



February 5, 2018

Dockets Clerk
Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
Rockville, MD 20852

VIA Regulations.gov

Re: Review of Existing Center for Veterinary Medicine Regulatory and Information Collection Requirements; Docket No. FDA-2017-N-5104

Dear Sir or Madam:

The American Feed Industry Association appreciates the opportunity to submit comments to the Food and Drug Administration's Center for Veterinary Medicine on ways the agency can reduce the regulatory burden, both on the center and regulated industry, while not compromising animal food safety. AFIA hopes the center will review these comments in the spirit they are offered, and appreciates the agency's offering to consider changes.

AFIA, based in Arlington, Va., 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. Founded in 1909 as the American Feed Manufacturers Association, the name changed to the American Feed Industry Association in 1985 to recognize the importance of all types of companies involved in the feed manufacturing industry—from commercial and integrated feed manufacturers, to ingredient suppliers, pet food manufacturers and equipment manufacturers. AFIA is also recognized as the leader on international industry developments and holds membership in the International Feed Industry Federation (IFIF), and AFIA's president and CEO just completed serving as IFIF's chairman.

AFIA members include more than 670 domestic and international companies and state, regional and national associations. Member companies are livestock feed and pet food manufacturers, integrators, pharmaceutical companies, ingredient suppliers, equipment manufacturers and companies that supply other products, services and supplies to feed manufacturers.

The animal food manufacturing industry is a major contributor to U.S. food and feed safety, nutrition and the environment, and it plays a critical role in the production of healthy, wholesome meat, milk, fish and eggs. AFIA recently released the results of a study commissioned by the Institute for Feed Education and Research (IFEEDER), AFIA's education and research arm, which found that the U.S. animal food manufacturing industry produced over 236 million tons of

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ready-to-eat feed for nine animal species in 2016. Information and more data about species, ingredients and state feed production can be found on our website at afia.org. AFIA members manufacture a majority of this feed and make a majority of the non-grain ingredients.

We have categorized our comments as follows:

Food Safety Modernization Act's Animal Food Rule Specific Concerns

In AFIA's comments to the agency during the rulemaking periods, we listed a number of specific changes that needed to be made to align the rules with not only best industry practices, but to reduce the economic burden on the industry, as the rules would not achieve the intended effect without costing an excessive amount. AFIA offered alternatives, and in fact, the FSMA statute itself offers alternatives in section 418 (m), which the agency did not choose to use for animal food. We offer below some specific changes needed and the rationale based on our review of the rule, meetings with industry members and gauging the long-term interests of both the agency and the animal food industry.

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals Final Rule ("animal food rule")

Generally, AFIA is pleased with the current good manufacturing practices (CGMPs) subpart of the final animal food rule. However, it would have been much better for the agency to align this final rule with that of the medicated feed CGMPs (21 CFR Part 225) for two reasons: 1) The largest feed mills are already quite familiar and have rare compliance issues with these rules; and 2) The agency investigators would not have to learn two sets of CGMP rules, nor would the facilities. We continue to urge the agency to align the CGMPs to achieve practicality in implementation by the industry and investigators.

21 CFR § 507.31 Food Safety Plan

This section requires, among other things, "...written preventive controls..." which, by the agency's own admission may not be required in every facility based upon the product produced, the type of hazard and/or the methods used to mitigate the risks of those hazards. This section and subsection § 507.34 should be rewritten to detail when such controls are and are not required, otherwise, state and federal investigators may not understand such preventive controls are not required in every instance or type of facility. Providing such examples in the guidance for industry preventive controls chapters will also be important.

Similarly, a "...written supply-chain program," is required in this subsection, when again, the agency admits it may not be required frequently in the animal food industry. This subsection and Subpart E should be written to detail when such controls are required, otherwise, state and federal investigators may not understand such a supply-chain program is not required.

21 CFR § 507.33 Hazard Analysis

AFIA believes certain elements of the hazard analysis requirements in this section of the rule are overly costly and burdensome on the animal food industry. IFEEDER, funded a comprehensive literature and public information search along with the development of a database with the University of Minnesota's Center for Animal Health and Food Safety in the university's College

of Veterinary Medicine. Among others things, the study did not find unknown animal food safety hazards for which the industry was unaware.

Several requirements that must be considered in the FDA's hazard analysis in 507.33 drove up the cost of this study considerably and make it very unlikely for small or very small facilities to be able to conduct such analyses on their own. Among these were the requirements for the following: illness data, scientific reports and the probability of such occurrences, which requires a substantive assessment and sometimes a crystal ball. The agency is requesting an assessment and determination of the probability of hazards that may have only ever appeared once in feed, such as with melamine, which was the result of a serious quality-control breach and likely would not have been prevented by FSMA. AFIA believes that a hazard analysis beyond what is sufficient for HACCP is unnecessary if the facility has developed a robust animal food safety plan that can readily determine if unknown or unreported hazards could challenge the system. We believe the specific requirements for illness data, scientific reports and probability of hazards should be removed from this subsection, since they are costly and require enormous amounts of data with little impact on food safety.

In subsection (a) (1), the rule mentions, "...each type of animal food manufactured..." AFIA believes this phrase without delineation makes the hazard analysis unnecessarily long and cumbersome. The phrase, "each type of," should be removed, to leave "animal food manufactured, processed, packed or held."

21 CFR § 507.34 Preventive Controls

The costliest section of this rule is the preventive controls section, due to the requirements for monitoring, corrective action plans, validation of controls, verification that the preventive controls are working, reanalysis of the controls and recall plans. AFIA believes the full implementation of this section would cost the industry in excess of \$800 million with very little benefit, as described in the only independent economic analysis conducted of the rule. This analysis, performed by the Mercatus Center at George Washington University, was filed during the comment period for the proposed rule.

The agency has admitted few, if any, feed facilities should have preventive controls, but this is not stated in the final animal food rule, and it should be stated clearly as such in the regulation. The nuances of when a preventive control is or is not required in the animal food industry need to be fully described in the guidance for industry preventive control chapters and in the training program for investigators.

21 CFR § 507.36 (a)(2)(ii), (3)(ii), (4)(ii), § 507.37 and 1.507 §1, Subpart L, specifically 1.507 (a)(2)(ii), (3)(ii), (4)(ii), and 1.507 (b)(i, ii, and iii) Written Assurances

AFIA appreciates the enforcement discretion offered by the agency, as notified on Jan. 4, while it works out solutions to the identified issues. AFIA continues to recommend that these FSMA written assurance provisions be repealed because these requirements do not have meaningful food safety benefits, do very little to deliver improvements in public health, and are extremely burdensome for the industry. The complexity and scale of this requirement as written could cause a severe disruption of commerce because of the significant resource and administrative challenges to implement such assurances. While we have specifically cited the regulations

impacting the animal food industry above, we support FDA being consistent and repealing the relevant sections in the human food preventive controls and produce safety regulations.

Elimination of Part 11 Requirements for Veterinary Feed Directive and Medicated Feed Records

AFIA has filed two citizen petitions requesting an exemption for Part 11 VFD and medicated feed CGMP records, based on the wholesale exemption FDA granted for FSMA records. FDA, on its own initiative, granted an exemption to the Part 11 requirements in the final FSMA rules for produce and human and animal food. The animal food industry believes FDA should also grant such an exemption for VFD and medicated feed records and urges swift rulemaking to reduce this onerous requirement.

Initial responses to both petitions were received, and the agency mentioned "...legal and policy..." issues need to be reviewed. AFIA believes the removal of these regulatory burdens should be simple policy changes that would bring meaningful regulatory reform for the licensed medicated feed mills and those facilities handling VFD records. We urge swift action on these measures.

Elimination of Drug Establishment Registration for Feed Mills

Medicated feed mills which manufacture feed using Category II, Type A medicated articles are required to submit duplicative information to the FDA for the annual Drug Establishment Registration (DER) and Medicated Feed Mill License applications. AFIA believes this complicated DER process is not necessary for feed mills, and FDA can eliminate the requirement as allowed by rule and by law, since the DER requirement is primarily meant for drug manufacturers.

The major concern is the overly complicated system FDA has adopted to accomplish this annual feat of reregistration. After working for several years to merely get it to operate, many times, FDA's computer personnel merely tell firms they will accomplish the reregistration after receiving the paper records.

Over the past several years, the number of licensed medicated feed mills has dropped by about 300. AFIA expresses concern that these facilities may not be able to reregister their facilities due to the exceedingly cumbersome nature of the DER process. Many firms tell us they have outsourced this effort at considerable expense.

In 2017, near the time of reregistration, AFIA members reported receiving notices from FDA about their "drug listings." Such listings are not required for medicated feed manufacturers. Similar requests of this nature are received each year. These requests that are non-sensical take time for the agency and the industry to respond to and add to the confusion of why this requirement is in place for feed manufacturers. It is time to remove this DER requirement from medicated feed manufacturers, and the agency should do so expeditiously.

Review of Ingredients for Use in Animal Food

The Center for Veterinary Medicine places an important role in the review and approval of ingredients used in animal food through the food additive petition, generally recognized as safe notification program and the ingredient review process of the Association of American Feed Control Officials (AAFCO). Over the last several years, resources within CVM's Division of Animal Feed have been pulled away from ingredient reviews to other priority issues or positions or not replaced as people retire or leave the division. This tightening of resources in combination with several areas where CVM has excess policy interpretations on animal food ingredients has caused significant delays in gaining approvals for new animal food ingredients. According to a study conducted by Informa Economics, for every year of delay in the approval process, the submitting company is losing an average \$1.75 million in revenue. We have identified the areas below where the agency can work smarter with the resources allocated while maintaining appropriate submission requirements for safety determinations and allowing innovation to occur. We look forward to more in-depth conversations with CVM staff on each of these topics.

- As food additive regulations and AAFCO ingredient definitions are non-proprietary and do not include detailed manufacturing information, the manufacturing information that is required in such submissions should be consistent with the regulatory requirements of the ingredient that is used as the basis of marketing and manufacturing. Currently, the Division of Animal Feeds manufacturing requirement for food additive petitions and the AAFCO definition requests is extremely comprehensive, resulting in significant resources for the petitioner and bottlenecks in the Division review process. We believe this section could be more appropriately applied, which would reduce the time for compiling and reviewing the submission package while still providing a consistent determination for the safety of the product.
- The Food and Drug Administration Amendments Act (FDAAA) of 2007 required the agency to establish ingredient standards for pet food. FDA should not expend any valuable resources trying to duplicate the reviews or classify currently approved ingredients. Instead, the FDA should adopt through rulemaking and/or a guidance document, the ingredient definitions in AAFCO's *Official Publication* as the FDAAA compliant ingredient standards. Conducting this action would be consistent with the intent of Congress.
- AFIA members are interested in bringing to market innovative ingredients that improve animal nutrition, the safety of animal food, as well as the animal food products humans eat. Others want to provide claims on products that challenge the boundary of traditional thinking in the agency regarding nutrition, taste and aroma. Currently, the Policy and Procedure Guide 1240.3605 (specifically footnote 3 on the "Policy Matrix") prohibits animal production claims for food. AFIA believes this and interpretations of other policies regarding health, structure/function or other claims provide a significant impediment to bringing valuable and highly desired animal food ingredients to the companion animal nutrition and the animal agriculture industry.

AFIA appreciates the opportunity to respond to the agency. We hope these comments and many others are not stored somewhere and never reviewed. The development of meaningful regulatory reform ideals would provide tremendous benefit in time and resources, not just to the regulated industry, but to the FDA. AFIA urges the agency to seriously review these comments and others and move toward a concerted effort to make positive changes in regulations.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Sellers". The signature is fluid and cursive, with a large initial "R" and "S".

Richard Sellers, PAS, Dipl., ACAN
Sr. Vice President, Public Policy and Education
American Feed Industry Association