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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

March 31, 2014

Re: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food Animals, FDA-2011-N-0922

To Whom It May Concern:

On behalf of The Humane Society of the United States (HSUS), the nation's largest animal protection organization, we would like to thank the Food and Drug Administration (FDA) for the opportunity to comment on the proposed rule, Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food Animals. 78 Fed. Reg. 64736 (proposed October 29, 2013).

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With 179 million cats and dogs (in addition to 60 million small animals and horses) that are part of American households, pet food safety is a very important issue to the HSUS and its members. The HSUS is a leader in animal welfare and we are often the organization pet owners turn to for information. Our website contains everything from "winter pet protection" tips to the current pet foods that have been recalled.¹ During the 2007 melamine outbreak, when thousands of dogs and cats were sickened or died and nearly 150 brands of pet food were recalled, the HSUS took more than 6000 calls and routed people to veterinary care and the foods recall list to ease their concerns. As a leader in animal welfare, we believe the proposed rule will offer benefits to the pet food industry and to pet owners by focusing on prevention, which will decrease the incidence of food safety outbreaks and recalls.

The laws governing pet food have been almost nonexistent, however, all that changed in 2010 when Congress passed the Food Safety Modernization Act (FSMA) -- the most significant reform to food safety laws since 1938 -- when Congress gave the FDA the power to oversee the safety of food under the

¹ The Humane Society of the United States, *Pets* (2014), <http://www.humanesociety.org/animals/pets/>; The Humane Society of the United States, *Pet Food Safety* (2014), http://www.humanesociety.org/animals/resources/facts/pet_food_safety.html.

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Federal Food, Drug, and Cosmetic Act (FD&C Act).² The FSMA amends the FD&C by shifting the focus from reacting to outbreaks and adulteration to preventing them. The FSMA gives the FDA authority to establish prevention-based controls across the food supply and conduct inspection of food producers, 21 U.S.C. § 2201 *et seq.*

When it comes to pet food safety, a preventative approach is an absolute essential requirement. Looking back the last few years, there have been several high profile pet food safety incidents. For example, one of the most recent outbreaks of dog illnesses is related to jerky treats – involving more than 3,500 dogs, 10 cats, and nearly 600 known fatalities. The FDA has been receiving reports of illnesses associated with the consumption of jerky pet treats since 2007. The agency has yet to discover the source or the cause. This proposed rule and the new preventative approach to regulating pet food will hopefully prevent these types of pet food illnesses in the future.

The FSMA directed the FDA to promulgate regulations within 18 months yet the agency has failed to meet this statutory deadline by nearly 18 additional months. Now that the FDA is moving forward with the regulatory process, the HSUS implores the agency to release its final rule and begin immediate implementation and enforcement in order to help prevent any further outbreaks.

A. Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls

The HSUS supports the establishment of Current Good Management Practices (CGMPs) and preventive controls proposed by the rule. Basic sanitation measures should be applied to facilities handling animal food and the areas covered by the proposed rule – including sanitary operations, equipment and utensils³ – are common sense requirements necessary to keep pet food free of contaminants and hazardous material. CGMPs for animal food should be similar to that of human food due to the high level of care people provide and demand for their pets. Also, often pet food is stored close to human food and pet owners will use the same plates, counters, and other surface areas to prepare both pet and human food.

The proposed rule implements the requirements of the FSMA for animal food facilities that must register under § 415 of the FD&C Act (21 U.S.C. 350(d)) to establish and implement a food safety plan that includes a hazard analysis and risk-based preventative controls.⁴ The HSUS particularly supports the requirements to prepare and implement a written food safety plan, evaluate known or reasonably foreseeable hazards for each type of animal food, and prepare a recall plan for animal foods with a hazard that is reasonably likely to occur. It is critical that a food plan is developed in order to ensure that if there is a contamination or adulteration to the pet food, then manufacturers and owners can act quickly to address this problem and initiate a recall

² Pub. L. No. 75-717, 52 Stat. 1040 (Codified at 21 U.S.C. § 301 *et seq.*).

³ 78 FED. REG. 64749-64750.

⁴ *Id.*

plan if necessary. These regulations are at the heart of what Congress envisioned with the FSMA.⁵

The FSMA gives much-needed mandatory recall authority to the FDA.⁶ Before the FSMA was enacted, food recalls were done by food companies on a voluntary basis. We applaud the FDA for exercising this recall power last year against a pet food company that was producing salmonella-tainted pet treats.⁷ We strongly encourage the FDA to continue to exercise its authority and hope that with the swift implementation of this proposed rule that the number of contaminated pet treats and food will significantly decrease.

B. Supplier Verification

The HSUS recommends that the FDA implement a supplier approval and verification program in order to address contamination issues that may arise throughout the pet food supply chain. As the FDA points out in the Appendix of the proposed rule, “many facilities acting as suppliers procure their raw materials and ingredients from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor.”⁸ We support requiring each supplier in the chain to implement preventive controls appropriate for hazards reasonably likely to occur for raw materials or other ingredients. In order to ensure suppliers are complying with the supplier verification program, regular third-party audits, inspections, ingredient testing and a review of records should be required. These recommendations, working in conjunction with FDA’s proposed Foreign Supplier Verification Program, will help protect against food animal food contamination and adulteration.

After the 2007 melamine outbreak, nearly one hundred brands of pet food were recalled. Investigations determined that one pet food production plant was the source, and that the pet food was contaminated with melamine, a chemical used in production of fertilizers and plastics. China was the source of the adulterated pet food ingredients wheat gluten and rice protein. Had a supplier approval and verification program been in place, many of those deaths could have been prevented.

C. Economic Adulteration

The proposed rule does not address substances which may be intentionally introduced into animal food for economic reasons. The most notable example of economic adulteration to pet food has been referenced above and involved contamination of food after melamine and cyanuric acid were incorporated into pet food in order to increase the protein concentration of the product. While the HSUS recognizes that protecting against unknown economic adulteration can be challenging, we recommend looking at common adulterants and protein fillers that are known.

⁵ “The focus of this legislative measure is to prevent contamination of food before it occurs, which is a departure from the current system today that responds after a food-borne illness outbreak.” 156 CONG. REC. E2249-01 (Dec. 21, 2010) (statement of Congressman Davis).

⁶ 21 U.S.C. 2243 (c)(3) (2012).

⁷ *Annual Report to Congress on the Use of Mandatory Recall Authority – 2013*, U.S. Food and Drug Administration, available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm382490.htm>.

⁸ 78 FED. REG. 64736 (Appendix).

The FDA should implement something similar to that proposed for protecting food for humans against intentional adulteration.⁹ This would include requiring domestic and foreign facilities to address vulnerable processes in their operations and also to implement a written food defense plan that addresses vulnerabilities in pet food operations. Another way to combat economic adulteration is through a supplier verification program, which is recommended above.

E. Compliance Dates

The HSUS strongly encourages a speedy finalization of this proposed rule and implementation period, including making the rule effective 60 days after the publication in the Federal Register.¹⁰ The staggered compliance dates for smaller animal food businesses are certainly more than enough time to comply with the new requirements, especially with the FDA working closely with industry to facilitate implementation.¹¹ We would discourage any extensions or prolonging of compliance dates any further than those already stated in the proposed rule.

Conclusion

The HSUS supports and applauds the FDA for the proposed Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food Animals rule. The FSMA was enacted in order to better protect human and animal health by preventing food safety problems before they occur. With the finalization and implementation of this rule, the FDA will be making necessary changes to the way we think about food safety for humans and animals alike. On behalf of our members and pet owners, we support these historical regulatory changes and encourage strong and consistent enforcement by FDA.

Thank you for the opportunity to comment.

Sincerely,



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⁹ 78 FED. REG. 3646 (proposed Jan. 16, 2013).

¹⁰ 78 FED. REG. 64751.

¹¹ *Id.*