April 13, 2020

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

Via Regulations.gov

Re: FDA Docket Number FDA-2020-D-0064 Pre-Submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe Notices; Draft Guidance for Industry; Availability

Dear Docket Clerk:

The American Feed Industry Association (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 food 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 manufacturers of commercial and integrated feed and pet food to ingredient suppliers to equipment manufacturers. AFIA is also recognized as the leader on international industry developments, representing the industry at global forums, including within the International Feed Industry Federation.

AFIA's members include nearly 700 domestic and international companies, such as livestock feed and pet food manufacturers, integrators, pharmaceutical companies, ingredient suppliers, equipment manufacturers and supply companies that provide other products or services to feed manufacturers. Several state, national and regional associations are also AFIA members. The feed industry plays a critical role in the production of healthy, wholesome meat, milk, fish and eggs and supports policies that uphold U.S. food and feed safety, ensure the proper nutrition of animals and protect the environment. More than 75% of the feed in the United States is manufactured by AFIA members. AFIA's members also manufacture approximately 70% of the country's non-whole grain ingredients, including soybean meal, distillers' co-products, vitamins, minerals, amino acids, yeast products and other miscellaneous and specialty ingredients.

AFIA commends the Food and Drug Administration's Center for Veterinary Medicine (CVM) for issuing the draft guidance for industry "#262 Pre-Submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe Notices." Improving the efficiency of the ingredient review processes is a top priority for AFIA. A 2016 study performed by Informa Economics found that on average it takes three-to-five years to get an ingredient reviewed by the CVM. In that time, ingredient suppliers lose an average $1.75 million annually in revenue per product. These delays and expenses stifle the industry's ability to innovate and address some of the most pressing challenges and opportunities in the animal agriculture

American Feed Industry Association • 2101 Wilson Blvd., Suite 810, Arlington VA 22201 USA
T: (703) 524-0810 • F: (703) 524-1921 • afia@afia.org • afia.org

industry. Left unchecked, this delay reduces choices in the marketplace, especially for farmers, ranchers and consumers who are looking for innovative ingredients to keep their animals healthy and support sustainable production practices.

The Animal Drug and Animal Generic Drug User Fee Act (H.R. 5554) made technical improvements to the animal food ingredient review process. These changes increased transparency in the application process, removed conflicting language surrounding ingredients and provided further clarity on the submission process for pre-submission consultations and the submission of foreign data in food additive submissions. ADUFA was a great first step in working toward a better review process and AFIA appreciates the CVM's work to implement these improvements, including publishing this draft guidance. AFIA urges the agency to finalize the guidance as soon as possible.

AFIA is appreciative of the timelines published in the guidance in order to provide the animal food industry with an idea of response time when pursuing a consultation with the agency. We believe the processes described in the guidance accurately reflect the system detailed by those AFIA members that have used the pre-submission consultation process. As the agency adds staff for the purpose of completing ingredient reviews in a timelier manner, we look forward to seeing the progress of achieving these goals. AFIA urges the agency to reduce the review time goals even further when finalizing the guidance.

The study protocol content detailed in Appendix 2 is very helpful to understand the agency's expectations for the quality of study design and therefore the data generated for the ingredient submission. Having this detail in a guidance document should assist submitters in understanding what is required in a properly designed study and ultimately should improve the overall quality of ingredient submission packages.

Similarly, the information provided in Appendix 3 will improve the final reports on the studies and therefore ease the agency's review.

One specific edit is suggested in Part III. B. 3. 2nd paragraph, 4th line. The point is made that for using existing data from previously conducted studies, the procedures should reflect animal feeding and husbandry practices used in the U.S. AFIA would request that the phrase "similar to those" be inserted in this sentence, since the agency has indicated that feeding and husbandry practices do not necessarily need to be identical to practices in the U.S. The sentence would read: "…(2) procedures were followed that reflect animal feeding and husbandry practices similar to those used in the United States, and…"

Overall, AFIA believes this guidance document will be very useful for the industry and urges the agency to finalize the guidance as soon as possible.

Sincerely,

Leah Wilkinson

Leah Wilkinson
Vice President, Public Policy and Education