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

Re: FDA's Notice titled Agency Information Collection Activities; Proposed Collection; Comment Request; Testing Communications on Food and Drug Administration-Regulated Products Used in Animals (Docket No. *FDA-2010-N-0420)*

The Pet Food Institute (PFI) appreciates the opportunity to provide comments regarding the Food and Drug Administration's (FDA's or the Agency's) Notice titled Agency Information Collection Activities; Proposed Collection; Comment Request; Testing Communications on Food and Drug Administration-Regulated Products Used in Animals, published in the Federal Register on June 16, 2014 (79 Fed. Reg. 34312) and hereafter referred to as the "Notice."

Established in 1958, PFI is the voice of US cat and dog food manufacturers. PFI members account for more than 98 percent of the cat and dog food produced in the United States. Among its members are twenty-four dog and cat food producers 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, including approximately $1.5 billion in exports.

Pet food makers share FDA's commitment to pet food safety and quality, and we are proud of the strong safety record of pet food. PFI strongly supports the Food Safety Modernization Act (FSMA) and looks forward to working with FDA for the successful implementation of this landmark law. We also support FDA's efforts to communicate with stakeholders and consumers regarding FDA-regulated products used in animals.

General Observations

PFI agrees with FDA that effective communication with consumers is a critical element in fulfilling the Agency's mission to protect the public health. This communication must be targeted, consistent and it must be supported by science. As with information on product labels, communication with consumers or veterinary professionals must be limited to pertinent information that addresses any hazards that may pose a significant risk to human and animal health. As shown in our comment on FDA's Draft Approach regarding identification of high-risk foods, submitted earlier this year, PFI members take significant steps to ensure the safety of their products. Accordingly, we urge FDA to ensure its communications studies and information collection activities with consumers and veterinary professionals are accurate and focused on significant risks to human and animal health.

FDA states its expectation in this Notice, that "improving communications about the safety of regulated animal drugs, feed, food additives, and devices will involve many research methods, including individual indepth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys." (79 Fed. Reg. 34312) PFI members have significant experience developing and executing successful campaigns designed to share/gather information with/from consumers and veterinary professionals. PFI believes there may be opportunities for collaborative work to identify effective communications strategies regarding the safety of pet food. PFI is ready to work with FDA to ensure the effectiveness such strategies, provided they are risk- and science-based.

FDA Specific Requests for Comment

(1) "Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;"

Effective communication with stakeholders is essential to the fulfillment of any entity's mission, whether that mission involves selling pet food or ensuring its safety. PFI members have as their mission to sell safe, high quality pet food and we support FDA's efforts to fulfill its mission of protecting public health. Part of FDA's mission under section 393(d)(2)(D) of the Federal Food, Drug and Cosmetic Act involves conducting "educational and public information programs relating to the safety of CVM-regulated products." (79 Fed. Reg. 34312) As FDA further states in this Notice, "FDA must conduct needed research to ensure that such programs have the highest likelihood of being effective." (79 Fed. Reg. 34312)

PFI fully supports FDA in its efforts to ensure that its messaging to consumers and veterinary professionals is effective. We also urge FDA to exercise discipline in this messaging regarding FDA-regulated products for use in animals. Such messaging must be science-based and should focus on significant risks to human and animal health. While we generally agree with FDA that information collection on CVM-regulated products is necessary for the proper performance of FDA's functions, such information collection, as well as the communication campaigns the information collection intends to serve, must be proportionate to the risk each product poses to human and animal health.

As indicated in PFI's comment to FDA on its Draft Approach to identify high-risk foods, pet food – especially pet food that is subjected to a pathogen mitigation/kill step – represents an extremely low foodborne illness risk to humans or the animal(s) for which the food is intended. FDA notes in its own collection and analysis of pet food that only 2.23% tested positive for *Salmonella* spp. in fiscal year 2012[1] and that no human illnesses were attributed to dog or cat food during this period or during the period covered in the most recent Reportable Food Registry Annual Report. By PFI's calculation, even assuming an average of 15 confirmed human illnesses per year attributed to pet food since 1999, pet food-related illnesses represent 0.00003 percent of the estimated 48 million annual cases of foodborne illness in the United States.

These data relate to FDA's question of the utility of the information collected by FDA that relate to CVM-regulated products. To have practical utility, the information FDA collects – as well as the communications campaigns it carries out – must be science-based and related to significant human and animal health concerns. Pet food represents such a small portion of the foods associated with human and animal foodborne illness that PFI questions the need for information collection related to it. At the very least, PFI urges FDA to carry out communications studies and information collection activities based on the risk that any CVM-regulated product actually poses to human and animal health.

(2) "the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;"

In Table 1 of the Notice, FDA estimates the annual reporting burden for its planned information collection. While PFI has no reason to question the accuracy of FDA's estimates of the burden associated with the proposed information collection activities,

1 FDA CVM Presentation to the 2014 International Production and Processing Expo. January 28, 2014. Slide 22.

we request that FDA share information regarding the proportion of each activity that will be devoted to each CVM-regulated product. As noted above, pet food poses a very small (and declining) risk to human and animal health. Communications studies and information collection activities targeting consumers and veterinary professionals should be risk- and science-based and the burden for each information collection activity must be commensurate with the risk to human and animal health posed by the product in question.

Finally, the Notice states that there are no capital costs or operating and maintenance costs associated with this collection of information. PFI assumes from this statement that FDA does not plan to consult independent experts or relevant stakeholders in the preparation of survey and interview instruments, PFI questions why FDA is choosing to rely exclusively on in-house expertise and suggests that FDA consider consulting with experts in surveys/interviews as well as stakeholders who produce the FDA-regulated products that will be the subject of the surveys/interviews. Obtaining this outside knowledge and expertise will greatly enhance the effectiveness of this information collection as well as the design of FDA's communication strategies, messages, labels and labeling.

(3) "ways to enhance the quality, utility, and clarity of the information to be collected;"

FDA seeks input from stakeholders regarding ways to enhance the quality, utility and clarity of information to be collected. FDA states that "[k]nowledge of consumer and veterinary professional decision-making processes will provide the better understanding of target audiences that FDA needs to design effective communication strategies, messages, labels, and labeling." (79 Fed. Reg. 34313)

PFI members have extensive experience in the field of communications studies and information sharing/gathering activities. This experience could be of value to FDA in terms of providing possible approaches that will generate useful information. PFI is ready to work with FDA, in a spirit of shared interest regarding science-based food safety regulation, to discuss interview and survey approaches specific to buyers of pet food that will facilitate greater knowledge of and familiarity with significant risks to human and animal health that pet food may pose.

(4) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The use of information technology (IT) to gather and share information is both ubiquitous and a very effective means to reach target audiences. However, use of new IT-based methods by no means guarantees target audience participation. Automated collection techniques in particular can yield unsatisfactory results, especially if the automated collection technique resembles impersonal "robo-dial" methods to gather or share information. Moreover, IT based collection of information relies solely on the quality of the questions posed to the respondent, since there is no human interaction. While such an information collection technique may reduce the burden on the entity seeking the information – in this case, FDA – it may be viewed by the target audience as a nuisance.

This question of minimizing the burden of information collection on survey respondents/interviewees is critical since FDA states in the Notice that this information collection will provide a better understanding of target audiences for which "FDA needs to design effective communication strategies, messages, labels, and labeling." (79 Fed. Reg. 34312-34313) PFI reiterates that any information collection related to pet food must be science- and risk-based. We urge FDA to conduct this information collection in an unbiased manner, using the significant human and animal health risks posed by the CVM-regulated product as a guide to determining whether and how surveys and interviews will be carried out.

PFI Areas of Interest and Concern

FDA identifies three major purposes the information collected will serve:

(1) It will "provide critical knowledge needed about target audiences to develop messages and campaigns about the use of FDA-regulated products for use in animals." (79 Fed. Reg. 34312)
(2) It will "allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences." (79 Fed. Reg. 34313)
(3) It will "allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objective of the message campaign." (79 Fed. Reg. 34313)

PFI agrees with the proposed rationale for this information collection. Understanding one's target audience is essential to developing effective communications strategies, especially when the topic of such communications relates to public health. PFI is concerned, however, about the content of the questions FDA will pose to consumers and veterinary professionals. The questions asked of consumers and veterinary professionals – and the specific phrases/language used in these questions – are critical

to yielding information that is accurate and useful to FDA's educational and public information programs relating to the safety of CVM-regulated products.

The American Association for Public Opinion Research (AAPOR), in its treatment of the topic of surveys and polls, stresses that, "[b]eyond their specific content, … the manner in which questions are asked, as well as the specific response categories provided, can greatly affect the results of a survey. Concepts should be clearly defined and questions unambiguously phrased. Question wording should be carefully examined for special sensitivity or bias." (AAPOR discussion of Best Practices, at http://www.aapor.org/Best_Practices1.htm#.U9kD_vldUWJ) Along those lines, PFI requests that FDA make available the questions related to pet food that it intends to pose to consumers and veterinary professionals in the proposed information collection activities. This request is consistent with AAPOR guidance, which recommends disclosure of "the questionnaire and/or the exact, full wording of all questions asked, including any visual exhibits and the text of any preceding instruction or explanation to the interviewer or respondents that might reasonably be expected to affect the response." (AAPOR discussion of Best Practices, at http://www.aapor.org/Best_Practices1.htm#.U9kD_vldUWJ)

Although FDA has expressed tacit agreement with PFI that pet food – especially pet food subjected to a pathogen mitigation/kill step – poses a relatively low risk to public health, messaging from FDA and the Centers for Disease Control and Prevention (CDC) consistently presents facts about incidents involving pet food without accurate and appropriate context regarding risk. FDA Compliance Policy Guide 690.800 and recent CDC and FDA statements related to pet food convey the message to FDA investigators and consumers alike that pet food poses a significant risk to public health when FDA's own data indicates this is not the case. These documents are the basis for our concern that FDA's decision whether/how to conduct information collection targeting consumers and veterinary professionals might not be guided by FDA and industry data indicating that pet food poses an extremely low risk to human and animal health. We therefore urge FDA to include producers of CVM-regulated products in the process of developing and carrying out these information collection activities, especially as they relate to FDA's communication strategies, messages, labels and labeling of these products.

Conclusion

PFI wishes to thank FDA for this opportunity to comment on this Notice. We trust that this comment is received and reviewed in the spirit in which it was drafted, that of working together to ensure the effective use of a science- and risk-based approach for

CVM-regulated products. We look forward to continued dialogue on this and other topics that relate to FDA-regulated products intended for use in animals.

Sincerely,

Peter Tabor
Vice President, Regulatory & International Affairs

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