February 4, 2020

Susan Thixton
Association for Truth in Pet Food
P.O. Box 954
Safety Harbor, FL 34695

RE: Docket No. FDA-2016-P-3578

Dear Ms. Thixton:

This letter responds to your petition for reconsideration filed on July 12, 2019[1] (Petition for Reconsideration). The Petition for Reconsideration requests that the Food and Drug Administration (FDA, the Agency, or we) reconsider its April 30, 2019, response to the citizen petition that you submitted on October 27, 2016, as amended July 10, 2017 (Citizen Petition). Your Citizen Petition requested that FDA: (1) revoke specified Compliance Policy Guides (CPGs); (2) work with the Association of American Feed Control Officials (AAFCO) to modify specified feed ingredient definitions; (3) prohibit the use of diseased animals and/or animals that have died otherwise than by slaughter in pet food or animal feed and require renderers who process or distribute such material to meet labeling and recordkeeping conditions; and (4) establish a "standard of identity" for pet food and treat products, and an optional pet food verification system.

We have reviewed the Petition for Reconsideration and other relevant information in the administrative record. As described more fully below, we are denying your petition for reconsideration.

I. Standard for Reconsideration

The Commissioner may grant a petition for reconsideration if the Commissioner determines reconsideration is in the public interest and in the interest of justice. In addition, the Commissioner will grant a petition for reconsideration if the Commissioner determines that all the following apply:

(1) The petition demonstrates that relevant information or views contained in the

[1] You originally sent your Petition for Reconsideration directly to the Center for Veterinary Medicine (CVM) via the AskCVM@fda.hhs.gov mailbox on June 17, 2019. On June 20, 2019, CVM notified you that FDA regulations require that such petitions be submitted to FDA's Dockets Management Staff. The Center provided you with the name of a contact within that Staff who could assist you if you needed help filing your Petition for Reconsideration. Pursuant to 21 CFR 10.33(b), "Each request for reconsideration must be submitted … no later than 30 days after the date of the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days." The Agency accepted your Petition for Reconsideration for filing on July 12, 2019, despite it being filed more than 30 days after the date of the decision involved.

administrative record were not previously or not adequately considered;

(2) The petitioner's position is not frivolous and is being pursued in good faith;

(3) The petitioner has demonstrated sound public policy grounds supporting reconsideration;

(4) Reconsideration is not outweighed by public health or other public interests.

(See 21 CFR 10.33(d).)

II. Discussion

A. The Citizen Petition and FDA's Response

Your Citizen Petition requested that we withdraw two Compliance Policy Guides (CPGs), CPG Sec. 675.400 ("Rendered Animal Feed Ingredients") and CPG Sec. 690.300 ("Canned Pet Food"). We withdrew the CPGs for the reasons explained in our April 30, 2019, response (Citizen Petition Response).

Your Citizen Petition also requested that we work with AAFCO to modify certain ingredient definitions to require that the ingredients be derived from slaughtered animals. In support of your request, you argued that the current ingredient definitions for meat meal, meat and bone meal, animal fat, animal digest, poultry by-products, and poultry by-product meal are "manifestly contrary to the [FD&C Act] and all of these ingredients do not adhere to the Supreme Court ruling [Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984)] of government agency interpretation of law." You also argued that FDA has authority to request modification of existing feed ingredient definitions under the Memorandum of Understanding (MOU) between FDA and AAFCO. We denied this request.

Your Citizen Petition also requested that FDA prohibit diseased animals and animals that died otherwise than by slaughter for use in animal food by imposing certain requirements on renderers who process such animals. The requirements you are requesting appear to be modeled after the requirements of 21 CFR 589.2000 ("Animal Proteins Prohibited in Ruminant Feed") and 21 CFR 589.2001 ("Cattle Materials Prohibited in Animal Food or Feed to Prevent the Transmission of Bovine Spongiform Encephalopathy"). For example, you requested that renderers be required to label certain materials "Do not feed to animals." You also requested FDA impose certain records requirements on these renderers. We denied this request.

Finally, your Citizen Petition requested that we establish a standard of identity and an optional fee-based ingredient verification system. In support of your request, you argued that "feed grade" ingredients are commonly used in pet food, but that consumers are not provided with labeling information disclosing that the ingredients contain diseased animal material or material from non-slaughtered animals. You stated that instead, pet food labeling is "often covered in pictures of human grade foods when often the actual products are feed grade." You also argued that "'[f]or the purpose of promoting honesty

and fair dealing in the interest of consumers' feed grade pet products must be clearly designated on the product label and all marketing material," pointing to an example in which you allege a pet food manufacturer told consumers the meat ingredients were "human grade" but the food contained meat sourced from animals that died other than by slaughter. We denied this request.

B. Petition for Reconsideration

Your Petition for Reconsideration requests that FDA reconsider its decision with respect to your Citizen Petition, in full, and asks the Agency to:

(1) "fully revoke its allowance of diseased animal material and material from animals that have died otherwise than by slaughter in pet food/animal feed,"

(2) "use [our] authority through the Memorandum of Understanding Agreement with AAFCO to modify all pet food (animal protein) ingredient definitions to include the requirement '*derived from slaughtered animals*,'"

(3) "require ingredient providers who process or distribute prohibited materials to properly label '*Do not feed to animals*' and maintain sufficient records to assure prohibited material is properly disposed of outside of pet food/animal feed," and

(4) "provide pet owners pet product standard of identity of 'pet feed' or 'pet food' ... with the option for verified exception of Dog Food/Cat Food Verified (human grade ingredients)."

1. Use of material from diseased and non-slaughtered animals

Your Petition for Reconsideration requests that FDA "fully revoke [FDA's] allowance of diseased animal material and material from animals that have died otherwise than by slaughter in pet food/animal feed." This request goes beyond the request you made in your Citizen Petition. Although your Citizen Petition requested revocation of the referenced CPGs, your Petition for Reconsideration essentially requests revocation of the underlying policy described by the CPGs. The underlying policy is not dependent upon the existence of the CPGs. Nonetheless, because the Citizen Petition Response fully explained the rationale behind our policy, we are treating your request to "fully revoke [FDA's] allowance of diseased animal material and material from animals that have died otherwise than by slaughter in pet food/animal feed" to be a request to reconsider the underlying policy described in the Citizen Petition Response. That underlying policy is one of enforcement discretion for the use of diseased animals or animals that died otherwise than by slaughter in pet food, as long as food safety hazards are controlled, and the animal food is not otherwise adulterated. If you are requesting that the Agency initiate enforcement action over the use of material from diseased animals or animals that died otherwise than by slaughter in animal food, we note that requests for the Agency to take enforcement action are not within the scope of FDA's citizen petition procedures. As stated in 21 CFR 10.30(k), § 10.30 does not apply to "referral of a matter to a United States Attorney for initiation of court enforcement action and related correspondence." Agency decisions to take, or refrain from taking, enforcement actions are related to referral of a matter to a United States Attorney for the initiation of court enforcement action for violations of Federal law. Therefore, we are denying your request for reconsideration of this decision.

2. Modification of pet food ingredient definitions

Your Petition for Reconsideration requests that FDA reconsider its decision and "use [its] authority through the Memorandum of Understanding Agreement with AAFCO to modify all pet food (animal protein) ingredient definitions to include the requirement '*derived from slaughtered animals.*'" You argue that, although the Citizen Petition Response "defers responsibility of pet food/animal feed ingredient definitions to AAFCO," the MOU itself shows that FDA is "fully empowered to require ingredient modifications." The Citizen Petition Response discussed FDA's role in the AAFCO ingredient definition process, with reference to the MOU. Your Petition for Reconsideration does not contain relevant information or views that were not previously adequately considered. Therefore, we are denying your request for reconsideration of this decision.

3. Labeling and recordkeeping requirements

Your Petition for Reconsideration requests that FDA reconsider its decision and require ingredients containing material from diseased or non-slaughtered animals to be labeled, "*Do not feed to animals*," and require those who process or distribute such material to maintain records to assure these materials are properly disposed of (i.e., are not used in pet food/animal feed). You do not, however, further address this request or state the grounds upon which you request reconsideration of our previous denial of this request. Your Petition for Reconsideration does not demonstrate that we failed to consider or adequately consider relevant information. Therefore, we are denying your request for reconsideration of this decision.

4. Standard of Identity for pet food

Your Petition for Reconsideration requests that FDA reconsider its decision and establish standards of identity for "pet feed" and "pet food." You would like pet foods that are "Human Grade" to be termed "Pet Food" and those that are not human grade to be termed "Pet Feed." You also request an optional ingredient verification system.

You challenge the statement in the Citizen Petition Response that you did not provide "*evidence that human consumers believe that all pet food is equivalent to human food or that it would help consumers to know specifically how pet food differs from human food.*" You say that you did provide such evidence to FDA, specifically:

- a meeting with FDA in approximately 2017 during which a consumer, participating by phone, said that "she never would have believed a pet 'food' could contain a euthanized animal,"
- more than 56,000 signatures and comments in favor of a food/feed standard of identity that you provided to FDA at an August 2017 AAFCO meeting,
- concerns of pet owners that were previously submitted or discussed with the Agency, including examples of misleading labels and historical evidence about consumer perception of pet food, referencing FDA meetings with consumer representatives at the 2014 and 2015 AAFCO meetings, and

- the fact that many feed grade pet foods are sold in grocery stores, which you say is evidence that most pet owners believe pet food is equivalent to human food.

To rebut FDA's assessment that you provided insufficient evidence in support of standards of identity for pet food, you argue that a standard of identity to promote honesty and fair dealing in the interest of consumers is necessary and that, although "feed grade" pet food ingredients are common, there is no information on labels disclosing this to consumers. You say that diseased and non-slaughtered animals are "a standard of identity VERY different than the common or usual ingredient name." You also argue that, "if these ingredients are so safe and the Agency is so certain the public understands what they are buying – why not label the ingredients on pet food products with their true standard of identity '*diseased chicken*' or '*condemned beef*'?" and that "[t]he fact that FDA has further hidden the potential for consumer awareness of the allowed use of these ingredients by withdrawing the Compliance Policies but not revoking their allowance proves that FDA is fully aware many consumers believe pet food is equivalent to human food." Moreover, you say that you agree with the statement we made in the Citizen Petition Response about FDA's authority to take action against misbranded food; however, you say that the Agency has not taken any such action and that "had the Agency historically '*pursued remedies*' under section 403 of the FD&C Act Misbranded Food, perhaps a standard of identity clarification for consumers would not be necessary."

To summarize, the Petition for Reconsideration asserts that we failed to consider certain information relevant to your request for standards of identity for pet food in the Citizen Petition Response. These materials were not submitted to the Docket in support of the Citizen Petition and they are not part of the administrative record of that Citizen Petition. For example, the signatures and comments were not submitted to the docket. There are no administrative records from the 2014, 2015, or 2017 meetings. Furthermore, the 2014 and 2015 meetings predated your 2016 Citizen Petition and were not used in reviewing it. The fact that grocery stores sell pet food was not previously discussed in the administrative record by you or FDA. A petition for reconsideration may not be based on information and views not contained in the administrative record on which the decision was made (21 CFR 10.33(e)). Therefore, we are denying your request for reconsideration of this decision.

5. Comment received on the Citizen Petition

In addition, the Petition for Reconsideration asserts that FDA did not consider the comment submitted by a pet owner in support of the Citizen Petition, noting that the Citizen Petition Response did not acknowledge or respond to the pet owner's comment. FDA did review the comment before responding to the Citizen Petition. Although the Citizen Petition Response itself does not describe the contents of the comment, it does note that in considering your requests, we reviewed, among other things, comments received on your Citizen Petition. To the extent the comment reiterated requests made in the Citizen Petition, those requests were thoroughly considered by FDA. To the extent that the comment requested actions beyond the scope of the Citizen Petition (e.g., prohibit growth hormones, antibiotics, plate waste, poultry litter), the requests were not considered or addressed as part of the Citizen Petition Response. Requests for different administrative action must be submitted as a separate petition. (See 21 CFR 10.30(d).)

III. Conclusion

We conclude that all relevant information and views in the administrative record were adequately considered when we reviewed and denied the Citizen Petition. Accordingly, we need not address whether the other criteria in 21 CFR 10.33(d) apply to the Petition for Reconsideration.

Your Petition for Reconsideration introduces new information and arguments not submitted in or with your Citizen Petition.[2] In responding to the Citizen Petition, FDA considered and extensively discussed all the issues raised in the Citizen Petition. Therefore, we further conclude that granting the Petition for Reconsideration would not be in the public interest and in the interest of justice.

For these reasons, the Agency denies your Petition for Reconsideration.

Sincerely,

Lowell J. Schiller, J.D.
Principal Associate Commissioner for Policy

[2] Your Petition for Reconsideration consists primarily of new information and arguments intended to rebut the Citizen Petition Response. Such information and arguments would more appropriately be included in a new citizen petition. (See 21 CFR 10.33(e).)