September 10, 2014

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National Grain and Feed Association
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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Re: Docket No. FDA-2013-D-1009; Draft Guidance for Industry (GFI #220) on "Use of Nanomaterials in Food for Animals."

Dear Docket Clerk:

The American Feed Industry Association (AFIA), the National Grain and Feed Association (NGFA) and the Pet Food Institute (PFI) appreciate the opportunity to comment on the U.S. Food and Drug Administration's (FDA) draft guidance for industry (GFI #220) on the use of nanomaterials in food for animals. All animal food stakeholders – including regulators, technology providers, animal food manufacturers, animal food customers, animal food consumers and human food consumers (for animals used in human food production) – need clear guidance for how the products of nanotechnology may be reviewed for use in the animal food industry. We encourage FDA to continue to communicate with stakeholders regarding the development of policies and procedures for the use of nanomaterials in animal food. We also encourage FDA to be flexible in its approach toward the regulation of this new technology and its use in animal food.

In general, our associations find this draft guidance document helpful in understanding the requirements for the review and use of nanomaterials in animal food. We provide the following specific comments and recommendations on selected sections, which we believe would further enhance the information provided to the industry.

Scope of the draft guidance

We appreciate FDA's acknowledgement that conventional animal food manufacturing processes sometimes result in particles in the nanoscale range. We agree with FDA's conclusion that this draft guidance is not intended to question the regulatory status of products that naturally exist in

the nanoscale range or that contain incidental amounts of particles in the nanoscale range, and that have already been determined to be generally recognized as safe or GRAS or approved in response to a food additive petition. Our associations also agree with FDA's determination that "[m]aterials or end products that naturally occur or naturally contain substances in the nanoscale range and are not further manipulated or engineered are not within the scope of this guidance." AFIA, NGFA and PFI believe when considering whether an FDA-regulated product involves the application of nanotechnology, FDA should focus on whether the product was deliberately manipulated to control its dimensions to produce specific technical effects.

Nanotechnology and GRAS Substances in Food for Animals

FDA states in one section of its draft guidance that it "does not categorically judge all products containing nanomaterials or otherwise involving the application of nanotechnology as intrinsically benign or harmful" but rather "considers the characteristics of the finished product and its safety for its intended use." AFIA, NGFA and PFI agree with these statements, since they reflect a reasoned approach that does not make assumptions regarding the safety of animal foods containing the products of nanotechnology.

FDA later states that, "[a]t present, for nanotechnology applications in animal food, there are questions related to the technical evidence of safety as well as the general recognition of that safety that are likely to be sufficient to warrant formal premarket review and approval by FDA, rather than to satisfy criteria for GRAS status." AFIA, NGFA and PFI note an inconsistency here between FDA declining to pre-judge all products containing nanomaterials as benign or harmful on the one hand and instituting a *de facto* premarket approval requirement on the other. We are concerned that FDA is essentially ruling out the GRAS notification program as a legal option for approving these new ingredients. CVM states in the draft guidance that "at this time" no public data is available to meet the "generally recognized" standard. While such data may not be available at this time, it is very likely to be available in the future. Accordingly, we urge FDA to elaborate further on the data (including data related to the conventional counterpart to a nanomaterial) that can be used to seek and obtain GRAS status for a nanomaterial to be used in animal food.

Labeling

Section V of the draft guidance details information that should be considered in developing a submission for a food additive petition for a nanomaterial food animal ingredient. Subsection C states that FDA may require the label or labeling of such a food additive to include information necessary to ensure the safe use of the food additive in animal food. We urge FDA to acknowledge and adhere to the labeling requirements for animal food and animal food ingredients as detailed in 21 CFR parts 501 and 502. Specifically, we urge FDA to elaborate on the specific conditions that would warrant labeling regarding the presence of a nanomaterial food additive in animal food, noting that a labeling requirement should be limited to alerting animal food customers to specific product safety issues, not the mere presence of a nanomaterial. Any

special considerations for intended use or use level can and should be included on the animal food ingredient label.

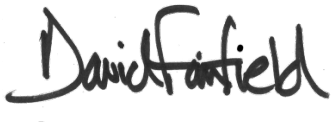
Conclusion

AFIA, NGFA and PFI appreciate that FDA has published this draft guidance for industry. The comments within this statement represent our initial review of the information provided. As our member companies utilize the information to develop the use of nanomaterials over the coming months, we will pass along any additional comments and clarifications that are identified to further strengthen this guidance document.

AFIA, NGFA and PFI appreciate FDA's consideration of our comments.

Sincerely,

Leah Wilkinson
Director, Ingredients, Pet Food and State Affairs
American Feed Industry Association



David Fairfield
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About AFIA:
The **American Feed Industry Association** (AFIA) is the world's largest organization devoted exclusively to representing the business, legislative and regulatory interests of the U.S. animal feed industry and its suppliers. AFIA also is the recognized leader on international industry

developments. Members include more than 575 domestic and international companies and state, regional and national associations. These members manufacture over 75 percent of the nation's 158-million tons of feed annually. Member-companies are livestock feed and pet food manufacturers, integrators, pharmaceutical companies, ingredient suppliers, equipment manufacturers and companies which supply other products, services and supplies to feed manufacturers.

About NGFA:
The **National Grain and Feed Association** (NGFA), established in 1896, comprises more than 1,050 member companies that operate more than 7,000 facilities and handle more than 70 percent of the U.S. grain and oilseed crop. The NGFA's membership encompasses all sectors of the industry, including country, terminal and export grain elevators; commercial feed and feed ingredient manufacturers; biofuels producers; cash grain and feed merchants; end-users of grain and grain products, including processors, flour millers, and livestock and poultry integrators; commodity futures brokers and commission merchants; and allied industries that provide goods and services to the industry. The NGFA also consists of 26 affiliated State and Regional Grain and Feed Associations, and has strategic alliances with Pet Food Institute and the North American Export Grain Association.

About PFI:
Established in 1958, the **Pet Food Institute** (PFI) is the voice of US cat and dog food manufacturers. PFI members account for approximately 98 percent of the cat and dog food produced in the United States. Among its members are twenty-four dog and cat food manufacturers and more than 100 affiliates who supply ingredients and raw materials to dog and cat food producers. Our members sell more than $20 billion in dog and cat food annually, including approximately $1.5 billion in exports – Canada accounts for nearly one-half of these exports, more than $600 million annually.