THE VOICE OF FOOD RETAIL

Feeding Families Enriching Lives

December 15, 2014

Division of Dockets Management (HFA–305)
U.S. Food and Drug Administration
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852

Re: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals[1]

Docket No. FDA–2011–N–0922

Dear Sir or Madam:

On September 29, 2014, the Food and Drug Administration (FDA or the Agency) published in the Federal Register a supplemental rule entitled Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (the "Supplemental Rule"). The Supplemental Rule would establish requirements for current good manufacturing practice in manufacturing, processing, packing, and holding of animal food. The Food Marketing Institute (FMI) appreciates the opportunity to comment on this important matter.

FMI proudly advocates on behalf of the food retail industry. FMI's U.S. members operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost $770 billion. Through programs in public affairs, food safety, research, education and industry relations, FMI offers resources and provides valuable benefits to more than 1,225 food retail and wholesale member companies in the United States and around the world. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores. For more information, visit www.fmi.org and for information regarding the FMI foundation, visit www.fmifoundation.org.

FMI supported the enactment of the Food Safety Modernization Act (FSMA). We believe the regulations issued to implement section 103 of FSMA, if crafted in a manner consistent with the following comments, will enhance public health and strengthen our nation's food safety regulatory system.

[1] 79 Fed. Reg.58476 (September 29, 2014).

Food Waste

In the Supplemental Rule, human food facilities already complying with FDA human food safety requirements would not need to implement additional preventive controls or Current Good Manufacturing Practices (CGMPs) when supplying a by-product for use as animal food, other than protecting it against contamination by means such as using appropriate containers, segregating it from sources of contamination such as trash, labeling the containers, and inspecting shipping containers before use. FMI supports this revision and agrees that because these foods are subject to the human preventive controls regulations up to the point of diversion, they should only be subject to selective good manufacturing practices regulations related to the holding and distribution of animal food.

Food retailers and wholesalers divert significant amounts of human food waste into the animal food supply chain. According to the BSR Analysis of U.S. Food Waste Among Food Manufacturers, Retailers and Wholesalers, retailers and wholesalers in the U.S. divert 154,000,000 pounds of food waste into the animal food supply chain every year. While most food waste is generated at the retail level, and thus exempt from the Proposed Rule, other waste is generated by manufacturing and processing facilities owned and operated by retailers.

Diversion of food waste into the animal food supply chain not only makes good business sense, it also helps food retailers and wholesalers meet their sustainability goals. FMI is concerned that if final rules impose significant new regulatory requirements on this practice, food retailers and wholesalers will be forced to dispose of human food waste in landfills, at a significant direct cost to them and will result in significant environmental costs, including wasting landfill space, and increased greenhouse gas emissions. We are equally concerned that new regulatory requirements for transporters of animal food from food processors directly to the farm by means of sanitary transport vehicle would either add significant costs to the industry without added public health benefit, or it would also contribute to more food waste. Reducing the availability of animal food ingredients would drive up costs for animal food manufacturers leading to higher prices for animal food users. These higher costs are likely to be passed down the supply chain to consumers in the form of higher prices at retail.

FMI believes that the revisions in the Supplemental Rule will alleviate significant burdens for our members when supplying a by-product for use as animal food.

Supplier Verification

FMI agrees with the revisions in the Supplemental Rule that supplier verification for the holding of animal food is not necessary. Food manufacturers supplying by-products for animal food or ingredients as proposed would still have to adhere to cGMPs to prevent physical and chemical contamination when holding and distributing the by-product, for example ensuring the by-product is not co-mingled with garbage. In the Supplemental Rule, FDA proposes to limit a supplier program for raw materials and ingredients for which the receiving facility has identified

a significant hazard when the hazard is controlled before receipt of the raw materials or ingredients. FDA defines a receiving facility as a facility that manufactures/processes a raw material or ingredient that it receives from a supplier. A supplier is defined as the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment; except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimus* nature. FMI agrees that a supplier program should be limited to these circumstances.

FMI supports the decision to exclude facilities like warehouses and distribution centers holding animal foods from the supplier verification provisions and believes this will alleviate significant burdens for our members in addition to representing a more risk-based approach consistent with FSMA.

We appreciate your consideration of these comments. Please do not hesitate to contact me at sbarnes@fmi.org or (202) 220-0614 if you have any questions.

Sincerely,

Stephanie Barnes

Stephanie K. Barnes
Regulatory Counsel