



September 12, 2022

Harry Duty
3697 Family Circle Road
Vernon, FL 32462

Re: Docket No. FDA-2022-P-0395

Dear Mr. Duty:

We are denying your Citizen Petition (FDA-2022-P-0395) filed with the Food and Drug Administration (FDA) on March 21, 2022.

The petition requests FDA to “comply with FOIA law and post publicly on the FDA FOIA reading room ... ‘*Testing Records From 2019 Warning Letter Against Answers Pet Food Due To FDA-CVM Regulating By Their Opinion Instead Of Law.*’”

As grounds for the petition, you claim the “information has 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.” 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[.]”

FDA did not issue a warning letter to Lystn, LLC, doing business as Answers Pet Food, in 2019. Elsewhere in your petition you state that the warning letter is available at https://www.fda.gov/animal-veterinary/outbreaks-and-advisories/fda-cautions-pet-owners-not-feed-one-lot-answers-straight-beef-formula-dogs-due-salmonella?elg=64f9clacfc4149a1988c6b3d48353235&elgCampaignId=5284&elgTrackId=36D622A1932BECE560614F0F106491CC&elgaid=6476&elgat=l&utm_campaign=1-14-2019-petfood&utm_medium=email&utm_source=Elogua. The document at this link is not a warning letter, but an FDA public health alert entitled “FDA Cautions Pet Owners Not to Feed One Lot of A+ Answers Straight Beef Formula for Dogs Due to Salmonella.”

Your petition did not provide the control numbers¹ for, or otherwise identify with any specificity, the FOIA requests that you claim triggered this provision of the FOIA. Any “testing records” related to the public health alert to which you linked would involve lot 2018 02/08 20 of A+ Answers Straight Beef Formula for Dogs. However, we were unable to locate at least three FOIA requests (or even one FOIA request) for these records. Therefore, in accordance with 21 CFR 10.30(e)(3), we are denying your petition.

Sincerely,

Judith McMeekin, PharmD
Associate Commissioner for Regulatory Affairs

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