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Submitted Electronically via Regulations.gov
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements **(Docket Number: FDA-2002-N-0153; RIN 0910–AG73)**

The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the Food and Drug Administration's (FDA's) issuance of a final regulation that adopts, without change, the Interim Final Rule (IFR) entitled "Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements." (79 Fed. Reg. 18,799-18,802, April 4, 2014), (hereafter referred to as the Final Rule). While PFI supports FDA's efforts to ensure the safety of the US food supply, including food for animals, we are concerned that Final Rule and associated guidance contain no criteria (other than reference to a case-by-case basis) for the standard FDA will use to exercise its expanded records access authority under the Food Safety Modernization Act (FSMA). We seek further clarification from FDA as to what criteria it will apply and we urge FDA to issue these criteria for public comment.

Established in 1958, PFI is the voice of US cat and dog food manufacturers. For more than 55 years, PFI has worked with its members to educate the world about pet nutrition and health, the need to balance pet ownership rights with responsibilities, and to maintain the highest standards of product integrity, safety and quality control. PFI members account for approximately 98 percent of the cat and dog food produced in the United States. Among its members are 24 dog and cat food manufacturers and more than 100 affiliates who supply ingredients and raw materials to dog and cat food producers. Our members sell more than $20 billion in dog and cat food annually and export an additional $1.5 billion.

Pet food makers share the FDA's commitment to pet food safety and quality, and we're proud of the strong safety record of pet food. PFI

strongly supports the objectives of FSMA and looks forward to working with FDA for the successful implementation of this landmark law. We appreciate FDA's engagement with stakeholders during the rulemaking process and its readiness to engage in open dialogue during the public comment period. We share FDA's goal of establishing a regulatory framework that protects public health, is science and risk-based, and is both practical and practicable.

We note with interest FDA's publication of the Final Rule and are writing to express concern with FDA's continuing refusal to establish criteria under which it will use its expanded records access authority under FSMA. PFI believes FDA's response to a comment received – that "[b]ecause such decisions are fact-specific, FDA has not, therefore, amended the regulation to provide additional explanation of the records access authority" – fails to appreciate the concerns expressed, resulting in the absence of a standard to which FDA will hold itself in determining how to exercise its records access authority and creating uncertainly for industry members. (79 Fed. Reg. 18,801)

In the Interim Final Rule (IFR), issued February 23, 2012, FDA stated that "[d]ecisions regarding whether FDA 'reasonably believes' a food is affected in a similar manner to cause serious adverse health consequences or death to humans or animals would be made on a case-by-case basis because such decisions are fact-specific." (77 Fed. Reg. 10,659) FDA, in issuing the Final Rule, responded to comments received on the IFR. One comment requested that the Agency

> "clarify the meaning of the new records access authority in section 414(a) of the FD&C Act, and in particular, the phrases 'reasonably believes is likely to be affected in a similar manner' and 'reasonable probability that the use of or exposure to an article of food will cause serious adverse health consequences or death.'" (79 Fed. Reg. 18,800)

FDA responded to this request for clarification by referring to its statement in the IFR, quoted above, adding that it "will consider the individual facts in each particular situation to inform its decisions. Because such decisions are fact-specific, FDA has not, therefore, amended the regulation to provide additional explanation of the records access authority." (79 Fed. Reg. 18,801)

PFI is concerned with the potential implications of FDA's decision not to provide any additional explanation of its records access authority. Even accepting that FDA must deal with a multitude of scenarios that necessitate FDA making records access decisions on a case-by-case basis, we believe that the Agency could establish criteria to help guide its investigators in making these case-by-case determinations and to provide some level of transparency and predictability for industry. Accordingly, we request that FDA develop criteria based on food safety risks that will guide FDA investigators in their decision making to exercise their expanded records access authority. Development and use of such criteria would help ensure that FDA investigators consistently apply the same standards in determining whether to request additional records under FDA's expanded records access authority. As noted above,

such criteria also would be useful to industry as it tries to ensure compliance with the FDA regulation.

Our request that FDA develop clear criteria for determining when it will exercise its expanded record access authority under FSMA echoes comments we made to FDA when it issued the IFR in 2012. At that time, PFI wrote that "FDA should have scientifically valid evidence that an article of food manufactured, processed, packed, distributed, received, held or imported by a person does indeed present a risk of serious adverse health consequences or death." We went on to state that it "would not be appropriate or 'reasonable' to invoke Section 414 authority based on preliminary reports, unconfirmed consumer complaints, unsubstantiated blog activity or data that identifies widely scattered point sources and extrapolate that out to an 'outbreak.'" We reiterate these comments because they remain as relevant now as they were two years ago. We urge FDA to develop and implement criteria that address our concerns.

FDA acknowledged in the IFR that "it is contrary to the public interest to require those members of the public whose records are requested under FDA's expanded authority to produce records without regulations explaining how to comply with FDA's new authority." (77 Fed. Reg. 10,660) PFI agrees completely with FDA that the public interest would be best served if stakeholders understand FDA's new records access authority. We believe that the criteria FDA investigators will use to determine when to exercise this expanded authority are an essential element of this information sharing process. FDA's decision not to issue standards or criteria that it will apply in determining whether it "reasonably believes" a food poses a risk (therefore justifying use of expanded records access authority) is inconsistent with FDA's own stated intent on the matter. Compliance with FDA's new authority will be enhanced if transparent, consistently applied criteria exist for FDA to determine whether to exercise this expanded records access authority. In addition, as we stated in our May 2012 comment to FDA in response to issuance of the IFR, "[t]horough training must be provided to [FDA's] inspectors and other staff concerning the criteria and parameters established within the final guidance document that define the scope and limits of the agency's records access authority." Both FDA and industry would greatly benefit from additional clarification and subsequent training.

As stated in this and other comments on FDA proposed regulations related to FSMA implementation, PFI shares FDA's interest in using transparent, science-based regulation to improve the safety of the United States food supply. Development of standards or criteria FDA investigators would use to determine whether to exercise expanded records access authority will ensure fair, consistent application of this authority and provide both FDA officials and food producers with the guidance and information they need to effectively operate under this rule.

As always, PFI is willing and able to provide further input that can facilitate FDA's effective and efficient implementation of FSMA.

Sincerely,

Duane Ekedahl
President

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