

December 12, 2018

Jenny Murphy
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Pl.
Rockville, MD 20855

Via Electronic Filing at <http://www.regulations.gov>

RE: Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Supply-Chain Program; Draft Guidance for Industry; Availability, Docket No. FDA-2018-D-1861

Dear Ms. Murphy:

The National Association of Chemical Distributors (NACD) submits the following comments in response to the Food and Drug Administration (FDA) request for public comment regarding Docket No. FDA-2018-D-1861, Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Supply-Chain Program; Draft Guidance for Industry; Availability (guidance).

About NACD

NACD is an international association of nearly 450 chemical distributors and their supply-chain partners. NACD members represent more than 85 percent of the chemical distribution capacity in the nation and generate 93 percent of the industry's gross revenue. NACD members, operating in all 50 states through more than 3,000 facilities, are responsible for nearly 75,000 direct and indirect jobs in the United States. NACD members are predominantly small regional businesses, many of which are multi-generational and family owned.

NACD members meet the highest standards in safety and performance through mandatory participation in NACD Responsible Distribution®, the association's third-party-verified environmental, health, safety, and security program. Through Responsible Distribution, NACD members demonstrate their commitment to continuous performance improvement in every phase of chemical storage, handling, transportation, and disposal operations.

Approximately 63 percent of NACD distributor member companies distribute or process chemicals that will ultimately become ingredients in food; the food market is a substantial and growing part of NACD members' business. Keeping the U.S. food supply safe through Responsible Distribution and compliance with FDA food safety regulations is of utmost importance to NACD members.

FDA Should Modify the Requirements for Verification and Approval of a Supplier's Supplier

FDA should modify the guidance to allow more flexibility in satisfying the requirement for approval and verification of a supplier's supplier. The guidance as currently written in Section V.D. requires companies to "obtain documentation of an appropriate verification activity from

another entity, review and assess the documentation and document that review and assessment.” This practice is resource intensive and may not be feasible due to non-disclosure agreements or because of limitations such as a lack of a contractual relationship between the importer or receiving facility and their supplier’s supplier or other entity. Further, it would be prohibitively difficult to check on each individual company that supplies ingredients to a direct supplier, and even more so to try to verify the supply-chain applied control for each product. The FDA should modify its interpretation of 21 CFR 507(c) to allow firms to meet these requirements by confirming and documenting that their direct suppliers have good supplier approval and verification programs in place.

FDA Should Revise Its Ingredient Testing Recommendations

The guidance includes a recommendation under Section VI.B.2. “Sampling and testing of the raw material or other ingredient (21 CFR 507.110(b)(2))” on when it may be appropriate for firms to conduct testing on food or raw materials obtained from suppliers. FDA should revise these recommendations to be consistent with the industry practice of “test and hold” to avoid recall situations. Typically, if an importer tests a product, they will hold the rest of the lot in that batch in case a positive result is received. FDA should revise the guidance, specifically in relation to ingredient or raw material testing, to reflect this standard industry practice.

Conclusion

NACD appreciates FDA’s efforts to provide guidance for complying with the Preventive Controls for Animal Food rule. We believe the recommendations outlined above would significantly improve industry compliance.

Thank you for the opportunity to comment on the guidance. If you have questions or need additional information, please do not hesitate to contact me.

Sincerely,



Jennifer C. Gibson
Vice President, Regulatory Affairs