the two beef products referred to FDA by USDA in particular.

The Food Additives Amendment of 1958 (Section 7) states that nothing in the amendment shall be construed to exempt any meat product from any requirement imposed under the Poultry Products Inspection Act or Meat Inspection Act. A food additive used in a meat (or poultry) product is subject to both FDA and USDA jurisdiction. Either agency may accede to the other's food additive regulation, or may publish its own regulation. In the absence of either agency taking such action, a meat product may not contain a food additive that has not been approved by both agencies.

With respect to adulteration and misbranding, Section 902(b) of the Federal Food, Drug, and Cosmetic Act states meat and meat products are exempt to the extent they are covered by the Meat Inspection Act. This had been construed since 1938 as meaning that USDA has exclusive jurisdiction up to the time a meat or meat product leaves a USDA inspected plant. Thereafter, FDA asserts its jurisdiction which, until 1967, was also exclusive. The Wholesome Meat Act of 1967 extended USDA jurisdiction over meat and meat products beyond the plant, to include their subsequent adulteration and misbranding (comparable to FDA jurisdiction over all other foods).

The 1967 WMA (Section 409(8)) provided that Section 902(b) of the Federal Food, Drug, and Cosmetic Act notwithstanding, the provisions of the WMA shall not derogate from any authority conferred by the FDC Act prior to enactment of the WMA. This was included to be certain that the expanded jurisdiction conferred on USDA by the WMA would not have the effect of ousting FDA from jurisdiction it previously had. In an opinion letter dated August 17, 1972 to the Secretary of Agriculture, the Attorney General has set out the legislative history showing that Congress intended to give USDA and FDA concurrent jurisdiction over misbranding and adulteration of meat products after inspection.

POLICY:

FDA will inform USDA Food Safety and Inspection Service (FSIS) when an apparent violation is encountered involving a meat or poultry product that has left a USDA inspected establishment. This will prevent duplication of effort should USDA prefer to handle the problem, or already have regulatory action underway in the matter. FDA will not normally initiate action involving such products unless USDA does not wish to handle it.

When appropriate, FDA may exercise its jurisdiction under the FD&C Act over meat and poultry products in interstate commerce. Before initiating any regulatory action the matter should be discussed with CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605).

Material between asterisks is new or revised

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