ATPF
advocating for pet food consumers.

June 17, 2019
Petition for Reconsideration
Docket ID: FDA-2016-P-3578

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drugs in Docket ID: FDA-2016-P-3578. Note the delay in this request for reconsideration is due to the Agency agreeing to mediation on May 20th, 2019 (via Neil Kaufman HHS/DAB requested by Association for Truth in Pet Food on May 1, 2019) and then the Agency canceling opportunity for mediation 20 days later on June 10, 2019.

A. Decision involved

We the undersigned, on behalf of pet food consumers, ask the FDA to reconsider its decision in full to subject Citizen Petition and Addendum Docket ID: FDA-2016-P-3578– denying our request for the proper enforcement of federal law in pet food and our request based on federal law definitions and standards for food to properly label pet products with a feed/food standard of identity for promoting honesty and fair dealing in the interest of pet food consumers.

B. Action requested

1. We ask the Agency to 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. We ask the Agency to use their 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. We ask the Agency to 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.
4. We ask the Agency to provide pet owners pet product standard of identity of 'pet feed' or 'pet food'. Pet products that meet the requirements of "Human Grade" would be termed "Pet Food" (Example: cat food, dog food). Pet products that do not meet the full requirement of Human Grade would be termed "Pet Feed" (Example: cat feed, dog feed) with the option for verified exception of Dog Food/Cat Food Verified (human grade ingredients).

C. Statement of grounds

FDA response to Citizen Petition provided details to the Agency withdrawing multiple Compliance Policy Guides, while still allowing diseased animals and animals that have died otherwise than by slaughter into pet foods/animal feeds with no warning or disclosure to the consumer. FDA stated "*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*." As representative of pet owners who are unknowingly purchasing products that could contain adulterated ingredients, it is our belief the Agency removed the subject CPGs to remove any public evidence the Agency itself is the sole responsible party that facilitates a means for industry to profit from the sale of adulterated pet food/animal feed in interstate commerce. By withdrawing the actual Compliance Policies, FDA has removed public record of what the Agency allows into pet food/animal feed. By removing public record, but not revoking the FDA's allowed use of adulterated ingredients in pet food/animal feed – the Agency has made a bad situation worse facilitating a larger cloak of secrecy over what is in many pet food/animal feed products preventing pet owners from making informed decisions.

Discussed in depth below, the Agency puts blame on us (representatives of consumers) for not providing evidence that consumers believe pet food is similar to human food. We challenge the Agency, 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 labels with

their true identity such as "*diseased chicken*" or "*condemned beef*"? We argue that we both (FDA and Association for Truth in Pet Food) know why these ingredients are used under the FDA facilitated cloak of secrecy; "d*iseased chicken*" or "*condemned beef*" on a label would not sell pet food. By allowing these ingredients not labeled with their true identity (example 'diseased chicken' or 'condemned beef'), the Agency is enabling pet food to be an illegal waste disposal system unbeknownst to the individuals purchasing these products (pet owners).

FDA response to subject Citizen Petition stated *"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…"* We argue the FDA has not adequately considered that the Agency's '*belief*' is very different than scientific fact and law.

As grounds, subject Citizen Petition evidenced FDA's belief that diseased animals or animals that have died otherwise than by slaughter in pet food/animal feed poses no safety concern is founded with no scientific evidence. We remind the Agency in 2016 we filed a Freedom of Information Act request (Control Number: 2016-4226) with FDA asking for "*the CVM 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*." FDA response to FOIA: "*After searching our files, we did not find the requested records*." The FDA provided no scientific evidence in FOIA request.

Significantly, in FDA response to Citizen Petition and Addendum the Agency repeatedly discussed their '*belief*' subject pet food/animal feed material is safe, but **the Agency failed to provide any scientific evidence to support the Agency's belief**. In a recent FDA Voices post published on the FDA website, the Agency stated: "*Science forms the basis for decisions at the U.S. Food and Drug Administration (FDA) and is paramount when it comes to making decisions that will impact the health and safety of the American public. We apply this rigorous, science-based approach to matters large and small that come before the Agency*…" Contrary to what FDA tells the public, science has not been "*paramount when it comes to making decisions*" about what the Agency allows in pet food. There has been no "*rigorous, science-based approach*" used to validate the safety of diseased animal material and material from animals that have died otherwise than by slaughter FDA allows into pet food with no warning/disclosure to the pet owner. With no evidence to validate this adulterated material is truly safe, FDA's '*belief*' is anecdotal at best. Therefore, until these ingredients are subject to rigorous, science-based safety testing and all risks are known and provided to the public, the ingredients must be promptly removed from the marketplace.

The Agency repeatedly stated in the response to Citizen Petition that these illegal ingredients pose no safety concern as long as hazards are controlled. We argue that:

1. FDA has not clearly defined **all** hazards associated with diseased animal material or material from animals that have died otherwise than by slaughter. The only risk (outside of some pathogenic bacteria) acknowledged by the Agency is pentobarbital, and this risk was only acknowledged **after** multiple pentobarbital pet food recalls occurred – after pets died. It must be noted that these recalls were not discovered by regulatory or industry monitoring/testing of pet food for hazards. The Evanger's pentobarbital discovery was initiated by a pet owner after a pet death and the Big Heart Brands pentobarbital discovery was initiated by television station WJLA. This should be sufficient evidence in itself that the Agency has not considered all potential hazards linked to these adulterated ingredients.
2. FDA does not have the expertise required to properly evaluate the risk of this material as these materials/ingredients are actually within the jurisdiction of USDA, not FDA. Using one example the FDA does not acknowledge that the USDA openly acknowledges is the risk of endotoxins directly linked to these types of ingredients in pet food. The USDA states: "*The cooking step of the rendering process kills most bacteria, but does not eliminate endotoxins produced by some bacteria during the decay of carcass tissue. These toxins can cause disease, and pet food manufacturers do not test their products for endotoxins."*

We argue that FDA's response to our Citizen Petition has not properly considered they are not the regulatory authority with sufficient expertise to determine risk of condemned ingredients the Agency allows into pet food, thus the Agency could not/does not fully understand the risks involved or chooses to minimize known risks.

1. We provided the Agency a wealth of scientific evidence proving these allowed illegal materials are dangerous in a phone conference meeting with the Agency in October 2016. Dr. Anthony Hepton PhD provided FDA with a multitude of scientific resources linking the risk of endotoxins to animal illness. Despite the scientific evidence provided, FDA's most significant concern in this meeting was disposing of this material in landfills; an attitude that would have been expected from the EPA, not the FDA. (This meeting was recorded without disclosure to FDA per my rights as a Florida resident to record a government authority and we hold that recording as evidence

of FDA's lack of concern to the scientific evidence provided.) This meeting validates our argument FDA is not equipped to determine the risk of allowed adulterated ingredients in pet food/animal feed, and we argue the ingredients should be immediately removed from the marketplace until the proper authority determines if they are safe for pets/animals to consume.

2. In March of 2018 we alerted FDA to multiple tularemia diagnosed pet food manufacturing (former) employees confirmed to these individuals by Centers for Disease Control (CDC) to have been exposed to the tularemia bacteria at the pet food plant. We alerted FDA the CDC also confirmed direct exposure of tularemia from the pet food ingredient Meat and Bone Meal (a rendered ingredient often sourced from diseased animals and animals that have died otherwise than by slaughter). Confirmed cases of tularemia exposure directly linked to subject pet food ingredients (per CDC) validates our argument FDA is not equipped to determine or is incapable to understand the significant risks surrounding subject adulterated ingredients in pet food. We argue the ingredients should be immediately removed from the marketplace until the proper authority determines if they are safe for pets to consume and safe for consumers to bring into their homes.

Most significant of all, as expressed in our Citizen petition, the Federal Food, Drug, and Cosmetic Act **does not** – under any circumstances of further processing – allow a diseased animal or animal that has died otherwise than by slaughter into food. While the FDA does allow this material in pet food/animal feed based on unscientific belief, it remains fact that federal law does not.

> Chapter 9 – Federal Food Drug and Cosmetic Act – Subchapter II – Definitions; generally
> "*(f) 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.*"
>
> Chapter 9 – Federal Food Drug and Cosmetic Act – Subchapter IV – Food
> Section 342. Adulterated food
> "*(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;*"

FDA response stated "*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*." While it could be true the Agency had no evidence of a disease or other illness resulting from properly rendered or canned tissues from diseased animals or animals that died otherwise than by slaughter at the time the CPGs were originally released, the Agency has received more than sufficient evidence since.

1. Pet deaths and illnesses linked to Evanger's Pet Food pentobarbital recalls
2. Pet deaths and illnesses linked to Big Heart Brands Pet Food pentobarbital recalls
3. Human tularemia illnesses, confirmed by CDC linked to rendered pet food ingredients, exposure at pet food manufacturing plant

FDA response stated "*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*." We argue the ongoing "*safety problems*" of "*pentobarbital*" are a direct result of the Agency choosing enforcement discretion allowing the use of diseased animals and animals that have died otherwise than by slaughter into pet food/animal feed. This FDA statement is – in essence – acknowledgement that the allowed adulterated ingredients are indeed a safety problem.

FDA response stated "*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*." In a complete search of 21 CFR part 507, there is no mention of "*tissues from animals that have died otherwise than by slaughter*".

FDA response stated "*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*." FDA response suggests we read 21 CFR 507.33 and 507.34. We argue:

1. Part 507 Subpart C Section 507.33 Hazard analysis (b) states (bold added for emphasis): "*The hazard identification must consider: (1)(ii) Chemical hazards, including radiological hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, **decomposition**, unapproved food or color additives, and nutrient deficiencies or toxicities (such as inadequate thiamine in cat food, excessive vitamin D in dog food, and excessive copper in food for sheep)".* We argue, "*decomposition*" is an unavoidable hazard of "*animals that have died otherwise than by slaughter*". Because decomposition is an unavoidable hazard of animals that have died otherwise than by slaughter, the material must promptly be removed from the marketplace.

2. Part 507 Subpart C Section 507.34 Preventive controls states (bold added for emphasis): "*(a)(1) You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by your facility **will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act***."
   We remind FDA of the exact language of section 402 of the Federal Food, Drug and Cosmetic Act; quoting section 402 (a) (3) and (5):
   "*(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (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;*".
   Part 507 Section 507.34 clearly and concisely states "***will not be** adulterated under section 402*". Therefore, on the basis of violation of the FD&C Act and FSMA, the Agency should promptly forbid the use diseased animals and animals that have died otherwise than by slaughter as pet food/animal feed ingredients.

FDA response to subject Citizen Petition stated "*FDA will take action against animal food products when necessary to protect human and animal health*." We argue that "*when necessary*" historically has been after pets have died and deaths were reported to the Agency. We argue a "w*hen necessary*" approach to regulation is a haphazard method of protecting human and animal health.

FDA response continued "*However, as long as hazards are controlled, 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*." As stated previously, FDA has not clearly defined all "*hazards*" linked to diseased animals and animals that have died otherwise than by slaughter in pet food and is perhaps unequipped to determine such hazards.

We challenge FDA's statement "*as long as hazards are controlled, and the animal food is not otherwise adulterated…*". As evidenced by pentobarbital and tularemia, all hazards associated with diseased animals in pet food or animals that have died otherwise than by slaughter in pet food have not been clearly defined by FDA. The Agency is expecting industry to predict the future with potential hazards linked to adulterated ingredients at the expense of pet and potentially human health. Responsibility to fully disclose any and all potential hazards linked to federal law defined adulterated pet food/animal feed ingredients allowed by FDA - falls solely on FDA's shoulders. The Agency has not provided industry or consumers this information, therefore until all potential hazards are clearly and concisely defined – all risk cannot be avoided. Until all risk can be avoided, pet food ingredients sourced from diseased animals and animals that have died otherwise than by slaughter must be removed from the marketplace.

FDA response stated: "*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*." FDA response defers responsibility of pet food/animal feed ingredient definitions to AAFCO, however the MOU agreement proves the Agency is fully empowered to require ingredient modifications. Quoting "*Agreement*" item "*B*": "*Requests for new feed ingredients or requests to modify an existing feed ingredient definition are reviewed by AAFCO investigators chosen by the AAFCO Board and FDA scientists assigned by the Agency's division director or team leader in the Division of Animal Feeds (DAF)*." Quoting item "*G*": "*Disagreements on existing feed ingredient definitions, the establishment of new ingredient definitions, or modifications of existing definitions*

between the FDA and AAFCO will be referred to a review board."

FDA admits in this statement it has the "ability" to enforce law; "*Nonetheless, FDA has the ability to take action under any applicable provisions of the FD&C Act, including section 402 (a)(5)…*" But in another statement the Agency states it chooses to focus resources elsewhere; "*will continue to focus resources on new and established programs to regulate animal food*." By stating the Agency "*has the ability*" but ultimately *chooses* not to enforce law, the Agency is admitting they are choosing to allow the pet food industry to profit from the sale of adulterated products sold in interstate commerce without notifying the public.

We argue the Supreme Court ruled that federal agencies cannot interpret law that is manifestly contrary to statute. The FDA allowance of diseased animal material and material from animals that have died otherwise than by slaughter is directly opposite – word for word – of federal law. There is no grey area with consideration of diseased or non-slaughtered animal material in any food within law; a food that contains 'in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter' is adulterated. The material itself is adulterated no matter what further processing is used.

FDA response stated: "*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.*". With certainty, we did provide FDA with that evidence.

The addendum submitted to Citizen Petition was at the request of FDA - Dr. Dan McChesney - during a meeting with the Agency in Rockville, MD. At no point during this meeting did FDA request us/require us to provide "*evidence that human consumers believe that all pet food is equivalent to human food*" with the addendum. However, example of this consumer perception was evidenced to FDA during the meeting through the participation of pet owner Nikki Mael via phone. In fact, because this pet owner repeatedly stated she could not understand how her situation could have happened, that she never would have believed a pet 'food' could contain a euthanized animal during this meeting, Dr. McChesney lost his patience with the pet owner and raised his voice asking "*What do you want from us?*". Dr. McChesney's loss of patience with the pet owner is evidence the Agency is fully aware many consumers believe that pet food is equivalent to human food. In fact, Dr. McChesney's loss of patience could be interpreted that this consumer perception of pet 'food' is something the Agency doesn't want to accept/acknowledge.

The FDA did not take into consideration in their response to Citizen Petition and Addendum the 56,163 signatures and comments in favor of a food/feed standard of identity (the Addendum) we provided the Agency in August of 2017 at the AAFCO meeting. These signatures and comments specific to the Addendum were hand delivered to FDA by myself (Susan Thixton) personally via a flash drive. Just a few of the consumer comments in support of a feed/food standard of identity we provided to FDA in 2017 are quoted below (note: these are exact quotes from pet owner comments specific to the Addendum):

- *Because it shouldn't be a question, secret or guess as to what goes into our pets food or how it is made.*
- *My dogs and Cats are family members. It sickens me that I may be feeding them 4D meat unfit for consumption by anything. The FDA needs to step up and stop the practice of pet food companies buying this poison to use in pet food. To most of us our pets are our adopted children. You wouldn't feed this poison to your human children. Why should we feed it to ours.*
- *My dogs and cats are my family. I don't want my family to be fed poison and or garbage. It makes me sad that this even has to be a concern.*
- *I want to know that my pet's are eating food and not feed, so that they remain healthy.*
- *Food is vital to life. I'm disgusted to read of the abuses the FDA regularly turns a blind eye to.*
- *Our pets deserve safe pet food. Tricking owners as to what they are buying is unjust. The pain that pets and their owners go through from contaminated and poor quality food is nothing less than cruel. It is the governments responsibility to enforce the laws and protect its citizens.*
- *Pet owners deserve truth in labeling and claims regarding all feed products.*
- *What's in our animal's food!?!? When buying any product we have a right to know what our dollars are supporting.*
- *Pet food companies should not be allowed to force garbage on consumers and call it 'food'.*

- *I should have the right to know what I'm putting in my dog's stomach and the PFI doesn't like to be transparent about what's in the food. As a consumer, I have a right to know whether I'm poisoning my dog with illegal ingredients.*
- *Without passing this standard, AAFCO will be sanctioning the rampant mislabeling and false advertising in the industry. It is distressing to see AAFCO and FDA abetting this corruption.*
- *Wow, what a tricky thing to do to people and the dogs they love! Make it clear which it is, feed or food!*
- *You need to be told exactly what is in your pets food so that you can make an informed choice. You should eat what you pass off as 'food'.*

The full 56,163 signatures and comments from pet owners in favor of the Addendum must be considered by the Agency.

Further, the FDA took no consideration in their response to Citizen Petition to the comment received directly on Regulations.gov website from a pet owner that was in full support of our Petition. FDA did not provide any acknowledgement or response to this pet owner comment in their response. Shockingly, the pet owner comment has since been removed from Regulations.gov "*at the request of the Food and Drug Administration*".

FDA response to Citizen Petition stated "*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*." We argue "*new evidence*" was not requested or needed as we have presented this serious concern in pet food for years to the Agency. We argue that FDA actually is now or should be fully aware that many/most human consumers believe that pet food is equivalent to human food. We argue that FDA has not adequately considered years of concerns of pet owners including misleading pet food labels exampled below that we have previously submitted/discussed with the Agency the Citizen Petition and Addendum are based on:

We have challenged the Agency continuously over the years asking how it can be allowed that any one of the above exampled products labeled with human food images could contain a diseased animal or an animal that has died otherwise than by slaughter with no warning or disclosure for the pet owner. Evidence the Agency is fully aware of consumer perception of pet 'food'.

We argue the FDA did not consider in your response to our Citizen Petition historical evidence known by the Agency about consumer perception of pet 'food'. In 2014, at an AAFCO meeting in Sacramento, CA, the FDA (Dr. Daniel McChesney and Dr. William Burkholder) met with consumer representatives. During this meeting the same argument of misleading labels was shared with FDA. The Agency argued that pet owners are not being misled. Witnessed by all in attendance (including FDA), I (Susan Thixton) personally stepped to the hotel front desk and asked for a couple of employees (two) that owned pets to follow me to our FDA meeting table (in the lobby). With no advance warning, these pet owning hotel employees were asked if they believe that a picture of roasted chicken displayed on the label implied the pet food contained roasted chicken. Both stated "*yes*". They were also asked how they would feel if they learned the pet food contained diseased chicken instead of what was displayed on the pet food label; one did not respond, the other stated "*I'd be mad*".

We argue the FDA did not consider in its response to our Citizen Petition historical evidence known by the Agency about consumer perception of pet 'food'. In 2015, at an AAFCO meeting in Denver, CO, the FDA (Dr. Daniel McChesney and Dr. William Burkholder) met with consumer representatives. During this meeting the Agency was again questioned about misleading images on pet food labels – specifically the images of human food on feed grade products. The FDA stated during this meeting the images of human food on feed grade pet products were considered "*freedom of expression*".

In the same meeting as above, witnessed by all consumer representatives in attendance, an FDA employee was asked: "*What do you feed your pets?*" While he did not disclose a brand name, he joked that "*I have access to inside information. I know what to buy*."

We do not believe the Agency has fully considered the fact many feed grade pet foods are sold in grocery stores - the exact location they purchase 'food'. This in itself is evidence that not only do most pet owners believe pet food is equivalent to human food, this concept is validated each time they go into a grocery. Other feed products, such as chicken feed/cattle feed (which are properly labeled with the standard of identity of feed), are NOT sold in human food stores.

Thus, we find it unacceptable for FDA to assert that much of the pet owning public <u>does not</u> "believe *that all pet food is equivalent to human food".* The Agency is fully aware of consumer beliefs – or it certainly should be. We argue our request for a feed/food standard of identity to promote honesty and fair dealing in the interest of consumers has been soundly proven as necessary.

We stated as grounds in our addendum to Citizen Petition "*Feed grade pet food/treat ingredients are "common" ingredients within the industry, however no disclosure to the consumer is provided on product labels or websites or marketing material. These pet products are marketed to consumers as food, including feed grade products that contain diseased or non-slaughtered animal material (adulterated per the FD&C Act)*." On the FDA webpage Pet Food Labels – General, it states "*Ingredients must be listed by their "common or usual" name*." In no uncertain terms, diseased animals or animals that have died otherwise than by slaughter pet food/animal feed ingredients are a standard of identity VERY different than the common or usual ingredient name. This further validates a need for a feed/food standard of identity in pet food/animal feed to promote honesty and fair dealing in the interest of consumers.

We again remind the Agency of a previously stated argument we feel the Agency did not consider in their response: 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*"? Why are the true common names of these ingredients hidden from consumers? The 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. And this proves that a uniform standard of identity is necessary to promote honesty and fair dealing in the interest of consumers.

FDA states in their response to subject Citizen Petition "*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*." We agree the Agency is "*authorized to pursue remedies*", we find however that the Agency has not taken any such action in regards to misleading pet food labels even though we have alerted the Agency to misbranded foods many times over many years. The marketplace is flooded with "*misbranded food*" - pet feed products that could contain diseased or non-slaughtered animal material labeled with images of human food.

We argue 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. However, that is not the case as we have evidenced in this response and over years of discussion with the Agency. We argue a standard of identity – Dog Feed or Cat Feed – would indeed provide pet owners with a more honestly labeled product. Dog Feed or Cat Feed is an accurate standard of identity that alerts the consumer this is not a 'food' product, does not abide by 'food' regulation.

FDA stated in their response to subject Citizen Petition, "*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. 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*."

We remind FDA that the human grade claim on pet food labels was initially standardized and verified by FDA, not the states. Only after several years of FDA verification of the claim did the Agency release the responsibility to the states. And contrary to FDA's statement the standard of identity of dog feed/cat feed "*would not offer any additional assurance that a given pet food product is accurately labeled*", human grade labeled products validate that standard of identity is an effective means to communicate truthful labels to consumers. Human grade products are thoroughly verified and actually THE most accurately labeled pet food product on the market. The very same assurance could and would be provided to pet owners with a standard of identity of dog feed, cat feed, dog food and cat food.

FDA response stated "*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*." We established in this Petition for Reconsideration that FDA has not fully focused on protecting animal and human health as the Agency has not provided any scientific evidence to the safety of the allowed (but illegal/adulterated) feed ingredients and FDA has not provided industry or consumers with a comprehensive list of risks/hazards associated with these allowed (but illegal/adulterated) feed ingredients. We established in this Petition for Reconsideration that consumers are being misled by the lack of any current standard of identity with pet food/pet feed. We argue that the Agency must provide consumers with a feed/food standard of identity in part due to the fact that the Agency has not properly educated the consumer to the risks associated with feed grade ingredients, as apparently the risks are unknown to the Agency, perhaps outside of the

Agency's ability to determine risk. Until a comprehensive list of risks/hazards associated with the allowed (but illegal/adulterated) feed ingredients are established, shared with industry to enable manufacturers the ability to establish risk preventative controls, and shared with the pet owning public, the Agency must promptly establish a feed/food standard of identity to promote honesty and fair dealing in the interest of consumers.

On behalf of pet food consumer members of Association for Truth in Pet Food,

Susan Thixton

(Digital Signature)

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