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On behalf of pet food consumers, the following is submitted as clear evidence FDA/CVM is in violation of a Supreme Court ruling to government agency interpretation of law. We request your immediate investigation.

Supreme Court Justice J. Stevens provided the following opinion (Chevron U.S.A. v. Natural Resources Defense Council):

> "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.
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> "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.
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> "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;".

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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.

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.

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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.

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.

We believe FDA/CVM is in clear violation of the directives for government agencies to interpret law as outlined by the Supreme Court. As a result, pet food consumers all over the US are purchasing cat and dog foods that are a direct violation of federal law. Pet food consumers are being misled and their pets are at risk. The only resolve is immediately revoking CPG 675.400 and CPG 690.300, modifying associated pet food/animal feed ingredients and actively prohibit diseased and non-slaughtered animal material ingredients as law requires.

On behalf of pet food consumers,

Susan Thixton

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Association for Truth in Pet Food