



(Sent 4/5/2016 via. E-mail with hardcopy to follow in the mail or overnight delivery)

April 5, 2016

Robin M. Rivers
Compliance Officer
U.S. Food and Drug Administration
U.S. Customhouse, Room 900
2nd & Chestnut Street
Philadelphia, PA 19106

Anne E. Johnson
Acting District Director-Philadelphia District Office
U.S. Food and Drug Administration
U.S. Customhouse, Room 900
2nd & Chestnut Street
Philadelphia, PA 19106

Re: Supplemental Letter to Response to WARNING LETTER of Lystn's Complaint in the FDA's Handling of Investigation

Dear Ms. Rivers and Ms. Johnson:

This letter is intended to supplement our responses to the March 17, 2016 WARNING LETTER in an attempt to share with the FDA our ongoing complaint and position as to how the FDA has handled the investigation into Lystn's products and operations. We offer this letter for all parties to reflect upon actions taken to date, and assist the FDA in its decision if to terminate its present case with Lystn, LLC.

Lystn wishes to first reiterate what we communicated to the FDA in our first written response to the FDA back on September 28, 2015:

Lystn is a small, but competent family business and we would take immediate action on our own if we believed or have been provided any evidence that any of our products presented a potential health risk to humans or their pets. We are one of the few (if not the only) raw pet food manufacturers whose Quality Control (QC) representative (as well as company owner) has a Masters' Degree in Food and Dairy Science and came out of the food consulting industry. Our other owner/management personnel also has significant experience in the science of microbiology. One of our recognized tag lines on our new product packaging is that we are "Integrating Raw Feeding & Science". We are not obstinate and do not wish to be combative with any state or federal regulatory agency. In fact, we invite such agencies to join us in researching and pursuing what innovative processes will improve food safety that may benefit various food related industries. We would be glad to further discuss with the FDA what future opportunities may exist to work together.

From actions of the FDA over the past 7 months, Lystn's frustration with the FDA has grown due to the following events.

The FDA's Ongoing Efforts to Link Lystn, LLC to some type of Federal Law Violation

- ***As a result of Lystn questioning the FDA because of test result inconsistencies, Lystn raising concerns whether our actual product was being handled correctly and our questioning if the product being discussed is indeed a product of Lystn, the FDA would not address our concerns or correct the inconsistent reported test results but rather pursued continuing to test some of our other products in an effort to deflect the errors of the FDA making multiple attempts to find another alleged violation that might favor the FDA's position (essentially a "do over"). (See September 28, 2015 Lystn letter to Sean Duke)***
- ***When Lystn requested a proof of chain of custody for the samples tested by the FDA because of inconsistent and conflicting results, the FDA not only would not provide such proof but rather alleged our eggs were from a questionable source in Iowa. Lystn does not buy its eggs from [REDACTED] Dairy in Iowa. Again we questioned if this was our product. (See September 28, 2015 Lystn letter to Sean Duke)***

- ***Even after exhaustive steps by Lystn proving our product fits into the exemption of not being considered Adulterated (including quantifying the Salmonella through our quantitative tests using XLT4 agar), the FDA indicated it was the policy of zero tolerance of Salmonella (essentially regardless of what the federal law states). When we expressed our disagreement and that we were having difficulty understanding why the FDA was insisting Lystn "mitigate" a risk, when we received no reports of illness or problems and our tests support that outcome (no basis for illness or problems to exist), the FDA ignored the law and arbitrarily with no scientific evidence elevated the findings of their investigation from a potential health risk to the level of being a "public health risk".***
- To date, we have never seen any paperwork, test results, or criteria required to be met by the FDA to unequivocally determine this matter as a concluded health risk nor a conclusion that our products present any wider public health concern. ***The fact that the FDA has prolonged this matter for more than 7 months and that neither the FDA, any state agency or Lystn has received any type of report of illnesses in humans or pets, nor reports of disease or injuries, only supports our findings, and yet even in the WARNING LETTER the FDA continues to state such health risk claims*** knowing there has been no evidence presented to Lystn of whether any existing conditions involving Lystn and its products could contribute to a clinical situation that could expose humans or animals to a health hazard which is to be supported by scientific documentation and/or statements; no assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed; no assessment of the likelihood of occurrence of the hazard; no assessment of the consequences or occurrence of the hazard.
- The federal legislation indicates the conclusion by the FDA of a health hazard and risk be supported by an ad hoc committee of Food and Drug Administration Scientists including statements and/or scientific documentation. ***When we respectfully and repeatedly requested the FDA please provide the required paperwork and name and credentials of the individual(s) that have conducted and concluded the investigation of Lystn and its products as a public health risk, not only did the FDA not provide Lystn with the required information or findings as to this conclusion, other than an e-mail, claiming a health risk, but the FDA is now introducing new alleged violations with inaccurate information for which we have not previously received any written notification.***
- ***When Lystn attended a face-to-face meeting at the Philadelphia District 3 offices of the FDA on November 3, 2015 in an attempt to seek clarification and discuss and resolve differing views, our team of 4 owners and our attorney were confronted with 25 representatives of the FDA or parties working with the FDA (see attached participation list) who attempted to intimidate us into a recall. Again when Lystn questioned why the FDA was not following the above language and provisions in the federal law, all the representatives of the FDA were silent refusing to address our question until an FDA representative said our product was not in violation of the FD&C Act (21 U.S.C. 342 (a)(1)) but rather Lystn was in violation of item (4) addressing a product being prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. When Lystn responded that this was the first time we heard such a claim and was very concerned because we never received any such paperwork supporting such a claim, such as a 483 Report, and the fact that our pet food was produced at an USDA approved and inspected plant, after the FDA realized it could not support this claim, then another FDA representative claimed Lystn was in violation of using non-approved ingredients. Except for this brief comment, Lystn never received any paperwork making such claims until now, 7 months after the initial claims of the FDA. To compound this action, the FDA is now indicating Lystn has never expressed the intended corrective action for this alleged violation when Lystn never received any paperwork on such a claim until the March 17, 2016 WARNING LETTER.***
- Regardless of our continued position that Lystn's pet food was not adulterated under the language of federal law, Lystn agreed that it would issue language addressing a recall based on negotiated language agreed upon by the FDA, ***when it came time to include the previously agreed upon negotiated language of a recall, the FDA reneged on the agreement with Lystn to allow the statement: "Lystn's decision to implement this recall should not be construed as an admission that its sale of these products was in violation of law and Lystn has undertaken this voluntary recall solely out of an abundance of caution and in deference to the FDA's stated concerns."***

April 5, 2016 Supplemental Letter of Lystn's Complaint in the FDA's Handling of Investigation

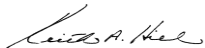
- Because of the FDA's intentional default in their agreement with Lystn and not knowing if the FDA intended to follow-up with a response to the interpretations and positions raised by Lystn to the FDA in our November 17, 2015 letter, at that time Lystn reported it was suspending our intention to initiate a Firm-initiated recall until the FDA responds in writing. ***Rather than the FDA addressing our concerns, the FDA now issued the subject WARNING LETTER containing more inaccurate statements and additional alleged violations.***
- ***While the FDA is trying to raise question on known healthy ingredients used by a small up and coming raw pet food company such as Lystn to protect pet food and the public, the FDA looks the other way on large pet food companies (represented by powerful trade associations) with significant egregious misbranding*** by having millions of tons of pet food on the market claiming use of "meat and bone meal", "soybean meal", "chicken-by-product meal" and much more. ***In addition, the FDA and State Departments of Agriculture overlook serious violations of law such as non-slaughtered/4-D animal ingredients in pet food.*** (See attached Publications).

While certainly the FDA has broad powers and authority, thankfully the United States constitution also provides recourse for U.S. citizens. Whether intended or not, from our perspective this concerted effort and continued pursuit by the FDA is an example of a federal government agency unfairly profiling and targeting groups that disagree with the philosophical position of an enforcement agency. It is assumed if the FDA believes a Lystn product warrants seizure or our operations warrant pursuing an injunction, then as previously and repeatedly stated Lystn requests such notification to consider appropriate action including seeking due process assured under federal law and the United States Constitution. Lystn will first attempt to resolve the matter with the FDA, but reserves any and all of its legal rights including to seek remedy for loss of monetary revenues, defamation of reputation and character damages, remedies for anti-trust violations by the government, class action suit and to seek criminal and abuse of power charges filed against individuals knowingly advancing such false statements, as well as petitioning the members of the Congress, testifying at congressional hearings, and filing a grievance with the U.S. Department of Justice. This is not in any way intended to be threatening, but rather Lystn is stating its intended position in response to the FDA's continual harassment and threatened regulatory actions.

Lystn was willing to conduct a firm initiated recall and submitted all the required paperwork until suspending our intention to initiate a Firm-initiated recall because of the FDA's renegeing on the agreed upon language of the recall, as well as not knowing if the FDA intended to follow-up with a response to the interpretations and positions raised by Lystn in our November 17, 2015 letter. Lystn indicated the suspension of the Firm-initiated recall was in-place until the FDA responded in writing to our questions and concerns outlined in the previous correspondence including the November 20, 2015 letter to the FDA. To date, the FDA is unwilling to address our concerns and supply the supporting documentation requested and required under federal law.

Lystn is willing to continue to discuss and address any recommendations from the FDA that will improve our products and manufacturing processes without compromising our principals to satisfactorily resolve all concerns. Please feel free to contact me for further discussion, questions or concerns. Thank you for your time and consideration.

Sincerely,
Lystn, LLC



Keith A. Hill
President

Attachments: Attachment: FDA Representatives and Others that Participated in November 3, 2015 Meeting
Truth about Pet Food.com Articles - Get Out of Enforcement, Free 3/23/2016
- FDA, It's Wrong! 3/10/2016
- The Most Absurd 3/11/2016
- It's So Bad, All We Can do Now is Warn 2/22/2016
- The Truth about Why Dead/Diseased Animals goes to Pet Food 3/25/2016

Lystn, LLC
356 Maiden Creek Rd Fleetwood, PA 19522

**ATTACHMENT #2 - LIST OF ATTENDEES FOR THE REGULATORY
MEETING HELD ON NOVEMBER 3, 2015**

Colorado Department of Agriculture, Feed and Meat Program Representatives

Mr. Scott Ziehr, Program Administrator

Pennsylvania Department of Agriculture Agronomics & Regional Service Representatives

Ms. Erin Bunn, Chief

Office of Chief Counsel

Sonia W. Nath, Associate Chief Counsel for Enforcement

Center for Veterinary Medicine, Division of Animal Feed Representatives

Ms. Linda A. Benjamin, Supervisory Chemist
Dr. Xin Li, Microbiologist
Mr. Randall A. Lovell, Veterinary Medical Officer
Ms. Sharon A. Benz, Supervisory Animal Scientist
Mr. David B. Edwards, Supervisory Animal Scientist

Center for Veterinary Medicine, Division of Compliance

Mr. Eric Nelson, Director
Ms. April Y. Hodges, Supervisory Consumer Safety Officer
Ms. Darlene L. Krieger, Consumer Safety Officer

Denver District Office Representatives

Mr. Thomas R. Berry, Supervisory Consumer Safety Officer
Ms. Kathryn M. Mogen, Consumer Safety Officer (Emergency Response Coordinator)
Ms. Kristen E. Szenderski, Consumer Safety Officer
Mr. Nathan R. Moon, Consumer Safety Officer (State Liason)

Philadelphia District Office Representatives

Mrs. Anne E. Johnson, Acting District Director
Mr. Michael D. O'Meara, Supervisory Consumer Safety Officer, Wilmington Resident Post
Mr. Sean D. Duke, Consumer Safety Officer, Wilmington Resident Post
Mrs. Ann Marie Karnick, Supervisory Consumer Safety Officer, Wilkes Barre Resident Post
Ms. Cara M. Minelli, Consumer Safety Officer, Wilkes Barre Resident Post
Ms. Judith A. Paterson, Consumer Safety Officer, Emergency Response Coordinator
Mrs. Rochelle L. Cross, Acting Recall and Emergency Coordinator
Mr. Steven L. Carter, Director Compliance Branch
Mr. Joseph A. Morkunas, Compliance Officer
Ms. Robin M. Rivers, Compliance Officer



Truth about Pet Food

Recalls

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Dr. Michael W. Fox

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Breaking News

Fromm Dog Food Recall

Purina Wet Dog Food 10-oz. Tub Voluntary Recall

Home » Pet Food Regulations » Get Out of Enforcement, Free

Get Out of Enforcement, Free

March 23, 2016 Pet Food Regulations 12 Comments 1,517 Views

Are some of the biggest manufacturers of pet food given a ‘get out of enforcement free’ card from regulatory authorities? Here are some flagrant pet food label violations that have gone unnoticed by regulatory authorities.

Pet food regulation states: “A vignette, graphic, or pictorial representation of a pet food or specialty pet food label shall not misrepresent the contents of the package.” (source: AAFCO Official Publication 2016 PF2.c)

Many pet food manufacturers pay no attention to the above regulation...mostly because they don’t have to. FDA and State Department of Agriculture (each of the 50 states!) don’t bother enforcing this law (and several others). Below are some flagrant violations of pet food labeling laws...

Pedigree Adult Complete Nutrition Chicken Flavor

Ingredients of this pet food (in bold are the animal protein ingredients): Ground Whole Grain Corn, **Meat and Bone Meal** (Source of Calcium), Corn Gluten Meal, **Animal Fat** (Source of Omega 6 [Preserved with BHA & Citric Acid]), Soybean Meal, Natural Flavor (Source of Meatier Flavor), **Chicken By-Product Meal**, Dried Plain Beet Pulp, Ground Whole Grain Wheat, Salt, Brewers Rice, Potassium Chloride, Dried Peas...

This pet food has no ‘meat’ ingredient – it only contains ‘meat meal’ ingredients (**Meat and Bone Meal** and **Chicken By-Product Meal**).



Meat and Bone Meal looks like this:



Chicken By-Product Meal looks like this:

But...the Pedigree Label shows roasted chicken on the label – when nothing inside that bag of pet food looks even close to roasted chicken. ‘Get out of enforcement, free’.

Mars Petcare Pedigree
tells consumers this is in
the dog food...



Law

"A vignette, graphic, or pictorial representation of a pet food label shall not misrepresent the contents of the package." (source: AAFCO Official Publication 2016 PF2.c)



Do regulatory authorities give Pedigree a...

Chance
of FDA or State Department of Agriculture enforcing law

**Get Out
Of Enforcement, Free**

This card can be reused...for multiple violations
© TruthaboutPetFood.com

But what's really in **Pedigree**
is this...

Meat and Bone
Meal

Chicken By-Product
Meal

Pedigree has 11 different varieties of dry dog food, none of which contain a meat ingredient – however all have been allowed to display a meat ingredient on the label.

Another example – Purina’s Friskies 7 Cat Food

Purina Friskies
tells consumers this is in
the cat food...



Law

"A vignette, graphic, or pictorial representation of a pet food label shall not misrepresent the contents of the package." (source: AAFCO Official Publication 2016 PF2.c)



Do regulatory authorities give Friskies a...

Chance
of FDA or State Department of Agriculture enforcing law

**Get Out
Of Enforcement, Free**

This card can be reused...for multiple violations
© TruthaboutPetFood.com

But what's really in **Friskies**
is this...

Meat and
Bone Meal

Chicken
By-Product
Meal

Fish Meal

And Big Heart Brands Kibbles 'n Bits...

Big Heart Kibbles n'Bits tells consumers this is in the dog food...

Law
"A vignette, graphic, or pictorial representation of a pet food label shall not misrepresent the contents of the package." (source: AAFCO Official Publication 2016 PF2.c)

Do regulatory authorities give Kibbles n'Bits a...

Chance
of FDA or State Department of Agriculture receiving law

Get Out Of Enforcement. Free

This card can be reused...for multiple violations
© EntrepreneurialFood.com

But what's really in Kibbles n'Bits is this...

Meat and Bone Meal

Animal Digest

These three pet food manufacturers are some of the largest, most powerful pet food manufacturers on the planet. They also have powerful trade associations working for them (Pet Food Institute, American Feed Industry Association, National Renderers Association).

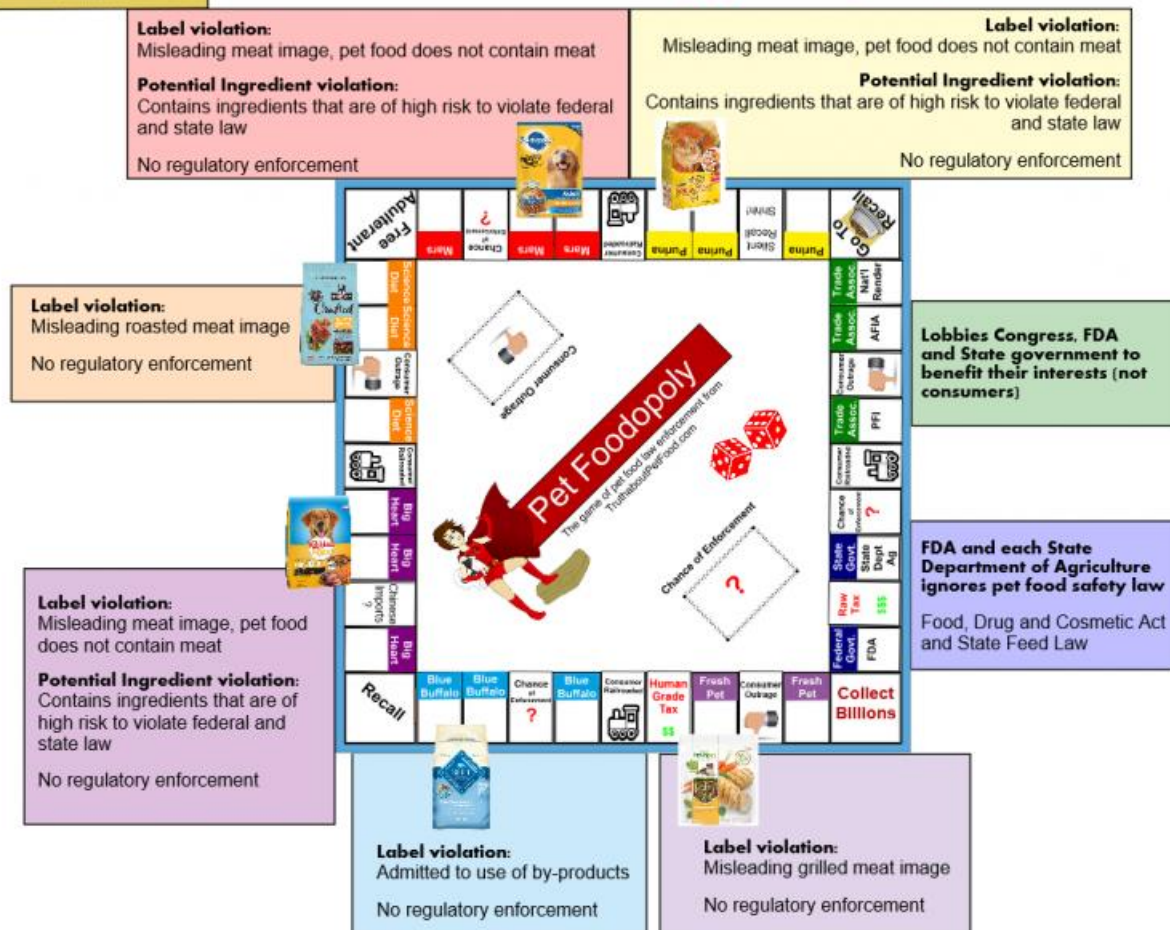
Is it simply oversight that the FDA and 50 different State Department of Agriculture offices happened to overlook these serious misleading label violations? And is it oversight that FDA and 50 different State Department of Agriculture offices overlook serious violations of law such as non-slaughtered/4-D animal ingredients into pet food?

Or do regulatory authorities give some in pet food a 'Get Out of Enforcement, Free' card?



Because of FDA and State Dept of Agriculture the Largest Pet Food Manufacturers in the U.S. use their 'Get Out of Enforcement, Free' card (every day)

Consumers have to roll the dice buying safe/honestly labeled pet food



Wishing you and your pet(s) the best,

Susan Thixton

Pet Food Safety Advocate

Author Buyer Beware, Co-Author Dinner PAWSible

TruthaboutPetFood.com

Association for Truth in Pet Food

What's in Your Pet's Food?

Is your dog or cat eating risk ingredients? Chinese imports? Petsumer Report tells the 'rest of the story' on over 4000 cat foods, dog foods, and pet treats. 30 Day Satisfaction Guarantee. www.PetsumerReport.com



The 2016 List

Susan's List of trusted pet foods. [Click Here](#)



- Recalls
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- Pet Food Regulations
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- Pets
- Dr. Cathy Alinovi
- Dr. Michael W. Fox
- Kim Kalendar

FDA, It's Wrong!

March 10, 2016 Pet Food Regulations 12 Comments 2,487 Views

When you ask the tough questions to regulatory authorities...questions they don't want to answer...my experience has been they do one of two things: ignore your questions or give you a very lame excuse. Here's the latest lame excuse.

Federal and State law is crystal clear – a pet food is considered adulterated/illegal if it contains the tiniest portion of a non-slaughtered animal. But pet food regulatory authorities refuse to enforce law. Their lame excuse...there is no legal definition for what a slaughtered animal is.

Last week, AAFCO President and the AAFCO Animal Ingredients Investigator told consumer advocates they cannot enforce law because there is no legal definition to "slaughter". This week FDA told us a similar response.

My question sent to FDA...

The Federal Food Drug and Cosmetic Act – Title 21, Chapter 9, Subchapter IV, Section 342 (adulterated food) states "A food shall be deemed to be adulterated-

(a) Poisonous, insanitary, etc., ingredients

(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;"

So – my question is – what does 'otherwise than by slaughter' mean? How does FDA define 'otherwise than by slaughter' in regards to food? How does FDA determine a food would be adulterated due to containing an animal which has died otherwise than by slaughter? How does FDA define a slaughtered animal and how does FDA define an animal that has died otherwise than by slaughter?

FDA responded with...

The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that all animal foods, like human foods, be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled. Processed pet food goes through a kill step, such as rendering, which is designed to kill harmful bacteria. In addition, canned foods, whether intended for animals or humans, must be processed in conformance with the low acid canned food regulations to ensure the food is free of viable microorganisms.

Let me stop here with FDA's response. For the FDA to say that "all animal foods, like human foods, be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled" is very wrong. 'Animal foods' such as cattle feed are allowed to contain chicken poop. 'Animal foods' such as cat and dog food are allowed to contain 4D animals (dead, diseased, dying and disabled). Chicken poop and 4D animals are not in the least 'like human foods'. Chicken poop and 4D animals are breeding grounds for dangerous bacteria that when "goes through a kill step, such as rendering" produces

dangerous endotoxins that can sicken or kill pets. And 'truthfully labeled'? No again. There is not one pet food that 'truthfully' informs the consumer the pet food could contain diseased animals or non-slaughtered animal material.

The FDA continued...

The Federal Food, Drug & Cosmetic Act does not define "animal which has died otherwise than by slaughter." The United States Department of Agriculture regulates meat and poultry products intended for human food, and you may wish to contact them as well with this question.

My response to FDA: No, you can't pass this off to USDA. FDA is responsible for enforcing the laws of the Federal Food, Drug & Cosmetic Act. I am confident FDA would swiftly take action against a human food that contained a non-slaughtered animal. Why are they not enforcing the same law with pet food?

Plus – FDA has written Compliance Policies that use the very same terminology as law. [FDA's Compliance Policy 690.300 Canned Pet Food](#) states: "**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.**"

FDA cannot claim the agency has no definition for a term they have written further policy on. Wrong.

And lastly FDA stated...

The Association of American Feed Control Officials (AAFCO) maintains the most complete list of animal food ingredients with their definitions to ensure consistency across all states. We recommend you contact AAFCO for examples and more information about how common this practice may be.

FDA works in cooperation with AAFCO. There is little done at AAFCO without FDA approval. Also, AAFCO is not charged with enforcement of the FD&C Act – FDA is. To further pass the buck to AAFCO is wrong.

FDA – accept your legal responsibility. Enforce the FD&C Act with pet food.

And by the way...Pet food regulatory authorities claim they don't have a legal definition to what a slaughtered animal is, but [Wikipedia](#) provides details that slaughter facilities began to include "*good standards of hygiene*" as early as 1852. So for more than 150 years, the slaughter of animals for food has been an industrialized method.

Pet food regulatory authorities claim they don't have a legal definition to what a slaughtered animal is, but there are detailed laws that govern the humane methods of slaughter – the [Humane Methods of Slaughter Act](#).

The (lame) excuse there is no definition to slaughter is **no excuse**. It's time to clean up pet food. Non-slaughtered animals recycled into pet food are a violation of state and federal law. Animals should NOT become living landfills to dispose of waste. Who is pet food regulatory authorities protecting? Pets or the Pet Food Industry?

FDA refuses to enforce law with pet food allowing illegal and dangerous non-slaughtered animal material into pet food with no warning to the consumer.

Pet food ingredients sourced from non-slaughtered animal materials are **illegal** and have a high risk to contain life threatening **endotoxins**.

These pet food/treat ingredients can contain non-slaughtered animal material:

Chicken By-Products
Chicken By-Product Meal
Turkey By-Products
Turkey By-Product Meal
Poultry By-Products
Poultry By-Product Meal
Beef Meal
Lamb Meal
Meat Meal
Animal By-Product Meal
Meat and Bone Meal
Animal Fat
Animal Digest



We have a meeting this afternoon with FDA regarding endotoxins ignored in pet food – will share details of this meeting as soon as I can.

Wishing you and your pet(s) the best,

Susan Thixton
Pet Food Safety Advocate
Author Buyer Beware, Co-Author Dinner PAWsible
TruthaboutPetFood.com
Association for Truth in Pet Food

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The Most Absurd

March 11, 2016 Pet Food Regulations 25 Comments 3,425 Views

Imagine an hour long conversation with a federal agency defending its action of ignoring law. That was what happened yesterday with our FDA meeting.

For the first 15 minutes or so of our hour long meeting (3/10/16), the FDA listened to our evidence proving the serious risk to FDA's practice of allowing 4D animal material into pet food – which by the way, is a direct violation of law (that FDA is charged with enforcing). For the following 45 minutes, the FDA defended their 'aiding and abetting' practice of allowing pet food to violate federal law.

We provided the FDA with evidence that their sister federal organization – the USDA – was concerned about the risk to pets when dead livestock is rendered into pet food. The USDA feels decaying animal carcasses are a risk to pets due to the cooking process producing endotoxins; *"these toxins can cause disease and pet food manufacturers do not test their products for endotoxins"*. FDA was unconcerned. The FDA stated *"some of this material is safe"*. (Notice they did not say 'all'.)

We shared that Donald R. Strombeck, DVM, PhD, Professor Emeritus, University of California, Davis, School of Veterinary Medicine has stated endotoxins in pet food can cause *"damage to the liver"*. FDA was unconcerned sharing *"We are aware of his research and his feelings about dry dog food."*

FDA told us we have a *"theory"* that perhaps can be investigated, but shared it would be a multi-million dollar testing project that is not within the FDA budget; it was suggested we ask Congress to give FDA more money. A little guilt was thrown in to deflect us, FDA sharing to test the risk of 4D animal material to pets a *"terminal study"* would need to be performed. A *"terminal study"* means dogs and cats would be killed to determine how the illegal pet food material actually effects the pets consuming the foods.

We shared with FDA 'no millions of dollars needs to be spent; no pets need to give their lives. The 'fix' to this is FDA enforcing the law. Stop allowing bacteria filled, putrid (and illegal) dead livestock into pet food.'

(brace yourself) FDA stated (a direct quote): *“So 3 billion plus animals should go to landfills?”*

To which I responded (a direct quote): *“So you want pets become living landfills? Is that what you are saying?”*

Another FDA representative quickly stepped in and deflected the conversation. At this point, FDA stated that all meats even for human consumption contain endotoxins.

Again, we steered the conversation back on track stating the true risk to pets is not low levels of endotoxins (our bodies and pets bodies have natural methods to safely handle low levels of endotoxins) – we again told FDA high levels of endotoxins in rendered 4D animals, as warned by the USDA, is the risk we are bringing to their attention.

And FDA again steered the conversation away from the fact that illegal bacteria contaminated material is being dumped into pet food stating *‘Endotoxins are not just from just one potential source – I don’t think you can blame that one source.’* (Meaning FDA doesn’t feel dead livestock that has laid in the field for days prior to rendering, contaminated with bacteria – resulting in dangerous levels of endotoxins – resulting in pet death – are more of a risk that rendered bits and pieces from a slaughtered animal. The law does, but not FDA.)

FDA adamantly stated they will not do a testing project that will kill pets to determine if dead livestock are a risk.

FDA was reminded that their sister federal agency – the USDA – has stated endotoxins cause disease in pets. FDA was unmoved except suggesting that perhaps USDA should be the one to do the testing (reminder, it is FDA responsibility – not USDA’s – to assure consumers pet foods are safe).

Besides myself in this FDA meeting, there was a pet owner whose own dog died from eating a pet food he firmly believes was highly contaminated with endotoxins. This pet owner gathered more scientific evidence than anyone can image – all of that evidence was provided to FDA. He provided FDA the clinical lab results from his dying dog matching every symptom of endotoxemia, he provided studies proving that some pet food ingredients (example propylene glycol) increase the absorption of endotoxins into the blood stream, study after study was provided. My patience with FDA stopped quickly when FDA kept asking this pet owner for more (more studies, has the pet owner tested the pet food himself, necropsy results).

I interrupted FDA and told them *‘This is a pet owner, it is not his responsibility to test pet foods, it is not his responsibility to provide FDA with data proving illegal ingredients are a risk to pets. That is FDA’s responsibility. It is our responsibility to bring serious concerns to FDA’s attention and we certainly hope you listen to us.’*

We asked FDA what they are going to do about the very serious risk of endotoxins. They told us *“we might”* add it to the testing schedule for 2017, sharing they would only test *“a handful”* of products. FDA stated perhaps this could be a multi-year project.

I thanked FDA for this effort, but shared I felt sorry for all the pets and their grieving families that are going to die between now and then due to illegal, endotoxin contaminated pet foods. At this point, FDA reminded me (scolded me) for a statement (which I still stand by) said at an AAFCO meeting 8 months ago. I made a statement to the chair of the Pet Food Committee that they as individuals might have pets of their own, but they are nothing like the pet owners I represent. (AAFCO members

and FDA representatives that own a pet are in a position to do something about a bad pet food that might sicken or kill their pet. Pet owners that I represent don't have that benefit.) FDA told me they are pet owners too, and they didn't appreciate my accusations they are not. My response: 'No accusations intended – I simply stated I feel sorry for the pets that ARE going to die between now and when FDA decides to do something about this. One of those pets that die could be one of yours – depending on what pet food you feed' (hopefully leaving them with something to think about).

And lastly I directly asked the FDA – **“Is FDA going to continue to allow non-slaughtered, dead livestock – that are a direct violation of the Federal Food, Drug and Cosmetic Act – into pet food?”** The FDA told us **“We’re going to allow animals that have died other than by slaughter that are further processed, we will allow those ingredients in pet food.”** The FDA openly admitted they will continue to allow pet food to violate federal law.

I openly admit I wasn't the most pleasant person on that phone call. The pet owner on the call remained composed, even under direct assault by FDA. I did not. To this pet owner – my sincere thanks for your composure, and your very skilled knowledge on the topic of endotoxins. What a pity (what a crime) FDA did not take heed to the evidence you presented.

To FDA, I thank you for your time. I adamantly disagree with your opinion that 4D material is safe for pets to consume and I will continue with my battle asking FDA to enforce federal law with pet food. I will continue to question every authority on the planet if need be. I will be knocking on your door again and again – for as long as it takes.

Furious doesn't even explain it. The simple truth of this situation: with the aid of FDA, the pet food industry is allowed to make billions of dollars each year selling adulterated pet foods to unknowing consumers, and pets are dying because of it. Some would call that aiding and abetting a criminal.

We are not done with this battle.

Wishing you and your pet(s) the best,

Susan Thixton
Pet Food Safety Advocate
Author Buyer Beware, Co-Author Dinner PAWsible
TruthaboutPetFood.com
Association for Truth in Pet Food

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It's So Bad, All We Can do Now is Warn

February 22, 2016 Pet Food Regulations 50 Comments 16,969 Views

Each day in the U.S. millions of pounds of **adulterated pet foods** are sold to unknowing consumers; an estimated **\$19 Million dollars worth every single day**. Laws that govern pet food/animal feed have been ignored for so long, it's so bad – so big – it is probably too late for anything other than a warning.

The [American Pet Products Association](#) states in 2015 \$23 billion worth of pet food was sold in the U.S. An estimated 30% of those sales were for pet food and treats that legally should not have been sold. Should not have been sold because federal and state law define their ingredients as adulterated.

There are many laws governing pet food sold in the U.S. However these laws are of no benefit to consumers if they are not enforced. Consumer advocates Susan Thixton, Mollie Morrisette, Dr. Jean Hofve, Dr. Cathy Alinovi and Nina Wolf took a close look into state and federal law (governing pet food). We found lack of enforcement of pet food law to be so big, involving so many different pet foods and treats – that it is close to impossible to turn back now.

In the United States Code (law), [Title 21, Chapter 9, Subchapter IV, Section 342](#) (The Federal Food, Drug and Cosmetic Act) – the law states that a food (food would include animal/pet food) is considered adulterated if it is sourced from a non-slaughtered animal (Section 342 a-5). This law is in place to protect consumers and their pets from the risk to consuming diseased or decomposing animal tissues.

Below is a map of the U.S. regarding enforcement of the above federal law. The states with stars (all of them) are states that **do not enforce** the above law with pet food.



With research into State laws, we found that 14 States had the exact same law – clearly defining within state law a pet food as adulterated if it contains any part of a non-slaughtered animal. The following states are not only ignoring the above federal law, they are ignoring **their own state law** too: Arkansas, Connecticut, Florida, Idaho, Indiana, Kansas, Kentucky, Michigan, Minnesota, Mississippi, Missouri, Montana, New Mexico, and North Dakota.



How do we know that states are ignoring federal and state law? We know – because of the legal definition of seven commonly used ingredients in pet food.

Pet food ingredient definitions are quite specific. The concern with federal and state law enforcement is the legal requirement – within the pet food ingredient definition – to whether it is required or not required to be sourced from a slaughtered animal. Pet food ingredients sourced from a slaughtered animal would be legal (per federal and state law). Pet food ingredients sourced from a non-slaughtered animal would **not be legal** (per federal and state law).

Examples of non-slaughtered animals we know with certainty are allowed to be included in the pet food ingredients listed below – are livestock animals that have died in the field and spent laying hens. At the AAFCO meeting in August 2015, all consumer advocates in attendance (Susan Thixton, Mollie Morrissette, Dr. Jean Hofve, Nina Wolf, Dr. Cathy Alinovi, Dr. Karen Becker, Dr. Judy Morgan, BC Henchen and Rodney Habib) were witness to the discussion of **non-slaughtered** spent laying hens ground whole – feathers, feet, feces and all – becoming the pet food ingredients chicken/poultry by-products and chicken/poultry by-product meal.

The legal definition of another ingredient – meat and bone meal – allows the inclusion of “*hair, hoof, horn, hide trimmings, manure ...*” **Manure** – on the non-slaughtered animal body and in the animal – becomes part of the pet food ingredient. Non-slaughtered animals are also most likely to contain high levels of pathogenic bacteria such as Salmonella and E. coli. Though the bacteria is killed in the cooking process of the pet food, there remains potentially dangerous levels of endotoxins that can sicken or kill pets. 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.*” (To read more about the risk of endotoxins, [Click Here.](#))

Below is a chart of some (not all) commonly used pet food meat/animal protein ingredients. Per their legal definition they are listed in a column that requires them to be sourced from a slaughtered animal (black), or listed in a column that does not require them to be sourced from a slaughtered animal (red). **Red/non-slaughtered animal material ingredients are considered adulterated per federal law and state law in 14 states.**

**Legal Definition
requires sourced from
Slaughtered Animal**

Chicken/Turkey/Poultry
Chicken/Turkey/Poultry Meal
Beef/Lamb/Meat
Beef/Lamb/Meat By-Products

**Legal Definition does not
require sourced from
Slaughtered Animal**

Chicken/Turkey/Poultry
By-Products
Chicken/Turkey/Poultry
By-Product Meal
Beef/Lamb/Meat Meal
Animal By-Product Meal
Meat and Bone Meal
Animal Fat
Animal Digest

We are not stating that every pet food that uses one of the above ingredients is sourcing from an illegal non-slaughtered animal. That is part of the problem – pet food consumers are not told who is sourcing from adulterated/illegal non-slaughtered animals and who isn't. **All we know with certainty** is what the legal requirement of the ingredient is – if the ingredient definition requires the animal source to be a slaughtered animal or if the ingredient definition **does not require** the animal source to be slaughtered.

Example: Florida – my home state – defines an adulterated pet food as (in part):



Florida Law

580.071 Adulteration

(h) If it is, in whole or in part, the product of a diseased animal or of an animal that has died by a means other than slaughter

BUT...in every grocery store, every big box retail store, every big box pet food store in Florida are pet foods that contain ingredients that can be sourced from a non-slaughtered animal. As example: Beneful Dog Food.

Beneful Dog Food (original, chicken recipe) contains three ingredients whose legal definition allows them to be sourced from non-slaughtered animals; chicken by-product meal, animal fat and animal digest. Instead of enforcing federal law and enforcing state law, Florida is allowing this pet food and perhaps thousands of other pet products to contain non-slaughtered animal ingredients – **with no concern to the consumer purchasing the pet food or the pet consuming it.**

One more example: Missouri defines an adulterated pet food as (in part):



Missouri Law

When used in sections 266.152 to 266.220 the following terms mean:
(21) "Pet food", any commercial feed prepared and distributed for consumption by dogs and cats;

266.180 A commercial feed shall be deemed to be adulterated:

(i) If it is, in whole or in part, the product of a diseased animal or of an animal which dies other than by slaughter

But...in every grocery store, every big box retail store, every big box pet food store in Missouri are pet foods that contain ingredients that can be sourced from a non-slaughtered animal. As example: Meow Mix Cat Food.

Meow Mix Cat Food contains four ingredients whose legal definition allows them to be sourced from non-slaughtered animals; chicken by-product meal, animal fat, animal digest and turkey by-product meal. Instead of enforcing federal law and enforcing

state law, Missouri is allowing this pet food and perhaps thousands of other pet products to contain adulterated ingredients – **with no concern to the consumer purchasing the pet food or the pet consuming it.**

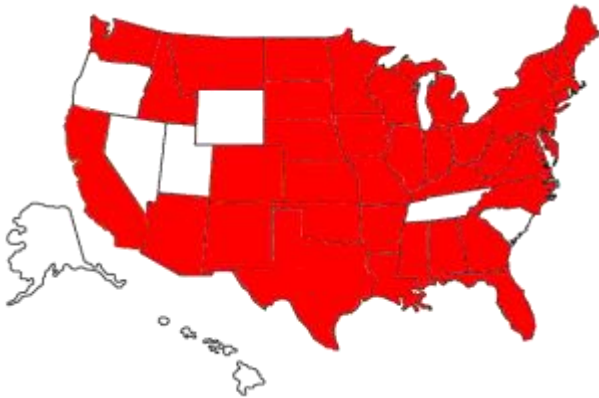
How can this be? How can so many commonly used pet food/treat ingredients included in thousands of pet products be considered adulterated/illegal per federal and state law? We tried asking, but our questions went unanswered. Before I get to that...there's more law being ignored.

In the same United States Code (law), Section 343 defines a food whose labeling is false or misleading in ANY manner to be misbranded. A misbranded pet food would be illegal. Again, this federal law is in place to protect consumers and their pets.

The following image shows in red the states (all of them) that **do not enforce** the above federal law with pet food.




We found 42 states had very similar misleading labeling laws as the federal law. Most states had law that declared a pet food adulterated if an image on the label reflects a quality different from what is in the pet food. Example: if grilled chicken was shown on the label, and the pet food is not made from grilled chicken – that pet food *should be* declared adulterated because its label reflects a quality different than the pet food. In the following graphic, red indicates state labeling laws specific to pet food ignored.



Example: Georgia law states:

Georgia Law

2-13-1. Definitions.
(17) "Pet food" means any commercial feed prepared and distributed for consumption by dogs or cats.



2-13-10. When commercial feed deemed adulterated.
(7) If its composition or quality falls below or differs from that which it is purported or is represented to possess by its labeling;

BUT...in every grocery store, every big box retail store, every big box pet food store in Georgia is (as example) varieties from Pedigree Dog Food, Hill's Science Diet Crafted Pet Food, and FreshPet Pet Food. Varieties of these pet foods show grilled meat or roasted meat on the label, but there is no grilled or roasted meat in the pet food. The 'quality' of the pet food falls below what is 'represented on the label'. Instead of enforcing federal and state labeling law, Georgia is allowing these pet foods

and hundreds of others to display misleading images on the label – **with no concern to the consumer purchasing the pet food or the pet consuming it.**

How can this be happening? How can so many states ignore their own state law allowing thousands of pet food and treat products to be adulterated? We asked two states, but they did not respond.

An email was sent to Florida Department of Agriculture on February 15, 2016 asking why state law is not being enforced with pet food. On Tuesday February 16, 2016 a follow up phone call was made to FL Department of Agriculture – message left. To date, no response has been received.

An email was sent to Missouri Department of Agriculture on February 17, 2016 asking why state law is not being enforced with pet food. A Missouri Department of Agriculture representative is the co-chair of AAFCO’s pet food committee, we thought certainly this person could provide us with information...an explanation. To date, no response has been received.

Assumption: they cannot respond because they would have to admit their own state laws are not being enforced. They can’t tell us why, they can’t tell us anything – it would be very incriminating if they did.

The FDA website tells us that most states have adopted the federal laws we have discussed above. [Click Here](#) to view. This FDA webpage also tells us that most states have adopted full federal law as state law, but not all. Without the aid of a legal genius, it’s challenging to determine which states follow all federal law. **What we are certain of**, the red states in the graphic below are ignoring their own state pet food labeling laws – and the starred states are ignoring their own state law allowing adulterated ingredient pet foods to be sold to unknowing consumers.



Question. Why do all of you and I have to abide by law, and federal/state agencies do not?

What can consumers do?

Specific to the state and federal law that requires all pet food ingredients to be sourced from slaughtered animals, because state and federal authorities have ignored enforcement for so long, the ‘problem’ has grown to an estimated 30% of all pet foods and treats now contain an adulterated (non-slaughtered animal) ingredient. It is impossible at this point – to swiftly remove or recall all of the adulterated pet foods and treats. The problem is out of control. Though it is what all pet food consumers (and their pets) deserve, this cannot change in an instant.

We must consider that many, many families can only afford this type of pet food. We must consider too that animal shelters can only afford the cheapest of pet foods – which are most likely to contain one of the non-slaughtered animal/illegal ingredients. It is not our goal to financially damage a family, a shelter, the pet food industry or the pet food ingredient supplier industry just because regulatory authorities have not enforced law.

The only thing to do at this point – is to require pet foods that include an ingredient allowed to contain a non-slaughtered animal to place a warning on the label. And this warning needs to be implemented immediately. **This is – at the very least – what pet food regulatory authorities can do to protect unknowing consumers.**



We ask consumers to report the violations of law to state authorities – our representatives in Congress and our State Attorney General. We can make them very aware of these serious laws being ignored and ask them to...

1. We ask authorities to require all pet foods/treats with ingredients whose definition does not require it to be sourced from a slaughtered animal (a violation of federal and state law) to include a warning on the label. Example warning label: 'Warning. This pet food could contain ingredients that are in violation of federal and state law. Handle and store with care.' The consumer warning should be required to be implemented immediately, and placed in a highly visible area on the pet food label.
2. We ask authorities to enforce federal and state labeling laws, making certain that a pet food displaying grilled meat on the label actually contains grilled meat.

We have provided pet food consumers with the laws of each state for these issues. And we have provided an example letter for your representatives in Congress and your State Attorney General specific to the laws in each state.

Please click on the link below to your state – send your emails. Please share this post asking every single pet food owner to do the same. A warning notice on these pet foods is the VERY LEAST thing that authorities should do for pet food consumers. But they won't do it on their own – **we must ask.**

Alabama	Louisiana	Ohio
Alaska	Maine	Oklahoma
Arizona	Maryland	Oregon
Arkansas	Massachusetts	Pennsylvania
California	Michigan	Rhode Island
Colorado	Minnesota	South Carolina
Connecticut	Mississippi	South Dakota
Delaware	Missouri	Tennessee
Florida	Montana	Texas
Georgia	Nebraska	Utah
Hawaii	Nevada	Vermont
Idaho	New Hampshire	Virginia
Illinois	New Jersey	Washington
Indiana	New Mexico	West Virginia
Iowa	New York	Wisconsin
Kansas	North Carolina	Wyoming
Kentucky	North Dakota	

Wishing you and your pet(s) the best,

Susan Thixton
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The Truth about Why Dead/Diseased Animals goes to Pet Food

March 25, 2016 Pet Food Ingredients 29 Comments 5,934 Views

The real reason dead, decomposing animals are dumped into pet food: the material is too dangerous to landfill. The FDA has decided pets are living landfills, the best place to dispose of dangerous animal material.

In a recent meeting with FDA, the agency stated some haunting things. One: when FDA was asked directly... if the agency will continue to ignore law allowing (illegal) diseased, dead animals to become pet food ingredients after certain risk was discussed (endotoxins) – the agency said...

“We’re going to allow animals that have died other than by slaughter that are further processed; we will allow those ingredients in pet food. But hopefully people would not use that protein in a raw pet food diet.”

In the same meeting when FDA was questioned about the massive amounts of dead/diseased livestock being sent to pet food, the agency stated: *“So 3 billion plus animals should go to landfills?”*

Here’s the truth to why FDA ignores federal law and allows “3 billion plus animals” (dead livestock, road kill, euthanized animals) a year into pet food instead of landfills...

Colorado government website states disposal of dead animals *“must be managed in a manner that prevents the spread of infection and contamination of soil and ground water.”*

Texas states: *“Animal carcasses must be handled properly to prevent harm to people, herds, flocks, water, and the overall environment. Several problems can arise if dead livestock and poultry are disposed of improperly:*

- *Diseases can be spread to people and animals.*
- *Carcass fluids can leach into and pollute groundwater (wells).*
- *Bacteria and viruses can be transmitted to surface water (creeks, ponds, lakes, or rivers).*
- *Obnoxious gases and odors can be emitted to the atmosphere.”*

Michigan has specific laws regarding the disposal of dead animals: *“The Bodies of Dead Animals Act, establishes guidelines for the proper disposal of dead animals, to protect human, animal and environmental health.”*

If you do a Google search for “landfill animal carcasses” you find page after page after page of state regulations discussing the risks (and requirements) to disposal of dead animal carcasses.

It boils down to this...dead/diseased animal carcasses must be disposed of safely. Animals can be buried, but this has to be done properly and is close to impossible on modern feed lot farming operations, some with high animal mortality rates. Dead/diseased animals can be incinerated, but this method is a significant expense to the farmer.

Rendering dead/diseased animals is a safe method of disposal. **BUT ONLY for disposal.** Rendered dead/diseased animals are a certain risk for high levels of endotoxins and a certain risk to pets consuming those materials in a pet food (as stated by USDA). In our meeting, when we pushed FDA to enforce existing law the agency stated “So 3 billion plus animals should go to landfills?”

My initial response was “So you want pets become living landfills?” After the meeting, as I learned more, this is exactly what is happening. Pets have become living landfills for material that is too dangerous to ground landfill and too much of an expense to farmers to dispose of properly/safely.

FDA has chosen – without remorse – to allow pets to consume dangerous, illegal pet foods. FDA has chosen pets to be living landfills. All pet food consumers deserve to know which pet foods/treats contain dangerous, illegal ingredients. A pet food/treat **warning label is required.**

Do you know why FDA ignores law and allows this material into pet food?



Disposal of dead/diseased animal carcasses into pet food is illegal (per federal law) and can sicken or kill pets (endotoxins).

Because it's so dangerous to dispose of!

“Animal carcasses must be handled properly to prevent harm to people, herds, flocks, water, and the overall environment. Several problems can arise if dead livestock and poultry are disposed of improperly:

- Diseases can be spread to people and animals.
- Carcass fluids can leach into and pollute groundwater (wells).
- Bacteria and viruses can be transmitted to surface water (creeks, ponds, lakes, or rivers).
- Obnoxious gases and odors can be emitted to the atmosphere.”

Pets should not be treated as Living Landfills to dispose of material considered too dangerous for ground landfill.

A Warning Label should be required on all pet foods that contain dead/diseased animal carcasses.

TruthaboutPetFood.com



Wishing you and your pet(s) the best,

Susan Thixton
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