pet food institute
Promoting long and healthy lives since 1958.

26 February 2018

US Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
Office of Regulatory Affairs

Re: Refusal of Inspection by a Foreign Food Establishment or Foreign Government: Guidance for Industry – *Draft Guidance*

Dear Sir or Madam:

The Pet Food Institute (PFI) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on its *Draft Guidance* titled Refusal of Inspection by a Foreign Food Establishment or Foreign Government: Guidance for Industry, hereafter referred to as the Draft Guidance.

As the voice of US pet food makers, our mission is to help dogs and cats live long and healthy lives. We rely on FDA's use of science and risk-based analysis as the basis for its regulations, including in the updates to the Food, Drug and Cosmetic Act (FD&C Act), embodied in the regulations promulgated under the Food Safety Modernization Act (FSMA). Below are our observations regarding the Draft Guidance.

PFI understands and supports FDA's role in ensuring the safety of the US food supply, including foreign foods and facilities. FDA data indicate about 20 percent of the US food supply is imported, including 35% of fresh produce and 70% of seafood. USDA data indicate the United States imported more than $800 million in dog and cat food products. FDA oversight of all these imported foods helps to ensure these products are safe.

PFI notes that this Draft Guidance applies to foreign facilities and governments only and we agree with this approach. Foreign facilities and governments (to the extent they oversee them) can present inspectional challenges (distance, accessibility, availability of English language interpreters) compared to their domestic counterparts. In light of these challenges, PFI recognizes FDA's authority under section 807(b) of the FD&C Act, requiring it to refuse entry of foods from facilities "of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals duly designated by the Secretary, upon request, to inspect such factory, warehouse or other establishment."

We have concerns with FDA's approach in the Draft Guidance regarding the role of photography during inspections. Although a domestic facility may permit a FDA

investigator to take photographs during an inspection, we are aware of no statutory language or case law expressly permitting FDA to take photographs during inspections of domestic facilities or requiring a domestic facility to allow such photography in the absence of a validly issued warrant. Nor are we aware of any statutory language or case law expressly permitting FDA to take photographs during inspections of foreign facilities or requiring a foreign facility to allow such photography.

The Investigations Operations Manual 2017 provides guidance for FDA investigators seeking to take photographs as part of the inspectional process. This guidance includes citing to facility personnel, if necessary, references to two court cases that FDA believes support its contention that taking photographs during inspections is allowed. The matter at issue in *Dow Chemical Co v US* (476 US 227 (1986)) was the right of the Environmental Protection Agency to take aerial photographs – it did not, in our view, establish the right of all federal agencies to take all types of photographs as part of the inspectional process. In *US v Acri Wholesale Grocery Co* (409 F Supp 529 (SD Iowa 1976)), the issue was whether photographs taken by FDA during an inspection, without objection by the plaintiff in the case, were admissible at trial. In our view, the court's decision in this case did not address FDA's right to take photographs during any inspection – the court's decision was limited to the circumstances in the case brought before it.

We recognize that FDA must gather information it needs to assess a facility's compliance with applicable regulations. Specifically, we agree that FDA investigators, in the course of inspecting an animal food facility, can and must collect evidence to document potential violations. We believe FDA can complete such an assessment in a manner consistent with a facility's policies, including those policies regarding photography. We urge FDA investigators to acknowledge and abide by facility policies with respect to photography on their premises, regardless of the facility's location.

From the FSMA rulemaking process through to implementation and now compliance and enforcement activities, PFI thanks FDA for the many opportunities it has provided for stakeholder input. PFI members rely on FDA's science-based regulation as the basis for our food safety efforts. To that end, we look forward to continuing to work with FDA to improve the safety of all dog and cat food offered for sale in the United States.

Sincerely,

Cathleen Enright, PhD
President & CEO