April 27, 2022

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- Asking FDA-CVM To Act and Answer Question as To How FDA-CVM Concluded That Salmonella Is An "Added" Substance, Under 21 U.S. Code § 342 - Adulterated food.

To whom it may concern:

The undersigned submits this petition under both the Federal Food, Drug, and Cosmetic Act (the Act), § 553 of the Administrative Procedure Act., and in accordance with 21 C.F.R. § 10.30(b), to request the FDA-CVM to clarify how the agency concluded that salmonella is an "added" substance under ***federal law 21 U.S. Code § 342 - Adulterated food***.

A. Action Requested

Petition requests FDA-CVM to take action and answer this question, which FDA-CVM failed to answer for me when I asked FDA-CVM this question on April 15, 2022 via the askcvm email address.

The undersigned submits this petition under both the Federal Food, Drug, and Cosmetic Act (the Act), § 553 of the Administrative Procedure Act., and in accordance with 21 C.F.R. § 10.30(b), to request the FDA-CVM to clarify how the agency concluded that salmonella is an "added" substance under ***federal law 21 U.S. Code § 342 - Adulterated food***.

B. Statement of Grounds

FDA-CVM has concluded that salmonella in "animal feed" is an "added" substance. FDA-CVM held no public meetings, and issues no official rulemaking, in coordination with this conclusion reached under 21 U.S. Code § 342 - Adulterated food. FDA-CVM does not provide any publicly available education or information explaining in clear detail how the agency reached the conclusion that a "non added" substance of salmonella is going to be classified as a "added" substance by FDA-CVM when it comes to pet food, specifically raw pet food.

On April 15, 2021, I wrote FDA-CVM asking, "*I am looking to understand how FDA-CVM came to the conclusion that salmonella in raw pet food is an "added' substance*." No one from FDA-CVM wrote me back. There is no guarantee I will ever receive an answer back, so I now request FDA-CVM provide me an official answer in response to my petition submitted today.

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 is to be submitted only when requested by FDA following review of the petition. The undersigned will promptly provide this information if requested.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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Ronald Brock (Apr 27, 2022 10:07 CDT)

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