March 25, 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- Requesting FDA Office of Human and Animal Food Operations- West Division 5 To Un-redact Various Aspects Of MARCS-CMS 615550, Issued On FEBRUARY 23, 2022, In Accordance With FOIA Law.

To whom it may concern:

The undersigned submits this petition under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and in accordance with 21 C.F.R. § 10.30(b), Requesting FDA Office of Human and Animal Food Operations- West Division 5 To Un-redact Various Aspects Of MARCS-CMS 615550, Issued On FEBRUARY 23, 2022, In Accordance With FOIA Law.

A. Action Requested

Petition requests requesting FDA Office of Human and Animal Food Operations- West Division 5 to un-redact various aspects of MARCS-CMS 615550, issued on February 23, 2022, in accordance with FOIA law.

B. Statement of Grounds

On February 23, 2022, FDA published a "warning letter" pertaining to OC Raw, a raw pet food manufacturer.

This is a link to the warning letter: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/oc-raw-dog-llc-615550-02232022

Various aspects of the warning letter improperly use a **(b)(4)** redaction.

The warning letter states the FDA issuing office for this warning letter is ***Office of Human and Animal Food Operations- West Division 5***. The warning letter states: "If you have questions regarding this letter, please contact Rochelle R. Blair, Compliance Officer at rochelle.blair@FDA.hhs.gov, or (949) 608-4496." The letter is signed by Darla R. Bracy, District Director, FDA San Francisco District, Office of Human and Animal Food Operations-West Division 5.

It is assumed that by signing this warning letter, Darla R. Bracy improperly applied the **(b)(4)** redactions at issue here.

Under FOIA law, "Exemption 4 Protects trade secrets and confidential commercial or financial information."

In the second paragraph of the warning letter at issue here, FDA states, "*This inspection was conducted in response to a Class I recall initiated on **(b)(4)** of **(b)(4)**, lot number **(b)(4)**, due to the presence of **Salmonella** and **Listeria monocytogenes (L. mono)** detected by the **(b)(4)**.*"

FDA has improperly redacted information in the second paragraph of this warning letter. Specifically, FDA has redacted two dates in the first sentence, "*This inspection was conducted in response to a Class I recall initiated on **(b)(4)** of **(b)(4)**."* Voluntary recall dates are not "trade secrets and confidential commercial or financial information", and therefore do not fall under exemption 4 of FOIA law. FDA should un-redact this information. Additionally, FDA has redacted a lot number. A lot number associated with a public, voluntary recall is not "trade secrets and confidential commercial or financial information", and therefore does not fall under exemption 4 of FOIA law. FDA should un-redact this information. FDA has also redacted information regarding what or who specifically detected the presence of potentially nonpathogenic bacteria, stating "*the presence of **Salmonella** and **Listeria monocytogenes (L. mono)** detected by the **(b)(4)**.*" Again, FDA has redacted information that is not exempt under exemption 4, which "*protects trade secrets and confidential commercial or financial information*." How FDA detected the presence of what they're claiming is not a trade secret, nor is it confidential commercial information, nor is it confidential financial information. FDA should un-redact this information.

In what appears to be the 9th paragraph, FDA states, "*You stated that these fans are cleaned and sanitized **(b)(4)**. Our Investigator observed these fans in use during production on **(b)(4)**, and you stated that the fans are left on during production and sanitation.*" Again, FDA has redacted a date. Under FOIA law, exemption 4 under FOIA law "Protects trade secrets and confidential commercial or financial information." A date in which an investigator conducted an inspection, and observed production, is not exempt under FOIA law exemption 4. FDA should un-redact this information.

Later in the letter, FDA states, "*On **(b)(4)**, a sample of **(b)(4)** manufactured at your facility was collected by the **(b)(4)** and was found positive for **Salmonella** and **Listeria monocytogenes**. You recalled this lot on **(b)(4)**.*" Again, FDA has for some reason redacted dates under the claim of exemption 4 under FOIA law. Voluntary recall dates are not "trade secrets and confidential commercial or financial information", and therefore do not fall under exemption 4 of FOIA law. FDA should un-redact this information. FDA has also redacted information as to who collected a sample of this company's pet food, and found salmonella and listeria monocytogenes. That information is not exempt under exemption 4 of FOIA law, and FDA should un-redact this information. The date on which a sample was taken from the pet food company's facility is also not exempt under exemption 4 of FOIA law, and FDA should un-redact this information.

Further in the letter, FDA provided comments. FDA specifically stated, "*2. On **(b)(4)**, you performed a recall as described above. Your written recall procedure entitled "Product Withdrawal and Recall", Section 6.9, dated February 22, 2021, states that "… a summary of the recall will be prepared by the Recall Coordinator. This summary will include a root cause analysis to generate corrective actions". Additionally, section 8.4 requires that the Senior PCQI may need to include the "Results of investigation into cause of adulteration" in initial and follow up reports for the **(b)(3)(A)**. However, it appears that your firm did not conduct a root cause analysis to determine a possible source and route of contamination. Your June 10, 2021 response did not include any update to your root cause investigation. A root cause investigation is an important step toward addressing the cause of the recall.*" Again, FDA has redacted a date. Under FOIA law, exemption 4 under FOIA law "Protects trade secrets and confidential commercial or financial information." A date in which this pet food company performed a recall is not information protected under exemption 4, and FDA again improperly redacted this information. FDA should un-redact this information. FDA also improperly redacted information when stating "*"Results of investigation into cause of adulteration" in initial and follow up reports for the **(b)(3)(A)**."* Follow up report dates are not exempt under FOIA law, exemption 4. FDA should un-redact this information.

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 25, 2022 11:10 MDT)

Chelsea Kent

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