ATPF

advocating for pet food consumers.

October 27, 2016

The undersigned submits this petition on behalf of pet food consumers requesting the Commissioner of The Food and Drugs Administration to revoke Compliance Policies 675.400 Rendered Animal Feed Ingredients and 690.300 Canned Pet Food, modify existing pet food/animal feed definitions related to these compliance policies, and ask the agency to clearly and actively prohibit the recycling of rendered diseased and non-slaughtered animals into pet food/animal feed.

Action Requested

(1) This petition requests the Commissioner to fully revoke FDA Compliance Policy 675.400 Rendered Animal Feed Ingredients. *"Policy: No 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."*

(2) This petition requests the Commissioner to fully revoke FDA Compliance Policy 690.300 Canned Pet Food. *"Policy: Pet food consisting of material from diseased animals or animals which have died otherwise than by slaughter, which is in violation of 402(a)(5) will not ordinarily be actionable, if it is not otherwise in violation of the law. It will be considered fit for animal consumption."*

(3) This petition requests the Commissioner to work with AAFCO through FDA's Memorandum of Understanding Agreement to immediately modify the pet food/animal food ingredients listed below to include the requirement *"derived from slaughtered animals"*.

Ingredient definitions requested to be modified: meat meal, meat and bone meal, animal fat, animal digest, poultry by-products, poultry by-product meal.

(4) As outlined in the Federal Food, Drug and Cosmetic Act, we request the Commissioner to clearly and actively prohibit diseased animals and/or animals that have died otherwise than by slaughter to be processed into pet food/animal feed placing the following requirements on renderers who process or distribute the prohibited material:

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.

In addition, renderers that separate prohibited and non-prohibited material are required to provide for measures to avoid commingling or cross-contamination of prohibited material and non-prohibited material and maintain written procedures that document these measures.

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Statement of Grounds

Revoke CPG 675.400 and 690.300

Supreme Court Justice J. Stevens provided the following opinion (Chevron U.S.A. v. Natural Resources Defense Council) to government agency's interpretation of law:

> *"When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.*
>
> *"The power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress.*
>
> *"If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute."*

The Federal Food, Drug and Cosmetic Act defines food as: *"The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."*

The same Act defines an adulterated food (in part) as: *"A food shall be deemed to be adulterated- (5) 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;".*

We do not believe "*Congress has explicitly left a gap*" in the above definition of food or the above definition of an adulterated food requiring a need "*for the agency to fill*". However, the FDA/CVM has most certainly interpreted the FD&C Act with regards to pet food/animal food making the following statement: "*the Center for Veterinary Medicine does not believe that Congress intended the Act to preclude application of different standards to human and animal foods*".

Yielding to FDA's belief 'Congress intended animal food/pet food and human food to be held to different standards' (though only for sake of discussion), the Supreme Court decision '*Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute*' is grounds for FDA revoking stated Compliance Policies.

FDA Compliance Policy 675.400 Rendered Animal Feed Ingredients and FDA Compliance Policy 690.300 Canned Pet Food are completely 'arbitrary, capricious, and manifestly contrary to the statute'.

Grounds to CPG 675.400 and CPG 690.300 are arbitrary and capricious: The undersigned filed Freedom of Information Act Request 2016-4226 asking FDA/CVM for "*data that these Compliance Policies were based on – specifically the data that proves rendered diseased or non-slaughtered animals is not a risk to pets. It is assumed CVM has science to prove diseased and/or non-slaughtered are of no risk to pets (proof this material is of no risk to pets)."*

FDA's response to FOIA Request 2016-4226: *"After searching our files, we did not find the requested records."* FDA's lack of response (providing no scientific evidence to the safety of Compliance Policy allowed ingredients) is evidence the agency arbitrarily and capriciously interpreted the FD&C Act.

Grounds to CPG 675.400 and CPG 690.300 are manifestly contrary to the statute: The FD&C Act's definition of food clearly and concisely (unambiguously) includes articles consumed by animals/pets. The FD&C Act clearly and concisely (unambiguously) states any part of a diseased animal or any part of a non-slaughtered animal would deem the food as adulterated.

In complete and total contrast to the statute, FDA interprets the FD&C definition of food and adulterated food as *"Pet food consisting of material from diseased animals or animals which have died otherwise than by slaughter, which is in violation of 402(a)(5) will not ordinarily be actionable…"* Law clearly states a diseased or non-slaughtered animal is prohibited; FDA interpretation of law is directly contrary stating a diseased or non-slaughtered animal is allowed. It is more than evident; CPG 675.400 and CPG 690.300 are manifestly contrary to the statute. Clear grounds for revoking stated Compliance Policies.

Grounds for Modification of Pet Food/Animal Feed Ingredient Definitions
The pet food/animal feed ingredients meat meal, meat and bone meal, animal fat, animal digest, poultry by products, and poultry by-product meal do not include the requirement to be 'derived from a slaughtered animal' within their legal definition. All of these pet food/animal feed ingredient definitions are manifestly contrary to the Federal Food, Drug and Cosmetic Act and all of these ingredients do not adhere to the Supreme Court ruling of government agency interpretation of law.

FDA works in partnership with the Association of American Feed Control Officials (AAFCO) under a *"Memorandum of Understanding Agreement"*. Under Item G of that agreement, FDA has authority to request modifications of existing feed ingredient definitions.

Based on the above evidence stated FDA Compliance Policies are arbitrary, capricious, and manifestly contrary to the statute, pet food/animal feed ingredient definitions must be edited to include the legal requirement 'derived from a slaughtered animal'. The following feed ingredient definitions are currently without the requirement 'derived from a slaughtered animal' – thus each are manifestly contrary to the statute: meat meal, meat and bone meal, animal fat, animal digest, poultry by-products, poultry by-product meal.

Grounds for Prohibiting Rendered Diseased and Non-Slaughtered Animals with Public Accountability
As evidenced, the FD&C Act prohibits the use of diseased or non-slaughtered animals in human or animal food.

"The term "food" means (1) articles used for food or drink for man or other animals…"
"A food shall be deemed to be adulterated- (5) 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;…"

As evidenced, the Supreme Court ruling clearly prohibits a government agency interpretation of law if it is "arbitrary, capricious, or manifestly contrary to the statute."

As evidenced, FDA did not provide scientific foundation to the safety of rendered diseased or non-slaughtered animals in FOIA Request 2016-4226 proving Compliance Policies allowing the use of these ingredients in pet food/animal feed are arbitrary and capricious.

As evidenced, CPG 675.400 and CPG 690.300 are overtly contrary of the FD&C Act definition of a prohibited adulterated food; manifestly contrary to the statute.

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FDA does not have authority to issue policy that is manifestly contrary to law. As further grounds, evidenced in United States v. Franck's Lab, Inc. the court ruled FDA policy was contrary to statute stating "*traditional pharmacy compounding in the context of a pharmacist-veterinarian-patient relationship is contrary to [the] congressional intent*" of the Federal Food, Drug, and Cosmetic Act ("FDCA"). The court affirmed FDA did not have the authority to issue policy 'manifestly contrary' to law (congressional intent). We are without doubt the court would rule the same with CPG 675.400 and CPG 690.300.

Per federal law, all material sourced from diseased or non-slaughtered animals would be deemed prohibited in food, similar to other Specified Risk Material. As federal law has been unlawfully ignored for decades, consumers deserve verification the agency is truly and actively enforcing law. The following requirements are necessary for renderers who process or distribute the prohibited material:

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.

Environmental Impact
The prohibited material (from diseased or non-slaughtered animals) needs to be properly disposed of, there are certain environmental risks involved with the disposal of diseased and/or dead animal carcasses. However, as evidenced within this citizen petition, disposal of diseased or non-slaughtered animals is illegal within food or feed. Law or FDA's interpretation of law does not allow the use of prohibited material in food or animal food; an alternative use will need to be found. We are confident the agency can work with industry to properly and legally dispose of diseased and/or non-slaughtered animal carcasses to resolve any environmental concerns.

Certification
The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Susan Thixton
(digital signature)

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