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

Re: Docket No. 2011-N-0922 and RIN 0910-AG10 Current Good Manufacturing Practice and Hazard Analysis Risk-Based Preventive Controls for Food for Animals

Dear Food and Drug Administration:

The Agribusiness Association of Iowa (AAI) submits this statement in response to the Food and Drug Administration's (FDA) proposed rule that would establish Current Good Manufacturing Practices (CGMPs) and Hazard Analysis and Risk-Based Preventive Controls regulations for animal feed and pet food.

AAI's membership consists of over 1,100 business locations across the state that supply feed, seed, crop protection chemicals, grain, fertilizer, equipment and additional products and services that benefit agriculture, as a whole. A large percentage of our members have a direct interest in FDA's regulation, particularly as the proposed requirements would apply to facilities involved in storing raw agricultural commodities, such as grain elevators, and feed mills that manufacture and distribute animal feed.

We believe that FDA's proposed regulations should be revised significantly to reflect the intent of the Food Safety Modernization Act's (FSMA) statutory language and provide sufficient flexibility to allow facilities to adopt animal feed and pet food safety practices that are practical and effective for their specific, individual operations. As proposed, we believe that the regulations would establish an extremely burdensome and costly regulatory framework that is not necessary to ensure the safety of animal feed and pet food. Further, the proposed requirements would divert limited resources away from industry practices that have effectively assured the safety of such products. As such, we offer the following recommendations and comments.

- We support FDA's proposed exemption for the "holding" of raw agricultural commodities other than fruits and vegetables intended for further processing or distribution, but the definition of "holding" should be revised to encompass activities customarily performed for the safe and effective holding of such products, like grains and oilseeds. Among the activities that should be included with FDA's definition of "holding" are drying, screening, fumigating, and others that do not change the raw agricultural commodity into a processed food.

- FDA should exempt packing of raw agricultural commodities other than fruits and vegetables intended for further processing or distribution, since packing is part of the normal distribution activity and represents a low risk to animal and public health.

- FDA's proposed CGMPs should establish reasonable and practical requirements for **animal feed and pet food**, and not be based upon requirements necessary for **human food**. The hygienic standards necessary for human food are **not** necessary to ensure the safety of animal feed. For example, the practice of "sanitizing" is not necessary at the vast majority of animal feed facilities that will need to comply with the final rule. If sanitizing is necessary to control an animal feed hazard within a given facility, that facility can address that hazard within its animal feed safety plan.

- FDA should closely follow the authority provided by FSMA when establishing its preventive controls regulation. FSMA does not mandate that facilities implement regulatory hazard analysis and critical control point (HACCP)

plans. FDA's regulation should focus on "known or reasonably foreseeable hazards" and provide firms with appropriate flexibility to manage feed safety risks in a manner commensurate with the hazard.

- We strongly oppose any required electronic submission of a facility's animal feed safety plans to FDA. We believe that FDA does not have authority to inspect records outside the context of the facility. We also believe that it is not possible to reach accurate and meaningful conclusions about such information without observing the facility's operation.

- FDA should re-propose the regulations in their entirety after considering comments due to the magnitude of changes that need to be made to the proposed requirements and allow ample time for stakeholders to fully review the revised proposed rules and offer thoughtful comments.

- FDA should provide different compliance phase-in periods for its CGMPs and preventive control requirements. After the final regulations are published, facilities should, based on company size, be given one to three years to come into compliance with the CGMPs. For the preventive controls requirements, facilities, based on company size, should be given two to four years to comply with requirements after the rule is final. This staggered compliance phase-in approach is needed to provide adequate time for firms to implement programs to comply with CGMPs requirements before being expected to comply with the preventive control requirements.

AAI's members continue to be committed to ensuring the safety of their animal feed and pet food inputs and finished products; however, the proposed rule needs to be revised to reflect the differences between grain and feed safety and that of human food so as not to create unnecessary, burdensome and costly regulations that would greatly hamper the productivity and profitability of the companies and individuals who make up our industry.

We thank you for providing the opportunity to comment on this important rulemaking.

Sincerely,

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