Ohio AgriBusiness Association

Advocating for Ohio agribusiness by creating a sustainable business climate through collaborative policy leadership, continuous education and effective communication.

December 11, 2014

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 and Risk-Based Preventive Controls for Food for Animals

Dear Food and Drug Administration:

The Ohio AgriBusiness Association submits this statement in response to the Food and Drug Administration's (FDA) supplemental notice in which the agency proposes to amend its 2013 proposed rule for current good manufacturing practice (CGMPs) and hazard analysis and risk-based preventive controls for animal feed and pet food.

OABA members include businesses in manufacturing, wholesale and retail, which represent business sectors including agronomic inputs, livestock feed and nutrition, grain marketing and operations, insurance, equipment and financial services. 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.

Although the requirements proposed by FDA within its supplemental notice are an improvement in comparison to those issued in the agency's 2013 proposed rule, 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 the regulations would establish a burdensome 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 strongly support FDA's proposed exemption from its regulations for the storage of raw agricultural commodities other than fruits and vegetables intended for further processing or distribution. We also strongly support the agency's revised definition for "holding" that would encompass activities customarily performed for the safe and effective storage of such products, like grains and oilseeds.

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- FDA should provide a clear exemption for 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 for such products and represents a low risk to animal and public health.

- FDA should replace the term "contamination" with "adulteration" throughout its proposed CGMPs regulation. The term "contamination" is not a defined, legal term.

- FDA's proposed CGMPs must 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** needed to ensure the safety of animal feed. Many of FDA's proposed CGMPs requirements inappropriately focus on the hygienic design and construction of equipment and facilities, and would establish standards that are required for human food. We strongly believe that FDA must make significant revisions to the proposed CGMPs so that the final regulation does not add unnecessary requirements that would cause animal feed and pet food companies to expend millions of dollars towards attempting to comply with regulatory obligations that are not needed to assure the safety of animal feed.

- FDA should closely follow the authority provided by FSMA when establishing its hazard analysis and preventive controls regulation for animal feed and pet food, and issue requirements that are realistic for our industry. We generally support FDA's new proposed term "significant hazard," because it would better define those hazards for which rigorous management control activities may be needed. However, we believe the proposed regulation should be further revised to provide firms with appropriate flexibility to manage feed safety risks in a manner commensurate with the hazard.

- We believe any requirements for firms to consider the potential for hazards that may be intentionally introduced into products for economic gain should only be applied to "significant hazards," if any, for which there has been a historical pattern of occurrence.

- We believe any product testing requirements should only be applied to "significant hazards," if any, that are present within the firm's operation.

- We believe any environmental monitoring requirements should only be applied to "significant hazards," if any, that are present within the firm's operation.

- We believe that any supplier program requirements should only be applied to "significant hazards," if any, that the firm relies upon its supplier to control.

- 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.

In closing, the proposed regulations will be a significant burden for many of our small grain and feed businesses in Ohio. Even larger facilities could have to scale back their operations causing unnecessary economic distress to the community and a potential loss of jobs.

I appreciate the opportunity to submit comments on behalf our members.

Sincerely,

Christopher Henney
President and Chief Executive Officer