pet food institute
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Friday, December 4, 2020

U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Docket No. HHS–OS-2020–0012-0001, Securing Updated and Necessary Statutory Evaluations Timely – Notice of Proposed Rulemaking; RIN 0991-AC24; Federal Register Number: 2020-23888

Dear Sir or Madam:

The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the Department of Health and Human Services (HHS) Notice of Proposed Rulemaking (NPRM) titled Securing Updated and Necessary Statutory Evaluations Timely (85 FR 70096), which was published on November 4, 2020.

Established in 1958, PFI is the trade association and the voice of U.S. cat and dog food manufacturers. Our 25 members account for the vast majority of the dog and cat food made in the United States, with more than $35 billion in domestic annual dog and cat food sales and annual exports of around $1.6 billion to more than ninety countries. PFI membership also includes companies that supply ingredients, equipment and services to dog and cat food makers. We are proud of our strategic alliance with the National Grain and Feed Association, as well as our coordination with the American Feed Industry Association and the North American Renderers Association on a range of issues.

Our members, who account for well over 90 percent of U.S. dog and cat food production and feed the vast majority of the 180 million pets in U.S. households, operate under regulations issued by the U.S. Food and Drug Administration and enforced by both federal and state officials. This means dog and cat owners throughout the United States and around the world benefit from science-based regulation that provides the safest animal food supply available anywhere.

We recognize and generally agree in principle with the proposed rule's goals of requiring some form of retrospective regulatory review for the department and the agencies under it. However, if finalized as written, the proposed rule will cast a long shadow of uncertainty over entire swaths of U.S. food and drug regulation, at a time when more, not less, trust and confidence in federal food and drug regulation is desperately needed.

We noted during our remarks in the public meeting on November 23 that the United States is entering a crucial period of pandemic response, with one or more coronavirus vaccines on the verge of receiving federal regulatory approval. Accordingly, we urge HHS to extend the comment period for this proposed rule to a full six months. This extension will allow the broad range of affected stakeholders and consumers to provide thoughtful comments and to facilitate a meaningful dialogue on regulatory reform that satisfies statutory intent, inspires consumer confidence and provides regulatory certainty for all affected stakeholders.

HHS, in issuing this NPRM, states it is doing so in order to ensure regulatory agency compliance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 610, and various other executive orders that require retrospective agency review of regulations to determine if they are still timely, may require updating or may be rescinded. HHS cites past efforts dating back decades that sought to encourage agency compliance with the RFA, all of which met with limited success. HHS also states that one of the lessons learned from prior regulatory reform efforts is that "… one of the most important factors for ensuring agencies conduct retrospective reviews of their regulations is to provide for the sunset or automatic expiration of certain regulatory requirements after a period of time unless a retrospective review determines that the regulations should be maintained." While this observation may be supported by the historical record – agency compliance with RFA requirements has been limited – PFI believes this NPRM resorts to drastic measures that will introduce significant marketplace uncertainty among consumers and manufacturers, while requiring agency officials to abandon their enforcement duties in order to conduct reviews of existing regulations, the absence of which could lead to the collapse of the U.S. regulatory system for everything under HHS agency regulatory purview, including foods, drugs and medical devices.

The proposed rule would require HHS and its agencies to conduct detailed reviews and assessments of all regulations to prevent their automatic expiration in coming years. The scope of this proposed rule would include FDA regulations issued under sections 21, 42, and 45 of the Code of Federal Regulations (CFR). As with virtually all human and animal food offered for sale in the United States, dog and cat food is subject to regulation under section 21 of the CFR. These regulations were recently updated pursuant to legislation passed by Congress and signed into law in early 2011 by then President Obama. The Food Safety Modernization Act required FDA to update its human and animal food regulations, specifically to employ a science-based, proactive approach to food safety, with the objective of identifying and eliminating foodborne hazards before they pose a risk to human or animal health.

PFI estimates that our member-driven committees cumulatively spent more than 3,000 hours over a five-month comment period analyzing the proposed rule, drafting and reviewing our response, and consulting with our U.S. food and agriculture partners to align on messaging to FDA. Our comment, along with those of hundreds of food producers, food safety experts and consumers, prompted FDA to make substantial changes to the rule, resulting in a final rule that advances the safety of animal food while acknowledging the unique characteristics of animal food production.

The entire FSMA rulemaking process described above took two years. The proposed rule at issue today would require HHS agencies, including FDA, to analyze and justify, in just two years, virtually all substantive regulations that have been issued over the past 80 plus years. This review would create tremendous uncertainty here and abroad regarding the safety and oversight of the U.S. food, drug and medical device supply. The implications of such uncertainty are huge for U.S. pet food makers, who serve the $36 billion domestic market and feed pets around the world, from close neighbors (Canada and Mexico) to distant partners (Australia, Japan and Korea) and many others. Any loss in confidence in the safety of U.S. pet food could result in lost sales and new requirements by foreign regulators seeking assurances that the pet foods they import from us are safe.

Our review of the NPRM also notes the reliance in several instances on examples of documentation requirements, specifically, the requirement to submit multiple paper copies of documents to HHS agencies. We agree that the use of technology has far outpaced some regulatory provisions but we believe that, rather than require wholesale review of all HHS regulations, HHS could employ simple solutions across its agencies to address issues related to advances in technology. We urge HHS and its agencies to explore simple solutions to improve efficiency, perhaps by eliminating requirements for paper document submissions.

The U.S. food supply is arguably the safest in the world, due in large part to the robust rulemaking process, which produces science- and evidence-based regulations that are then enforced by federal and state officials. This NPRM may be incorrectly interpreted by domestic and foreign stakeholders as a fundamental questioning of the effectiveness of the U.S. regulatory system for everything under HHS agency regulatory purview, including pet food. While HHS may be correct in stating that many factors, notably technology, may mean a regulation is ripe for amendment or rescission, requiring HHS agencies to conduct a comprehensive review of all their regulations could indicate to U.S. consumers, U.S. and foreign food producers, and foreign importers of U.S. foods, drugs and medical devices that the U.S. regulatory system for these products is ineffective when that is not at all the case.

Our request is twofold. First, as PFI and other stakeholders stated during the November 23rd public meeting, we urge HHS to provide a full 180-day comment period for this proposed rule in order to allow all stakeholders to provide thoughtful review and comment. Second, we urge HHS to revise this proposed rule to seek input from the regulated community and consumers as to which HHS agency regulations are most in need of review. Entities, including small businesses, regulated by HHS agencies, as well as consumers, can provide HHS agencies with valuable input that can facilitate a more efficient use of resources in the effort to achieve meaningful regulatory reform.

On behalf of PFI members, whose nearly 25,000 employees in 32 states provide safe food for hundreds of millions of dogs and cats in the United States and around the world, we thank you for this opportunity to share our views. We support HHS efforts to streamline regulations in a manner that facilitates the production and availability of safe foods here and abroad. We trust our comments are considered in the manner intended, that is, to encourage HHS to continue to engage constructively with the regulated community and with consumers to ensure regulatory reform is carried out in a way that meets the needs and expectations of regulators and stakeholders.

Sincerely,

Dana Brooks

Dana Brooks
President & CEO
Pet Food Institute