U.S. FOOD & DRUG ADMINISTRATION

April 30, 2019

Ms. Susan Thixton
AssociationforTruthinPetFood.com
1208 Georgetown Drive
Safety Harbor, FL 34695

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

Dear Ms. Thixton,

This is a final response to the Citizen Petition (Petition) (FDA-2016-P-3578) you filed with the Food and Drug Administration (FDA or Agency) on October 27, 2016, as amended on July 10, 2017. For the reasons explained below, we have withdrawn Compliance Policy Guides (CPG) Sec. 675.400 ("Rendered Animal Feed Ingredients") and Sec. 690.300 ("Canned Pet Food") and deny your remaining requests.

Background

Your October 27, 2016, petition requests that we:

1) Revoke CPG Sec. 675.400 ("Rendered Animal Feed Ingredients");
2) Revoke CPG Sec. 690.300 ("Canned Pet Food");
3) Work with the Association of American Feed Control Officials (AAFCO) to modify the following feed ingredient definitions to require that the ingredients be derived from slaughtered animals: meat meal, meat and bone meal, animal fat, animal digest, poultry by-products, and poultry by-product meal; and
4) Prohibit diseased animals and/or animals that have died otherwise than by slaughter from being processed into pet food or animal feed and require that renderers that process or distribute "prohibited material" meet certain labeling and recordkeeping conditions.

Your July 10, 2017, addendum additionally requests that we:

5) Establish a standard of identity for pet food and treat products. You request that pet products that meet the definition of "Human Grade" as published by AAFCO be termed "Pet Food" and those products that do not meet the definition of human grade be termed "Pet Feed." Your petition would also allow for the option of a fee-based verification system, whereby products that complete the verification process (verifying all human grade ingredients) would be allowed to label and market their products with a "Verified Pet Food" claim.

On April 10, 2017, we sent you a tentative response in accordance with Title 21, Code of Federal Regulations (21 CFR) 10.30(e)(2)(iv), stating that, because of the complexity of the issues

involved, we required additional time to issue a final response. In considering your requests, we reviewed your petition (as amended), comments received on your petition, and other relevant information.

Discussion

A. Withdrawal of Compliance Policy Guides

Your petition requests us to revoke CPG Sec. 675.400 ("Rendered Animal Feed Ingredients") and CPG Sec. 690.300 ("Canned Pet Food"). You argue that FDA has interpreted the Federal Food, Drug, and Cosmetic Act (FD&C Act) inappropriately, and in a way that is "arbitrary, capricious, and manifestly contrary to the statute." [Petition, page 2]. You argue that, under Chevron v. Natural Resources Defense Council, 467 U.S. 837 (1984), FDA can interpret the law only if Congress left a gap for the Agency to fill in interpreting statutory provisions—in this case, the statutory definition of "food" (section 201(f) of the FD&C Act (21 U.S.C. § 321(f)) and a particular statutory provision setting out conditions under which food is deemed adulterated (section 402(a)(5) of the FD&C Act (21 U.S.C. § 342(a)(5)). [Petition, page 2]. You state that the following quote from CPG Sec. 675.400 indicates that FDA has provided its own interpretation of the FD&C Act: "the Center for Veterinary Medicine does not believe that Congress intended the Act to preclude application of different standards to human and animal foods." [Petition, page 2]. Finally, although you maintain that Congress did not leave such a gap that FDA needed to fill, you argue that even if there were a gap to fill, the CPGs are "arbitrary, capricious and manifestly contrary to the statute." [Petition, page 2].

Without detailing our concerns with your interpretation of the Chevron doctrine,[1] we point out that the two CPGs you reference are not based on application of the Chevron doctrine. Instead, the two CPGs involve FDA's ability to control its limited resources and decide how best to achieve its public health goals, in this instance by applying enforcement discretion to the use of certain ingredients in animal food under certain circumstances. The decision to take or refrain from taking enforcement action is a matter of Agency discretion and is not subject to judicial review under the Administrative Procedures Act. Heckler v. Chaney, 470 U.S. 821 (1985).

The Agency's policy to apply enforcement discretion to the use of certain products by the rendering and pet food canning industry was based on the long history of safe use of the products as animal food. Rendering uses wet or dry heat to convert tissue from animals (e.g., livestock, poultry, and seafood) into fats and protein meals. Rendered tissues include material that may not be aesthetically pleasing to some humans, but which animals normally eat, such as blood, offal, bones, and carcasses. The rendering process minimizes or eliminates pathogens and facilitates the use of the proteins and fats in animal food. Rendered fats and protein meals are incorporated into many pet foods, including canned pet food. The canning process and resulting animal food must be in compliance with the low-acid canned food regulations found in 21 CFR part 113 (also used for human food). These regulations require the use of specific temperatures and pressures

[1] In general, the Chevron doctrine provides that, when a statute is silent or ambiguous about a specific issue, an administrative agency charged with implementation of the statute should get judicial deference to its interpretation, if that interpretation is based on a permissible construction of the statute. Chevron v. Natural Resources Defense Council, 467 U.S. 837 (1984).

during processing that are designed to lead to a commercially sterile and shelf-stable product that does not require refrigeration.

Because the rendering and canning processes adequately dealt with any microbiological contamination, FDA concluded that applying enforcement discretion to the use of tissues, including from animals that were diseased or died otherwise than by slaughter, for rendering and canning would not present any food safety concerns, if the animal food was not otherwise adulterated. At the time the CPGs were originally released, FDA had no evidence of a disease or other illness resulting from properly rendered or canned ingredients, despite the use of tissues from diseased animals or animals that died otherwise than by slaughter. CPG Sec. 675.400 ("Rendered Animal Feed Ingredients")[2] and CPG Sec. 690.300 ("Canned Pet Food")[3] were issued in 1980 to document our policy approach to properly rendered and canned animal tissues, including tissues from diseased animals and animals that died otherwise than by slaughter.

Nonetheless, we believe CPG Sec. 675.400 and CPG Sec. 690.300 are outdated, and therefore, in accordance with 21 CFR 10.115(k), we have withdrawn these CPGs. The reasons for our withdrawal of these two CPGs are explained below.[4]

Since these CPGs issued in 1980, knowledge of, experience with, and focus on preventing safety problems with animal food has increased. Examples of safety problems include the presence of pathogens, melamine, pentobarbital, and thyroid hormones in animal food.

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[2] CPG Sec. 675.400 ("Rendered Animal Feed Ingredients") states that "[n]o regulatory action will be considered for animal feed ingredients resulting from the ordinary rendering process of industry, including those using animals which have died otherwise than by slaughter, provided they are not otherwise in violation of the law." The CPG notes that, prior to the appearance of bovine spongiform encephalopathy (BSE), we had no evidence of human or animal disease associated with properly rendered animal feed ingredients despite the use of tissues from diseased animals or animals that have died otherwise than by slaughter. The CPG goes on to say, however, that when rendered animal feed ingredients contain harmful microorganisms, toxins or chemical substances, they may be adulterated under section 402(a)(1) or (2) of the FD&C Act, and that "[w]here a rendering procedure itself raises a question of disease transmission, the ingredient made may be deemed adulterated under Section 402(a)(4)." In 1998, the following language was added to CPG Sec. 675.400 after the Agency published regulations to address BSE: "Animal proteins that are prohibited from use or intended use in ruminant feed by [Title 21, Code of Federal Regulations] 589.2000, are unapproved food additives as defined in Section 201(s) of the Act. The use or intended use of these proteins in ruminant feed causes the feed to be adulterated under Section 402(a)(2)(C)."

[3] CPG Sec. 690.300 ("Canned Pet Food") acknowledges that the canned pet food industry uses animal tissues from various sources, including from animals that may have died otherwise than by slaughter. At the time the CPG was published, we said that we were not aware of instances of disease or other hazards occurring from canned pet food containing the tissues of animals that may have died otherwise than by slaughter. Given the existence of low-acid canned food regulations (21 CFR part 113), we said that "[w]hen properly processed in accordance with these regulations, [FDA's Center for Veterinary Medicine] considers canned pet foods, otherwise not in violation of the statute or regulations, to be safe and suitable for consumption by pets regardless of the origin of animal tissues used."

[4] Please note that we also have, on our own initiative, withdrawn CPG Sec. 690.500, "Uncooked Meat for Animal Food." We have determined that this CPG is outdated, and its policy statement is simply a statement of existing law. Further information about the withdrawal of all three CPGs (Secs. 675.400, 690.300, and 690.500) is available on FDA's website at https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm055752.htm.

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.[5]

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.

We have determined that the CPGs that we have withdrawn are outdated because they do not inform animal food manufacturers of the part 507 regulation, a new, integral part of the animal food safety framework. Furthermore, they are incomplete because they highlight only one type of hazard (biological) that has been associated with tissues of animal origin. Rather than update these CPGs, we have been providing other, more comprehensive, guidance. In CPG Sec.

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[5] 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)).

690.800 "Salmonella in Food for Animals," issued in July 2013, FDA explains that pet food contaminated with *Salmonella* that will not subsequently undergo a commercial heat step is considered to be adulterated under section 402(a)(1) of the FD&C Act because of the significant risk to human and animal health. As part of its implementation of the part 507 regulation, in January 2018, FDA's Center for Veterinary Medicine (CVM) issued draft guidance for industry (GFI) #245, "Hazard Analysis and Risk-Based Preventive Controls for Food for Animals," which extensively covers a variety of hazards, including those associated with animal tissue ingredients, as well as information for manufacturers on establishing and managing preventive controls. FDA also has issued, among others, GFI #67, "Small Entities Compliance Guide for Renderers" (1998); GFI #195, "Small Entities Compliance Guide for Renderers—Substances Prohibited from Use in Animal Food or Feed" (2009); GFI #158, "Use of Material from Deer and Elk in Animal Feed" (2016); draft GFI #239, "Human Food By-Products for Use as Animal Food" (2016); GFI #241, "Small Entity Compliance Guide – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" (2016); GFI #235, "Current Good Manufacturing Practice Requirements for Food for Animals," (2017); and draft GFI #246, "Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Supply-Chain Program" (2018). Thus, since the two withdrawn CPGs were originally released, we have issued regulations and other more extensive guidance and draft guidance that are directly relevant to animal food safety.

FDA will take action against animal food products when necessary to protect human and animal health. However, as long as hazards are controlled[6], and the animal food is not otherwise adulterated, we do not believe that the use of diseased animals or animals that died otherwise than by slaughter to make animal food poses a safety concern and we intend to continue to exercise enforcement discretion where appropriate. Nonetheless, FDA has the ability to take action under any applicable provisions of the FD&C Act, including section 402(a)(5), when necessary to protect animal and human health, e.g., in the face of a foodborne animal disease outbreak.

B. Modification of AAFCO ingredient definitions

Your petition requests that FDA work with AAFCO to modify the ingredient definitions for meat meal, meat and bone meal, animal fat, animal digest, poultry by-products, and poultry by-product meal to require that the ingredients be derived from slaughtered animals. You argue that the current definitions are "manifestly contrary" to the FD&C Act and "all of these ingredients do not adhere to the Supreme Court ruling of government agency interpretation of law."[7] [Petition, page 3].

As explained on the AAFCO website (www.aafco.org), AAFCO is an association of state and federal agencies that are charged by law with regulating the sale and distribution of animal food

[6] For purposes of this document, the phrase "hazards are controlled" means, "hazards requiring a preventive control are controlled." We are using the shorter phrase for readability.

[7] We assume this is another reference to the Chevron doctrine. As explained above, we do not believe the Chevron doctrine is applicable because FDA's acceptance of the AAFCO definitions you list is based on the Agency's ability to exercise enforcement discretion when warranted. FDA's acceptance of the definitions does not prevent us from bringing an enforcement action against an ingredient that is adulterated.

and animal drugs. FDA is a member of AAFCO and serves in an advisory role on the AAFCO Board. In addition, under a Memorandum of Understanding (MOU) with AAFCO, FDA provides scientific and technical assistance to AAFCO as part of the ingredient definition establishment process. The MOU can be found at https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm439961.htm. Many states refer to the AAFCO ingredient definitions when deciding which ingredients may be used in animal food manufacturing.

We do not agree at this time that changes are needed to the current ingredient definitions for meat meal, meat and bone meal, animal fat, animal digest, poultry by-products, or poultry by-product meal; therefore, we deny your request that we work with AAFCO to modify the ingredient definitions to include the requirement that the ingredients be "derived from a slaughtered animal." As described in section A above, we do not believe that the use of diseased animals or animals that died otherwise than by slaughter to make animal food poses a safety concern as long as hazards are controlled, and the animal food is not otherwise adulterated. Moreover, although FDA collaborates with AAFCO on the ingredient definition process by providing its expertise in the safety review of the ingredients, the definitions are not FDA definitions. As such, even if we agreed with your request in principle, it would need to be addressed via the process for ingredient definition modification found in the MOU and AAFCO's procedures.

C. Prohibition of diseased animals and animals that died otherwise than by slaughter for use in animal food

Your petition requests that FDA "clearly and actively prohibit diseased animals and/or animals that have died otherwise than by slaughter to be processed into pet food/animal feed" and asks that we place requirements on renderers similar to those placed on renderers by the so-called "BSE regulations" (21 CFR 589.2000 and 2001).[8] [Petition, page 1.] Specifically, you request that we impose the following requirements on renderers who process diseased animals or animals that died otherwise than by slaughter:

1. Label all products that contain or may contain prohibited material (diseased and/or non-slaughtered animals) with the following cautionary statement "Do not feed to animals."

2. Maintain records sufficient to track the materials throughout their receipt, processing, and distribution, and make them available for inspection and provide to FDA.

3. Renderers maintain the records for a minimum of one year; FDA maintains the records for public view on the FDA website for a minimum of one year. [Petition, page 1].

In addition, you want "renderers that separate prohibited and non-prohibited material…to provide for measures to avoid commingling or cross-contamination of prohibited material and

[8] 21 CFR 589.2000, "Animal Proteins Prohibited in Ruminant Feed." 21 CFR 589.2001, "Cattle Materials Prohibited in Animal Food or Feed to Prevent the Transmission of Bovine Spongiform Encephalopathy." BSE (bovine spongiform encephalopathy) is also known as mad cow disease.

non-prohibited material and maintain written procedures that document these measures." [Petition, page 1].

We deny this request.

First, we do not agree that the grounds that you provide support the imposition of these requirements on renderers that process tissue from diseased animals or animals that died otherwise than by slaughter. Your grounds consist of the contention that FDA must enforce section 402(a)(5) of the FD&C Act to rendered tissues for animal food for essentially the same reasons you provided for withdrawal of the CPGs. As explained above, we do not believe that the use of this rendered material to 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).

Second, there are significant differences between tissues from diseased animals or animals that died otherwise than by slaughter and tissues whose use is prohibited or restricted from use in animal food by the BSE regulations. These differences do not support imposing the same restrictions on tissues from diseased animals and animals that died otherwise than by slaughter as are used with materials prohibited by the BSE regulations. The agent that causes BSE (i.e., a prion) cannot be easily detected or deactivated. Thus, the only effective control is to prohibit the use of certain animal tissues in specific types of animal food, as detailed in the BSE regulations. In contrast, other types of hazards that may be found in tissues from diseased animals or animals that died otherwise than by slaughter may be controlled (i.e., significantly minimized or eliminated) through proper mitigation strategies, and thus not present a food safety concern. Facilities that are subject to part 507 must identify the known or reasonably foreseeable hazards for their animal food (whether raw materials and ingredients or finished food), determine if those hazards require a preventive control, then implement preventive controls to control the hazards. Establishments not subject to part 507 must still ensure the animal food they introduce, or deliver for introduction, into interstate commerce is not otherwise adulterated under the FD&C Act.

Third, even if we agreed that tissues from diseased animals or animals that died otherwise than by slaughter should be banned in animal food, we would not need to issue new regulations to prohibit such animal tissues from entering the food supply. The FD&C Act already provides that food from diseased animals or animals that died otherwise than by slaughter is adulterated under section 402(a)(5) (21 U.S.C. § 342(a)(5)) and the introduction of such adulterated food into interstate commerce is prohibited by section 301(a) (21 U.S.C. § 331(a)). However, as stated above, provided the animal food is in compliance with all other requirements of the FD&C Act and any applicable regulations, we do not believe that the use of diseased animals or animals that died otherwise than by slaughter to make animal food poses a safety concern as long as hazards are controlled, and the animal food is not otherwise adulterated. If FDA has safety concerns regarding such animal food, it can address those concerns absent any new regulations (e.g., FDA can initiate a seizure or injunction action using its existing regulatory authority).

D. Establishment of Standard of Identity and Optional Fee-Based Verification Process

In July 2017, you amended your petition, adding the request that FDA establish a standard of identity for pet food/treat products. You ask that pet products meeting the definition of "human grade" as published by AAFCO receive a standard of identity as "pet food" and that all other products (i.e., products that are not "human grade") receive a standard of identity as "pet feed." Your request also provides for an "optional fee-based pet product ingredient quality verification system." Your petition requests that animal food for pets be classified as "Dog Feed/Cat Feed, or Dog Food/Cat Food, or Dog Food Verified/Cat Food Verified" instead of the current system where all the products are classified as "food." You also ask that the definitions and standards of identity of "pet food," "pet feed," and "pet food verified" be made public on FDA's website.

You reference section 401 of the FD&C Act (21 U.S.C. § 341), which provides that "[w]henever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food . . . a reasonable definition and standard of identity, a reasonable definition of quality, or reasonable standards of fill of container.... In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label."

One premise of your request for pet food standards of identity is that purchasers of pet food should be able to distinguish "human grade" from "non-human grade" products. You also assert that pet food labels contain pictures of human grade food and that at least one pet food manufacturer told consumers it used human grade meat in its pet food, when the pet food was later determined to be adulterated with a chemical hazard. To the extent images of pet food ingredients or text in labeling are misleading, FDA is authorized to pursue remedies under section 403 of the FD&C Act, "Misbranded Food." Having standards of identity for pet food would not offer any additional assurance that a given pet food product is accurately labeled.

You do not present significant new evidence that standards of identity for "pet food," "pet feed," and "pet food verified" would promote honesty and fair dealing in the interest of consumers. For example, you provided no 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. Furthermore, it is possible that consumers would find three different classes of pet food confusing.

Further negating the necessity of issuing standards of identity for pet food products, some states already allow for the voluntary use of the term "human grade" on pet food, provided certain conditions are met (e.g., every ingredient and the resulting product is stored, handled, processed, and transported in compliance with CGMP requirements for human food; the food is labeled for its intended use as animal food; and the reference to grade does not appear in the ingredient statement). Provided the "human grade" statement contained on the label and in all of the product labeling is truthful and not misleading, FDA does not object to such voluntary labeling. Having standards of identity for pet food would not offer any additional assurance that a given pet food product is accurately labeled.

You also have proposed that we create a voluntary program to verify whether pet food is human grade and that we collect fees to run such a program. Congress has not authorized FDA to collect and spend fees for this purpose. Legislation would be needed to establish a new program of fees relating to pet food "grade" verification; therefore, this suggestion would be more appropriately directed to your representatives in Congress.

There are currently no standards of identity for animal food nor are there any regulations detailing a framework for issuing standards of identity for animal food. FDA's Center for Food Safety and Applied Nutrition (CFSAN), which is responsible for regulating human food, has decades of experience with regulations relating to the process for proposing and issuing standards of identity for human foods and has established approximately 300 standardized human foods (see 21 CFR parts 130, *et seq.*). CFSAN's program likely would inform any standard of identity program that CVM wanted to establish for animal food. However, CFSAN has recently embarked on an effort to re-think its approach to standards of identity. Commissioner Scott Gottlieb has asked for an exploration of whether the current framework may be outdated and insufficiently flexible to allow innovation to produce more healthful foods while maintaining the essential characteristics and nutritional integrity of key food products. On July 26, 2018, FDA held a public Nutrition Innovation Strategy meeting, with one of the primary goals being to seek input on approaches for modernizing standards of identity. (See https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm611227.htm.) Thus, FDA considers that it may be premature at this time for CVM to engage in what would be the first standard of identity regulations for animal food.

Regardless, the FD&C Act and FDA regulations contain diverse requirements relating to the safety of animal food ingredients and finished animal food, such as requirements for animal food and color additives; tolerances; animal food production, packaging, storage, and transportation practices; canning; labeling; BSE prevention; food facility registration; mandatory reporting of certain food-related adverse health events; imports; and inspections. Thus, FDA already has numerous authorities to allow it to regulate the safety of pet food.

At this time, we do not consider that issuing regulations to identify certain pet food as human grade would address a substantial threat to public health. To the extent your petition is based on concerns regarding the safety of pet food, we share those concerns, but rather than issue the requested regulations setting standards of identity for pet food, we believe Agency resources are better spent focusing on activities to protect animal and human health. Some of these activities are animal food inspection programs, including those for: medicated feed manufacturing, BSE regulation compliance, low-acid canned animal food production, and compliance with the new animal food regulations in part 507. Violations found during inspections can result in warning letters to firms or legal actions. Further, CVM reviews animal food additive petitions, monitors animal food for the presence of contaminants, and evaluates information from investigations, such as labeling and sample test results. CVM investigates complaints related to animal food and monitors for safety reporting trends, initiating recalls when needed. CVM also is continually involved in preparing guidance documents and engaging in outreach to educate industry and consumers regarding animal food safety. These activities and more are focused on enhancing

animal food safety, including pet food safety. Examples of recent actions FDA has taken to protect animal and human health include:

December 3, 2018, FDA Alerts Pet Owners about Potentially Toxic Levels of Vitamin D in Several Dry Pet Foods.
https://www.fda.gov/AnimalVeterinary/NewsEvents/ucm627485.htm

October 17, 2018, FDA Warns Two Firms about Monensin Contamination in Horse Feed.
https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm622743.htm

July 27, 2018, FDA Investigating Six Horse Deaths Due to Contaminated Feed from Gilman Co-Op Creamery.
https://www.fda.gov/AnimalVeterinary/NewsEvents/ucm614978.htm

July 12, 2018, FDA Investigating Potential Connection Between Diet and Cases of Canine Heart Disease.
https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm613305.htm

March 27, 2018, FDA Alerts Pet Owners about the Presence of Thyroid Hormones in Certain Milo's Kitchen Pet Treats.
https://www.fda.gov/AnimalVeterinary/NewsEvents/ucm602872.htm

February 16, 2018, FDA Alerts Pet Owners About Potential Pentobarbital Contamination in Canned Dog Food Manufactured by The J.M. Smucker Company, Including Certain Gravy Train, Kibbles 'N Bits, Ol' Roy, and Skippy Products.
https://www.fda.gov/AnimalVeterinary/NewsEvents/ucm597135.htm

February 13, 2018 (updated November 6, 2018), FDA Investigates Pattern of Contamination in Certain Raw Pet Foods Made by Arrow Reliance Inc., Including Darwin's Natural Pet Products and ZooLogics Pet Food.
https://www.fda.gov/AnimalVeterinary/NewsEvents/ucm596555.htm

February 9, 2018, FDA Investigates Outbreak of Salmonella Linked to Raws for Paws Ground Turkey Food for Pets.
https://www.fda.gov/AnimalVeterinary/NewsEvents/ucm596071.htm

March 27, 2017, FDA Alerts Veterinarians and Pet Food Manufacturers about Potential Presence of Thyroid Hormones in Pet Foods and Treats.
https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm548883.htm

March 2, 2017, FDA Cautions Pet Owners and Caretakers Not to Feed Certain Evanger's or Against the Grain Canned Pet Foods
https://www.fda.gov/animalveterinary/newsevents/cvmupdates/ucm542265.htm

After considering factors such as the non-existence of an animal food standard of identity program, the changes anticipated in the human food standard of identity program, the lack of evidence presented that pet food standards of identity are necessary to promote honesty and fair dealing for consumers, and other pet food regulatory activities requiring Agency resources, we do not plan to issue pet food standards of identity at this time. Thus, we are denying your request.

Conclusion

For the reasons explained above, we have withdrawn CPG Sec. 675.400 ("Rendered Animal Feed Ingredients") and CPG Sec. 690.300 ("Canned Pet Food"). In accordance with 21 CFR 10.30(e)(3), we deny your requests to help establish new AAFCO definitions, issue regulations for renderers, and set standards of identity for pet food, and will continue to focus resources on new and established programs to regulate animal food.

Sincerely,

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