



October 25, 2022

Chelsea Kent
[REDACTED]

Re: Docket No. FDA-2022-P-0451

Dear Ms. Kent:

This is a tentative response to the Citizen Petition (FDA-2022-P-0451) filed with the Food and Drug Administration (FDA) on March 24, 2022.

The petition requests that 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.”

Pursuant to the administrative regulations at 21 CFR 10.30, FDA is required to respond to your petition within 180 days. FDA is currently considering the issues raised by your citizen petition; however, the Agency will require additional time to issue a final response.

FDA will issue a final response to your citizen petition after completing the analyses of all the issues raised in the petition.

Sincerely,

Steven Solomon
-S

Digitally signed by Steven
Solomon -S
Date: 2022.10.25 14:25:39
-04'00'

Steven M. Solomon, DVM, MPH
Director, Center for Veterinary Medicine