FDA Virtual Listening Session on the Oversight of Pet Food

00:09:48.840 --> 00:09:59.820
Walter.Ellenberg@fda.hhs.gov: Good afternoon, everybody, we still have a lot of individuals signing in for this session and so we're gonna wait about three more minutes before we start our meeting, thank you.

00:13:10.710 --> 00:13:16.950
Walter.Ellenberg@fda.hhs.gov: Good afternoon, and thank you for attending this virtual listening session on FDA's oversight of pet food.

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Walter.Ellenberg@fda.hhs.gov: Before I go any further, I want to make certain that those who are participating and have asked to speak and present today, make sure that when you enter this meeting room that you use your full name, so that we don't have any kind of misunderstanding. There are a few who have

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Walter.Ellenberg@fda.hhs.gov: typed in just their initials and so we're not certain who those people are. So if you do that, that would be great.

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Walter.Ellenberg@fda.hhs.gov: Again, good afternoon, and thank you for attending this virtual listening session. My name is Walt Ellenberg and I'll serve as a moderator for today's meeting, and although I'm employed at the Center for Veterinary Medicine,

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Walter.Ellenberg@fda.hhs.gov: my official duties are not connected in any way to the topic of today's meeting.

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Walter.Ellenberg@fda.hhs.gov: The objective of today's meeting is to provide the public the opportunity to share information, comments, and insights on this important topic.

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Walter.Ellenberg@fda.hhs.gov: With the exception of the introductory remarks by our Center leadership, the balance of this entire meeting will be dedicated to the public presentations. FDA will not make any comments at today's meeting regarding potential regulatory plans or projections or actions nor timelines.

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Walter.Ellenberg@fda.hhs.gov: This is a very, very large meeting and we've made every effort to make certain that it runs smoothly; however,

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Walter.Ellenberg@fda.hhs.gov: in reality, we all know that the unexpected issues are always possible, and please know that we will do everything we can, everything we can in our power to correct any issues that might come up.

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Walter.Ellenberg@fda.hhs.gov: It's also important to know that we made every effort to accommodate as many attendees as possible; however, to preserve the bandwidth and the webinar functionality, we did have to limit the registration to approximately 1000 attendees.

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Walter.Ellenberg@fda.hhs.gov: In order to accommodate those who are unable to register, it's important to note that this meeting is being recorded and the video transcript will be posted on the CVM website in the next few days.

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Walter.Ellenberg@fda.hhs.gov: Now the format for today's meeting is actually very straightforward. In just a few minutes you'll receive opening remarks from our director,

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Walter.Ellenberg@fda.hhs.gov: Dr Steven Solomon. Following Dr Solomon's remarks, I'll play a short video presentation from Tracey Forfa, the Deputy Director of CVM,

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Walter.Ellenberg@fda.hhs.gov: and Jenny Murphy, the Deputy Director for Food in the Office of Surveillance and Compliance in CVM. Although their presentations been recorded, they are in attendance at today's meeting. Following their video I will briefly review the process for each presentation.

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Walter.Ellenberg@fda.hhs.gov: Today's agenda has been subdivided into five sections,

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Walter.Ellenberg@fda.hhs.gov: which really are based on the requests that we receive from the public. CVM initially received 19 requests from individuals who wanted to speak; however, two individuals had to recently withdraw.

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Walter.Ellenberg@fda.hhs.gov: Each presenter will give an oral or a slide presentation at their pre-assigned time. All presenters have been given six minutes to make their presentation.

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Walter.Ellenberg@fda.hhs.gov: Today's topics will include contaminants, ingredients, labeling, safety, and other miscellaneous topics that were of interest individuals who wanted to speak.

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Walter.Ellenberg@fda.hhs.gov: At this time,

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Walter.Ellenberg@fda.hhs.gov: I’m going to turn the microphone over to Dr Solomon and turn off my camera and Dr Solomon, you have the floor.

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Steven.Solomon@fda.hhs.gov: Good afternoon, everyone, and thanks Dr Ellenberg, as you mentioned I’m Steve Solomon I’m the director of FDA Center for Veterinary Medicine.

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Steven.Solomon@fda.hhs.gov: And, on behalf of the Center for Veterinary Medicine and the Food and Drug Administration I’d like to welcome everyone to this virtual pet food listening session. We're pleased by your overwhelming interest and participation in this event.

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Steven.Solomon@fda.hhs.gov: American households have nearly 400 million domestic pets. That includes 94 million cats and 89 million dogs plus many other species.

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Steven.Solomon@fda.hhs.gov: It actually equates to around two thirds of American households that have pets.

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Steven.Solomon@fda.hhs.gov: Surveys indicate that of these households, more than 95% of you view your pets as part of the family.

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Steven.Solomon@fda.hhs.gov: While the pandemic has had significant impacts on all of our personal and work lives, the one bright spot has been that during the pandemic more than 11 million US households have added a new pet.

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Steven.Solomon@fda.hhs.gov: We understand that pet food safety is a very important topic for all pet owners and it's a critical part of the work that we do at the Center for Veterinary Medicine.

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Steven.Solomon@fda.hhs.gov: In a moment you'll be hearing from Tracey Forfa, CVM’s Deputy Director, and Jenny Murphy, the Deputy Director for Food in CVM’s Office of Surveillance and Compliance.

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Steven.Solomon@fda.hhs.gov: They will be providing a very brief and high level overview of FDA’s framework for the oversight of pet food safety.

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Steven.Solomon@fda.hhs.gov: Due to our limited time and because we want to hear from you, this overview won't be all inclusive, but will only highlight some of the foundations of CVM’s responsibility for pet food safety.

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Steven.Solomon@fda.hhs.gov: CVM, however, does not do this work alone. All stakeholders have an important role in the safety of animal food.

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Steven.Solomon@fda.hhs.gov: CVM highly values perspectives from consumers, domestic and international public health and regulatory officials, other US government entities,

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Steven.Solomon@fda.hhs.gov: the scientific and research community, academia, the veterinary profession, the pet food industry and including the entire supply chain from food ingredient suppliers to growers and importers to manufacturers, distributors and retailers.

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Steven.Solomon@fda.hhs.gov: I've spent a significant portion of my time, more than 30 years at FDA, working with all these stakeholders to bring about a fully integrated food safety system built upon the foundation of a shared mission of protecting human and animal health.

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Steven.Solomon@fda.hhs.gov: The oversight of animal food is a shared responsibility of domestic and international regulators. Our state regulatory partners also play a major role in both our inspectional work, our response activities, particularly when there's an issue with pet food.

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Steven.Solomon@fda.hhs.gov: The framework of an integrated food safety system is built into the Food Safety Modernization Act, commonly known as FSMA, along with the premise that manufacturers bear the responsibility for identifying and controlling many hazards.

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Steven.Solomon@fda.hhs.gov: FDA simply doesn't have enough resources to be everywhere at once,

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Steven.Solomon@fda.hhs.gov: but we continue to do the very best we can to respond to food borne incidents, to conduct surveillance and inspections of the industry, to fill scientific gaps in our knowledge, and develop new guidance and regulations when needed to address emerging public health issues.

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Steven.Solomon@fda.hhs.gov: While we work to respond quickly to problems when they occur, our hope is that, with the continued drive towards preventing and controlling hazards before they occur, we'll continue to reduce the number of pet food safety events.

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Steven.Solomon@fda.hhs.gov: This meeting has been delayed due to the ongoing response to Covid-19 and we're looking forward to hearing from all our registered speakers today.

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Steven.Solomon@fda.hhs.gov: This dialogue helps strengthen the foundation for a strong food safety system, as we continually work on any enhancements that may be necessary.

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Steven.Solomon@fda.hhs.gov: Looking through today's agenda and topics, it seems as though the speakers are going to address many of the very same issues that we're concerned about.

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Steven.Solomon@fda.hhs.gov:H, including bacterial contaminants, toxins, and excessive or insufficient amounts of vitamins or other essential nutrients, are some of the top ongoing concerns.

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Steven.Solomon@fda.hhs.gov: While I believe we've demonstrated that when these issues occur, we're taking appropriate action with the tools we have available, we're interested in your thoughts and comments.

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Steven.Solomon@fda.hhs.gov: Our response teams continue to encourage swift and complete recalls or market withdrawals when issues occur. These prevent further exposure to product and provide warning and other information to the public as soon as possible so that you can make informed decisions.

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Steven.Solomon@fda.hhs.gov: We also conduct inspections and sampling in facilities to get industry to initiate corrective actions and understand the root cause of the problem.

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Steven.Solomon@fda.hhs.gov: However, we recognize that we have more work to do and I look forward to a day, collectively, we can prevent these incidents from happening in the first place.

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Steven.Solomon@fda.hhs.gov: The review of ingredients themselves continues to be a priority for the Center.

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Steven.Solomon@fda.hhs.gov: Congress recently gave CVM some additional resources to increase our staffing levels.

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Steven.Solomon@fda.hhs.gov: With additional staff members we've reduced the time it takes to complete our ingredient review and we hope to continue that trend into the future.

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Steven.Solomon@fda.hhs.gov: And while we don't formally approve the labeling on pet food products, we do ensure that they comply with the regulations.

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Steven.Solomon@fda.hhs.gov: We recognize that complete labeling of ingredients of pet food helps consumers to understand what the food contains and, hopefully, in consultation with your veterinarian, helps you choose the appropriate product for your pet's particular nutritional needs.

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Steven.Solomon@fda.hhs.gov: Pet food safety is a high priority for CVM. We recognize there are limitations on time for each speaker today, but I personally want to also request that you submit comments to the open docket.

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Steven.Solomon@fda.hhs.gov: This helps us build a bigger picture of the various perspectives on FDA's oversight of the pet food industry.

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Steven.Solomon@fda.hhs.gov: Again, my thanks for your ongoing interest and engagement. Now I'll turn it back over to Dr Ellenberg to continue the program, with my wishes for a positive and productive session. Thank you very much.

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Walter.Ellenberg@fda.hhs.gov: Thank you, Dr Solomon and at this time I'm going to shift gears and we're going to make certain that we have the next presentation up, which is the video that I mentioned from Ms. Forfa and

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Walter.Ellenberg@fda.hhs.gov: Jenny Murphy.

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Good afternoon, everyone and good morning to some of you. We are very happy to have you with us today in this virtual listening session regarding FDA's oversight of pet food.

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My name is Tracey Forfa, I'm the Deputy Director of FDA's Center for Veterinary Medicine and in the interest of full disclosure, I want to let you know that this

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part of the session has been pre-recorded, but I want to assure you that my colleague Jenny Murphy, who you will hear from shortly, and I will both be listening in on the live session,

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we will be reviewing the recording, and we will be monitoring the submissions to the docket, along with all of our colleagues at CVM who work on pet food.

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Before we turn this meeting over to our guest speakers, Jenny and I will give a short snapshot into our regulation of pet food.

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As you know, FDA is the federal government authority responsible for the oversight of animal food, which includes pet food.

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We are both a regulatory agency and because there is no CDC for animals, we are also a public health agency, and we keep science

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as our foundation and risk-based decisions at our core as we oversee the United States animal food supply,

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including products made both domestically and those that are imported.

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To get started, I wanted to give you a quick snapshot of some of the existing laws and regulations that establish a framework for FDA regulation of animal food in the United States.

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As you can see it's a pretty comprehensive list. These laws and regulations cover items such as definitions which are established in the Federal Food, Drug, and Cosmetic Act, compliance inspections, recordkeeping requirements, hazard control, and traceability.

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Not all of these apply to pet food, such as medicated feed, current good manufacturing practice,

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and the veterinary feed directives, but they are listed to show the various laws and regulations that inform the regulatory framework for the oversight of the US animal food supply.

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Today, most of our comments will focus on the two bolded items, the Federal Food, Drug, and Cosmetic Act and the Food Safety Modernization Act’s preventive controls for animal food regulation.

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FDA’s authority for the oversight of animal food comes from the Federal Food, Drug, and Cosmetic Act, which we often refer to as the FD&C Act.

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In the FD&C Act, food is defined as articles used for food or drink for man or other animals, so food is food and there is not a delineation in the FD&C act between food for humans and food for animals, including no delineation between food for livestock animals and pets.

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In 2015, FDA published the Food Safety Modernization Act's preventive controls for animal food or PCAF regulations, in which we define animal food.

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Animal food is defined in that regulation, and this is the definition we have been broadly using to be food for animals other than man and includes pet food, animal food, and raw materials and ingredients.

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There are several examples of animal food, including food for cattle, poultry, and aquaculture species.

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Animal food also includes pet food and pet treats and, yes, includes other species too, such as wild birds, exotic animals, reptiles, and aquarium fish. And the components that make up a diet or final product, such as the raw materials and ingredients, are also considered food.

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Under the FD&C Act, food, and for purposes of today's conversation I will say animal food, must be safe to eat and truthfully labeled.

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Under the FD&C Act, FDA has authority to take various actions against any food in interstate commerc, that is adulterated or misbranded.

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Some of our tools include mandatory recall, detention, seizure, injunction, or suspension of registration. Again, under the FD&C Act, food has to be safe and the preventive controls for animal food regulation has set up a framework to help ensure safety.

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Not only do animal food producers need to consider the safety of the animal food for feeding the animals, they also have to consider the safety impact of animal foods on humans too. For pet food, the food has to be safe for the pet to eat, and it also has to be safe for the pet owner.

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When making a pet food, the food needs to be safe for the owner to handle and have in the home. We don't want people sick from handling food

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and we don't want our pets to eat something that could pass on something harmful to their owners, such as the bacterial pathogens Salmonella, Listeria, or E. coli,

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because the pets shed these bacteria through their feces and saliva, especially when they lick our faces.

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So the expectation for safety is pretty high, as we want to make sure that pets food is safe for pets and us. And now I will turn it over to my colleague, Jenny Murphy. My name is Jenny Murphy, and I am the Deputy Director for Foods in CVM's Office of Surveillance and Compliance.

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Just to give you a little bit about our regulatory framework, because we get a lot of questions on what is within our purview and what is not, I wanted to get some quick examples of things we can do, and things we can't do.

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Within our regulatory framework, FDA develops federal regulations and accompanying guidance.

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We also use data and information from inspections, sampling, and risk-based evaluations, to identify violative products and firms for regulatory or enforcement actions. FDA again uses risk-based decision making and the best science available to consider how to enforce federal regulations.

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The example I'm going to use now is inspections. At FDA inspectional resources for food are shared among human food and animal food and there's a lot of inventory to cover.

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Realistically, FDA cannot inspect every human and animal food facility daily or even every year, nor are we mandated to do so. Because our inspectional resources are limited, we have to utilize a risk-based approach to planning the inspections we do conduct.

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For animal food we have been evolving and modifying our risk model and have recently provided guidance to the investigators in our field staff on risk prioritization through our comprehensive inspection Compliance Program.

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Now, on the things we can't do because they're not within our regulatory purview for animal foods. FDA does not approve finished food products, both for humans or animals.

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This means for pet food, we do not approve pet food products, their formulations, or the nutritional adequacy of those products.

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And while we do provide regulations for labeling and manufacturers have to meet those requirements, we do not approve animal food labels, including pet food labels.

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Now I'm going to switch back to pet food safety. When we consider the "who" is responsible for keeping pet food safe, I break this down into two categories.

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First, there is industry. Under US law, industry is responsible for producing safe food. For pet food, this includes both the raw material and ingredient suppliers and manufacturers who are making the final pet food or pet treats that are fed to our pets.

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While industry is responsible for producing safe food, regulators, at both the FDA and state level, are responsible for putting the checks and balances system in place to make sure industry is following those laws and regulations that are designed to keep the food safe.

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For FDA, our key regulatory foundations for pet food come from the FD&C Act and the preventive controls for animal food regulation.

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The preventive controls regulation

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is relatively new, as it was finalized in 2015. This regulation applies to the majority of pet food manufacturers and ingredient manufacturers.

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While we've mentioned this one a couple times, I want to dig a little bit deeper into what is required under that regulation.

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This regulation established for the first time basic current good manufacturing practices requirements for animal food. These are baseline activities that ensure the safe production of animal food.

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And then the preventive controls regulation also require for us to take a more comprehensive look at their food safety systems

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by requiring them to conduct a hazard analysis, identify any hazards requiring a preventive control, implement an appropriate control, and then perform their checks and balances to make sure those controls are working.

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Since the regulation was finalized, FDA has been working to develop tools that can help both industry and regulators with implementation, including training, guidance documents, and our Compliance Program.

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This regulation is still in its infancy when compared to other food safety regulations, but there is power in what it can provide and the overarching framework for safe food that it requires of manufacturers.

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We have passed all our compliance dates for this regulation, so anybody subject to this regulation should now be in compliance.

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So with this regulatory foundations in place, we also have tools at our disposal to help us oversee the industry. The first tool that we'll spotlight today is a relatively newer tool, which is our comprehensive animal food inspection Compliance Program.

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This Compliance Program is essentially a way to promote consistency in our program across our field staff from FDA's Office of Regulatory Affairs and our state partners, both during our inspections and in our regulatory compliance process.

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This comprehensive approach to inspections is new and we consider it to be modernizing the animal food safety inspectional approach, as it does require a holistic approach to an animal food facility versus just looking at a singular set of requirements.

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The comprehensive Compliance Program sets criteria to prioritize facility inspections from a comprehensive viewpoint,

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creates the framework to perform a comprehensive inspection to all the requirements based on a facility's activities,

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and sets the public health significance of violations to ensure consistent approach across our program areas.

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The comprehensive approach to field inspections at all of our animal food facilities improves field staff efficiency, provides a more complete picture of compliance at a facility,

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eliminates facilities receiving more than one routine inspection in a fiscal year, therefore allowing us to inspect more facilities, and it also ensures that facilities have a complete understanding of their compliance at the close of inspection.

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The second tool listed here is surveillance activities and that encompasses a lot of different things.

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As part of our routine surveillance, we monitor and look for what we call signals to detect any problem in the animal food supply.

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We receive and review complaints, both from veterinarians and pet owners, we have the reportable food registry system in place that requires industry to report to us when they detect problems with their food, and we also utilize sampling and testing of pet food to see if there are any issues.

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And the last example of a tool that we have for us is that I'm going to give today is one of our greatest tools, which is our partnership with state animal food regulators.

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Of the inspections of animal food facilities that we conduct each year. historically about 80% of those inspections are conducted under contract by our state partners.

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Simply put, we need help from our state partners to provide oversight and coverage of the animal food industry. They are incredibly valuable, not only to the FDA as partners, but to consumers who want an increased regulatory presence in the pet food industry.

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Through both collaboration with FDA and under their own regulatory authorities in their state, they increase in inspectional coverage of the industry,

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They surveil and detect industry for problems, they help to remove unsafe products from commerce, and they provide education and outreach to industry and consumers. The US animal food supply is safer because of their hard work and we are really grateful for all they do and their partnership.

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As I wind down this presentation on behalf of CVM, Tracey and I wanted to thank each of you attending today's session.

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We bet that everybody attending today, regardless of whether you're a regulator, a member of the animal food industry, or a consumer, that we share a common goal in safe pet food.

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For me personally, safe animal food is not only at the core of my job of what I do here at FDA, but I'm also a pet owner and I am a mother.

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These two lovely kitties on the screen are my cats. They are cherished by my children, my children feed them, my children may have eaten their food as small kids,

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and they pretty much cuddled up in someone's lap up every day. I want the food to not only be safe for them, but for my kids as well.

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So when we go back and think about it, really and truly wanting a safe pet food is the tie that binds us here today, and with that we will turn it over to Walt for the purpose of today's call, which is hearing from you.

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Walter.Ellenberg@fda.hhs.gov: Alright folks, now I've got a few things to go over for the general audience, as well as a few things to go over for the presenters and I'll start now.

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Walter.Ellenberg@fda.hhs.gov: Both the Food and Drug Administration and the public believe in a transparent process for information gathering and decision making.

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Walter.Ellenberg@fda.hhs.gov: To ensure such transparency at the open public meeting, FDA believes that it's important to understand the context of an individual's presentation.

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Walter.Ellenberg@fda.hhs.gov: For this reason, FDA encourages you at the beginning of your presentation to advise the audience of any financial relationship that you may have with any firm, group, product, or if known, competing products.

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Walter.Ellenberg@fda.hhs.gov: If you do not have a financial relationship as such, you can simply make a statement to that effect. It should be noted, however, that if you choose not to address this issue of financial relationships at the beginning of your presentation, it will not preclude you from speaking.

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Walter.Ellenberg@fda.hhs.gov: During this webinar, all microphones for the general audience have been muted, with the exception of the presenters and myself and the chat functionalities are also disabled.

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Walter.Ellenberg@fda.hhs.gov: At the appropriate time I'll introduce each speaker so that they can begin their presentation.

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Walter.Ellenberg@fda.hhs.gov: Now for the presenters, this is a little bit of information that may help you. We greatly appreciate your interest at speaking at today's meeting.

00:40:13.380 --> 00:40:26.250
Walter.Ellenberg@fda.hhs.gov: We think it's important and we also recognize that emotions are always strong we discuss matters pertaining to pets and pet foods and as such we strongly encourage you

00:40:27.570 --> 00:40:45.420
Walter.Ellenberg@fda.hhs.gov: to observe the following items, so that we can have a really highly productive meeting. First of all, when it's your turn to speak, please state your name and your affiliation at the beginning of your presentation. The six minute timer will not begin until after you introduce yourself.

00:40:46.770 --> 00:40:51.780
Walter.Ellenberg@fda.hhs.gov: Secondly, we ask that you honor your time limit and demonstrate respect towards your fellow speakers.

00:40:53.130 --> 00:40:59.970
Walter.Ellenberg@fda.hhs.gov: We will give you a 30 second notice for every single speaker so that they can then wrap up the presentation.

00:41:01.470 --> 00:41:13.500
Walter.Ellenberg@fda.hhs.gov: For those of you who submitted slides, your slide presentations have been pre-loaded into this meeting agenda and when prompted by you, I will advance the slides through your presentations.

00:41:14.490 --> 00:41:20.700
Walter.Ellenberg@fda.hhs.gov: The master agenda has been designed so that subsequent presenters will know their position in the queue.

00:41:21.570 --> 00:41:34.080
Walter.Ellenberg@fda.hhs.gov: Remember to speak clearly and efficiently so that you can deliver your entire presentation within the time limit. Should you run out of time, you're welcome to submit the balance of your presentation to the docket.

00:41:36.120 --> 00:41:47.550
Walter.Ellenberg@fda.hhs.gov: Throughout the afternoon, we expect that the presentations will likely generate additional ideas and should this happen, we really encourage you to submit your information to the docket.

00:41:48.120 --> 00:42:00.030
Walter.Ellenberg@fda.hhs.gov: And again for those you who may be wondering, that docket number is FDA-2021-N-0859.

00:42:01.320 --> 00:42:05.010
Walter.Ellenberg@fda.hhs.gov: The docket is currently open, but it will close on October 25th.

00:42:06.600 --> 00:42:13.050
Walter.Ellenberg@fda.hhs.gov: And so, at this point I'm going to turn off my camera and we're going to shift into the public presentations.

00:42:17.190 --> 00:42:29.190
Walter.Ellenberg@fda.hhs.gov: And the public presentations for the first section of this meeting will deal with contaminants. We actually have two speakers who request a time to present. Our first speaker is Jessica sleater.

00:42:31.440 --> 00:42:32.850
Walter.Ellenberg@fda.hhs.gov: Miss Sleater are you present?

00:42:34.770 --> 00:42:38.310
Walter.Ellenberg@fda.hhs.gov: If so, unmute your microphone and you can begin to talk.

00:42:42.030 --> 00:42:43.140
Walter.Ellenberg@fda.hhs.gov: Your microphone should be open.

00:42:43.410 --> 00:42:44.550
01_Jessica Sleater: Yes, can you hear me.

00:42:45.240 --> 00:42:46.140
Walter.Ellenberg@fda.hhs.gov: Yes, we can.

00:42:46.350 --> 00:42:58.320
01_Jessica Sleater: Okay, great um Thank you so much to the FDA for hosting this listening session, my name is Jessica Slater and my law firm is anderson's later so jani.

00:42:58.770 --> 00:43:22.140
01_Jessica Sleater: And I'm a consumer protection attorney and I represent pet owners, whose pets have become sick and, sadly, some have died after they eat pet food that was found in several cases to be contaminated so that's I guess my my background and my potential conflict.

00:43:22.980 --> 00:43:24.960
Walter.Ellenberg@fda.hhs.gov: excellent start your timer now.

00:43:25.170 --> 00:43:26.220
01_Jessica Sleater: Okay, thank you.

00:43:28.110 --> 00:43:37.830
01_Jessica Sleater: So if you could move to the first slide please one issue that i've noted in my practice involves.

00:43:38.340 --> 00:43:47.070
01_Jessica Sleater: The issue of pentobarbital has been found in pet food and for those listening pentobarbital is actually a drug that is used to euthanize the animals.

00:43:47.730 --> 00:43:58.290
01_Jessica Sleater: The FDA states on its website that there's zero tolerance for pentobarbital as well as some other potential contaminants that are found that have been found in pet food.

00:43:59.700 --> 00:44:00.420
01_Jessica Sleater: A lot of.

00:44:01.590 --> 00:44:06.960
01_Jessica Sleater: kind of issues that cropped up recently involving what to zero tolerance mean.

00:44:08.220 --> 00:44:12.150
01_Jessica Sleater: One of those is what testing sensitivity.

00:44:13.560 --> 00:44:14.760
01_Jessica Sleater: is required.

00:44:16.080 --> 00:44:24.480
01_Jessica Sleater: From what i've gleaned one of the lowest testing sensitivities is two parts per billion which the FDA has used to test.

00:44:25.140 --> 00:44:38.520
01_Jessica Sleater: pet foods, and I believe that it would be helpful to manufacturers as well as the public to understand that what that zero means and that it's actually at the lowest level that as possible.

00:44:39.750 --> 00:44:43.080
01_Jessica Sleater: Can you please move to the next slide for me thank you.

00:44:44.190 --> 00:44:54.480
01_Jessica Sleater: And one of the other issues that crops up when we're talking about contaminants is corn, and what does that mean on the FDA website there's a study that was conducted in the late 90s.

00:44:55.140 --> 00:45:04.020
01_Jessica Sleater: It was published in 2002 that looked at pentobarbital that was found in DR pet foods and what kind of harm that would cause.

00:45:04.770 --> 00:45:19.680
01_Jessica Sleater: The study it was only conducted over eight weeks to months and it only involves dry pet food, so we aren't sure, with respect to pentobarbital what it means, if a pet is eating.

00:45:20.640 --> 00:45:28.290
01_Jessica Sleater: Any amount of pentobarbital over a long period of time which is often the case, because pet owners give their pets, the same food.

00:45:29.940 --> 00:45:32.850
01_Jessica Sleater: So if you don't mind moving to the next slide please.

00:45:35.130 --> 00:45:44.310

01_Jessica Sleater: And one of the biggest questions that I received from clients and concern pet owners, is what about that, what does that mean.

00:45:45.810 --> 00:45:58.050
01_Jessica Sleater: to emphasize the zero tolerance, I think, would be useful to also states that is that zero for reason it's at zero because it could potentially cause harm.

00:45:59.280 --> 00:46:06.450
01_Jessica Sleater: there's been some recent recalls, though, that involves other potential contaminants and toxins.

00:46:06.780 --> 00:46:23.490
01_Jessica Sleater: And sometimes it stated that they can cause death even so pet owners are obviously when they find out that they have purchased a product that was recalled, because if you know is potentially harmful to their pets, they want to know what level, it is actually harmful.

00:46:25.110 --> 00:46:26.190
01_Jessica Sleater: Next slide please.

00:46:27.990 --> 00:46:41.730
01_Jessica Sleater: One of the issues that cropped up particular Lee with respect to pentobarbital is the process of rendering and I recognize that that's EA has limited resources in what it can do.

00:46:42.900 --> 00:46:52.230
01_Jessica Sleater: But one of the issues that I think is inconsistent with the law is the use of animals and pet food that have not died by slaughter.

00:46:52.560 --> 00:47:05.580
01_Jessica Sleater: And this is what we've kind of uncovered is an issue of the contamination with pentobarbital because that involves the animals that have been euthanized so to the extent that the FDA could step up.

00:47:06.120 --> 00:47:17.430
01_Jessica Sleater: Its enforcement of the use of animals that have not died by slaughter and pet food, I think he could help prevent a lot of the issues of the contaminants as well.

00:47:18.600 --> 00:47:19.560
01_Jessica Sleater: Next slide please.

00:47:21.060 --> 00:47:27.120
01_Jessica Sleater: And lastly, I just was kind of brainstorming based on my own experience what the FDA might be able to do.

00:47:28.200 --> 00:47:39.990
01_Jessica Sleater: One aspect which I know that the FDA does is inspections in some sampling and if there's an issue that's reported, it does test some pet food to determine if there is a contaminant in it.

00:47:40.530 --> 00:47:54.990
01_Jessica Sleater: But one thing I think it could do is implement random testing a pet foods, I think that this would help to be more proactive rather than reactive after pets have become sick or died.

00:47:56.640 --> 00:48:14.760
01_Jessica Sleater: As I mentioned, I think a clarification on the zero tolerance policy that's out there that it actually dictates that at the most sensitive levels that zero you know contaminants including pentobarbital are allowed in pet food.

00:48:15.810 --> 00:48:24.210
01_Jessica Sleater: Some pet food manufacturers can claim that their pet food tested zero if it tests at a less sensitive.

00:48:25.650 --> 00:48:37.680
01_Jessica Sleater: You know parts per billion, and I know that that's not what the FDA intended, so I think addressing that would be a goal long way to understanding what that zero tolerance means.

00:48:38.700 --> 00:48:51.090
01_Jessica Sleater: As I mentioned, the only study that i've seen with respect to the harm that benchmark hulking cause was going going back to the 90s, and the publication from.

00:48:52.620 --> 00:49:11.940
01_Jessica Sleater: But that's the number one concern that I hear from pet owners, is that they want to know you know, is this just going to make my pet potentially you know throw up or you know, have you know some issues, or is it something where my pet might die.

00:49:12.030 --> 00:49:12.840
You know, it might.

00:49:14.430 --> 00:49:25.770
01_Jessica Sleater: have that kind of issue so to the extent that the FDA could perform more studies and notify the public as to like the level of harm that potentially exists with some of these recalls.

00:49:26.760 --> 00:49:36.510
01_Jessica Sleater: Regarding contaminants I think that'd be very useful, as I mentioned, exercising its enforcement over the use of animals that did not die by slaughter and pet food.

00:49:36.900 --> 00:49:47.040
01_Jessica Sleater: And also publishing guidance for pet owners, so that they can know what they should do if they suspect their pet a pet food that might have been contaminated Thank you.

00:49:49.800 --> 00:49:50.520
Walter.Ellenberg@fda.hhs.gov: Thank you.

00:49:54.660 --> 00:50:01.500

Walter.Ellenberg@fda.hhs.gov: And now I'll turn it over to our next speaker is mollie morissette who has an oral presentation.

00:50:03.000 --> 00:50:06.690
Walter.Ellenberg@fda.hhs.gov: Ms. morrissette, are you online and is your microphone active.

00:50:09.240 --> 00:50:10.290
02_Mollie Morrissette: Yes, can you hear me.

00:50:10.800 --> 00:50:16.170
Walter.Ellenberg@fda.hhs.gov: Yes, we can you maybe go ahead and introduce yourself and we'll start the timer afterwards.

00:50:17.700 --> 00:50:30.120
02_Mollie Morrissette: Oh I'm molly more aside the author of poison pads a website and I mom to break X Angelica now A, B and C your personality.

00:50:31.080 --> 00:50:45.030
02_Mollie Morrissette: So I want to thank you for this opportunity it's it's something i've really been looking forward to um I'm going to read off when I wrote, rather than just do it off the top my head so here goes.

00:50:47.790 --> 00:50:59.280
02_Mollie Morrissette: Behind the steaks and chicken wings, we see in the supermarket lies of vast fancy maths of meat and poultry parks, then consider inedible but still getting up he made into food.

00:51:00.150 --> 00:51:09.240
02_Mollie Morrissette: At least that's what we're told after all that would otherwise go to waste landfill status turn into something useful like fertilizer and pet food.

00:51:10.830 --> 00:51:21.030
02_Mollie Morrissette: We hear a lot today about what's considered edible and inedible in the pet food industry under USD rule meat and poultry are separated into two types.

00:51:21.600 --> 00:51:39.210
02_Mollie Morrissette: One inspectors being edible and inedible one is suitable for human food and the other is condemned and eventually diverted into animal food, unfortunately, the gulf between the two definitions what is edible versus inedible is vast.

00:51:40.230 --> 00:51:51.810
02_Mollie Morrissette: An animal meat and poultry identified as US condemned refers to livestock that has been quote inspected and found to be in a dying condition or to be affected, with any other condition or disease.

00:51:52.290 --> 00:52:04.680

02_Mollie Morrissette: That would require the condemnation of its carcass quote or quote any livestock showing symptoms of certain metabolic toxic nervous or circulatory disturbances nutritional imbalances.

00:52:05.220 --> 00:52:16.830
02_Mollie Morrissette: or infectious or parasitic diseases quote such as Anna plasma says ketosis leptin Paris lists gives me leptospirosis listeriosis pseudo rabies.

00:52:17.700 --> 00:52:26.910
02_Mollie Morrissette: Brady scraping tetanus grass Kenny transport techniques strangles and stuff oh my lightest acute inflammatory lameness or extensive fistula.

00:52:27.690 --> 00:52:37.830
02_Mollie Morrissette: The US inspected and condemned term refers to carcasses visceral and other parts of the carcass that had been inspected found to be adulterated and condemned.

00:52:39.420 --> 00:52:42.870
02_Mollie Morrissette: Now us inspected and condemned carcasses who show.

00:52:44.070 --> 00:52:50.250
02_Mollie Morrissette: Conditions such so conditions of such diseases include.

00:52:51.300 --> 00:53:02.280
02_Mollie Morrissette: But are not limited to anthrax carcasses who skin or high it's are infected with larvae or external parasites and another pathological skin conditions.

00:53:03.060 --> 00:53:15.780
02_Mollie Morrissette: brains cheek meat and had trimmings from animals done by lead sponge iron ore frangible bullets carcasses infected with tuberculosis color a black light blue Tang hemorrhage except to see MIA.

00:53:16.260 --> 00:53:23.640
02_Mollie Morrissette: toxic and Stephen mellitus tapeworm says liver flukes good bladder worms abscesses unhealed vaccine lesions mange.

00:53:24.330 --> 00:53:39.570
02_Mollie Morrissette: And scab on board and stillborn animals livestock, that is, amid exposed to radiation biological Bridget residues and carcasses so infected that meat consumption may cause with poisoning and that's directly from.

00:53:40.800 --> 00:53:43.650
02_Mollie Morrissette: usda title nine excuse me.

00:53:45.450 --> 00:53:54.690
02_Mollie Morrissette: So there are only three outcomes from meat and poultry once it's been condemned it must be disposed of by rendering chemical donating or by incineration.

00:53:55.080 --> 00:54:05.760
02_Mollie Morrissette: While condemn material could be burned it rarely is rendering converts the condemned to see you in the meeting bone meal meal and animals that therefore.

00:54:06.600 --> 00:54:12.990
02_Mollie Morrissette: Chemical to nature and is required when the condition of sorry that condemned material is shipped from a usda establishment.

00:54:13.410 --> 00:54:26.280
02_Mollie Morrissette: To an animal food process there to prevent it from entering the human food chain that he gave us use me they do nature and can be, for example, kerosene dies diesel carbonic acid.

00:54:26.730 --> 00:54:35.940
02_Mollie Morrissette: or Christ Philip disinfectant this leaves the question of what happens to all the render protein meals and animal fats tragically.

00:54:36.660 --> 00:54:42.240
02_Mollie Morrissette: Much of it forms the basis of animal feed and pet foods sold in the United States today.

00:54:42.780 --> 00:54:59.550
02_Mollie Morrissette: Meeting bone meal is the most used rendered protein ingredients in pet foods, followed by chicken by product meal to meal and poultry broad product meal by weight meat and bones is the third most used ingredient in dog and cat foods.

00:55:00.420 --> 00:55:11.070
02_Mollie Morrissette: The issue is the disparity between usda regulations under Title nine and FDA regulations governing food under Title 21 of the CFR.

00:55:11.550 --> 00:55:25.860
02_Mollie Morrissette: Yes, this fight these two divergence regulating bodies, under the current status as the food contains meat and bone meal or animal fat derived from usda establishment is containing inedible condemn tissue.

00:55:26.280 --> 00:55:33.570
02_Mollie Morrissette: would render the food under the with Brenda sweet adulterated under section for two of the federal food during cosmetic APP.

00:55:34.050 --> 00:55:45.330
02_Mollie Morrissette: Like was the fd and C act for bids quote for the sale of any product if it contains, in whole or in part of any filthy putrid or decomposed substance or if the product.

00:55:46.710 --> 00:55:58.440

02_Mollie Morrissette: Or if it is the product of a of a diseased animal or an animal which has died, otherwise I my slaughter quote at one point, the FDA had compliance policies are guides which for the most part.

00:55:58.950 --> 00:56:15.300
02_Mollie Morrissette: allowed for an enforcement discretion with pet food that would ordinarily have been considered adulterated However, the agency last year with through the three compliance policy guides about using adultery to animal tissue and passes.

00:56:15.810 --> 00:56:16.890
Walter.Ellenberg@fda.hhs.gov: Thirty seconds.

00:56:18.600 --> 00:56:22.290
02_Mollie Morrissette: 30 seconds and this the FDA said, the actual was.

00:56:23.370 --> 00:56:33.090
02_Mollie Morrissette: intended to remind that pet food animals eat industry about the agency's expectations of manufacturers who use materials from diseased animals and animals that have done otherwise done by slaughter.

00:56:33.840 --> 00:56:50.910
02_Mollie Morrissette: Like was the FDA guide for industry on the manufacturing labeling of raw meat pet foods, the agency recommends that manufacturers use sources of animal tissue that past usda inspection can minimize the risk of contamination for human consumption, in other words edible tissue.

00:56:52.740 --> 00:57:03.510
02_Mollie Morrissette: boy I’m not going to make it, however, compliance policies guides a conversion of animal adulterated food to accept what animal of view sorry no feed us remains in effect.

00:57:04.200 --> 00:57:10.980
02_Mollie Morrissette: Well, I was pet food and animal feed manufacturers to petition the FDA to divert food considered adulterated freeman's they use okay I’m going to.

00:57:11.550 --> 00:57:22.290
02_Mollie Morrissette: i've only got like a minute half a minute left if an edible kiss us, which often included the carcasses of condemned animals found to be dead dying disabled disease at the time slaughter.

00:57:22.680 --> 00:57:28.320
02_Mollie Morrissette: are allowed to be used as petfood, how can the FDA assure consumers that pet food is considered safe.

00:57:29.040 --> 00:57:37.710
02_Mollie Morrissette: What potential health consequences will there be for humans, animals and animal by products derived from condemned inedible analyst issues remain in the food chain.

00:57:38.370 --> 00:57:42.900

02_Mollie Morrissette: The question remains how to address the vast divergence and overlapping jurisdiction of the federal.

00:57:43.410 --> 00:57:56.880
02_Mollie Morrissette: oversight system between the two agencies, particularly when condemned rendered meat and poultry from usda establishments used to manufacture petted meets the definition of an alternative food within the Federal food drug and cosmetic act.

00:57:57.240 --> 00:57:57.810
Walter.Ellenberg@fda.hhs.gov: Please read.

00:57:58.650 --> 00:58:09.660
02_Mollie Morrissette: I'm wrapping it up I'm encouraged by the FDA Steve mediums embrace, of the one health initiative which recognizes the interconnection between all humans and animals health.

00:58:10.080 --> 00:58:22.200
02_Mollie Morrissette: which aims to quote promote improve and defend the health and well being of all species it's a hope we share the one for a better, safer and healthier world Thank you.

00:58:24.480 --> 00:58:24.990
Walter.Ellenberg@fda.hhs.gov: Thank you.

00:58:28.110 --> 00:58:45.030
Walter.Ellenberg@fda.hhs.gov: And now we will shift gears into the next major topic of our afternoon meeting, and it involves ingredients, we have about nine presenters for this session Kathleen mccarran you're the first one Kathleen your microphone should be open.

00:58:46.830 --> 00:58:47.820
Walter.Ellenberg@fda.hhs.gov: And you may begin.

00:58:49.590 --> 00:58:50.340
03_Kathleen Mccarron: hi can you hear me.

00:58:51.120 --> 00:58:52.230
Walter.Ellenberg@fda.hhs.gov: Yes, we can thank you.

00:58:52.740 --> 00:59:01.950
03_Kathleen Mccarron: hi I'm Kathleen mccarran top dog at portland pet food company, we are a manufacturer of human grade pet food and treats here in portland Oregon.

00:59:02.400 --> 00:59:13.770
03_Kathleen Mccarron: First, I want to thank you for the opportunity to share my comments and present my concerns regarding ingredients, my message see is to bring transparency and that seems to be the theme of the last couple presentations today.

00:59:15.600 --> 00:59:21.030
03_Kathleen Mccarron: As I could only select one topic, I chose my concern to focus on ingredients at this point.

00:59:21.900 --> 00:59:29.460
03_Kathleen Mccarron: I just want to mention main ingredients are not qualified and pet food as a manufacturer of human grade ingredients that have passed inspection.

00:59:30.180 --> 00:59:41.250
03_Kathleen Mccarron: I am not allowed to specify in my ingredient list if an item is usda approved for human consumption, for example as a manufacturer only uses chicken thighs approved for human consumption.

00:59:42.120 --> 00:59:49.650
03_Kathleen Mccarron: I cannot list that on my ingredient list I may only use the term chicken chicken could be any grade, including food grade.

00:59:50.550 --> 00:59:59.550
03_Kathleen Mccarron: asco should approve human food manufacturers to be able to state that ingredients are usda approved for human consumption and the final products and meat should be graded.

01:00:00.390 --> 01:00:11.370
03_Kathleen Mccarron: As you know, ingredients can be usda meats, but do not pass inspection for human consumption upon the final product, and as we all know, condemned meats are commonly used in pet food.

01:00:12.450 --> 01:00:22.080
03_Kathleen Mccarron: This, to me, is a loophole that can be used by manufacturers to mislead consumers and does not permit human good producing companies to distinguish their ingredients from feed ingredients.

01:00:22.710 --> 01:00:33.240
03_Kathleen Mccarron: To complicate matters at the guidelines are interpreted by state regulators differently, and they are not uniform we struggle with this on a monthly basis with we re.

01:00:34.980 --> 01:00:41.190
03_Kathleen Mccarron: resubmitting our certification for States were able to work through it, because we have the all of the documentation.

01:00:41.820 --> 01:00:57.210
03_Kathleen Mccarron: asco also has working groups and recently in August, they had a meeting and i've had put together regulations for human food labeling, I would like to encourage Africa to invite more human food producing companies to participates.

01:00:58.530 --> 01:01:08.160
03_Kathleen Mccarron: and rendered me to be identified as such meat meal chicken mill should have to be listed as not meats, and these are typically organs in all parts of the animals.

01:01:09.630 --> 01:01:15.420
03_Kathleen Mccarron: meal is misleading non descriptive to general consumer most people do not even understand what the term meal means.

01:01:16.380 --> 01:01:24.510
03_Kathleen Mccarron: When a carcass is using rendering there is not much meat left and typically oregon's feathers be except etc are left, and that is what is the rendered.

01:01:24.990 --> 01:01:33.750
03_Kathleen Mccarron: chicken mele our chicken male, meet male etc, and it should be identified as such, we need to bring transparency to the pet food.

01:01:34.860 --> 01:01:46.050
03_Kathleen Mccarron: As you know, natural organic or on all sorts of labeling it only means that natural ingredients come from natural sources but they could be processed in any manner, there needs to be tighter regulations.

01:01:46.770 --> 01:02:01.050
03_Kathleen Mccarron: you'll see gravy several toppers are listed as gravy with meat typically this is water only thing with fancy new GM or tapioca starch gravy should not be allowed to be used as a description of an ingredient on packaging.

01:02:02.490 --> 01:02:09.300
03_Kathleen Mccarron: Splitting is very common within the pet food industry and it's so frustrating to see it when you take time to look at a label.

01:02:09.930 --> 01:02:17.370
03_Kathleen Mccarron: As you know, this allows companies to possibly lift a protein first when they split in ingredients such as rice into four different types of rice.

01:02:18.030 --> 01:02:35.580
03_Kathleen Mccarron: So, for example, if I had 25% meat, protein and 50% rice in my formula, all I would have to do a split the rice into four different types of rice listing them at lower percentages and now my meat ingredient is listed as the first ingredient in the predominance of the weights.

01:02:36.780 --> 01:02:48.300
03_Kathleen Mccarron: what's also very confusing for the consumer is the comparison of Dr versus wet comparison, as we all know, ingredients for pet food or less listed in dry weight per half go.

01:02:48.810 --> 01:02:59.220
03_Kathleen Mccarron: it's very difficult for the consumer to be able to compare a wet food product to a dry weight product, we all know, the calculation is fairly complicated unless they're walking around with a.

01:03:00.000 --> 01:03:08.070
03_Kathleen Mccarron: calculator they're not going to be able to convert this this should be should not be so confusing to compare ingredient percentages.

01:03:09.150 --> 01:03:18.300
03_Kathleen Mccarron: vitamins, minerals and supplements need to be identified, if not only made but sourced from USA ingredients of IBM path of vitamin packs and not be the only.

01:03:18.870 --> 01:03:27.810
03_Kathleen Mccarron: Item listed on a package all the vitamins should be listed and we know, several manufacturers list that they have a proprietary vitamin Pack.

01:03:28.500 --> 01:03:37.320
03_Kathleen Mccarron: In stating fresh whole food ingredients synthetic vitamins and minerals should be added to those statements in bold and not buried in the advertising.

01:03:38.700 --> 01:03:49.350
03_Kathleen Mccarron: Vitamins and minerals are extremely difficult to measure when added into a pet formula and it's speaking to very many companies that make these measurements, it is very, very difficult to measure vitamins.

01:03:50.610 --> 01:04:00.240
03_Kathleen Mccarron: It seems as if these vitamins and vision is not based upon sound science and listening in on an Africa President of meeting in August of 2021 it was very clear.

01:04:01.230 --> 01:04:10.470
03_Kathleen Mccarron: For example, in in trying to measure vitamin D and we know, most of our recalls come from a lot of these synthetic vitamins, minerals, being added.

01:04:11.910 --> 01:04:25.290
03_Kathleen Mccarron: silas violet all needs to be listed as toxic for particularly for dogs, I know, as recent as September 14 2021 a bill has been presented to Congress, and I think that this needs to be considered, and particularly for.

01:04:25.740 --> 01:04:41.640
03_Kathleen Mccarron: The toxic level that it has for dogs and I’m going to summarize, you know, lastly, if you can't pronounce it do not know what is, why would you feed it to your best friend, I know these are daunting task for one agency.

01:04:42.780 --> 01:04:43.290
03_Kathleen Mccarron: To.

01:04:43.950 --> 01:04:45.120
Walter.Ellenberg@fda.hhs.gov: Thirty seconds.

01:04:45.600 --> 01:04:50.910
03_Kathleen Mccarron: we're all here to work together, we want the best for our animals and for ourselves, thank you.

01:04:53.190 --> 01:04:53.760
Walter.Ellenberg@fda.hhs.gov: Thank you.

01:04:56.850 --> 01:04:58.800
Walter.Ellenberg@fda.hhs.gov: Our next speaker is Cheryl greenacre.

01:05:03.360 --> 01:05:04.380
Walter.Ellenberg@fda.hhs.gov: microphone ready.

01:05:06.090 --> 01:05:07.050
Walter.Ellenberg@fda.hhs.gov: ready to begin with you.

01:05:07.680 --> 01:05:08.640
04_Cheryl Greenacre: Can you hear me oh good.

01:05:10.650 --> 01:05:11.820
04_Cheryl Greenacre: alrighty um.

01:05:12.900 --> 01:05:21.720
04_Cheryl Greenacre: I am talking about pea protein associated with 16 stones and ferrets I know a lot of you have a main interest in dogs and cats but.

01:05:22.380 --> 01:05:31.380
04_Cheryl Greenacre: There are other pets out there and they're just as dare to the people, I have no financial relationship with any firm company group or product.

01:05:32.190 --> 01:05:47.340
04_Cheryl Greenacre: I have been a exotic animal practitioner in academia, for the last 30 years currently I'm at the University of Tennessee college of veterinary medicine, my concern on this topic arises from the alarming number of.

01:05:48.420 --> 01:05:49.050
04_Cheryl Greenacre: stones.

01:05:50.400 --> 01:05:55.050
04_Cheryl Greenacre: I'm seeing in ferrets and the number of surgeries that I am having to perform.

01:05:56.460 --> 01:06:04.980
04_Cheryl Greenacre: Since PS have been added to the diet of ferrets and then also to cat foods that a lot of ferrets.

01:06:06.150 --> 01:06:08.460
04_Cheryl Greenacre: are offered by their owners next slide please.

01:06:12.630 --> 01:06:23.730
04_Cheryl Greenacre: If you don't know ferrets are carnivores they're actually more of a carnivore than a cat and that they require more protein an animal source protein and more fat in their diet than cats even.

01:06:25.260 --> 01:06:33.150
04_Cheryl Greenacre: The prevalence of 16 year old with ISIS or stones is increasing and ferrets like I said i've been doing this for 30 years and I.

01:06:33.960 --> 01:06:43.650
04_Cheryl Greenacre: would say in the last 10 years me and even the last five years we have seen a really high number of assisting stones in in ferrets.

01:06:44.550 --> 01:06:54.540
04_Cheryl Greenacre: All the cases of 16 stones and at the University of Tennessee have been fair in ferrets that are fed a diet that contains pea.

01:06:54.840 --> 01:07:06.360
04_Cheryl Greenacre: Protein there was one that had lentil protein in the diet that they were being fed we're not the only ones, seeing this, there are other veterinary hospitals that have reported a similar experience.

01:07:08.190 --> 01:07:16.860
04_Cheryl Greenacre: And references here that I'm not the only one that is noticing this the Minnesota your left Center which is kind of like our.

01:07:17.550 --> 01:07:33.420
04_Cheryl Greenacre: clearinghouse of all stones from all over the country had an article in 20 1816 rising ferreting out the cause and where they described the very high incidence of 16 stones and ferrets.

01:07:34.620 --> 01:07:42.810
04_Cheryl Greenacre: Lately, it used to be that ferrets had only survived stones or mostly streetlights stones and those were ferrets that we're getting into.

01:07:44.280 --> 01:07:51.780
04_Cheryl Greenacre: dog food that are being fed foods that had soy protein in them instead of animal protein so fair to do also gets.

01:07:52.830 --> 01:07:54.210
04_Cheryl Greenacre: To provide stones but.

01:07:55.860 --> 01:08:08.730
04_Cheryl Greenacre: But the Sistine seems to be related to the peas in the diet, there was a recent summary type article and 2020 and their new clinics in North America exotic animal practice and it showed that.

01:08:09.180 --> 01:08:21.930
04_Cheryl Greenacre: 16 stones are increasing and ferrets and the very first warning sign was in 2013 That was the one of the first articles that came out saying that they had described 70 cases.

01:08:24.060 --> 01:08:26.910
04_Cheryl Greenacre: In the past of 16 stones and parents.

01:08:29.430 --> 01:08:30.330
04_Cheryl Greenacre: Next slide please.

01:08:32.700 --> 01:08:44.430
04_Cheryl Greenacre: So here's a picture of a radio graph X Ray picture of a ferret showing stones in the bladder there are usually multiple stones of varying sizes and it's a very difficult surgery.

01:08:44.910 --> 01:08:58.560
04_Cheryl Greenacre: it's not like there's one big stone and it's easy to get out it's a difficult surgery to make sure that you get every one of these little guys 16 stones also don't show up as well on X rays and other stones.

01:09:00.240 --> 01:09:09.180
04_Cheryl Greenacre: The key point I want to get across is that the 16 stones and ferrets are preventable by feeding and appropriate animal protein diet, with no pre or lentil protein.

01:09:10.650 --> 01:09:22.770
04_Cheryl Greenacre: The other point I want to get across is that the suffering of ferrets the financial and emotional cost to owners for the surgical removal of these is preventable by feeding and appropriate animal protein diet.

01:09:24.060 --> 01:09:29.700
04_Cheryl Greenacre: Therefore, I think that a P or lentil protein should not be allowed and ferret diets.

01:09:31.470 --> 01:09:33.570
04_Cheryl Greenacre: And there are a lot of.

01:09:35.760 --> 01:09:41.280
04_Cheryl Greenacre: There are a lot of owners out there that feel like well if I feed a high quality.

01:09:42.690 --> 01:09:49.860
04_Cheryl Greenacre: Grain free feline or cat diet to my ferret that that's better than some of the ferret diets out here, and those are.

01:09:51.420 --> 01:09:56.610
04_Cheryl Greenacre: Probably the majority of the cases that we're seeing the ferrets aren't even on a on a favorite food.

01:09:57.600 --> 01:10:12.270
04_Cheryl Greenacre: So further, I would like to say that feline diets with P or lentil protein should include a warning, not to feed it to ferrets, and this is the advice that I'm giving to my clients when they come to me with their ferrets that have 16 stones.

01:10:14.220 --> 01:10:17.490
04_Cheryl Greenacre: Thank you for your time, and thank you for listening.

01:10:19.680 --> 01:10:20.370
Walter.Ellenberg@fda.hhs.gov: Thank you.

01:10:25.320 --> 01:10:29.010
Walter.Ellenberg@fda.hhs.gov: Our next presentation will be from Harry duty.

01:10:30.720 --> 01:10:32.040
Walter.Ellenberg@fda.hhs.gov: Harry are you on the line.

01:10:35.820 --> 01:10:36.720
05_Harry Duty: Yes, I am.

01:10:37.230 --> 01:10:37.860
Excellent.

01:10:45.240 --> 01:10:46.410
05_Harry Duty: very short and sweet.

01:10:49.980 --> 01:10:53.250
05_Harry Duty: are supposed to be publicly available on regulations.

01:10:54.960 --> 01:11:12.000
05_Harry Duty: For almost all food ingredients FDA allows and to pit for the terms and definitions do not appear on regulations.com This is because almost all the regulations actually aren't federal regulations.

01:11:13.710 --> 01:11:17.070
05_Harry Duty: With a coordinate the administrative procedures.

01:11:18.330 --> 01:11:33.210
05_Harry Duty: FDA has been asked to continue to be asked to hold public meetings on your game regulations publicly and FDA only engages in a privatized process and the private corporation and.

01:11:34.830 --> 01:11:42.780
05_Harry Duty: So far, mta reduces to perform do you require public will my King for pet food ingredients regulations.

01:11:44.130 --> 01:11:46.080
05_Harry Duty: Instead mta.

01:11:47.100 --> 01:12:11.820
05_Harry Duty: And here on continuing the privatized regulation process with the private corporation and pro this privatized process charges to attend meetings, which is a violation of the administrative procedures and FDA allows this group to come from rock or Dan recognizes as acceptable regulation.

01:12:13.500 --> 01:12:17.070
05_Harry Duty: have been legal time and most likely will continue to be.

01:12:18.390 --> 01:12:22.950

05_Harry Duty: Over MCA allowing regulate regulatory to copyright.

01:12:24.480 --> 01:12:45.150
05_Harry Duty: Our Federal regulations FDA has been okay with failing or restricting access to certain Members, to top it all go hire a private attorney john Miller, who is the same attorney or the largest grain based lobbying group I get.

01:12:46.950 --> 01:12:53.490
05_Harry Duty: A response citizens to continue to speak out against STI are facing to public room.

01:12:55.140 --> 01:12:55.980
05_Harry Duty: Thank you for your time.

01:12:59.490 --> 01:13:00.150
Walter.Ellenberg@fda.hhs.gov: Thank you.

01:13:02.070 --> 01:13:05.580
Walter.Ellenberg@fda.hhs.gov: And now we will move to the next presentation.

01:13:06.960 --> 01:13:17.880
Walter.Ellenberg@fda.hhs.gov: It should be Martin alarcon however i've been informed that Mr alarcon is not online at this meeting at this particular time should Mr alarcon join us.

01:13:18.750 --> 01:13:30.540
Walter.Ellenberg@fda.hhs.gov: Later in this meeting, we will reserve is slot so that he can be recognized at the end so given that we will then move to Scheril Murray Powell.

01:13:33.570 --> 01:13:35.280
Walter.Ellenberg@fda.hhs.gov: Miss Powell, are you available.

01:13:43.380 --> 01:13:45.360
Walter.Ellenberg@fda.hhs.gov: We should have an open MIC for him as well now.

01:13:48.420 --> 01:13:49.740
07_Scheril Murray Powell, Esq.: Are you able to hear me.

01:13:50.370 --> 01:13:51.720
Walter.Ellenberg@fda.hhs.gov: Yes, we can thank you.

01:13:51.750 --> 01:14:06.660
07_Scheril Murray Powell, Esq.: Okay, thank you good afternoon to everyone, my name is cheryl Murray Pal esquire I’m a cannabis agricultural and dietary supplement attorney I am also President of green sustainable strong llc and agricultural consulting firm.

01:14:07.680 --> 01:14:18.420

07_Scheril Murray Powell, Esq.: My included might my clients include large and small hemp companies many to provide hemp derivatives for food for humans as well as animals.

01:14:19.410 --> 01:14:35.790
07_Scheril Murray Powell, Esq.: I'm a member of the hemp coalition and you will hear from hunter buffington after me with regards to the tremendous work of the hemp the coalition with regards to hemp derivatives being used for animal feed and, finally, I am a licensed hemp farmer.

01:14:37.080 --> 01:14:45.150
07_Scheril Murray Powell, Esq.: So when we discuss our pets they're not just our trusted companions our pets are really members of our family.

01:14:46.530 --> 01:15:00.180
07_Scheril Murray Powell, Esq.: As Dr Solomon mentioned earlier today manufacturers bear the burden for identifying and controlling hazards, and this is a responsibility that the hemp industry takes very, very seriously.

01:15:01.710 --> 01:15:13.410
07_Scheril Murray Powell, Esq.: On a personal note, as a consumer, and a pet owner, I have in my family a 15 year old dog named Tito and an 18 year old cat named Sylvester.

01:15:13.950 --> 01:15:31.170
07_Scheril Murray Powell, Esq.: They have both use hemp derived products, and not to make any medicinal claims, but we have seen an improvement in the agility and usefulness for these two pet store members of our family from the use of hemp derived products.

01:15:32.370 --> 01:15:50.640
07_Scheril Murray Powell, Esq.: My dog Tito used to need a thunder blanket for hurricanes and I reside in Florida, so you know, hurricanes are pretty prevalent, as well as storms, with the use of CBD we are now able to give him CBD hemp derived CBD prior to storms and that eases the things I.

01:15:51.900 --> 01:16:04.320
07_Scheril Murray Powell, Esq.: Now, when you look at hemp derivatives as pet food historically has been uses pet feed for livestock for centuries, this is something that is an undisputed fact.

01:16:05.730 --> 01:16:23.160
07_Scheril Murray Powell, Esq.: As far as recommendations, the reality, we need to embrace that products are being sold and US currently in the market and happen for years, so, as the saying goes, you cannot put toothpaste back in the toothpaste container.

01:16:24.600 --> 01:16:34.740
07_Scheril Murray Powell, Esq.: Now, I think we have an exciting opportunity with the embracing of real world evidence data to really match the anecdotal with the science.

01:16:36.090 --> 01:16:45.990
07_Scheril Murray Powell, Esq.: We have a community of users who are users of hemp products, who are ready to give their feedback on how they use hemp products for their pets health.

01:16:47.190 --> 01:16:57.300
07_Scheril Murray Powell, Esq.: In fact, many states are already registering retailers of hemp derived products, and that would be a great place to start as far as getting these anecdotally.

01:16:57.690 --> 01:17:10.920
07_Scheril Murray Powell, Esq.: As far as adverse effects and any types of returns due to issues with product these lists are readily available online and their public information and I encourage the FDA to start there.

01:17:12.510 --> 01:17:16.500
07_Scheril Murray Powell, Esq.: When you look at State law there's a tremendous amount of inconsistency.

01:17:17.640 --> 01:17:25.770
07_Scheril Murray Powell, Esq.: Some states are waiting for FDA permission, some states are waiting for asco to give permission and other States are doing their own thing.

01:17:27.180 --> 01:17:35.190
07_Scheril Murray Powell, Esq.: We need national consistency and approval of hemp derived products for pets due to the lack of documented adverse effects.

01:17:36.540 --> 01:17:43.050
07_Scheril Murray Powell, Esq.: The current testing process for Google is cost prohibitive to most industry participants.

36901:17:44.100 --> 01:17:50.910
07_Scheril Murray Powell, Esq.: And the I new dietary ingredient registration is a king's playground to the cost.

01:17:52.620 --> 01:17:57.870
07_Scheril Murray Powell, Esq.: I support FDA modernization, through the use of real world evidence.

01:17:59.040 --> 01:18:09.090
07_Scheril Murray Powell, Esq.: Again let's utilize the industry participants that have used in pet foods, since the Farm Bill of 2014 was passed by Congress and signed into law.

01:18:10.620 --> 01:18:20.880
07_Scheril Murray Powell, Esq.: We need the FDA to support and fund real world evidence studies to expedite the validation of the plethora of anecdotal.

01:18:21.930 --> 01:18:36.720

07_Scheril Murray Powell, Esq.: anecdotal feedback indicating that hemp in animal feed is extremely beneficial for the health of pets, it does not cause adverse effects, I thank you for your time this afternoon and have a wonderful day.

01:18:39.210 --> 01:18:40.560
Walter.Ellenberg@fda.hhs.gov: Thank you for your presentation.

01:18:43.260 --> 01:18:45.900
Walter.Ellenberg@fda.hhs.gov: Next, we have hunter buffington.

01:18:47.520 --> 01:18:51.270
Walter.Ellenberg@fda.hhs.gov: hunter we're making your microphone live, you should be good to go.

01:18:52.320 --> 01:18:53.430
08_Hunter Buffington: Excellent can you hear me.

01:18:54.000 --> 01:18:54.960
Walter.Ellenberg@fda.hhs.gov: Yes, we can.

01:18:55.530 --> 01:19:10.470
08_Hunter Buffington: All right, I am hunter buffington Executive Director of the hemp feed coalition 501 C three nonprofit with a mission to gain federal approval for heaven it's by products as animal feed by the FDA Center for Veterinary Medicine.

01:19:13.500 --> 01:19:14.910
08_Hunter Buffington: All right, Mike my time start now.

01:19:16.680 --> 01:19:17.370
Walter.Ellenberg@fda.hhs.gov: Yes, it does.

01:19:17.790 --> 01:19:29.820
08_Hunter Buffington: Okay, the Agency is a diverse set of stakeholders from across the United States and internationally, that has been brought together by a motivation to increase the health of the planet pets and production animals.

01:19:30.360 --> 01:19:37.410
08_Hunter Buffington: I am proud to share that we were able to complete and submit the first ever ingredient application for healthy meal for laying hands.

01:19:37.740 --> 01:19:46.290
08_Hunter Buffington: To the American association of fee control officials in December of 2020 and that we have received a response from FDA Center for Veterinary Medicine.

01:19:47.040 --> 01:19:52.050
08_Hunter Buffington: We have a meeting in October, and we will be working on a response to move the application forward.

01:19:52.680 --> 01:20:01.470

08_Hunter Buffington: Through that experience I have gained a unique perspective, which I will share today, the first thing to share with the audience is that we are.

01:20:01.830 --> 01:20:16.560
08_Hunter Buffington: really trying to overcome a request by the FDA Center for Veterinary Medicine for an additional data set above the required five to seven non-consecutive lot number samples that are necessary in the ingredient application.

01:20:17.310 --> 01:20:22.200
08_Hunter Buffington: While we were tasked with providing an additional data set to prove imagine at.

01:20:23.100 --> 01:20:36.960
08_Hunter Buffington: The issue is that as many of you know, this analytical chemistry is very expensive when investigating nutritional composition species specific anti nutritive in contaminants often costing thousands of dollars.

01:20:37.500 --> 01:20:51.420
08_Hunter Buffington: Unfortunately, the crest has really come to farmers to provide these certificates of analysis, so that we could get information from across the United States to provide variability between genetics farming practices.

01:20:52.110 --> 01:20:59.640
08_Hunter Buffington: manufacturing and processing So this has become quite a burden, not only for our organization.

01:21:00.030 --> 01:21:12.450
08_Hunter Buffington: But, especially for the farmers who have been asked to provide this information and who are already part of an industry that is not only in its infancy, but is a high risk with a non guaranteed reward.

01:21:13.500 --> 01:21:24.930
08_Hunter Buffington: Even with partnerships with agencies like you're often scientific and established manufacturers of hemp food, it still took us over two years together the requested information to complete our submission.

01:21:25.650 --> 01:21:34.410
08_Hunter Buffington: While this work was helpful to understand the nutritional and contaminant composition of hemp seeds not flower as food and feed.

01:21:35.010 --> 01:21:42.090
08_Hunter Buffington: It definitely provided an additional barrier that we are still working to overcome with the next ingredients that we intend to move forward with.

01:21:43.080 --> 01:21:57.600

08_Hunter Buffington: The second barrier that I want to address is the current assumption that cannabinoids are drugs and that an initial approval of dialects now prevents any other designation for ingredients containing even trace amounts of cannabinoids.

01:21:58.260 --> 01:22:07.290
08_Hunter Buffington: I would like to remind the audience that FDA acknowledged three have seen ingredients hearts oil and protein powder as generally recognized for safe and for humans.

01:22:07.620 --> 01:22:11.850
08_Hunter Buffington: In December of 2018 the same year, the EPA dialects was approved as a drug.

01:22:12.630 --> 01:22:26.190
08_Hunter Buffington: In its response, the FDA acknowledges that hemp direct seed derived ingredients contain only trace amounts of thc and CBD and that consumption of these hemp seed derived ingredients is not capable of making consumers hi.

01:22:27.450 --> 01:22:37.140
08_Hunter Buffington: This response by the FDA is now in opposition to statements issued in our own response in requesting for approval for hemp seed meal to be fed to laying hens.

01:22:37.860 --> 01:22:43.710
08_Hunter Buffington: In our application, we presented the evidence of nutritional composition as a food source, with an average of 32% protein.

01:22:44.070 --> 01:22:53.880
08_Hunter Buffington: 10% high quality mega fatty acids and quality fiber calories we also identify potential anti neutral tips for chickens and the action limits for contaminants.

01:22:54.330 --> 01:23:01.290
08_Hunter Buffington: These action limits included total cannabinoids and these cannabinoids again found in only trace amounts is echoed by the FDA.

01:23:01.770 --> 01:23:10.230
08_Hunter Buffington: we're set with limits of detection that were achievable for quantification provided by commercial labs accessible to our farmers and processors.

01:23:10.920 --> 01:23:15.630
08_Hunter Buffington: The total cannabinoid limit that we set for an action them, it was 50 parts per million.

01:23:16.170 --> 01:23:22.560
08_Hunter Buffington: To be clear, this is not the amount we anticipate to be found, but again, rather the testing limits that are currently achievable.

01:23:23.100 --> 01:23:31.260

08_Hunter Buffington: I also want to share that this is the same allowable limit of lead and drinking water set by the EPA 50 parts per million.

01:23:32.190 --> 01:23:39.690
08_Hunter Buffington: The most important thing to present to the FDA during this listening session is that we as industry and the regulars that I work closely with.

01:23:40.050 --> 01:23:43.920
08_Hunter Buffington: know that there are cannabis and hemp products flooding the market right now.

01:23:44.700 --> 01:23:54.720
08_Hunter Buffington: But in response, we also have to identify opportunities to provide solutions for feedstock supplies that have been compromised because of fires, floods and droughts.

01:23:55.650 --> 01:24:02.580
08_Hunter Buffington: We cannot afford to continue creating barriers that prevent hemp seed and it's by products that are already recognized as safe for humans.

01:24:02.940 --> 01:24:09.480
08_Hunter Buffington: and which supply high quality, nutritional sources to be set aside slow down or, worse, prevented.

01:24:10.200 --> 01:24:18.240
08_Hunter Buffington: We as an industry and regulators made clear standards to be set and the Agency is working to provide the nutritional and safety data.

01:24:18.510 --> 01:24:27.090
08_Hunter Buffington: To the FTC vm to move our application forward, as well as our intention to present additional applications focused on hemp seed products.

01:24:27.750 --> 01:24:31.950
08_Hunter Buffington: It is critical that we all work together as these products are entering the market right now.

01:24:32.580 --> 01:24:37.740
08_Hunter Buffington: As Colorado regulators have said, we need to define hemp seed ingredients and what is allowed.

01:24:38.280 --> 01:24:48.240
08_Hunter Buffington: This will provide clarity for industry and regulators safety for consumers and the ability to move forward have see products, providing a feed solution in the US and globally.

01:24:48.900 --> 01:25:00.870
08_Hunter Buffington: I want to say that I have appreciated the staff at the CVM working with us through this process and I look forward to

overcoming these barriers and allowing regulators to ensure public and pet safety together.

01:25:01.320 --> 01:25:12.960
08_Hunter Buffington: I'm also happy to provide any of the nutritional or contaminant composition that i've mentioned today and that can also be found on our website hemp feed coalition dot work, thank you for your time.

01:25:15.090 --> 01:25:15.750
Walter.Ellenberg@fda.hhs.gov: Thank you.

01:25:19.740 --> 01:25:24.030
Walter.Ellenberg@fda.hhs.gov: And now we're going to move to our next presentation from miss Sharon Center.

01:25:26.160 --> 01:25:28.680
Walter.Ellenberg@fda.hhs.gov: Center you should have opened microphone.

01:25:29.550 --> 01:25:31.080
09_Sharon Center: I believe I did you hear me.

01:25:31.590 --> 01:25:33.270
Walter.Ellenberg@fda.hhs.gov: Yes, we do you can begin.

01:25:33.660 --> 01:25:36.720
09_Sharon Center: Great you will be advancing my slides, please.

01:25:37.200 --> 01:25:59.550
09_Sharon Center: My name is Sharon Center my name is Sharon Center I'm a professor of veterinary internal medicine at Cornell University and I'm representing an international group working regarding excessive copper in canine foods that are beyond the tolerance for many healthy dogs, please advance.

01:26:00.690 --> 01:26:05.430
09_Sharon Center: We have no a financial conflicting relationship to disclose.

01:26:06.450 --> 01:26:11.970
09_Sharon Center: We published a White Paper in the journal of the American Veterinary Medical Association as an open.

01:26:12.360 --> 01:26:19.410
09_Sharon Center: An open access commentary in February of this year summarizing objective data to validate our concern.

01:26:19.770 --> 01:26:35.190
09_Sharon Center: That allowances for dietary copper mandated by regulatory agencies exceed physiologic tolerance for many healthy dogs since modification of food grade copper pre-mix supplements in approximately 1993 please advance.

01:26:36.480 --> 01:26:51.600

09_Sharon Center: Our mission is to generate awareness of this problem, encourage communications amongst clinicians pathologists and pet owners and to communicate the severity and urgency of this problem to the regulatory agencies, please advance.

01:26:53.160 --> 01:27:04.260
09_Sharon Center: Commercial dog foods as simplified the husband tree and improved health of pet dogs because dogs are fed the same daily ration dietary formulations can have a cumulative impact.

01:27:04.770 --> 01:27:24.240
09_Sharon Center: There is a notable relationship between dietary formulations and a progressive increase in liver copper concentration over time since the popularization of commercial dog food in the late 1940s highest values realized, since the most recent change in copper supplements, please advance.

01:27:25.740 --> 01:27:32.940
09_Sharon Center: As the liver adjust copper homeostasis this organ manifest the most serious and overt injury with copper accumulation.

01:27:33.510 --> 01:27:50.460
09_Sharon Center: copper provokes oxidative injury to a complex series of interrelated chemical reactions, importantly, the net reaction is generation of the injurious hydroxyl radical that can independently class cell death or worse than coexistence diseases, please advance.

01:27:51.810 --> 01:28:10.200
09_Sharon Center: copper associated liver injury and dogs is insidious and onset with chronic city, it can be lethal leading to cirrhosis middle panel or pan lobular necrosis far right panel I healthy dog liver is shown for comparison, please advance.

01:28:11.610 --> 01:28:18.900
09_Sharon Center: In 2013 a colleague and I published a manuscript where we use the Labrador retriever as the canary in the coal mine.

01:28:19.230 --> 01:28:28.710
09_Sharon Center: To demonstrate the impact of altered dietary copper regulations we measured liver copper and dogs with and without hepatitis in subsets representing errors.

01:28:28.920 --> 01:28:40.320
09_Sharon Center: Before and after altered copper guidelines significantly higher liver copper concentrations coordinated with the revised dietary copper recommendations you'll need to advance twice.

01:28:43.170 --> 01:28:56.580
09_Sharon Center: early recognition of this disorder is difficult disease dogs do not demonstrate signs of illness, rather they display increase serum lt activity, one of the liver enzymes that vacillates.

01:28:57.690 --> 01:29:07.200

09_Sharon Center: Notably, any of these dogs frolicking on the beach could have early copper associated have photography as could your dog right now at home.

01:29:08.430 --> 01:29:24.600
09_Sharon Center: With more advanced disease these dogs develop obvious laboratory and physical and imaging findings indicative of severe liver injury these dogs are more difficult to treat and have a more dismal prognosis we sent them.

01:29:26.790 --> 01:29:35.700
09_Sharon Center: definitive diagnosis requires liver biopsy this is typically by laparoscopic or open surgical methods, because needle biopsies or less accurate.

01:29:36.000 --> 01:29:49.890
09_Sharon Center: And mere aspects of the liver cannot ascertain this diagnosis definitive diagnosis requires pathologic inspection of tissues and reconciliation with the degree of hepatic copper accumulation these advanced.

01:29:51.540 --> 01:30:09.960
09_Sharon Center: costs associated with this disorder involved the diagnostic and treatment expenses that can each range as high as $5,000 this condition and also impacts pets with surgical and anesthetic risks and biopsy associated discomfort as well as owner emotional distress, please advance.

01:30:11.460 --> 01:30:16.320
09_Sharon Center: So the question is how did we get here, please advance.

01:30:18.060 --> 01:30:38.220
09_Sharon Center: This stems from modification of food grade copper additives and commercial dog food, based on a small study in purpose bread dogs in 1993 published only as an abstract that concluded low by availability of copper oxide precluding it's used as a dietary supplement.

01:30:39.720 --> 01:30:46.530
09_Sharon Center: This data was never published as a peer reviewed manuscript the baseline diet was not distinguished in the abstract.

01:30:46.980 --> 01:31:00.630
09_Sharon Center: The outcome recommendation was to replace copper oxide with highly bioavailable copper key lights, in application of this recommendation that baseline dietary corporate content is not considered.

01:31:01.590 --> 01:31:14.370
09_Sharon Center: And importantly, this change was instituted despite no evidence of copper insufficiency in any pet dog that we know of fed commercial diets before the recommended change, please and finance.

01:31:15.780 --> 01:31:30.720

09_Sharon Center: person manufacturers are obligated to follow NRC an ethical recommendations, the abstract recommendations were an active, irrespective of based diet corporate content typically not clearly defined by labeling.

01:31:31.200 --> 01:31:44.910
09_Sharon Center: At present, a standardized pre-mix containing bioavailable copper key later is added to can I formulated diets the net impact is an increase in bioavailable copper in commercial dog foods Lisa dance.

01:31:46.140 --> 01:32:03.720
09_Sharon Center: At this point, it's important to clarify that intolerance to dietary copper is not secondary to a more primary liver disease in the dog and cannot be assigned to more simple genetic mutations, with the exception of a single breed of bedlington terrier Lisa dance.

01:32:04.290 --> 01:32:05.490
Walter.Ellenberg@fda.hhs.gov: You have 30 seconds.

01:32:06.000 --> 01:32:13.440
09_Sharon Center: That food companies cannot independently make corrective changes without in our sea bass FDA recommendations for Africa regulation.

01:32:14.010 --> 01:32:17.970
09_Sharon Center: Historic data supports copper adequacy without copper additives.

01:32:18.360 --> 01:32:27.690
09_Sharon Center: As we are exceeding tolerate a copper intake for many dogs, we believe that copper should be scaled back to estimated intake before the recent change.

01:32:28.020 --> 01:32:37.620
09_Sharon Center: Because copper oxide lacks bio availability is probable that based diets deliver biologically adequate coppers intake there's one last slide.

01:32:41.070 --> 01:32:46.080
09_Sharon Center: change can and should be made without studies to determine minimum copper intake.

01:32:46.560 --> 01:32:55.650
09_Sharon Center: The FDA and Africa need to empower pet food companies to the client copper additives if governing actions are delayed we provide evidence in the White Paper, I cited.

01:32:56.220 --> 01:33:07.620
09_Sharon Center: I just would like to say that any of the members of our working group are available to assist with the mitigation of this avoidable and tragic nutritionally provoked canine wellness thanks so much.

01:33:10.500 --> 01:33:11.100
Walter.Ellenberg@fda.hhs.gov: Thank you.

01:33:12.540 --> 01:33:28.080
Walter.Ellenberg@fda.hhs.gov: Our next speaker is true jeet Nair i've been informed that Mr Aaron may not be online at this time and they just confirm that that he's not so, we will then move forward with our next presenter.

01:33:29.430 --> 01:33:31.260
Walter.Ellenberg@fda.hhs.gov: Which is Kristi smedley.

01:33:32.790 --> 01:33:34.770
Walter.Ellenberg@fda.hhs.gov: christy you should have an open microphone.

01:33:36.060 --> 01:33:37.830
11_Kristi Smedley: This is christy smuggling, can you hear me.

01:33:38.430 --> 01:33:41.220
Walter.Ellenberg@fda.hhs.gov: Yes, we can, would you speak up just a little more.

01:33:41.790 --> 01:33:43.080
11_Kristi Smedley: Okay I'll try this is.

01:33:43.980 --> 01:33:44.940
Walter.Ellenberg@fda.hhs.gov: Much better Thank you.

01:33:45.120 --> 01:33:55.020
11_Kristi Smedley: Okay I'm christy slightly I'm a consultant to companies that are regulated by the FDA especially focusing on animal food additives and food ingredients.

01:33:55.440 --> 01:34:02.970
11_Kristi Smedley: I'm a PhD animal nutritionist trained at Virginia tech I have worked in the animal feed area for 34 years.

01:34:03.390 --> 01:34:12.930
11_Kristi Smedley: The first 10 with FDA in the division of animal foods and in the policy development area and the last 24 consulting with a regulated industry.

01:34:13.470 --> 01:34:24.780
11_Kristi Smedley: Today, I want to share with the audience the important role FDA has and the regulation of beat ingredients and specifically their will and the active definition process next slide please.

01:34:27.120 --> 01:34:37.500
11_Kristi Smedley: This slide is intended to literally follow the history of FDA involvement involvement there wasn't formal involvement of FDA throughout the history of asco over 100 years.

01:34:37.800 --> 01:34:46.320

11_Kristi Smedley: But specifically after 1958 in the passage of the food additive amendments in the 1990s and early 2000 the involvement was more structured.

01:34:47.520 --> 01:34:56.760
11_Kristi Smedley: In 2007 FDA formalizes will with the memorandum of understanding with that with asco which ensures that new thing ingredient modifications.

01:34:57.120 --> 01:35:08.670
11_Kristi Smedley: or excuse me, which assures new field ingredients or modifications of existing definitions was safe and had utility, which is also considered fs efficacy next slide is.

01:35:09.720 --> 01:35:16.860
11_Kristi Smedley: An important point I wish to make is the FDA is the gatekeeper of the after definition process.

01:35:17.430 --> 01:35:26.280
11_Kristi Smedley: To use the after definition route FDA must initially find no apparent safety risk for target animal human food for the environment.

01:35:26.790 --> 01:35:39.030
11_Kristi Smedley: If there are any apparent safety concerns this regulatory path is closed and the new ingredient manufacturers much must use the food additive petition rick Ross knows regulatory.

01:35:39.930 --> 01:35:53.400
11_Kristi Smedley: A full data package is required and review before FDA will make their opinion on the adequacy of the data to support the safety and the utility of the new ingredient or change in the after definition.

01:35:54.270 --> 01:36:07.500
11_Kristi Smedley: This is an important point, I wish to make that FDA, even though this initial safety consideration was made a full day to pay package is realized is required to be submitted.

01:36:08.130 --> 01:36:24.480
11_Kristi Smedley: FDA can and has decided during the review process the aco route is not the correct path and have requested that a different regulatory pathway used if the manufacturer wants to pursue approval next slide.

01:36:26.520 --> 01:36:30.630
11_Kristi Smedley: So what is required to support and after definition request it's a lot of data.

01:36:31.050 --> 01:36:39.060
11_Kristi Smedley: There is a manufacturing area in which in detailed description, the manufacturing process, as well as the quality control measures, including is my compliance.

01:36:39.480 --> 01:36:48.570

11_Kristi Smedley: there's data on multiple batches of the ingredient, this was recently discussed by hunter it demonstrates the consistency of the manufacturing.

01:36:49.020 --> 01:36:57.660
11_Kristi Smedley: The specification, to ensure the safety is the stability of the product as package does the stability of the ingredients, when used in accordance with the directions.

01:36:57.960 --> 01:37:07.950
11_Kristi Smedley: The homage at home and the genetics, of the mix and especially validated analytical methods to support that identity and safety of the years next slide please.

01:37:09.240 --> 01:37:16.230
11_Kristi Smedley: I want to state that these manufacturing information is the same information that's required for food additive or grass submission.

01:37:16.740 --> 01:37:29.070
11_Kristi Smedley: Also, that you must have a significant data package to support target animal safety demonstration that we went that when used in accordance, to the directions of us.

01:37:29.580 --> 01:37:37.680
11_Kristi Smedley: are based on studies, with the animal species as well as physiological status of the intended species support of the safety assessment.

01:37:38.910 --> 01:37:49.680
11_Kristi Smedley: includes peer reviewed published studies and information essential nutrient safety assessment is based on the NRC documentation of nutrient requirements.

01:37:50.310 --> 01:37:59.760
11_Kristi Smedley: I would be remiss to not suggest or to stay that if the ingredient was going to be used the livestock feed also human food safety must be demonstrated.

01:38:01.260 --> 01:38:01.830
Next.

01:38:03.990 --> 01:38:20.820
11_Kristi Smedley: Thank you, studies on target animal safety are also required these demonstrate and support the intended use, for example, and I’m sorry I chose copper as a example, but it was just an example and if a new novel sorts of copper.

01:38:21.840 --> 01:38:31.920
11_Kristi Smedley: was going to be placed on the market, you would need to have studies with varying levels of that that proper compound it would be.

01:38:32.760 --> 01:38:50.460

11_Kristi Smedley: Compared with a negative control and a positive control, and that is to show that this new form of copper is bioavailable and, by the way, not overly bioavailable typically FDA reviews the appropriateness of the protocol prior to the study next slide please.

01:38:53.850 --> 01:39:14.130
11_Kristi Smedley: So to recap the role of FDA a new ingredient definitions and modifications of existing definitions include review of the manufacturing the safety and the utility or better understood, is advocacy data to ensure the new field ingredient will be safe, when used as intended.

01:39:15.180 --> 01:39:24.600
11_Kristi Smedley: If a safer intended us to terminations made the FDA provides that have been into acto supporting the establishment of a new one modified definition.

01:39:26.220 --> 01:39:39.090
11_Kristi Smedley: I want to reiterate the mo new language, it states after will seek advice and a letter of conclusions regarding the suitability of the field ingredient for its proposed us.

01:39:39.390 --> 01:39:48.540
11_Kristi Smedley: From the FDA Prior to adopting the new feed ingredient definitions or amending existing division definitions existing ones.

01:39:49.230 --> 01:40:04.620
11_Kristi Smedley: um it's important to realize that this the, this is a two way street after won't go forward with new definitions about FDA and FDA will review, hopefully in a timely manner, new after definition requests.

01:40:06.030 --> 01:40:07.290
11_Kristi Smedley: Banking next slide.

01:40:08.520 --> 01:40:14.460
11_Kristi Smedley: So why is this important because products that have no current safety risk need a.

01:40:15.210 --> 01:40:24.120
11_Kristi Smedley: Regulatory path because through it's important to realize that 1500 active in find ingredients are not the most of them are not based on food additives.

01:40:24.510 --> 01:40:42.000
11_Kristi Smedley: Regulations or grass regulations brass notices, there will be people would call simple foods barley host sanctuary alfalfa Dr data products on Black soldier fly all these types of products, but in all cases they are required to demonstrate safety next slide please.

01:40:43.410 --> 01:40:44.640
Walter.Ellenberg@fda.hhs.gov: And please try to wrap it up.

01:40:44.850 --> 01:40:56.730

11_Kristi Smedley: Okay, after the definition process conserves resources is sure safety and ensures the until utility also allows for the removal of the definition.

01:40:57.660 --> 01:41:13.590
11_Kristi Smedley: As an owner for dogs one cat for and goats one Doc a small flock laying hands and a small herd of Angus cattle, I am supportive of FDA will and it's showing the safety of for my animals, and for my family who eats their products, thank you.

01:41:15.990 --> 01:41:16.560
Walter.Ellenberg@fda.hhs.gov: Thank you.

01:41:17.670 --> 01:41:21.480
Walter.Ellenberg@fda.hhs.gov: And at this time we're going to take a scheduled 10 minute break.

01:41:22.500 --> 01:41:38.430
Walter.Ellenberg@fda.hhs.gov: And so, by my clock, we will begin in 10 minutes, which would be to 41 on my time so market on yours, the speaker who will be coming up next will be Daniel connors, so we will be back live in 10 minutes.

01:51:01.740 --> 01:51:21.720
Walter.Ellenberg@fda.hhs.gov: Alright, everyone we're back from the break and that will move to the next segment of this afternoon's meeting the next topic session deals with labeling we have one presentation from Daniel connors, I believe that you should have an open MIC can you verify that.

01:51:21.780 --> 01:51:23.820
12_Daniel Connors: I have an open MIC can everyone hear me.

01:51:24.420 --> 01:51:26.490
Walter.Ellenberg@fda.hhs.gov: Yes, we can thank you very much, you can begin.

01:51:26.880 --> 01:51:29.730
12_Daniel Connors: All right, wonderful and, hopefully, you have my slide set.

01:51:32.640 --> 01:51:34.320
Walter.Ellenberg@fda.hhs.gov: believe we do yep.

01:51:34.380 --> 01:51:46.140
12_Daniel Connors: All right, my name is Daniel connors and I am the Vice President of research and development, with the veritas farms as financial disclosure, we are a manufacturer of pet treats and pet supplements.

01:51:47.250 --> 01:52:01.140
12_Daniel Connors: I’m here to talk about the ingredient safety advocacy average reactions and really focus on the dosage form animal health care product area, and especially in the case of cannabinoids.

01:52:02.190 --> 01:52:04.470
12_Daniel Connors: If I can have you moved to the next slide.

01:52:06.240 --> 01:52:08.190
Walter.Ellenberg@fda.hhs.gov: and your timer begins now, thank you.

01:52:09.480 --> 01:52:16.830
12_Daniel Connors: What our intent is and why we chose to focus on the labeling is because we are speaking about the.

01:52:17.970 --> 01:52:30.210
12_Daniel Connors: Special Area of dosage form animal health products, this is a large market that has been developing in the last few years it's parallel to the humans nutritional supplement market.

01:52:31.140 --> 01:52:42.240
12_Daniel Connors: and covers a wide range of products for numerous animals obviously this is a little bit focused on dogs and cats and pets, but this is the broad market.

01:52:43.680 --> 01:52:55.080
12_Daniel Connors: So this has been created under the enforcement discretion of the FDA and puts a lot of the responsibility on the companies, which means that that transparency of.

01:52:55.380 --> 01:53:06.990
12_Daniel Connors: What the company is communicating to the consumer is really fundamental and working through the idea of what a label and how this special type of.

01:53:07.590 --> 01:53:22.350
12_Daniel Connors: pepper product needs to be marketed and regulated and how we would approach that is kind of paramount to the safety for consumers and their pets.

01:53:23.310 --> 01:53:36.300
12_Daniel Connors: We are a manufacturer of cannabinoid based pet supplements and we're not the only ones, but there are numerous companies that have been working with dosage for me, I will health products.

01:53:36.960 --> 01:53:50.760
12_Daniel Connors: And our argument is that not only do these type of products need to show the equivalent types of safety risk monitoring health protection as any other ingredient that might be used.

01:53:52.020 --> 01:54:02.400
12_Daniel Connors: That we really think that there's a lot of evidence that we can point to specifically with canaveral use for animal health products.

01:54:02.760 --> 01:54:21.150
12_Daniel Connors: We also want to argue that there's kind of a reasonable set of information that should be communicated to the consumer

and as well as to veterinary partners of what the relative point what the intent of an animal health care products should be based off of what information is shared.

01:54:22.500 --> 01:54:32.160
12_Daniel Connors: paramount to that is the dosage on it must be presented as effective but below levels that would be a risk for adverse reactions.

01:54:33.030 --> 01:54:39.510
12_Daniel Connors: The purity of the ingredients there's definitely been some discussion of that meets requirements appropriate for the usage.

01:54:39.900 --> 01:54:50.940
12_Daniel Connors: um it's in line with standard good manufacturing processes claims and labeling are demonstrating that there is a difference with this type of product between health support.

01:54:51.390 --> 01:55:11.610
12_Daniel Connors: And a clinical drug application and so being explicit in what is an acceptable structure function claims versus something that is much more explicit as a clinical drug ingredient the vehicle for the ingredient needs to be proven is safe and is.

01:55:12.990 --> 01:55:19.680
12_Daniel Connors: Ideally, is perfectly non toxic is anything else on so it doesn't contribute to adverse health risks.

01:55:20.160 --> 01:55:38.910
12_Daniel Connors: And finally, that the products are not marketed or intended as a replacement for any sort of total nutrition animal feed, so this is a type of products that are frequently marketed as choose as treats or as topical applications in no way do these represents a full health.

01:55:40.170 --> 01:55:52.140
12_Daniel Connors: replacement and they should not be applied to do so, so we think that those are the types of criteria that need to be discussed and need to be captured on the outside of any consumer product.

01:55:52.710 --> 01:56:03.780
12_Daniel Connors: On the rest of this presentation is a little bit of an example of how cannabinoids have some evidence based safety and efficacy and how we might be able to discuss that.

01:56:04.740 --> 01:56:10.650
12_Daniel Connors: As a potential ingredient, so thank you for coming forth on this is a comparison of.

01:56:11.400 --> 01:56:22.590
12_Daniel Connors: A couple of different ingredients that have been used in this type of dosage form animal health product, these are for studies and the citations are listed below.

01:56:23.100 --> 01:56:32.550
12_Daniel Connors: These are publicly available in peer reviewed there's a study of glucosamine chondroitin and collagen as a treatment regimen for.

01:56:32.940 --> 01:56:42.870
12_Daniel Connors: osteoarthritis and dogs so there's been two well received peer reviewed studies that showed that there was an advocacy at a published dosage.

01:56:43.560 --> 01:57:01.290
12_Daniel Connors: Canada dial, which is the CBD in in most frequently used as a cannabinoid in this type of supplement or health product also shows supportive effects one as part of an anti inflammatory regime and one is.

01:57:02.490 --> 01:57:14.910
12_Daniel Connors: actually has a treatment on its own, the important thing that was reported was that there was actual dosages associated with this, that means that this can be communicated to veterinary partners or it can also be.

01:57:15.750 --> 01:57:33.810
12_Daniel Connors: described as something that a consumer would be able to dose based off of their dogs size that can be publicly communicated and I think that is certainly within lines of what reasonable expectation of labeling would require in an animal health product.

01:57:34.950 --> 01:57:39.810
12_Daniel Connors: The other points that we wanted to bring up and if you move on to the final slide.

01:57:41.400 --> 01:57:42.780
Walter.Ellenberg@fda.hhs.gov: Yes, he has 30 seconds.

01:57:43.170 --> 01:57:52.770
12_Daniel Connors: Thank you, is that there is a distance with any of these ingredients for animal health products between the range of and where adverse.

01:57:53.490 --> 01:58:03.780
12_Daniel Connors: effects are expected and where there's a therapeutic or beneficial effect on these are three different studies again publicly available that show that there's.

01:58:04.290 --> 01:58:17.640
12_Daniel Connors: A range between the adverse reaction dosage and what we would expect people to use with their own pets and with that, I would like to wrap it up, and thank you for your time.

01:58:19.650 --> 01:58:20.910
Walter.Ellenberg@fda.hhs.gov: Thank you for your presentation.

01:58:25.080 --> 01:58:37.530

Walter.Ellenberg@fda.hhs.gov: Our next presentation shifts topics to safety with Catherine Alinovi for the next person presentation and miss alinovi your microphone should be open.

01:58:38.820 --> 01:58:40.050
13_Catherine Alinovi: I'm here can you hear me.

01:58:40.410 --> 01:58:41.850
Walter.Ellenberg@fda.hhs.gov: Yes, we can, please begin.

01:58:42.480 --> 01:58:57.300
13_Catherine Alinovi: Thank you and thank you for hosting this very important meeting so I'm Dr Katherine yellow Novi I'm a retired veterinarian and epidemiologist and I'm now the Executive Director of next generation pet food manufacturers association.

01:58:58.080 --> 01:59:11.010
13_Catherine Alinovi: Next gen P fema is a 501 C three dedicated to supporting manufacturers of fresh pet food, I remember companies use the same ingredients in their pet food that are used for human food.

01:59:11.910 --> 01:59:20.280
13_Catherine Alinovi: Our pet foods are raw or gently cooked, and this is in contrast to mainstream pet food products, which is dry kibble or canned food.

01:59:21.600 --> 01:59:39.810
13_Catherine Alinovi: Our manufacturers are in a unique position as they deal with usda past product, which has been held to a different standard under FDA jurisdiction raw pet food, while ready to eat for pets is not ready to eat for human consumption that is held the latter standard.

01:59:41.130 --> 02:00:02.130
13_Catherine Alinovi: Furthermore, it's unprecedented to regulate a product based on its potential impact to a non intended and consumer, as is currently being done by the FDA handling of our manufacturers raw pet food is identical to handling raw meat in the kitchen, as they are made from the same ingredients.

02:00:03.390 --> 02:00:13.410
13_Catherine Alinovi: Are manufacturers products consistent usda inspected and past ingredients which under usda rule may legally contain trace bacteria.

02:00:13.980 --> 02:00:23.160
13_Catherine Alinovi: Such bacteria have been determined by the Supreme Court to be inherent to the components does not an adulterous as defined by the Federal Food and Drug.

02:00:23.640 --> 02:00:41.490
13_Catherine Alinovi: federal food drug and cosmetic act once these usda ingredients are renamed as pet food, however, they enter FDA jurisdiction these pet food products are then deemed adulterated by the FDA to do there's zero tolerance opinion regarding the presence of any bacteria.

02:00:42.780 --> 02:00:50.040
13_Catherine Alinovi: Manufacturers are held responsible for the presence of an inherent compound as if they had added it intentionally.

02:00:51.270 --> 02:00:56.910
13_Catherine Alinovi: were asking for two changes to the regulatory environment for our manufacturers products.

02:00:57.450 --> 02:01:12.090
13_Catherine Alinovi: First, these two agencies, the usda and the FDA must develop consistent risk based standards for salmonella so that raw materials, producers and finished product producers are held to the same standard.

02:01:12.780 --> 02:01:24.810
13_Catherine Alinovi: The lack of consistency in the existing standards places a unique and undue burden on raw pet food manufacturers, no other industry experiences similar regulatory disparity.

02:01:25.920 --> 02:01:36.030
13_Catherine Alinovi: Second, we believe tolerance levels for salmonella and both raw materials and unfinished fresh pet food should be based solely on the risk to the intended consumer.

02:01:36.810 --> 02:01:46.980
13_Catherine Alinovi: According to the federal food drug and cosmetic Act, the food is not considered adulterated if the bacteria present do not ordinarily affect the intended consumer.

02:01:47.460 --> 02:01:57.390
13_Catherine Alinovi: The antenna consumers of raw pet food or dogs and cats, in most cases dogs and cats are biologically capable of tolerating certain levels of some bacteria.

02:01:58.080 --> 02:02:07.800
13_Catherine Alinovi: But the FDA regulates our products based on potential consequences to the most vulnerable human populations, the young, the elderly and the immune compromised.

02:02:08.700 --> 02:02:19.980
13_Catherine Alinovi: Certainly no one wants a child to become sick from handling law meet our manufacturers raw pet food products are no more risky than any other raw meat product intended for human consumption.

02:02:20.880 --> 02:02:29.070
13_Catherine Alinovi: That meat and the meat contained in the raw pet food likely even come from identical sources and maybe side by side in the refrigerator.

02:02:30.030 --> 02:02:37.380
13_Catherine Alinovi: Yet the mean is allowed to contain certain levels of background bacteria, while the raw pet food is regulated to the level of zero.

02:02:37.980 --> 02:02:40.890
13_Catherine Alinovi: Again, no other industry is held to this double standard.

02:02:41.880 --> 02:02:53.760
13_Catherine Alinovi: The right and fresh pet food industry is a bona fide pet food category deserving of consideration and involvement during any rulemaking process that affects fresh usda inspected and past meets.

02:02:54.450 --> 02:03:02.760
13_Catherine Alinovi: Our industry is fully supportive of efforts to ensure manufacturing practices consistently limit contamination pathogens, such as salmonella.

02:03:03.450 --> 02:03:17.400
13_Catherine Alinovi: But demands to eliminate an inherent component from raw materials, without demonstrating the presence of that component is harmful to the intended consumer shows intolerable bias against our industry.

02:03:18.300 --> 02:03:24.840
13_Catherine Alinovi: For this reason we asked to be held to the same standard as the rest of the raw meat industry, thank you for your time.

02:03:27.360 --> 02:03:27.810
Walter.Ellenberg@fda.hhs.gov: Thank you.

02:03:30.960 --> 02:03:35.430
Walter.Ellenberg@fda.hhs.gov: And now we're going to move to our next topic category, which is a.

02:03:36.570 --> 02:03:41.280
Walter.Ellenberg@fda.hhs.gov: it's an entitled other that we received a variety of different.

02:03:42.450 --> 02:03:48.060
Walter.Ellenberg@fda.hhs.gov: topics and we put them all in here, so our next speaker is Susan thixton.

02:03:49.200 --> 02:03:52.080
Walter.Ellenberg@fda.hhs.gov: miss Thixton you should have an open microphone can you verify.

02:03:52.740 --> 02:03:53.700
14_Susan Thixton: Can you hear me.

02:03:54.030 --> 02:03:55.110
Walter.Ellenberg@fda.hhs.gov: Yes, we can, please.

02:03:56.430 --> 02:04:08.490
14_Susan Thixton: My name is Susan thaxton I am speaking on behalf of pet food consumer members of association for truth and pet food and truth about pet food.com next slide.

02:04:11.850 --> 02:04:20.820
14_Susan Thixton: We surveyed our Members asking them multiple questions about the regulation of pet food and the challenges they face when selecting a pet food.

02:04:21.450 --> 02:04:32.760
14_Susan Thixton: 100% of our pet owners stated they did not believe regulatory authorities have their pets best interest in mind when regulating Petric next slide.

02:04:34.440 --> 02:04:40.800
14_Susan Thixton: When asked about their most important concern in pet food our pet owners who are split between three issues.

02:04:41.160 --> 02:04:49.020
14_Susan Thixton: 51% felt regulatory authorities, allowing pet food to violate Federal and State law was their biggest concern.

02:04:49.530 --> 02:05:08.700
14_Susan Thixton: 27% felt the lack of disclosure to the quality of ingredients on the pet food label was their biggest concern and 21% felt poor regulatory monitoring of known pet food contaminants such as mycotoxins and pentobarbital was their biggest concern next slide.

02:05:10.800 --> 02:05:20.340
14_Susan Thixton: 95% of our pet owners sell pet products should be labeled as feed dog feed cat feed if they do not meet the legal standards or food.

02:05:21.060 --> 02:05:38.220
14_Susan Thixton: 100% of our pet owners did not believe the pet food label provides them with sufficient information 78% of our pet owners stated their biggest concern with current pet food labels is no disclosure to quality of ingredients next slide.

02:05:40.320 --> 02:05:54.030
14_Susan Thixton: pet owners don't believe FDA has any understanding of how difficult things are for them, so we asked you to walk in our shoes for just a moment to set the stage for this I provided you with the following analogy next slide.

02:05:55.560 --> 02:06:03.420
14_Susan Thixton: There are many different types of pie apple pie cherry pie pizza pie and kalpa next slide.

02:06:05.280 --> 02:06:19.260
14_Susan Thixton: Now, imagine if you find your family pie, every day, imagine that the pies all look similar and imagine if there was no way for you to tell what type pie, you were buying and feeding your family by reading the label.

02:06:19.890 --> 02:06:32.790

14_Susan Thixton: He wouldn't intentionally give your family callback for dinner, but you aren't told what type of pilot is pi authorities don't require pie manufacturers to disclose the type of pie.

02:06:33.600 --> 02:06:48.900
14_Susan Thixton: And even though cow pie is not allowed to be sold as food per federal law pot authorities allow it through selective enforcement believing properly process cow pies do not pose a safety concern next slide.

02:06:50.550 --> 02:06:59.970
14_Susan Thixton: How would that make you feel how worried, would you be wondering if you were giving your family, the right path, or the wrong.

02:07:01.110 --> 02:07:01.770
14_Susan Thixton: Next slide.

02:07:03.570 --> 02:07:11.130
14_Susan Thixton: This is what it's like for pet owners directly because of regulatory decisions made without consumer input.

02:07:11.760 --> 02:07:19.590
14_Susan Thixton: pet owners are put into a position to blindly buy in feed to their pets unclassified ingredient pet foods.

02:07:19.920 --> 02:07:31.530
14_Susan Thixton: They worry is it edible are inevitable, is it inspected in past, or is it illegal diseased animals and animals that have done, other than by slaughter allowed by FDA enforcement discretion.

02:07:32.130 --> 02:07:38.760
14_Susan Thixton: We all deserve to be provided with full transparency to what we are feeding our families, whether it's pie or pet food.

02:07:39.420 --> 02:07:44.700
14_Susan Thixton: pet owners are the largest stakeholder in pet food, yet we are the most ignored stakeholder.

02:07:45.330 --> 02:07:53.970
14_Susan Thixton: pet food safety laws promised us in 2007 were never implemented and then deleted without a second thought of consumer opinion.

02:07:54.630 --> 02:08:12.750
14_Susan Thixton: FDA regularly speaks to industry, but is not provided pet owners equal time instead of being excluded pet owners deserve to be acknowledged and treated as a valuable stakeholder we hope we can move forward towards that goal, from today on next slide.

02:08:14.580 --> 02:08:28.500
14_Susan Thixton: I close with three quotes from pet owners, when asked what they would like the FDA to know I don't trust your organization to tell me the truth about what's in pet food you cater to the big companies rather than protects the consumer.

02:08:29.520 --> 02:08:35.880
14_Susan Thixton: If FDA is going to ignore regulations and violations and just consider pet food is feed for livestock.

02:08:36.420 --> 02:08:41.370
14_Susan Thixton: I would like their jurisdiction over pet food ended and transferred to the authority of usda.

02:08:41.970 --> 02:08:59.130
14_Susan Thixton: My dog is not livestock could be kept alive just long enough to be slaughtered enter the food chain, my dogs are members of my family and I'm trying to optimize their health, so they can live the longest healthiest wives possible, I do not believe the FDA has the same goals in mind.

02:09:00.180 --> 02:09:09.750
14_Susan Thixton: I'm guessing that most people in the FDA don't have animals as family members, because if they did they would understand, I thank you for your time.

02:09:13.230 --> 02:09:14.670
Walter.Ellenberg@fda.hhs.gov: Thank you for your presentation.

02:09:15.720 --> 02:09:19.440
Walter.Ellenberg@fda.hhs.gov: And at this point in time I'd like to recognize Mr Kohl harrington.

02:09:21.210 --> 02:09:25.110
Walter.Ellenberg@fda.hhs.gov: waiting to get verification all right, Mr harrington you should have an open microphone now.

02:09:25.470 --> 02:09:34.500
Kohl Harrington: My name is Cole harrington I'm an independent filmmaker I own pet schooled an independent continuing education platform for veterinarians and I'm ready to speak.

02:09:38.070 --> 02:09:43.200
Kohl Harrington: earlier speaker attorney JESSICA Slater for pointing out the ongoing issue with phenobarbital.

02:09:43.320 --> 02:09:52.530
Kohl Harrington: it's interesting in this meeting to hear Steve install and say he and FDA care about proactively identifying issues, because this issue in a Barber college just one example.

02:09:52.680 --> 02:10:00.030
Kohl Harrington: Where Mr psalm and it's on record saying he knows there's a massive issue that can lead to death, with pentobarbital in the pet food supply.

02:10:00.480 --> 02:10:07.740

Kohl Harrington: Mr Solomon has stated, he is aware that the issue stems from animals that have died, other than slaughter being used as ingredients and pet food.

02:10:07.920 --> 02:10:14.880
Kohl Harrington: We in the public are aware that animals that have died, other than slaughter are illegal, to be used in pet food under federal law.

02:10:15.270 --> 02:10:20.280
Kohl Harrington: Did Mr Solomon refuses to regulate that law proactively and instead says.

02:10:20.580 --> 02:10:25.920
Kohl Harrington: continuously that no they're going to allow the FDA animals that have died, other than by slaughter.

02:10:26.160 --> 02:10:34.590
Kohl Harrington: To continue to be used in pet foods so he knows where the contaminant comes from and continues to allow for the ingredient that contaminates that food.

02:10:35.040 --> 02:10:43.050
Kohl Harrington: But the matter I wish to speak about today is that, for years the FDA has been regulating the overall pet food sector by what the FDA calls there.

02:10:49.020 --> 02:11:00.180
Kohl Harrington: The FDA has a compliance policy on the issue of role pet food compliance policies 690 dash 800 Congress has confirmed to me that this compliance policy is neither wall nor legally binding.

02:11:00.360 --> 02:11:11.820
Kohl Harrington: In the FDA says it represents simply their current thinking, but in 2019 media release the FDA stated that a particular company had adulterated their product under federal law.

02:11:12.510 --> 02:11:20.280
Kohl Harrington: This was alive by the FDA the company's product was not adulterated under federal law, it simply didn't comply with FDA opinion.

02:11:20.820 --> 02:11:24.990
Kohl Harrington: federal on the issue of role pet food is clear, specifically with sound and ella.

02:11:25.260 --> 02:11:35.430
Kohl Harrington: It states that have food is only adulterated different non added substance as quantified and then render interest to help well the FDA is not quantifying when it comes to this issue.

02:11:35.640 --> 02:11:43.200
Kohl Harrington: And the FDA instead lately relies on their opinion, to try and regulate and bully companies in mislead the public and the process.

02:11:44.190 --> 02:11:54.090
Kohl Harrington: The FDA has been asked, on several occasions, including basis and petitions to perform actual public rulemaking on this issue, and please stop regulating by their opinion.

02:11:54.630 --> 02:12:03.570
Kohl Harrington: And FDA safety and specifically Stephen solvent has continuously refused to try and make their opinion and actual regulation.

02:12:04.110 --> 02:12:11.430
Kohl Harrington: it's clear at this point that Stephen Solomon Eric Nelson Charlotte conway crazy for can David edwards and FDA.

02:12:11.820 --> 02:12:20.280
Kohl Harrington: All know that they're cherry pick claims in severe lack of science, on this issue that's highlighted in their opinion cannot hold up in a federal court of law.

02:12:20.610 --> 02:12:29.760
Kohl Harrington: that's why it's apparent that they don't want to have public rulemaking on this issue, they don't want their science to be challenged if this is really about health.

02:12:30.300 --> 02:12:39.540
Kohl Harrington: getting an actual regulation on this issue shouldn't come with a battle and the FDA continually refusing to pass an actual public regulation on the issue.

02:12:40.620 --> 02:12:51.240
Kohl Harrington: I found it very interesting that, a few years ago, members of FDA CVs publicly announced that they were investigating certain green free diets for a potential link to heart disease.

02:12:51.780 --> 02:12:57.150
Kohl Harrington: How interesting how the zero tolerance policy in this investigation of DCM.

02:12:57.750 --> 02:13:07.140
Kohl Harrington: This is the FDA appearance to target the only two competing sectors to the major grain based dog food companies that have dominated the pet food industry sector for decades.

02:13:07.590 --> 02:13:15.960
Kohl Harrington: Both as your tolerance policy about Raul not a law, but a policy and DCM investigation again, not a law, not a policy.

02:13:16.530 --> 02:13:23.340
Kohl Harrington: allows for consistent and negative media to be produced about the competing sectors to the major grain based foods.

02:13:23.820 --> 02:13:27.270
Kohl Harrington: But what is FDA CV and accomplishing with both approaches.

02:13:27.690 --> 02:13:36.630
Kohl Harrington: Well, I wish to note here and it's already been pointed out by previous presenter that the FDA has long been and continues to be involved with a private corporation abkco.

02:13:36.960 --> 02:13:47.070
Kohl Harrington: Were FDA participate in rulemaking in private, which is in violation of federal administrative procedures act we making any kind by FDA should be entirely public.

02:13:47.520 --> 02:13:58.860
Kohl Harrington: But FDA is again refusing to perform rulemaking for pet food ingredients in compliance with federal law FDA is actually going to great lengths to keep as much private as possible.

02:13:59.550 --> 02:14:04.500
Kohl Harrington: And this private abkco scheme is where the potential corruption comes into play.

02:14:04.980 --> 02:14:14.280
Kohl Harrington: abkco, which is essentially public state and federal regulators hired a private attorney john Miller to represent them legally.

02:14:14.760 --> 02:14:21.120
Kohl Harrington: And this is the same attorney for asi the largest lobbying group for green bay's pet food.

02:14:21.450 --> 02:14:28.320
Kohl Harrington: Yes, you're hearing that correct state and federal regulators have the same private attorney for their private corporation Fo.

02:14:28.620 --> 02:14:42.480
Kohl Harrington: As the regulated major lobbying group asi that cares about their grain based pet foods another dog connected is that some of the fdic vm employees, including Eric Nelson hello, Mr Nelson.

02:14:42.810 --> 02:14:49.410
Kohl Harrington: used to be the President of this private scheme acco and he has long had question we close relationships with a foia.

02:14:49.590 --> 02:14:58.800
Kohl Harrington: It makes sense to me now that empty employees appear to be essentially acting on behalf of a major lobbying group continuously putting competing companies in negative news like.

02:14:59.190 --> 02:15:06.570
Kohl Harrington: Greatly benefits the financial interest of green bay's loving groups, Mr Solomon if you care about transparency in the FDA.

02:15:07.020 --> 02:15:16.290

Kohl Harrington: wise FDA performing rulemaking for animal ingredients in private or will you pass a simple public regulation on the issue of role pet food and stop regulated by your opinion.

02:15:16.500 --> 02:15:24.810
Kohl Harrington: Mr Solomon respectfully until you start commentating regulations publicly and begin holding public regulatory meetings and stop your legal actions and abkco.

02:15:25.080 --> 02:15:33.960
Kohl Harrington: You don't care about being transparent and you continue to be all talk with little to no action and it's unacceptable if you as a citizen agree with my argument made today.

02:15:34.140 --> 02:15:42.480
Kohl Harrington: you're going to have to continue to submit citizen petitions on this issue and continue to voice your opinion on this overall issue until actual change is made, thank you.

02:15:45.630 --> 02:15:47.400
Walter.Ellenberg@fda.hhs.gov: Thank you, Mr harrington for your presentation.

02:15:48.570 --> 02:15:49.290
Kohl Harrington: you're welcome.

02:15:52.920 --> 02:15:55.860
Walter.Ellenberg@fda.hhs.gov: Next, we have Catherine Castonguay here.

02:15:57.060 --> 02:15:59.940
Walter.Ellenberg@fda.hhs.gov: discussed in the way you should have an open microphone did you.

02:16:00.750 --> 02:16:01.290
spine.

02:16:02.490 --> 02:16:03.960
Walter.Ellenberg@fda.hhs.gov: Yes, we can you may begin.

02:16:04.650 --> 02:16:17.910
Catherine Castonguay: alrighty good afternoon I’m Katherine conway presenting on behalf of the diet associated DCM educational lines on the impact of dilated cardiomyopathy related messaging on dogs pet owners and veterinarians next slide.

02:16:20.190 --> 02:16:34.410
Catherine Castonguay: Our group consists of people from all backgrounds, including veterinarians acting as a hub for evidence based information on the issue compiling case information from effective owners and providing emotional support to those affected our main group has over 100,000 workers next slide.

02:16:36.810 --> 02:16:45.540

Catherine Castonguay: The FDA Center for Veterinary Medicine’s mission is to protect human and animal health, this presentation will cover how deal legitimate station of the DCM investigation.

02:16:45.840 --> 02:16:55.950
Catherine Castonguay: puts animal health on the line that's broad impact on human mental health, this issue has become a crucial example of why better pet food regulation enforcement and communication is critical next slide.

02:16:58.230 --> 02:17:07.560
Catherine Castonguay: In addition to the FDA work seven studies have been published, as recently as this year and continue to demonstrate are concerning link between certain diet types in a typical reversible DCM.

02:17:07.920 --> 02:17:15.750
Catherine Castonguay: All mechanism has not been identified curative reversal of disease following dietary interventions strongly suggests diet, to be the primary insight and cause.

02:17:16.080 --> 02:17:25.080
Catherine Castonguay: With individual outcomes likely affected by a variety of other factors, as is the case with any disease or group continues to see new effective owners on a daily weekly basis next line.

02:17:27.150 --> 02:17:36.660
Catherine Castonguay: Initially, the FDA intended to provide updates as information developed in 2020 it became if or when substantive scientific information comes to light what changed next slide.

02:17:38.550 --> 02:17:45.810
Catherine Castonguay: This quote comes from the opening remarks, the 2020 Kansas state for them, and this instance inaccurate repetition from third parties, seem to allude.

02:17:46.470 --> 02:17:55.200
Catherine Castonguay: To the impact on pet food manufacturers from sources broadly condemning the guidance and the chef meant to call that the pendulum has swung the opposite extreme next slide.

02:17:57.060 --> 02:18:05.910
Catherine Castonguay: here's an example from the Google results and 2024 FDA DCM and, as you can note the repeated theme is finding no evidence next line.

02:18:07.620 --> 02:18:12.240
Catherine Castonguay: Failure failure to emphasize the apparent role and diet in these cases, particularly disease reversal.

02:18:12.540 --> 02:18:22.530
Catherine Castonguay: has enabled companies and industry publications to run with the idea that the investigation was invalidated this has been further empowered by continued silence from the FDA on this issue next slide.

02:18:24.870 --> 02:18:32.460
Catherine Castonguay: Here are two more examples of particular know is the explicit statement that risk factors for DCM are not related to diet next slide.

02:18:34.350 --> 02:18:41.340
Catherine Castonguay: Dialogue exonerating these diets, particularly in light of continued cases is harmful or the FDA cannot control or regulate secondary reporting.

02:18:41.610 --> 02:18:50.340
Catherine Castonguay: They can mitigate misconstrue through clear on ambiguous messaging as well as issuing timely and routine updates on the investigation silence only enabled and empowered.

02:18:50.880 --> 02:19:05.040
Catherine Castonguay: Third parties to misrepresent the issue FDA cpm needs to leave how many additional reports have been received, how many more dogs have recovered these updates may not represent substantial scientific information, but they are still invaluable in the public interest next slide.

02:19:06.870 --> 02:19:14.370
Catherine Castonguay: limited time precludes exploring the full emotional impact of DCM so affected owners have left more complete statements and the associated comment bucket next slide.

02:19:16.350 --> 02:19:24.090
Catherine Castonguay: Julie, who lost her young golden Oliver to DCM leads to support our Member groups, she highlights that there is a seemingly endless creative affected dog owners.

02:19:24.420 --> 02:19:33.000
Catherine Castonguay: riddled with misplace Gil at the notion that their decisions could have contributed to the sickness or death of their best friend she element see seeing implicated brands remain on shelves.

02:19:34.020 --> 02:19:40.950
Catherine Castonguay: it's already incredibly painful, notwithstanding the continual advertisement that their brands have no connection to this ongoing health risk next slide.

02:19:42.840 --> 02:19:51.630
Catherine Castonguay: Martha has to labradors the survivors of DCM she expresses a devastating impact of being told the expensive food you chose, for your dogs was in fact slowly killing them.

02:19:51.990 --> 02:19:57.930
Catherine Castonguay: She questions or confidence that the FDA is taking this seriously and believe that too many pet owners have no idea, this was going on.

02:19:58.350 --> 02:20:05.970

Catherine Castonguay: She states that people should not have to be experts and to decide what to buy consumers deserve to trust the foods available for purchase are safe next slide.

02:20:07.980 --> 02:20:13.980
Catherine Castonguay: katie has been Lee are recovering well share your just questioned how something that was supposed to be healthy was killing her boy.

02:20:14.280 --> 02:20:26.490
Catherine Castonguay: to release the fear grief anger guilt and hopelessness her and her husband have grappled with she says that regulation of marketing and holding companies accountable, would be a small comfort and source of closer to those affected next slide.

02:20:28.110 --> 02:20:37.530
Catherine Castonguay: Giuliana who lost her mixed breed Bob to DCM believe she was writing nothing but the best her cardiologist, however, believe food to be the cause with Bob not the first case you've seen.

02:20:37.950 --> 02:20:49.320
Catherine Castonguay: Giuliana recounts the helplessness of wanting a do over and over and feeling actually always more to Bob she has found solace in our support group knowing she is not the only one carrying so many layers of next slide.

02:20:51.690 --> 02:20:59.850
Catherine Castonguay: shifting to the impact on veterinarians that's in our professionals group have repeatedly expressed struggling to counsel pet owners about nutrition, due to the wealth of.

02:21:00.150 --> 02:21:10.740
Catherine Castonguay: wealth of misinformation online particularly mischaracterization of the FDA statements, additionally, many have mentioned receiving threats are intimidating letters or calls from local pet shops.

02:21:11.070 --> 02:21:19.350
Catherine Castonguay: And pet food companies for simply making recommendations to their clients better any professional professionals are already at risk of mental health crises and harassment.

02:21:19.650 --> 02:21:30.210
Catherine Castonguay: As you can see from this information summarized by not one more event, you can see more information on their website, the contentions are rounding this issue or liable to further contribute to the next slide.

02:21:32.280 --> 02:21:43.860
Catherine Castonguay: A veterinarian within our group has contributed does incredibly disheartening to have to continually identify and correct false marketing claims will send your tediously treating patients for disease that could have been prevented next line.

02:21:46.350 --> 02:21:51.300
Catherine Castonguay: In summary, this issue is relevant and represents a continued threat to both animal and human health.

02:21:52.380 --> 02:21:52.950
Catherine Castonguay: Next slide.

02:21:55.200 --> 02:21:59.160
Catherine Castonguay: All the FDA CV and maybe a restricted and pursuing regulatory action again.

02:21:59.670 --> 02:22:08.700
Catherine Castonguay: Related to DCM you can still issue timely updates on the cases received and the ongoing research that you are conducting or a partner on we asked, most importantly.

02:22:08.940 --> 02:22:19.020
Catherine Castonguay: The CDs issue frequent less ambiguous updates to the public silence does not control the narrative prevent misinformation or protect good scientific communication speaking up does.

02:22:19.290 --> 02:22:27.720
Catherine Castonguay: Consumers deserve updates every 612 months we also asked that the reporting for portal on your device to be more user friendly so that.

02:22:28.380 --> 02:22:44.880
Catherine Castonguay: Affected owners and treating veterinarians are more able to report issues to the FDA as Julie emphasizes the hundreds of affected pet owners are suffering emotionally physically and financially and they and their beloved dogs deserve more than silence, thank you for your time.

02:22:46.980 --> 02:22:48.330
Walter.Ellenberg@fda.hhs.gov: Thank you for your presentation.

02:22:51.600 --> 02:23:03.810
Walter.Ellenberg@fda.hhs.gov: And at this time our last presentation is scheduled to be Marietta Walls. I've received information that Miss Walls is not online in attendance in the meeting.

02:23:04.410 --> 02:23:16.890
Walter.Ellenberg@fda.hhs.gov: So with that, what I would like to do is to go back real quickly and verify that those individuals that weren't present earlier in the meeting that we talked about,

02:23:18.150 --> 02:23:23.700
Walter.Ellenberg@fda.hhs.gov: and give them a chance to talk and see if they're present or not. The first one was under the ingredients section.

02:23:25.170 --> 02:23:28.440
Walter.Ellenberg@fda.hhs.gov: and his name is Martin Alarcon.

02:23:32.700 --> 02:23:34.230

Walter.Ellenberg@fda.hhs.gov: Is Martin Alarcon available.

02:23:36.720 --> 02:23:38.520
Walter.Ellenberg@fda.hhs.gov: I'm getting a negative response.

02:23:40.830 --> 02:23:43.320
Walter.Ellenberg@fda.hhs.gov: If not, then we'll move to the other one.

02:23:44.340 --> 02:23:45.750
Walter.Ellenberg@fda.hhs.gov: Sreejit Nair.

02:23:47.160 --> 02:23:48.960
Walter.Ellenberg@fda.hhs.gov: Is Sreejit Nair available?

02:23:52.620 --> 02:23:53.730
Walter.Ellenberg@fda.hhs.gov: No he's not available.

02:23:56.190 --> 02:23:56.700
Walter.Ellenberg@fda.hhs.gov: Alright.

02:23:59.460 --> 02:24:15.540
Walter.Ellenberg@fda.hhs.gov: Then, given that, we will get ready to close this meeting. I'd like to remind everybody that the docket will remain open until October 25th and we really do encourage you all to send information to us so that we have it and can review it.

02:24:16.680 --> 02:24:25.980
Walter.Ellenberg@fda.hhs.gov: All the meeting materials will in today's session will also be available in the docket, as well as the transcript of this meeting and the video recording of this meeting.

02:24:27.150 --> 02:24:32.010
Walter.Ellenberg@fda.hhs.gov: And again, I would like to thank everybody, and with that I will close this meeting, have a nice afternoon.