March 24, 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 Kentucky In Subsample 19B In Relation To The February 23, 2022 (MARCS-CMS 615550) Warning Letter Against OC Raw Dog LLC, 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 Kentucky in subsample 19B in relation to the February 23, 2022 (MARCS-CMS 615550) Warning Letter Against OC Raw Dog LLC, 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.

# A. Action Requested

Petition requests FDA-CVM to act on this matter and ensure the step of quantifying required law is taken in compliance with § 342 - Adulterated food, which requires FDA to quantify the non-added substance prior to rendering a "food" adulterated under federal law.

Petition requests FDA-CVM to quantify salmonella Kentucky in subsample 19B in relation to the February 23, 2022 (MARCS-CMS 615550) Warning Letter Against OC Raw Dog LLC, 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 has taken the stance, based on what FDA calls their opinion, that any trace of salmonella Kentucky, will be considered an adulterant by FDA-CVM. This opinion can be found in "compliance policy opinion" CPG Sec. 690.800

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 in animal feed.

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 kentucky 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 kentucky must be in when present in a raw pet food product, in which salmonella kentucky 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. FDA's interpretation of this law without engaging in required proper rulemaking requirements is a violateion of § 553 of the Administrative Procedure Act.

On February 23, 2022, FDA published a "warning letter" against OC Raw Dog Food LLC, providing MARCS-CMS 615550 in relation to the warning letter. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/oc-raw-dog-llc-615550-02232022. In that warning letter, FDA stated, "The FDA laboratory recovered Salmonella Kentucky in subsample 19B."

However, FDA did not quantify this sample which recovered "salmonella kentucky." According to federal law, 21 U.S. Code § 342 - Adulterated food states, salmonella kentucky falls under the clause of a non added substance, and "under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health."

Petition requests FDA-CVM to quantify salmonella Kentucky in subsample 19B in relation to the February 23, 2022 (MARCS-CMS 615550) Warning Letter Against OC Raw Dog LLC, 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.

## 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.

Chelsea Kent (Mar 24, 2022 08:15 MDT)

Chelsea Kent

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