Pet Schooled

February 23, 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 Quantify Salmonella Infantis, as it pertains to 21 U.S. Code § 342 - Adulterated food, which requires FDA to quantify the non-added substance prior to rendering a "food" adulterated under federal law.

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 quantify salmonella infantis, as it pertains to ***federal law 21 U.S. Code § 342 - Adulterated food***, which requires FDA to quantify the non-added substance salmonella infantis prior to rendering any "food" containing this substance adulterated under federal law.

A. Action Requested

Petition requests FDA-CVM to quantify salmonella infantis, as it pertains to 21 U.S. Code § 342 - Adulterated food, which requires FDA to quantify the non-added substance prior to rendering a "food" adulterated under federal law.

B. Statement of Grounds

FDA-CVM remains firm on its stance, based on an FDA "compliance policy opinion" CPG Sec. 690.800, that any trace of salmonella infantis, will be considered an adulterant by FDA-CVM.

The compliance policy opinion, CPG Sec. 690.800, is only FDA's opinion, and is not law. However, FDA-CVM maintains they consider their opinion in CPG Sec. 690-800 to be law under 21 U.S. Code § 342 - Adulterated food. To this date, FDA-CVM has not engaged in official rulemaking compliant with § 553 of the Administrative Procedure Act, when it comes to an actual rule/regulation pertaining to salmonella of any serotype in animal feed, even salmonella serotypes or quantities that my never reach the legal definition for "public health risk". FDA-CVM continuously refuses to engage in rulemaking on this issue related to FDA-CVM regulating by their opinion instead of law. FDA-CVM states they don't "need" to engage in rulemaking on this subject, involving more in depth science, citizens, or other citizen stakeholders.

21 U.S. Code § 342 - Adulterated food states, "A food shall be deemed to be adulterated—(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health."

FDA-CVM's CPG 690.800 does not comply with 21 U.S. Code § 342. FDA-CVM's CPG 690.800 interprets 21 U.S. Code § 342, in violation of § 553 of the Administrative Procedure Act.

Salmonella infantis is not an added substance. According to 21 U.S. Code § 342, "such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health."

To date, the FDA-CVM does not have any official quantification data in compliance with 21 U.S. Code § 342, specifically showing the quantification salmonella infantis must be in when present in a raw pet food product, in which salmonella infantis would "ordinarily render it injurious to health".

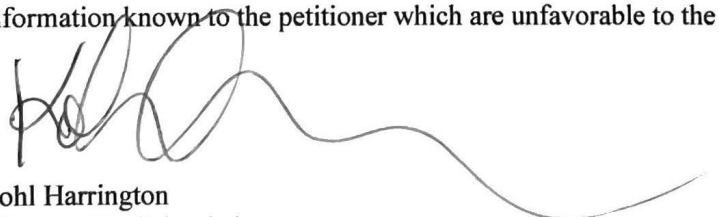
FDA-CVM has simply set a "zero tolerance" for this non-added substance, and this zero tolerance violates 21 U.S. Code § 342.

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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