November 17, 2022 Via Regulations.gov

Dr. Steven Solomon
Director, Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Place, HFV-236
Rockville, MD 20855

RE: Docket No. FDA-2022-N-2015

Dear Dr. Solomon:

The American Feed Industry Association (AFIA), based in Arlington, Va., is pleased to submit comments on Docket No. FDA-2022-N-2015 regarding the "Regulation of Animal Foods with Certain Types of Claims." The AFIA appreciates the Food and Drug Administration Center for Veterinary Medicine (CVM) considering this important topic by holding a listening session and opening this docket to gather important stakeholder input.

The AFIA 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, the AFIA represents over 650 domestic and international companies involved in the feed manufacturing industry—from manufacturers of commercial and integrated feed and pet food to ingredient suppliers to equipment manufacturers. The AFIA is also recognized as the leader on international industry developments, representing the industry at global fora, including within the International Feed Industry Federation. 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.

Animal nutrition plays a vital role in improving and promoting the health of our livestock, poultry, companion animals and fish. Research and development is looking at new and existing ingredients that can further support animal production and health, in addition to public and environmental health, and animal well-being. Many of these animal food ingredients go beyond the typical taste, aroma and nutritive value historically associated with animal food and ingredient companies are developing game-changing solutions that act solely on or in the digestive tract of animals.

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Unfortunately, in the United States, it is not possible to bring these safe and effective products to the marketplace in a timely way as they run into an insurmountable regulatory hurdle in the CVM Policy and Procedures Manual Guide 1240.3605. Written in 1998, the guide is long past its era of applicable oversight in the regulation of animal food ingredients. The CVM is overdue in revisiting its narrow path for regulatory approval of animal food ingredients as interpreted by Guide 1240.3605. The United States needs a regulatory system that is flexible, efficient and predictable to bring new animal food ingredients to market to support our farmers and ranchers in the global market.

In September 2020, the AFIA asked the CVM to review Guide 1240.3605 in order to best place the U.S. animal food industry and these products into the appropriate regulatory pathway and allow scientific advancement for our agricultural producers and companion animals to flourish. The AFIA is encouraged by the CVM's willingness to take public comments on this matter and urges a complete and thorough review as quickly as possible. The AFIA offers these comments to support that review.

Animal foods with certain types of claims play a role addressing food safety, environmental issues

Around the world, the role of animal nutrition to promote the health of livestock, poultry and aquaculture animals is expanding based on the scientific community's increasing understanding of the functionalities of animal food ingredients to support animal production and health, public and environmental health, and animal well-being. Researchers are rapidly developing these animal food ingredients and many different segments of the food chain are eager to include these products in their animal production strategies.

According to the Food and Agriculture Organization, and as applied by the FDA, a One Health approach is essential for controlling diseases that spread between animals and humans, ensuring food safety and preventing environment-related human and animal health threats. Unfortunately, current FDA policy limits the ability of U.S. farmers, ranchers and animal owners to employ the use of animal food ingredients, with proven safety and efficacy, to support the One Health approach to animal management. Currently, manufacturers of animal foods with production benefits are not allowed to be transparent in labeling regarding the benefits these ingredients can provide to support healthy animals.

Publicly available information demonstrates the robust advancement in animal nutrition science and provides evidence clearly supporting the beneficial effects of animal food and nutrition beyond those traditionally considered by FDA, which narrowly attributes the effects to taste, aroma, and the nutritive value of food. To feed a growing global population, the proven functions of animal food to support the efficient production of milk, meat and eggs must be recognized. Regulatory jurisdictions around the world identify the important role of animal food ingredients in the production of safe food for humans, and farmers and consumers benefit from the production efficiency they provide.

In 2021, the United States Department of Agriculture Food Safety Inspection Service (FSIS) mobilized a comprehensive effort to reduce *Salmonella* illnesses associated with poultry

products. A key component of this effort is identifying ways to incentivize the use of pre-harvest controls to reduce *Salmonella* contamination coming into the slaughterhouse. Our members point to their European counterparts, whom can effectively market feed ingredients proven to help in controlling *Salmonella* on the farm. The European Food Safety Authority recognizes that animal food ingredients constitute an important group of pre-harvest food safety measures across all livestock and poultry types. And yet, U.S. producers cannot use these products.

Animal food ingredients are a proven means to slow the progress of climate change as a methane reduction strategy. Secretary of Agriculture Tom Vilsack has spoken many times about the role feed ingredients can play in reducing greenhouse gas emissions and has urged the CVM to modernize its approach to ingredient review.

Feed ingredients with known efficacy to reduce enteric methane emissions in cattle cannot be sold with marketing claims for methane reduction. Current FDA policy is restricting accurate marketing of these products in the United States while farmers and ranchers around the world can knowingly and legally use them for their environmental benefits. The AFIA believes the three currently available regulatory pathways within the jurisdiction of the CVM and the Association of American Feed Control Officials (AAFCO) provide sufficient scientific review to confirm the safety and efficacy of animal food ingredients, including methane-reducing ingredients, and modernization of Policy Guide 1240.3605 will assist in bringing these products to the marketplace.

Current CVM policy lacks consistency

The new animal drug approval process is cumbersome and expensive for animal food ingredients. The AFIA believes that certain types of claims for animal food ingredients can be properly substantiated through the three available animal food review processes. The AFIA also believes that the Federal Food Drug and Cosmetic Act (FFDCA) and the First Amendment allow manufacturers and sellers to assert truthful, substantiated structure/function and other well-being, environmental and resiliency claims pertaining to animal food.

Currently, the CVM appears to have adopted an informal policy that considers digesta contents to be “part of the animal,” rather than a commonly held understanding that the digesta is part of the gastrointestinal tract and, therefore, considered “outside of the body” for determination of where a product works and if it is classified as a drug or a food. This policy has disincentivized research and innovation in the United States for products that would alter the contents of the digesta to improve animal production, well-being or resiliency. It should also be noted that for animal food ingredients, such as enzymes or emulsifiers, the CVM considers these ingredients to act on the digesta or the feed in the gastrointestinal tract and it reviews those products as animal food ingredients.

The CVM’s current policy fails to reflect the full impact of non-nutritive feed components on animals, creating a limiting regulatory mechanism for recognizing the direct or synergistic effects of diet components on animal maintenance requirements. Many ingredients have a beneficial influence on animals through enhanced digestibility or by altering physiology. Improved understanding of how animal food ingredients can have dramatic effects on tissue

responses to the diet through their roles in the lumen of the gastrointestinal tract, either directly or indirectly, point to the underlying complexity in how food ingredients impact animal productivity and well-being.

Regulation by the CVM of products that elicit change in the microbiome and digesta is inconsistent and not transparent. For instance, direct-fed microbial products, whose purpose is to affect the structure and/or function of the animal body other than the digesta, are regulated as new animal drugs. But direct-fed microorganisms, whose sole purpose is to be part of and favorably affect the intestinal microbiome, are regulated as animal foods, as are several other products, such as prebiotics and enzymes. In some instances, similar types of ingredients that offer comparable functionalities are not viewed by the CVM as animal food ingredients from a regulatory perspective. This inconsistent view is detrimental to efforts to innovate and provide solutions that benefit the health of humans and animals and support the agency mandate of promoting public health.

There are some instances in which the CVM has exercised regulatory discretion and worked with the industry to facilitate the labeling of truthful claims regarding the health or functional benefits of animal food. Cats have benefited from the CVM's adoption of the philosophy detailed in the Nutrition Labeling and Education Act of 1990 (NLEA), which allows the use of "urinary tract health," "hairball control" and "dental health" claims on cat food products. We appreciate that the FDA established 11 criteria allowing "therapeutic" pet foods to be treated as "foods" and not require firms to undergo the expense of the new animal drug application (NADA) process, as detailed in Compliance Policy Guide 690.150. Importantly, the CVM has reviewed and informally accepted a functional claim for an animal food ingredient demonstrated to support dry matter intake during lactation. The AFIA would like a level and consistent regulatory framework that is easily understood and can be achieved for all products and allows truthful labeling and marketing of products.

State officials play an important role in the regulation of animal feed and pet foods. The extensive state role in the regulation of animal food intensifies the need for clear and transparent CVM action on proposed claims. It is the AFIA's experience that the CVM is often unwilling to commit to a position in writing regarding claims associated with animal feed and pet foods and its interpretation of guidance and policies. As a result, state officials are often reluctant to accept a label claim, even after CVM review. First Amendment protections apply to both federal and state restrictions upon commercial speech. Thus, a clear and consistent CVM position would provide clearer guidance and avoid potential First Amendment issues with state regulators. Absent some form of formal acceptance through the existing food additive petition, generally recognized as safe (GRAS) or AAFCO ingredient review process, regulators in the many states that require product registrations are often reluctant to allow claims that have not received FDA "acceptance."

The CVM should modernize and improve its ingredient review policy

The AFIA is urging the CVM to adopt a modernized, science-based policy that utilizes the food additive petition, GRAS process and AAFCO ingredient definition pathways. By doing so, the agency can support industry innovation in safe animal food ingredients that will address existing

and emerging issues in the production, use and legally compliant labeling of animal food. Along with our customers, our industry believes this can be accomplished using the existing regulatory pathways that review the safety and efficacy of products.

The AFIA requests that the CVM modernize its regulatory policy based on the relationship to the body of the gastrointestinal tract's contents. Biologists consider the contents of the gastrointestinal tract separate from the body. Digestive enzymes and microbiota break down food components, external to the animal, for cellular absorption by the host. The digestive enzymes and the gut microbiome are active in the gastrointestinal tract, a cavity which is continuous with the animal's external environment and are not considered to be part of its structure.

CVM has the ability to act now

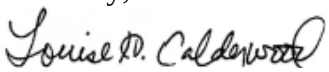
The AFIA believes the CVM has the existing statutory authority to regulate animal food ingredients that work within the gastrointestinal tract and provide public and environmental health benefits or promote animal growth, feed efficiency and well-being as foods instead of animal drugs, as current policy dictates.

The U.S. is lagging behind the rest of the world in regulating these products. Many developed countries have modernized their regulatory systems to allow for the proper review and regulation of animal food ingredients that support structure/function, well-being, food safety and environmental claims. These countries have acknowledged that advances in nutritional sciences can adequately support food claims for actions historically considered drug claims.

Across continents and animal management systems, animal food ingredients are making their mark by fostering improvements for animal care and environmental protection. Unfortunately, U.S. farmers and ranchers, who have long been considered leaders in the adoption of innovative animal husbandry practices, are hampered due to CVM's narrow definition of what is considered a "food" versus a "drug" when reviewing new animal food products, which can legally be considered both. We encourage the CVM's support in allowing them to regain their deserved position of global leadership in animal wellness and productivity while mitigating the environmental impacts of food production.

The AFIA believes the actions requested in this letter are in the interest of animal, public and environmental health and animal well-being and can be implemented without amending the FFDCA or FDA regulations. We are grateful for the opportunity to submit these comments and pledge our continued support of the manufacture of safe and wholesome animal food.

Sincerely,



Louise H. Calderwood
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