



JUL 2 2014

Susan Thixton

Re: Docket No. FDA-2010-P-0416

Dear Ms. Thixton:

This letter is in response to your citizen petition dated August 2, 2010 (Petition), submitted on behalf of yourself and other consumers. In the petition, you request that the Food and Drug Administration (FDA) take the following actions with respect to pet food and pet treats:

- Enforce all Federal Food, Drug, and Cosmetic Act (FD&C Act) laws with respect to pet foods and pet treats;
- Remove from store shelves all pet food and pet treats containing ingredients, such as, meat and bone meal, beef and bone meal, animal fat, and animal digest, until the manufacturer can provide complete and concise evidence that ingredients are within the guidelines of the FD&C Act;
- Consider any pet food/treat manufacturing sourcing ingredients from "dead stock" renderers and/or United States Department of Agriculture (USDA) rejected meat or meat products or "4-D"¹ animals (rendered or otherwise) to be adulteration high risk, requiring frequent FDA inspection and burden of evidence of compliance from the manufacturer.

FDA has reviewed the information you provided in your petition. In accordance with 21 CFR 10.30(e)(3), this letter is advising you that FDA is denying your petition without prejudice.

I. REGULATORY BACKGROUND

FDA regulations allow an interested person to petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. See 21 CFR 10.25(a). The definition of administrative action excludes the referral of apparent violations to U.S. attorneys for the institution of civil or criminal proceedings or an act in preparation of a referral. See 21 CFR 10.3(a). Furthermore, 21 CFR 10.30(k) specifically provides that the citizen petition process "does not apply to the referral of a matter to a United States attorney for the initiation of court enforcement action."

¹ The term "4-D" (i.e., dead, dying, disabled, or diseased) is used to describe animals that have died otherwise than by slaughter.

Requests for FDA to enforce the FD&C Act or to take enforcement action are not within the scope of FDA's citizen petition procedures. See 21 CFR 10.30. Furthermore, decisions with respect to enforcement actions are generally made on a case-by-case basis and are solely within the discretion of the Agency.

FDA takes enforcement action based upon Agency priorities and available resources. We do not advise the public in advance of our intentions to take enforcement action against a particular product.

II. DISCUSSION

A. Your request for FDA to enforce the FD&C Act with respect to pet foods and pet treats

In support of this request, the petition asserts that FDA compliance policy acknowledges violations of the FD&C Act in pet food in that it states that pet foods consisting of diseased animals or animals which have died other than by slaughter will not be actionable (Petition at 1-2).²

The petition further asserts that FDA allows pet foods that contain illegal ingredients sourced from diseased animals or animals that have died otherwise by slaughter to be marketed/sold to unknowing pet owners as 'premium', 'choice', and a long list of pleasing terms (Petition at 1). In addition, the petition asserts that pet food and treats that include ingredients sourced from diseased animals or animals that have died other than by slaughter, unless labeled as such would be a violation of labeling laws (Petition at 1). Furthermore, the petition acknowledges that there is no scientific evidence to prove pet foods/treats that contain an ingredient sourced from diseased animals or animals that have died other than by slaughter would have an adverse effect on the health of the pets that consume them (Petition at 3).

FDA denies your request for FDA to enforce the FD&C Act because, as stated above, a request for FDA to enforce the FD&C Act is not an appropriate request for a citizen petition. See 21 CFR 10.30.

B. Your request for FDA to remove from store shelves all pet food and pet treats containing ingredients, such as, meat and bone meal, beef and bone meal, animal fat, and animal digest, until the manufacturer can provide complete and concise evidence that ingredients are within the guidelines of the FD&C Act

Your request for FDA to remove from store shelves all pet food and pet treats containing ingredients, such as, meat and bone meal, beef and bone meal, animal fat, and animal digest, until the manufacturer can provide complete and concise evidence that ingredients are within the guidelines of the FD&C Act is a request for enforcement action.

² The compliance policy referred to in the petition is stated in Compliance Policy Guide (CPG), Sect. 690.300 *Canned Pet Food*, issued by FDA on October 1, 1980, and subsequently revised in March 1995 and June 2004, as follows:

Pet food consisting of material from diseased animals or animals which have died otherwise than by slaughter, which is in violation of [section] 402(a)(5) [of the FD&C Act] will not ordinarily be actionable, if it is not otherwise in violation of the law. It will be considered fit for animal consumption.

FDA denies this request because, as stated above, a request for enforcement action is not an appropriate request for a citizen petition. See 21 CFR 10.30.

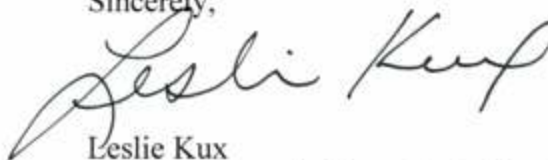
C. Your request for FDA to consider any pet food/treat manufacturing sourcing ingredients from “dead stock” renderers and/or USDA rejected meat or meat products or “4-D” animals (rendered or otherwise) to be adulteration high risk, requiring frequent FDA inspection and burden of evidence of compliance from the manufacturer

Your request for FDA to consider any pet food/treat manufacturing sourcing ingredients from “dead stock” renderers and/or USDA rejected meat or meat products or “4-D” animals (rendered or otherwise) to be adulteration high risk, requiring frequent FDA inspection and burden of evidence of compliance from the manufacturer, is denied because your petition does not provide sufficient data and information to support this request. Therefore, we believe that this requested action is not warranted at this point in time.

III. CONCLUSION

For the reasons discussed above, we are denying your petition without prejudice.

Sincerely,

A handwritten signature in cursive script that reads "Leslie Kux". The signature is written in black ink and is positioned above the printed name and title.

Leslie Kux
Assistant Commissioner for Policy