June 30, 2021

Kohl Harrington
Director - Pet Schooled
9663 Santa Monica Blvd #1267
Beverly Hills, CA 90210

Re: Docket No. FDA-2020-P-2360

Dear Mr. Harrington:

This letter is in response to your Citizen Petition (FDA-2020-P-2360), dated December 30, 2020, requesting that FDA "issue an official regulation on the matter of *Animals That Have Died Other Than [by] Slaughter, For Use In FDA Regulated Animal Feed, Dog, & Cat Foods*."

In support, you specifically point to the use of pentobarbital to euthanize animals and quote a hypothesis from an FDA investigation that "the most likely way [pentobarbital] could get into dog food would be in rendered animal products" since "[p]entobarbital seems to be able to survive the rendering process. If animals are euthanized with pentobarbital and subsequently rendered, pentobarbital could be present in the rendered feed ingredients."

You also point to section 402(a)(5) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 342(a)(5)], which provides that food is adulterated "if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter" and to FDA's response to a previous Citizen Petition (FDA-2016-P-3578), explaining our enforcement posture with respect to the use of such material to make animal food.

Finally, you say, "Given that FDA remains firm on the position of allowing illegal ingredients to be used in FDA regulated animal feed and pet food products, I request that FDA promulgate an official FDA federal regulation on the matter of *Animals That Have Died Other Than [by] Slaughter, For Use In FDA Regulated Animal Feed, Dog, & Cat Foods,* and ensure this regulation be in compliance with § 553 of the Administrative Procedure Act."

In considering your request, we reviewed your petition, the comments received on your petition, and other relevant information. For the reasons explained in this response, we deny your petition.

Background

FDA previously explained its framework for addressing pet food safety in its April 30, 2019, response to the Citizen Petition filed on behalf of the AssociationforTruthinPetFood.com, FDA-2016-P-3578, saying,

> Congressional focus on food safety issues such as the presence of pathogens in human

and animal food and melamine in pet food led to the passage of the FDA Food Safety Modernization Act (FSMA) in 2011 and FDA's subsequent publication and implementation of a new animal food regulation: "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" at 21 CFR part 507 (part 507). This comprehensive regulation addresses biological, chemical, and physical hazards in animal food, including the pathogens and chemical residues that can result from using tissues from animals that have died otherwise than by slaughter. The part 507 regulation requires many animal food manufacturers, including pet food manufacturers, to have a food safety plan in place before they begin producing animal food. The food safety plan must include an analysis of hazards for each type of animal food the manufacturer produces to identify known or reasonably foreseeable hazards and to determine if those hazards require the manufacturer to implement risk-based preventive controls to significantly minimize or prevent the hazards. A manufacturer also must validate that its preventive controls will be adequate against each hazard. Once preventive controls are established, the manufacturer must monitor them to ensure they are consistently performed and verify they are effective.[1]

A pet food manufacturer subject to part 507 that is using tissues from diseased animals or animals that died otherwise than by slaughter must consider, in its hazard analysis, known or reasonably foreseeable biological hazards (e.g., Salmonella) in such animal tissues. If the manufacturer determines that any identified biological hazards require preventive controls, the manufacturer must implement preventive controls to significantly minimize or prevent the biological hazards in the pet food it produces and ensure the pet food is not adulterated. See 21 CFR 507.33 and 507.34. Additionally, the pet food manufacturer must consider known or reasonably foreseeable chemical hazards, such as decomposed tissue, thyroid hormones, and unsafe residues from drugs (including those used for euthanasia) in such animal tissues. If the manufacturer determines any identified chemical hazards require preventive controls, the manufacturer must implement preventive controls to significantly minimize or prevent the chemical hazards in the pet food it produces and ensure the pet food is not adulterated.

That response also explained, with respect to rendered tissue material from animals that died otherwise than by slaughter, that "we do not believe that the use of this rendered material to

[1] 21 CFR part 507 applies to animal food facilities required to register under section 415 of the FD&C Act. Facilities that are a very small business, as defined by the regulation, are exempt from the preventive control requirements of the regulation but are still subject to the current good manufacturing practice requirements. They are required to submit an attestation to the Agency that the facility has identified the potential hazards associated with the animal food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective; or that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law. For the facilities that are not subject to the 21 CFR part 507 regulation, FDA intends to continue to use a risk-based approach to regulate animal food under the adulteration and misbranding provisions in the FD&C Act. Section 301(a) of the FD&C Act prohibits the introduction or delivery for introduction of adulterated or misbranded food into interstate commerce (21 U.S.C. § 331(a)).

make animal food poses a safety concern as long as hazards are controlled, and the animal food is not otherwise adulterated. However, when necessary to protect human and animal health, we will take action under any applicable provisions of the FD&C Act, including section 402(a)(5)."

Discussion

Your petition requests FDA to "issue an official regulation on the matter of Animals That Have Died Other Than [by] Slaughter, For Use In FDA Regulated Animal Feed, Dog, & Cat Foods." Your petition does not describe the nature of the regulation requested in any detail, how it would fit in with FDA's existing animal food regulations, how it would improve the safety of animal food, or what data support a benefit to public health or other public benefit, if FDA were to issue a regulation. Your petition provides us with almost no information that we could use to assess your request other than your concerns regarding pentobarbital in animal food.

As we explained in our response to Citizen Petition FDA-2016-P-3578, animal food manufacturers are already responsible for identifying and controlling hazards, including residues of pentobarbital, under the "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" regulation at 21 CFR part 507. Although contaminated rendered animal food ingredients is one way that pentobarbital residues could enter the animal food stream, we are not persuaded that we must issue a regulation regarding the use of animals that have died otherwise than by slaughter in animal food to address such residues. In addition to our already existing regulation at 21 CFR part 507, FDA is able to address the issue of residues of pentobarbital in animal food in other ways. For example, since 2017, FDA has sent three warning letters to firms after pentobarbital was found in animal food.[2]

In addition, because veterinarians and farmers have an important role in ensuring that animals whose tissues contain pentobarbital residues do not enter the food supply, FDA provides education and outreach to ensure these groups are aware of their responsibilities. We would like to be able to conduct more targeted communication based on current veterinary practices. To help us do more targeted future communications, we are gathering information regarding veterinarians' understanding of euthanasia methods, how veterinarians choose euthanasia method by species, and what recommendations veterinarians make for disposal of the resulting carcass.

Given the risk-based framework FDA already is using to help ensure the safety of animal food, the absence of any other data or information accompanying the petition supporting that an unspecified regulation is necessary to protect the public, and the tools already available to the Agency to address animal foodborne risks to the public health, including the risks associated with pentobarbital residue in animal food, FDA is unpersuaded that it should spend its limited resources as your petition suggests.

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[2] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/evangers-dog-cat-food-co-518544-06292017; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jbs-souderton-inc-dba-mopac-574386-04232019; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/valley-proteins-inc-582508-11182019.

Moreover, your petition does not conform to FDA regulations describing the format of citizen petitions. Those regulations provide that, "[i]f the petition requests the Commissioner to issue, amend, or revoke a regulation," the petition must contain "the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested." 21 CFR 10.30(b)(3)(A)(1). You did not provide the wording of the proposed regulation, or even its general tenor, to aid FDA in evaluating your request or to persuade FDA that such a regulation would be beneficial. In the absence of such information, we decline to speculate about the nature, scope, and content of the requested regulation.

Conclusion

For the reasons explained above, we deny your request.

Sincerely,

Steven Solomon -S

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Steven M. Solomon, DVM, MPH
Director, Center for Veterinary Medicine