

March 4, 2024

Via Electronic Submission
Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305) Rockville, MD 20852

Re: Citizen Petition - Request for Public Disclosure of FOIA Request 2020-5368 Records

To Whom It May Concern:

I, Kohl Harrington, hereby submit this petition under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and pursuant to 21 C.F.R. §§ 25.30 and 25.34 and 21 C.F.R. § 10.30(b), urging the Food and Drug Administration (FDA) to comply with FOIA law by publicly posting all records and response letters related to FOIA request 2020-5368.

A. Action Requested

This petition requests the FDA to adhere to FOIA law and promptly publish on the FDA FOIA Reading Room website all records and response letters related to FOIA request 2020-5368, as these records have been requested multiple times.

B. Statement of Grounds

The FOIA mandates that federal agencies make available for public inspection, in electronic format, copies of all records that have previously been released under FOIA and have been requested three or more times. (5 U.S.C. § 552(a)(2)(D)). FDA has provided this response letter three or more times.

FOIA Request 2020-5368 sought "All records of reports FDA CVM received of humans becoming sick from A+ Answers Straight Beef Formula for Dogs, lot 2018 02/08 20" (<https://www.fda.gov/animal-veterinary/outbreaks-and-advisories/fda-cautions-pet-owners-not-feed-one-lot-answers-straight-beef-formula-dogs-due-salmonella>). In response to this request, the FDA provided a response stating that the Center for Veterinary Medicine (CVM) had conducted a search and did not locate any responsive records.

This response is significant because CVM has been regulating the raw pet food sector of the pet food industry based on an agency compliance policy opinion instead of an actual law or regulation. Specifically, FDA-CVM has purportedly misinterpreted federal law to read as "every" serotype in "any" quantity when the law clearly states that a non-added substance needs to be quantified. FDA-CVM is currently refusing to quantify any serotype, even those serotypes known to never cause any harm, as adulterants. Such actions misinform the public and contribute to unnecessary panic.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment or environmental impact statement is made pursuant to 21 C.F.R. §§ 25.30 and 25.34.

D. Economic Impact

In accordance with 21 C.F.R. § 10.30(b), economic impact information will be provided promptly upon request by the FDA following a review of this petition.

E. Certification

I, Kohl Harrington, certify that, to the best of my knowledge and belief, this petition includes all relevant information and views upon which the petition relies. It also includes representative data and information known to the petitioner, even if unfavorable to the petition.

Your prompt attention to this matter is greatly appreciated. We believe that public access to these records is essential for transparency and accountability.

Sincerely,

Kohl Harrington

Kohl Harrington

(b) (6)

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