U.S. FOOD & DRUG ADMINISTRATION

June 13, 2024

Kohl Harrington
(b) (6)
[redacted]

Re: Docket No. FDA-2024-P-1960

Dear Mr. Harrington:

We are denying your Citizen Petition (FDA-2024-P-1960) filed with the Food and Drug Administration (FDA) on April 20, 2024.

The petition requests FDA to "to comply with FOIA law and post publicly on the FDA FOIA reading room all documents requested through various FOIA requests pertaining to Inspection Reports and documents of Lystn, LLC (Answer Pet Food), Address 356 Maidencreek Road, Fleetwood, PA 19522 (01.01.23-12.31.23)," (hereafter the "Lystn, LLC records").

As grounds for the petition, you state that "[t]he FOIA requires each agency to make available for public inspection, in electronic format, copies of all records that have previously been released under FOIA and '(I) that because of the nature of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records; or (II) that have been requested 3 or more times.' 5 U.S.C. § 552(a)(2)(D)."

You claim that the Lystn, LLC records have "been requested through FOIA '3 or more times' and FDA is now required to comply with 5 U.S.C. § 552(a)(2)(D) and publish these records on the FDA FOIA reading room."

Your request for FDA to make the Lystn, LLC records available for public inspection in an electronic format is denied. 5 U.S.C. § 552(a)(2)(D) states in part:

> Each agency … shall make available for public inspection in an electronic format … copies of all records … that have been released to any person under [FOIA]; and … that have been requested 3 or more times[.]

Your petition did not provide the control numbers[1] for the FOIA requests that you claim triggered this provision of the FOIA or any other information supporting your assertion that the Lystn, LLC records "ha[ve] been requested through FOIA '3 or more times' and FDA is now required to comply with 5 U.S.C. § 552(a)(2)(D)." Therefore, your citizen petition does not include factual

[1] In response to a FOIA request, FDA provides an acknowledgment letter that includes a unique control number for the request.

grounds supporting your contention that FDA is required to post the Lystn, LLC records. 21 CFR 10.30(b)(3).[2]

Nonetheless, when FDA determines that the posting requirement in 5 U.S.C. § 552(a)(2)(D) has been triggered, it posts the records in accordance with that requirement. Here, independent of your petition, we have identified at least three FOIA requests for the Lystn, LLC records described above. However, we have not released these records publicly, which is one of the conditions that must be met before public posting is required by 5 U.S.C. § 552(a)(2)(D) ("that have been released to any person under [FOIA]"). Once these records have been reviewed and released under FOIA, they will be posted in accordance with 5 U.S.C. § 552(a)(2)(D). Therefore, at this time, in accordance with 21 CFR 10.30(e)(3), we are denying your petition.

Sincerely,

Michael C. Rogers, MS
Associate Commissioner for Regulatory Affairs

[2] FDA regulations specify that a petition must request the Commissioner of Food and Drugs to "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action." 21 CFR 10.30(b)(3). Furthermore, a petition must contain "[a] full statement, in a well-organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position." We note that in the past, FDA has granted at least some citizen petitions requesting that the Agency post records consistent with 5 U.S.C. 552(a)(2)(D) regardless of whether the petition alleged sufficient factual grounds for that request. We believe that the current approach is more appropriate in light of the text of 21 CFR 10.30(b)(3), and it will enable FDA to better serve the interests of all petitioners.