U.S. FOOD & DRUG ADMINISTRATION

October 18, 2024

Susan Thixton
TruthaboutPetFood.com
AssociationforTruthinPetFood.com
P.O. Box 1191
Largo, FL 33770

Dear Ms. Thixton,

This is in response to your petition, FDA-2024-P-1916, dated April 17, 2024. Your petition states that "[b]eginning in approximately December 2023, pet food consumers began reporting serious health issues with their pets (cats and dogs) directly related to pet food," and that for "[o]ne brand of pet food in particular, pet owners have reported 1,679 cat and dog illnesses, 23% of those reports (390) resulted in the death of the pet."

Your petition requests that FDA "provide the public with an update(s) to their investigation of this current pet food concern, provide the public with similar information in this current issue as the agency has historically provided the public with past (and other current) issues." Your petition also requests "the FDA CVM to promptly issue a public notice into their investigation of current and ongoing reports of pets experiencing bloody vomiting, bloody diarrhea, seizures, and death linked to multiple pet food brands," and to "include in this public notice similar information the agency as provided the public in the past with other investigations including:

- the number of adverse events received;
- the symptoms reported;
- the number of pet deaths;
- the number of human illnesses reported;
- the brands reported linked to pet or human illness;
- the testing the agency has performed; and
- encourage the public to report any illness to the agency."

As support for your petition, you point to several other instances where FDA issued public notices about investigations, including investigations into applesauce contaminated with lead, the potential connection between animal food diet and cases of canine heart disease, and concerns over pet jerky treats. You state that all of those instances had fewer complaints associated with the investigated issue than the matter at issue in your petition. You state that, "[o]f significance, in the instance of the FDA investigation into diet and canine heart disease and in the instance of the FDA investigation into jerky treats, the agency kept the public informed even though the agency had no confirmed cause for the reports of illness and deaths of pets," but that "[i]n the past four and one half months since pet owners began reporting these serious pet and human health issues, the FDA CVM has not issued any public alert, the FDA CVM has not responded to FOIA requests regarding adverse events the agency has received, the FDA CVM has not

provided the public with any information to their investigation (if any) into these serious animal and human health reports."

We dismiss your petition in part as moot because FDA has released a summary concerning its investigation of adverse event reports for Purina brand pet food, which appears to be the "[o]ne brand of pet food in particular" referenced in your petition. 21 CFR 10.30(e)(2)(iii). We also deny your petition as outside the scope of the citizen petition process because an update to an investigation is not an administrative action. 21 CFR 10.30(b)(3).

On July 31, 2024, FDA released its "Summary of Purina Pet Food Adverse Event Reports (November 22, 2023 – April 15, 2024), FDA Actions and Findings." This summary renders the portion of your petition related to Purina brand pet food moot. We provided the public with the information that you requested, to the extent the information was provided to FDA by pet owners or veterinarians in their reports to the Agency. You can find FDA's summary of Purina pet food adverse event reports at https://www.fda.gov/about-fda/cvm-foia-electronic-reading-room/summary-purina-pet-food-adverse-event-reports-november-22-2023-april-15-2024-fda-actions-and. The summary describes FDA's ongoing commitment to notify the public of any new information that would provide actionable advice:

> Throughout its analysis, the FDA had a conscious commitment to notify the public if it uncovered information, such as laboratory results indicating contamination or a specific illness in pets that ate a particular lot, that could translate into actionable advice for veterinarians or pet owners. The agency has previously issued safety advisories in situations when there was a common link between the reports, such as findings of a pathogen, vitamin overdose, or disease agent that connected the food to the illnesses. In the recent situation regarding the adverse event reports mentioning Purina pet food, there was no direct or consistent connection between the wide range of adverse events submitted to the FDA, and evidence does not conclusively link the reported adverse events to Purina pet food.

Moreover, your petition is outside the scope of administrative actions that can be requested via citizen petition. Your petition asks FDA "to provide the public with an update(s) to their investigation of this current pet food concern, provide the public with similar information in this current issue as the agency has historically provided the public with past (and other current) issues," including seven specific pieces of information. Under 21 CFR 10.30, citizen petitions can request that FDA issue, amend, or revoke a regulation or an order, or take or refrain from taking an administrative action. Issuing a public update to an investigation is not an administrative action, so your request is outside the scope of the citizen petition process. *See* 21 CFR 10.3(a). Furthermore, citizen petitions must be resolved based on the information contained within the administrative record. 21 CFR 10.30(j). A request that FDA gather and disseminate information outside the administrative record is, by its nature, beyond the scope of a citizen petition.

FDA is committed to issuing accurate public health messages when an investigation results in specific, actionable steps consumers can take to protect themselves and their pets. As described in FDA's July 31, 2024, summary, existing evidence does not identify a public health concern that could explain the symptoms detailed in the adverse event reports FDA received about Purina

pet foods. FDA will continue to monitor and evaluate pet food adverse event reports and determine appropriate follow-up actions, as necessary. The agency encourages consumers and veterinarians to submit reports about issues with pet food electronically through the Safety Reporting Portal or by calling an FDA Consumer Complaint Coordinator. For an explanation of the information and level of detail that would be helpful to include in a report to the FDA, please see How to Report a Pet Food Complaint.

Sincerely,

William T. Flynn -S Digitally signed by William T. Flynn -S
Date: 2024.10.18 17:37:06 -04'00'

William T. Flynn, DVM, MS
Deputy Center Director
Center for Veterinary Medicine