FDA Virtual Listening Session on the Regulation of Animal Foods with Certain Types of Claims

Moderator: Dr. Walter Ellenberg
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10:00 AM Meeting Starts

MEETING WELCOME

[00:00:02] Walter Ellenberg (Moderator): Good morning and thank you for attending this virtual listening session on FDA's regulation of animal foods with certain types of claims. My name is Walt Ellenberg, and I'll serve as the moderator at today's meeting. The objective of today's meeting is to provide the public the opportunity to share information, comments and insight on this important topic.

The format of today's meeting is actually pretty straightforward. In just a few minutes you'll receive an opening remark from the director of CVM, Dr. Steven Solomon. Following Dr. Solomon's remarks, Dr. Timothy Schell, the director of CVM's Office of Surveillance and Compliance will give a policy overview for the topic of today's meeting. Following their presentations, I will briefly review. Following their presentations, I will briefly review the process for the public presentations.

And now what I would like to do is I will turn off my camera, and I will invite Dr. Solomon to activate his. Make sure your microphone is open and you may begin. Thank you, Dr. Solomon.

OPENING REMARKS

[0:01:28] Dr. Steven Solomon: Thanks. Am I coming through OK?

[00:01:31] Walter Ellenberg (Moderator): Yes, you are.

[00:01:34] Dr. Steven Solomon: Great. Thanks.

Thank you all for joining us today. This is a really important listening session on today's topic of whether an ingredient or product, when used in animal food is regulated as food or as a drug when that article makes certain claims about affecting the structure or function of the animal's body. This has been a topic of great interest across various stakeholder sectors, and I think it's demonstrated by the large number of folks that have registered for today's meeting. The registrants for today include veterinary pharmaceutical manufacturers, feed manufacturers, distributors, veterinarians, animal producers, academia, food safety advocacy groups, congressional staff, a number of Federal and State agencies, and many other key stakeholders. We welcome you all.

We appreciate especially all the stakeholders who are presenting today, and those who will or have already submitted to the public docket to share information and insight with the FDA on this important topic.

Some stakeholders have expressed interest in the development and marketing of safe and effective substances that can be used in animal food to improve the efficiency of livestock production. We also see a growing recognition that substances added to animal food could reduce emissions from animal's digestive processes. Recognizing CVM has a strong commitment to the One Health approach that environmental, human, and animal health are all interdependent. Such products hold the potential to have a significant impact on the environment and, in turn, on public health.

In addition, we're aware of advances in our scientific understanding and ongoing research to better understand how the gut microbiome contributes to the physiological processes of the body, and how articles then added to the food of animals can impact the microbiome of the gastrointestinal tracts and potentially impact animal health, productivity, and the environment.

As animal food and veterinary medical sciences advance, we are working to address practical challenges presented by our regulations. Our regulatory decisions should be based on the best science available, while ensuring the safety of the products that our animals are consuming and the foods that we are eating ourselves.

We recognize the significance of any potential changes to the existing policy. We put together a dedicated work group of experts from across CVM that have been evaluating existing policy, guidance and other documents regulating related to regulating certain claims for animal food including the Policy and Procedures Manual 1240.3605 and exploring ways in which our historic approach could change while still ensuring the safety and efficacy of products making those claims. We charged this work group with assessing a policy change could be accomplished under current authorities or if we would need to engage with Congress for new authorities.

This listening session is an important part of this process. Our opportunity to hear from you.
We have asked you to share with us any challenges the current policy has presented, and to suggest ways in which our policies could change to ensure that we are appropriately reviewing articles claiming to improve animal performance, provide environmental benefits, or impact the animal microbiome to some specified effect while ensuring safety and efficacy.

We will take the comments received today and those submitted to the associated public docket into consideration as we continue our review of the existing policy and examine potential revisions or updates. Rest assured that any proposed policy revisions resulting from our policy review and our analysis of stakeholder input, including your input today, will be shared publicly with an opportunity for comments prior to implementation.

We hope providing this opportunity for early input will allow us to gain insight that will facilitate implementing changes without undue delay. I'll also note that early next year CVM intends to provide the public with additional opportunities to share input on other animal food-related processes such as FDA's role in the AAFCO ingredient definition process. As details for these opportunities are finalized, the FDA will publicize them by posting information on our website. Once again, thank you for your willingness to weigh in on the critical work we do to protect human and animal health. We look forward to hearing your feedback today and reading the comments that are submitted to the docket.

Now, I'll turn it over to Dr. Tim Schell, the director of CVM's Office of Surveillance and Compliance, for an overview of CVM's regulatory classification system for animal food bearing structure and function claims.

Dr. Schell.

POLICY OVERVIEW

[00:06:59] Dr. Timothy Schell: Thank you, Dr. Solomon, and good morning, everyone. The subject of today's listening session is FDA's regulation of animal foods bearing structure, function, or other types of claims. I want to take a few minutes to provide an overview of the current policies used in our regulatory classification of these substances, and CVM's Policies and Procedures Manual 1240.3605, which is titled Regulating Animal Foods with Drug Claims.

FDA enforces the Food, Drug, and Cosmetic Act, commonly referred to as "the Act," which includes regulating animal food and animal drugs. To determine if an article marketed for use in animals in an animal's diet is regulated as a food or as a drug, FDA uses the definition for food and drug found in the Act.

The term, term food is defined in the Act as articles used for food or drink for man or other animals. This also includes components of such articles. Any article intentionally added to an animal food must be either an approved food additive or a substance that is generally recognized as safe.

The Act defines the term drug as articles intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; also as articles other than food intended to affect the structure, or any function of the body of man or other animals; and as articles intended for use as a component of the definitions I just mentioned.

The regulatory classification of an article as a food or a drug relies on the article's intended use. Intended use is shown by labeling claims, advertising materials, historical uses, and by oral or written statements. Labeling claims for animal foods for effects on the structure or function of the body of an animal are limited to the effects that can be attributed to the substance's food properties. The US Court of Appeals for the Seventh Circuit interpreted food to mean ingredients or products that are used primarily for taste, aroma, or nutritive value. These food properties are used to distinguish food articles that affect the structure or function of the body. If the labeling claims indicate that the ingredient or product is intended to mitigate, treat, prevent, or cure diseases in animals, we would regulate that article as an animal drug. And as described in the Policies and Procedures Manual 1240.3605, if the labeling claims indicate that the ingredient or product is intended to improve animal production, we would regulate that also as an animal drug. If it's determined that the article and its intended use are classified as a drug, it would follow the new animal drug approval process. For those articles with claims attributed to their taste, aroma, or nutritive value, they would usually be regulated as animal food through the food additive process.

Today we're focusing the scope of this listening session on animal foods with certain types of claims such as claims for environmental benefits, animal production, and effects on the animal microbiome.

We recognize some articles in animal diets with these types of claims are currently regulated as animal drugs. Our evaluation of our current policy includes whether there could be changes to allow some articles currently regulated as animal drugs to be regulated like animal food. We'd like to underscore our goal of ensuring human and animal safety as well as consistency with current laws and regulations.

We thank you for taking the time to share your input with us today. As Dr. Solomon stated, we will take the comments received today and those submitted to the associated public docket into consideration as we continue our review of the existing policy and examine potential revisions or updates. I remind you that we are accepting electronic and written comments to the docket until November 17th. Details are on FDA's website and we'll also include information in the chat feature on where to submit your comments. Again, thank you for your participation. Today we look forward to hearing from you.

Back to you, Walt.

MEETING OVERVIEW

[0:11:33] Dr. Walter Ellenberg (Moderator): Thank you Dr. Schell. I appreciate that. And now **I** like to express my appreciation for her by joining this meeting, and at this time I actually need to go through a few kind of, information that is going to help everybody who is presenting get through the meeting. This is a very large virtual meeting, and we've made every effort to make certain that it runs smoothly. However, the reality is that unexpected issues do happen electronically, and so, if they do, please bear with us as we'll correct them as quickly as possible. It's important to note that we made every effort to accommodate as many attendees as possible. However, to preserve the bandwidth and the Webinar functionality, we did limit the registration to 1,000 attendees. For those who were unable to register for the meeting. It's important, it's really important for you to realize that you can go in and see the actual video of this presentation and the transcript of the presentation, which will be available on the docket in the next few days. During this webinar, all microphones, except for the presenters, and my microphone will be disabled, and the chat function will also be disabled.

At the appropriate time, I'll introduce each speaker so that they can begin their presentations. So for the presenters, at the beginning of the presentation, I remind you, to please state your name and affiliation at the beginning of your presentation. I will not begin the eight-minute timer until you've actually given us your personal introduction, and then I ask you to honor your time limit to eight minutes. The slide presentations have been pre-loaded onto this meeting's slide deck the and we will be actually, what you will do, is you will actually tell me when to forward your slides throughout your presentations. I also remind you to speak clearly and efficiently, not only so that you can be heard by others, but this helps us in our ability to capture the appropriate transcript in an accurate manner. It also allows others to hear your presentation clearly.

I would also like to mention that if the docket closes, excuse me; the docket does not close until November 17th, however prior to that time, at the close of this meeting, I would ask that each of the presenters submit your slides to the docket ah, from you know your behalf rather than the FDA's behalf. This actually completes the docket, and actually allows you to have the input into the public comment At the beginning of your presentations, like I said, you will have eight minutes, and we are going to ask you to honor your times. At this point in time, we are going to begin the public presentations.

And so with that you will see that our next speaker is Alexia Akbay, and on the next um, you can tell by the bottom corner that the next speaker after that will be Jan Campbell.

So at this point in time, Ms. Akbay, if you will speak up so that we can hear you and um.

Ms. Akbay, are you available?

PUBLIC PRESENTATIONS

[00:15:21] Alexia Akbay: I am. Yes, with that good morning, can you hear me alright?

[00:15:26] Dr. Walter Ellenberg (Moderator): Yes, we can. Thank you very much for joining. You may begin.

[00:15:31] Alexia Akbay: Wonderful! Good morning, everyone. Thank you so much for this platform this morning. My name is Alexia Akbay. I have a background in green chemistry, and today I am representing Symbrosia as a chief executive officer. We are a technology um startup in the ag tech space and working on natural feed additives. I'm here today as a representative of this emerging industry and opportunity, seeking to share our experience in the growing sector.

And next slide, please.

And if you could just get one more. Thank you.

With global recognition of the climate change and its impacts, the pressures at varying levels of public and private sector to reduce greenhouse gas emissions are exponentially increasing. A few examples of this include that the Biden administration is targeting a 50 percent emissions reduction by 2030; 58 percent of Fortune 500 companies and most large beef and dairy livestock affiliated companies have emission reduction goals over the next decade. The SEC will likely require a disclosure of carbon footprint of publicly traded companies within the next five years and more specifically, California State Bill 1383 even requires a 40 percent reduction in methane emissions from the dairy and livestock industry. In order to meet these targets, new products and ways of manufacturing our food will be critical. Agriculture is responsible for over one-fourth of total global greenhouse gas emissions, and within agriculture livestock account for approximately half of the sector's greenhouse gas emissions. This puts many corporations on a clock to achieve drastic emission reductions in their supply chain in support of the Global Paris Agreement or other national or regional targets, as mentioned. Based on our experience, the existing US FDA regulatory framework around the environmental impacts of products is ambiguous and inconsistent with other national policies.

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In our case we're growing and processing an natural feed additive made from seed that functions both as the mineral or nutritive supplement while also reducing methane emissions created by ruminant livestock. The latter, which at current, would be an environmental claim and require additional regulatory drug approval. This reduction methane is directly correlated to improved nutritional intake by the animals a normal outcome of dietary adjustment.

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For innovators using natural products, we believe that PPM 1240.1306 misclassifies natural animal foods with claims from environment, environmental benefits as animal drugs. Beyond seaweed, other products like garlic, orange, essential oils would also be classified as drugs, products that could be naturally available to livestock in the wild. Polynesian and Northern European cultures have been using and implementing seaweed into livestock regiments for hundreds of years. Ultimately the groups that can continue to easily develop and bring products to market in this domain end up being larger corporations with sizable budgets for these products and we believe that this further disadvantages livestock growers. We remain skeptical of a monopolized marketplace.

Next slide.

We suggest a simple adjustment, categorizing natural feed ingredients with environmental benefits as animal food modernizes the policy without removing the necessary safety and consistency protocols. This modernization would bring transparency allowing us to reach private, local, and global climate goals within the needed timelines.

Next slide. Back one more.

Zooming out to a global lens. Um. The existing framework also just favors American companies and the producers in the global market. The European and Australia currently maintain a secondary claim system which allows the ingredients to be categorized as both nutritionally and environmentally beneficial.

Our direct competitors in these regions have received regulatory approval to sell a similar product as a feed ingredient with secondary environmental claims. As a result, livestock producers in these regions will receive these products earlier, differentiate with senior and receive the financial benefit way ahead of their American counterparts

Last side.

Further, we are not discussing or suggesting these concepts in a vacuum. This is an overwh. There is overwhelming industry and public support within our communities to integrate our sustainability solution as quickly as possible and do so in a safe and transparent manner.

We believe that the US can become a worldwide leader in sustainable animal agriculture with the simple adjustment of this policy. Thank you so much for listening today . That will be all from me.

[00:20:28] Dr. Walter Ellenberg (Moderator): Thank you. And now we'll open the microphone for Jan Campbell. Jan, if you can mute your microphone, I mean unmute. And also while we're having the pause here, just as a reminder, presenters will not be using their cameras uh so we're just going to capture your audio. Thank you.

So, Jan Campbell, are you ready?

[00:20:56] Jan Campbell: Yes, Good Morning. I'm Jen Campbell, manager of Regulatory Affairs for Purina Animal Nutrition. I'm sharing today how the FDA policy presents a challenge for the animal food manufacturers as well as their customers and producers. We can't provide necessary and important information about the value of our animal food products, and this puts undue pressure on our producers trying to produce food at an efficient cost.

Producers rely on the feed industry, universities, and research organizations to provide the research findings to help stay abreast of scientific developments, and to help them understand the important role of many ingredients for the well-being and health of their animals. Producers want to know how they can apply the research findings to solve nutritional and production challenges. Thus, allowing the free flow of data would help educate producers about ingredients and products, and would go a long way to increase animal health and performance.

CVM has historically regulated production claims as drug claims. However, this action was based on the non-food ingredients that form the basis for these claims, such as the sub-therapeutic use of antibiotics. Also, only the structure-function claims that relate to taste, aroma, or nutrition of the product are allowed by FDA.

With the implementation of the veterinary feed directive, producers have been urged to use alternatives to antibiotics; however, companies are limited in their marketing and labeling materials. Under the current policy, animal food manufacturers cannot fully describe the health or performance benefits for many of the ingredients and products they have to offer producers despite years of data confirming the health and or performance benefits. Furthermore, no claims can be made on the safety to humans and animals of these ingredients. This stifles research and industry is reluctant to start new projects or to develop new products because the cost of development is very high, and they cannot communicate the benefits of the products in the market.

There are a number of nutritional practices that provide a food basis for production claims, such as feeding animals a higher plane of nutrition will improve animal performance, improved fiber nutrition or mineral nutrient in an animal food will improve feed efficiency, also supplemental energy and protein will improve weight gain and feed efficiency, and range cows will produce more milk when they are fed products with better nutrition instead of just forage. Today, these examples, and based on the intended use, puts these products in the drug category, and there is somewhat of a blurred line between the animal food and a drug.

The new animal drug process is subject to a rigorous approval process and can be cost prohibitive for an animal food manufacturer. The process costs millions of dollars and can take many years to obtain approval. There is also the cost to maintain the approval which involves reporting requirements and inspections. In addition, the manufacturing facility must comply with more stringent current good manufacturing practices. So, there is little economic incentive, and it's really not practical for an animal food manufacturer to seek a new animal drug approval.

The statutory basis for allowing production claims, including structure-function claims, to be made without being deemed drug claims is Section 201(g) of the Federal Food, Drug, and Cosmetic Act. Section 201(g)(1)(C), defines a drug as articles other than food intended to affect the structure or function of the body of man or other animals. Other than food, indicates that under the act foods may be positioned to affect the structure or any function of the body of man or other animals without being characterized as drugs. We believe we are established with sound research and science, truthful and

non-misleading statements regarding the benefits of these ingredients and animal food products should be allowed.

We urge CVM to improve the current FDA Program Policy and Procedures Manual Guide by modifying the guidance and allowing animal food ingredients and food products with production benefit claims as well as substantiated structure-function claims. We also believe claims supported by research for ingredients that improve the health of the environment by altering the animal's digestive process to reduce emissions should be allowed. Promoting technology that improves the sustainability of animal production and promotes animal and environmental health is supported by a vast majority of consumers. In closing, I want to thank CVM for hosting this listening session, and I appreciate the opportunity to share our insights.

[00:26:12] Dr. Walter Ellenberg (Moderator): Thank you. At this time, our next speaker will be David Fairfield. Mr. Fairfield, would you open your microphone and make sure we can hear you.

[00:26:38] David Fairfield: Good morning. Can you hear me?

[00:26:40] Dr. Walter Ellenberg (Moderator): Yes, we can. Thank you. You may begin.

[00:26:43] David Fairfield: My name is David Fairfield, and I'm a Senior Vice President with the National Grain and Feed Association, or NGFA. The NGFA is a Washington, DC based trade association founded in 1986 representing the interests of the grain and feed industry. NGFA member companies operate more than 8,000 facilities that handle and or process over 70 percent of US grain and animal food products. Our membership includes grain elevators, feed and feed ingredient manufacturers, biofuels companies, grain and oil seed processors and millers, exporters, livestock and poultry integrators, and other associated firms that provide goods and services to the nation's grain, feed, and processing industry. The NGFA also consists of 34 affiliated state and regional grain and feed associations.

At the outset NGFA Wishes to commend FDA for conducting today's listening session. We believe this is a valuable first step in receiving stakeholder input related to the Agency's review of how it regulates animal foods with certain types of claims such as claims about environmental benefits, growth, promotion, and feed efficiency and effects on the animal microbiome. NGFA and stakeholder groups in recent years have advocated for additional appropriations from Congress for FDA's Center for Veterinary Medicine to enhance the animal food ingredient review and approval process and to modernize CVM Policy and Procedures Manual Guide 1240.3605, which is the subject of this session. We appreciate that FDA is hosting today's virtual meeting and providing a docket through which written comments on this topic may be submitted.

Since 1998, FDA has used the criteria provided in guide 1240.3605 to determine whether an animal food substance is considered a food or a new animal drug depending on the substance's intended use. Based on the criteria in the guide, FDA's current position is that animal food or ingredients that have an intended use of improving animal production are to be regulated as new animal drugs, and therefore these substances are subject to pre-market review, and approval through FDA's new animal drug application process. Further, FDA's current view is that animal food with intended use claims related to reducing greenhouse gas emissions or improving growth promotion, or feed efficiency, or effects on the animal microbiome, all fall within the category of production claims, and therefore such substances should be regulated as an animal drug. In contrast to FDA's current position, NGFA believes the agency

has latitude to define animal foods that have production benefits or other health benefits as animal food rather than animal drugs.

Clearly, in the federal statutory definitions for food and drug provide FDA with significant regulatory flexibility. As Dr. Schell reviewed, the Federal Food, Drug, and Cosmetic Act defines food to mean in part articles used for food or drink for man or other animals, and articles used for components of any such article, and the term drug is defined in part to mean articles other than food intended to affect the structure or any other function of the body of man or other animals. From an historic standpoint these definitions have provided the flexibility and means to transition substances with certain claims from one category to the other category based on evolving science and information. Animal food nutritional technology has continued to evolve. Products currently exist that are safe and that have scientifically demonstrated production, health, and environmental benefits. NGFA believes providing a more efficient regulatory framework to bring these products to market with such claims will benefit the wellbeing of animals, farmers and ranchers, consumers, and the public at large. FDA's characterization of these products as animal food would allow new technologies and innovation to reach the market sooner, resulting in increased efficiencies within US animal agriculture, enhanced safety of animal derived foods, and reduce greenhouse gas emissions and other environmental benefits. In comparison, FDA's current policy that characterizes these products as animal drugs tends to stifle investment in research, development, and innovation of products that are needed to address the issues of sustainability, health, and food safety.

By modifying its current policy to allow such products to be regulated as animal foods, FDA also would be aligning its regulatory framework with other developed countries. Regulations and policies of these countries allow for products with claims related to environmental benefits, production efficiency, modifying the digestive tract, and changes to the microbiome to be classified as animal food.

In closing, I want to thank FDA again for conducting today's listening session as a first step related to its review of how the agency relates to animal foods with certain types of of claims. We believe the agency has regulatory authority to modify its current policies to allow animal food with production and environmental claims to be regulated as an animal food rather than an animal drug. Such a policy change would benefit the well-being of animals, farmers and ranchers, consumers, and the public at large. Thank you again for the opportunity to provide these comments.

[00:33:15] Dr. Walter Ellenberg (Moderator): Thank you. And so at this time.

Sorry. I apologize about that.

At this time, since we are ahead of schedule by approximately 25 minutes, we would like to see if it's possible to ah promote the individuals who've been on the waiting list ah and we have three individuals who are on the waiting list and so to fill this gap I was I'm going to ask to see if Russell Taylor is available. Ah Mr. Taylor, if you're available and willing to speak at this time, we'll open, raise you up to the level presenter and let you give your presentation.

Mr. Taylor, you're still muted.

[00:34:27] Russell Taylor: Good morning. Yes, thank you for an opportunity to speak. My name is Russell Taylor. I represent the Humic Products Trade Association as President. We are an international

association for humic gas manufacturers. Humic substances are are currently used in animal feeds on a state-by-state basis and are not allowed for use of animal feeds at the Federal level. Humic substances are naturally occurring products that are ubiquitous in nature. They contain minerals and organic acids. We are an emerging industry and these products have been in use in animal feeds published since 1935. These products are commonly used for their mineral profile but are also contain carbon that helps absorbed certain nutrients. One common observation is a reduction of odor, and this has ah been very consistent with the use of humic substances. However, this observation has not been explored by the industry for fear of of being regulated as a drug. Currently, this practice is struggling to be used as an ingredient because the GRAS system is not viable, and policies and procedures are currently treating nearly all new uses as a drug. It would be beneficial for the humic substance industry to have favorable policies that would allow exploration of these emerging emerging benefits that would allow potentially to reduce some greenhouse gases. It is unfortunate that the GRAS procedure is not being allowed to be used as written, and we find that this could be a big benefit to the industry If not all new products were treated as drugs.

I would like to point out that humic substances again are ubiquitous in nature. They are in an animal's normal environment, soil and water, and any regulation or lack of regulation by the FDA will not change the fact that animals are exposed to humic substances in their natural environment. By changing the current policy and allowing some of these products to be used would be favorable to the industry that the Humic Products Association represents. In addition, it would also reflect some of the exposure to animals in their natural environment.

We'd like to thank the FDA for the opportunity for this listening session to make our opinions on this matter heard. Thank you.

[00:37:14] Dr. Walter Ellenberg (Moderator): Thank you and since we are still ahead of schedule, we would like to move to the next individual who is on our waiting list who is Peri Rosenstein of the Environmental Defense Fund.

Please unmute your microphone and you may begin.

[00:37:45] Peri Rosenstein: Thank you to CVM for conducting today's listening session, and for the opportunity to speak on this very important and timely topic. My name is Peri Rosenstein, and I'm a senior scientist of livestock systems at the Environmental Defense Fund. I'm a veterinarian by training and worked for Merck Animal Health and Clinical Research prior to joining EDF. In my professional capacity, I have designed and conducted clinical trials for a number of new animal drugs and interacted with CVM throughout the process.

As an environmental NGO focused on a vital earth for all, addressing the climate crisis with a science-based climate action plan to drastically reduce emissions of methane and carbon dioxide is our top priority. This includes a focus on agricultural emissions, as they are the largest source of anthropogenic methane emissions in the US with 70 percent of those emissions resulting from enteric fermentation from ruminants.

Many organizations, including EDF have committed to the 2030 claimant pledge, and meeting these goals hinges on the availability of solutions to reduce enteric methane emissions. While mitigating these methane emissions will require a multi-pronged approach, feed additives, referring here to any product added to cow feed, are likely to be an integral part of the solution in the near term. Leading solutions

will require products that are effective at reducing and enteric methane emissions, safe for humans and animals, widely adopted by industry, and accepted by consumers.

CVM has a critical role as the gatekeepers to regulatory approval of these enteric methane inhibiting products and ensuring consumer confidence. EDF supports the most appropriate and expeditious pathway while maintaining a robust review of safety and efficacy. While EDF is a strong climate advocate and acknowledges the urgency of addressing these issues with the current approval process, prioritizing speed to market above all else is inadequate to protect people, animals, and the environment. Based on our interviews with over 30 stakeholders, we understand that the current pathways can be time and cost-prohibitive and act as a barrier to research and development of essential innovation in this space. While the current conversation pertains to classification as drug verses feed ingredients, our outreach indicates that all product categories could benefit from clear direction, transparency, and modernization. Regulatory and guidance revisions that would dramatically increase the use of the GRAS pathway to market will undermine consumer confidence in these products and restrict the widespread adoption that is essential to reducing emissions and meeting industry targets.

EDF and other consumer protection and environmental nonprofit organizations have long pointed out the problems inherent in the FDA's GRAS process as written. Independently concluded GRAS assessments allow product sponsors a route to market without FDA review of essential testing for human health, animal health and efficacy. Conflict of interest, bias, and lack of transparency plague this option.

Under the current relationship with the States, there are inadequate checks and balances to accommodate for this risky approach to FDA's oversight obligations. Realizing the current regulatory pathways create challenging constraints and barriers to the adoption of solutions to reduce enteric methane emissions, EDF is convening stakeholders from the US dairy and beef industries, academia, regulatory agencies and NGOs to collaboratively identify and address those challenges. We will be holding a series of stakeholder meetings during three half-day sessions in November. The end in mind is to achieve consensus across the stakeholder groups to collaborate on potential solutions, to expedite approval, and adoption of efficacious climate, beneficial products for animals, which could include proposed language for agency, guidance, regulation, or legislation. While EDF has detailed thoughts on potential improvements and revisions to the guidance, we hope these will be further refined and strengthened through constructive conversation with stakeholders that share common goals. The stakeholder process will not be completed in time to submit collective written comments to the public docket, but comprehensive feedback will be available soon afterwards.

We are excited to see this effort by CVM and appreciate the work to modernize the current policy and potentially provide a more straightforward regulatory pathway for environmentally-oriented products that do not forego safeguards for human health, animal health, and the environment. Thank you very much.

[00:42:05] Dr. Walter Ellenberg (Moderator): Thank you and at this time we have one more individual on the waiting list, Miss Rachel Cumberbatch. Um one thing that I also want to announce is that for those who have been curious. Not all presenters for today's meeting provided slides. Some are strictly oral presentations. The presentations that you just received from ah those on the wait list as well as a couple of others. They did not provide slides. The slides will be provided for those speakers who provided them at the appropriate time and so at this time Miss Cumberbatch would you ah unmute and join the discussion.

[00:42:45] Dr. Rachel Cumberbatch: Good morning and thank you for the opportunity to provide comments. My name is Dr. Rachel Cumberbatch, and I am with the Animal Health Institute. AHI is the national trade association representing the manufacturers of pioneer animal health products. These are the pharmaceuticals, the vaccines, and even the feed additives that farmers and and pet owners use to keep their animals healthy. We recognize that the US farmers feed the world, and that us food producers have made ambitious commitments to reduce their environmental footprint. Healthy animals are imperative to achieving global food security while reaching these sustainability goals.

Like we have heard from other speakers, the American public trusts the US food producers to increase the food production for consumers at home and abroad, and enable for food producers to meet the challenges, it is important that they can adopt innovative production practices and rely on animal health producers to provide innovative products to help meet these demands. An efficient and modern regulatory system is imperative to meeting these challenges whether the challenges be food security or climate change. Today's conversation is an important one for exactly that reason. Clarifying the domestic policies and the procedures that govern what is regulated as food and what is regulated as a drug can support the development of new products by smoothing the regulatory pathway to bringing certain products to market, but there is also a risk to creating confusion in the market.

The next step should be taken carefully and with a clear strategy, and not only how to implement the policy, but also how to enforce it. As Dr. Schell said um and articulated very well at the beginning there is an existing legal framework. Claims that indicate that a product can be used to diagnose, cure, mitigate, treat, or prevent disease or claims indicating a product alters the structure or function of the body in a manner or extent that exceeds its nutritional value, are not permitted on animal feed labels and AHI supports maintaining this paradigm. Also has been stated, the animal health industry is very heavily regulated with requirements to meet a very high standard, including providing substantial evidence of effectiveness and meeting criteria for safety and quality. AHI does not see a need to lower these standards and strongly encourages FDA to promote the integrity of the FDA approval process.

Real-life current situations give us reason to call for proceeding with caution. Today, some companies compound large amount of product from bulk drug substances without a veterinary prescription and market these products as an alternative to FDA-approved medicine. This endangers animals, but it also undermines the FDA drug approval process. We also know from the compounding examples that many users do not understand the difference between what a compounded product is and what is an approved drug. FDA struggles to enforce their current policies in this area, and this offers an example of something that we can learn from a current situation and help us guide what steps are taken next in this area. And so AHI recommends that when considering future steps for how to modernize the approval process of foods with certain claims that FDA makes a clear commitment to protect the current standards for the FDA approval process to ensure customers understand the difference, and most importantly, to create a detailed enforcement plan on how the different processes will be enforced in real life.

And lastly, users of products need to know that they're going to do what they say they will. For drugs we know that there is a very high standard. Unfortunately, this high standard is not well understood by the public, and even some producers or veterinarians can be confused. For this reason, it is important that consideration is given to what the standards will be for the food claims, and how such requirements

will be articulated both to the sponsors of the products, the users of those products, and to the general public who will be a consumer um of the animal products that are fed these ah these certain products.

I want to thank you for the opportunity to join and provide comments today as a summary of AHI's main points. First, let's stay within the bounds of current law and regulation. Second, protect the FDA approval process by maintaining its standard and enforcing FDA policies, and third, prior to implementation, consider both what the standards for making a food claim will be, and how these standards will be enforced and communicated.

Thank you for the opportunity, and I turn it back.

[00:48:09] Dr. Walter Ellenberg (Moderator): Thank you.

I apologize about that. Ah the mute button on my computer is sticking, and so it's creating a problem. But at this time we're going to go ahead and take a break. Ah, I know that the slide says eight minutes. However, since we're still a little bit ahead of schedule, it's kind of create I mean to keep the ah the structure of the meeting, we're gonna have a break from now until 11:05. At that time, we'll crank back up. At that time, the next speaker will be Elizabeth Lewis. And so again, join us again at 11:05 and we will continue the discussion. Thank you.

[00:48:53] BREAK STARTS
[01:02:28] BREAK ENDS

[01:02:28] Dr. Walter Ellenberg (Moderator): All right, and we're back. I'd like to thank you everybody for joining us again for the second session of our public meeting and I want to make one thing clear to everybody is that um! I will be actually advancing the slides from here out on the meeting. We encountered a couple of technical issues with the slide deck, but things should be squared away now, so I'm going to move ahead.

As I said, our next speaker is ah Elizabeth ah Lewis and I'm going to at this time ask Elizabeth Lewis if you would go ahead and unmute yourself, and I will advance your slides for you.

[01:03:22] Elizabeth Lewis: Thank you very much. So I'm here today representing FutureFeed, and I'd like to thank you for this opportunity to contribute.

FutureFeed is a company born out of an IP partnership between the Commonwealth Scientific and Research Organization, which is an Australian Government agency, Meat and Livestock Australia and James Cook University. It's an IP technology company providing supply chain access to seaweed producers through license agreements.

In this presentation, we'd like to use algal-based or derived ingredients which favorably affect the environment as a case study to address some of the FDA's comments or questions as part of this virtual listening session, which is regarding the challenges of the current regulatory process for claims and considering ingredients, which would fit well into the new concepts. So, thank you.

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The algae are well-established primary, nutrient sources in animal food, by which we mean that they're well known for their fat, protein, mineral, carbohydrate-type content in animal feed. However, they do also contain many biologically active compounds which form part of the normal background diet of animals, including humans, and many of these will be known to people, polysaccharides, such as xylan, mannan, phycobillins, carotenoids, and organobromine compounds.

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These biologically active components influence the normal metabolic processes of healthy animals. They do not mitigate, cure, prevent, or treat disease. In that respect, they are not drug like in their functions. It would be appropriate, therefore, to regulate these ingredients making secondary claims on such biologically active components in healthy animals within the food framework.

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One example of the substances that we mentioned there are organobromine compounds, and many of you will be aware of bromoform. It's present naturally in algae such as paradoxus and influences rumen fermentation of healthy ruminants. It only alters the relative level levels of fermentation products. So, in other words, as shown in this short schematic, reducing methanogenesis and increasing a more energy-dense, volatile fatty acid production, e.g. acetate propionate ratio. So in this respect it's balancing within the rumen fermentation, not having a different type of effect.

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So in this sense, feed ingredients have evolved beyond meeting just those primary protein, fat, etcetera, and nutritional needs of the animal. And these feed ingredients play a critical role in influencing the digestion of animals which can favorably affect the environment. And this critical role of feeding ingredients has been recognized by a number of bodies and I've put two examples up here: the farm-to-fork strategy in the EU puts innovative feed additives central to some of its approaches to environmental sustainability, and recently there is a public consultation launched by the Department for Environment, Food, and Agricultural Affairs in the UK again focusing solely on feed products suppressing methane.

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Further examples are the New South Wales Department of Primary Industries that conducted a research paper to identify mitigation strategies, and again identified feed additives as playing a critical role. And we've also seen Canada proposed guidelines for the registration of gut modifier products, which these types of algal ingredients would fit well within with their modification within the rumen fermentation. So in this sense, processes for assessing the safety and utility of these products under the food regulatory framework are essential to allow these types of ingredients, innovative ingredients, to enter the market in a transparent and clear way, which will allow their safety and their utility to be clearly assessed.

And so thank you very much. That's the end of my presentation.

[01:08:04] Dr. Walter Ellenberg (Moderator): Thank you. And at this time our next speaker will be Kristy Smedley is going to be talking on behalf of NOMAD Biosciences. Miss Smedley, please unmute your phone and you may begin.

[01:08:26] Kristi Smedley: Hello. Thank you for holding this listening session for this important subject. I assume you can hear me?

[01:08:35] Dr. Walter Ellenberg (Moderator): Yes, I can. Thank you.

[01:08:36] Kristi Smedley: Thank you.

I'm Kristy Smedley, who is providing the presentation on behalf of NOMAD as Dr. Gleba is attending another meeting. He had looked forward to providing this information to FDA. I am the principal at the Center for Regulatory Services, and I consult with NOMAD on their successful GRAS anti-microbial products that are used in direct addition to animal food. Excuse me, human food.

NOMAD has been in conversation with CVM on their on their antimicrobial products in animal feed and similar to Elizabeth, this is just a case history of understanding how this impacts specific products.

Could I have the next slide?

Our request is for the Policy and Procedure Guide to clearly and consistently reflect that substances used to modify the digesta or the intestinal microflora be regulated as food substances. The current policy lacks clarity, transparency, and appears to be arbitrarily applied. Although there are a number of substances that CVM regulates as food that impacts the digesta and the microbiome. We have provided a few examples. However, other substances that all who stayed in impact is on the microbiome, or the intestinal contents have been deemed by FDA to be an animal drug.

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In a letter CVM states the substances that directly affect the microbiome of livestock are to be regulated as animal drugs based on their, and I quote, “effect on the structure or function of the body (specifically the microbiome).” This appears to be implausible as the lumen of the gastrointestinal tract is outside of the body, and the microbiome would not be considered a part of the body, but a part of the digesta, hence is outside of the body. In addition, CVM has historically permitted substances that have known impacts on the digesta microbiome to be regulated as food and not as drugs. The approach to me seems to be subjective and the the um policy and procedure manual needs to be clear on how these drugs that affect the digesta or the microbiome or fully within the lumen of the gastrointestinal tract are regulated.

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Here we have, I've provided a listing of no questions letters that NOMAD has received for their plant-produced antibacterial proteins. And you can see there's colicin, endrolysin, and salmocin. The um. The GRAS notices cover the safety of the product, the manufacturing safety, the usefulness as an antimicrobial when it’s used in the identified food matrix. These are highly selective, non-antibiotic, antimicrobial proteins that are effective and safe when applied to raw foods, vegetables, poultry, meats fish or liquid when in semi-solid foods and egg products. You can see that's listed. Hence these products are safe when used in direct addition to human different human foods.

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One potential use of these products is to feed them to livestock just prior to slaughter. Let's say one to three days to assure that any potentially pathogenic bacteria are not present in the intestinal contents of slaughter. This would reduce the risk of contamination and slaughter of animal products intended for human food. This is similar to the use of bacteria phages, which are sprayed on the backs of live animals at the slaughter facility, and is been agreed to by USDA. The Center of Veterinary Medicine determined under the existing policy that this type of product should be regulated as an animal drug. Recall the statement they affect the structure or function of the body specifically, the microbiome. Again, NOMAD questions how these products could possibly fit the legal definition of an animal drug as they don't um here diagnosed, cure, mitigate, or treat, or prevent disease in the target animal, and how they would affect the structure or function of the body of the animal, when it is only to reduce potentially pathogenic bacteria resident in the GI tract. We are not certain how the agency interpreted their current PPM. For that use, and we would use and and how that would be considered a drug claim. The antimicrobial use in this manner would require a new animal drug for marketing. By the way, we requested that CSFAN, the Center for Food Safety and Applied Nutrition, consider them to be human food additive that just happened to be administered through animal feed, but they declined.

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It is alarming that CVM has placed the regulatory barriers that inhibit regulatory processes for the use of safe antimicrobial substances to increase the safety of animal products. We are requesting that CVM modify the PPM 1240.3605 to reflect the appropriate regulation of product whose sole intent is to modify the contents of the gastrointestinal lumen, not not those across the intestinal barrier. It's the mode of action that's the most important in this understanding.

Moreover, the modifications of the microbial gut population by these products is only selected by destruction of pathogenic bacteria if present without impacting any beneficial or commensal organisms. It is our opinion that these products should be food if their purpose is not to diagnose, cure, mitigate, or treat, or prevent a disease, or modify the structure or function of the animal. Our request is for the policy and procedure guide to clearly and consistently reflect the substances used to modify the digesta or the intestinal microflora to be regulated as food substances.

Thank you for the opportunity to make these comments.

[01:15:31] Dr. Walter Ellenberg (Moderator): Thank you and our next speaker will be Ann Begley followed by Jamie Jonker. Miss Begley, please begin.

[01:15:51] Ann Begley: Thank you. Can you hear me?

[01:15:53] Dr. Walter Ellenberg (Moderator): Yes, I can. Thank you.

[01:15:55] Ann Begley: Thank you. Good morning. My name is Ann Begley, and I am here on behalf of the Enzyme Technical Association. ETA represents the majority of enzyme producers in the Americas. The ETA supports improving guide 1240.3605 to expand claims available for animal foods, to include production, environmental benefit, and animal microbiome effects.

Today we focus comments on access to production claims for animal foods. Under the guide, such claims are regulated as drugs, and are prohibited for animal foods and nutritional ingredients. However, where such products fall squarely within the definition of a food, this position is contrary to the Federal Food, Drug, and Cosmetic Act. Further, the guide is out of step with the Center for Food Science and Applied Nutrition's treatment of such claims for human foods and is inconsistent with the regulations and policies of many important US trading partners. Now is an ideal time for CVM to update the guide considering the growing need to expand global availability of safe, nutritious food. This is fueled spurred by recent world events, such as the global food supply chain disruptions caused by the pandemic and global conflicts, together with the expected world population growth in the next 30 years which will lead to global food insecurity without current action.

Updating the guide to proactively acknowledge that animal foods and ingredients to can support animal production has the potential to advance product innovation, drive advances in the production of healthy animals, and support a more stable supply of healthy and wholesome meat, fish, dairy, and egg products. A product intended to affect the structure or function of animals can either be a drug or food under section 201(g)(1)(C) of the Act. Therefore, determining such a product's regulatory status is a critical factor in evaluating cost and timing for bringing such a product to market. While the term food for both human and animals is defined broadly under 201(f) of the Act, to be inclusive of both common sense, meaning of food, as well as components of food, such as direct food additives, in a 1983 Seventh Circuit case, Nutrilab vs. Schweiker, the court determined that Congress intended to limit the meaning of food to the common sense meaning when such substances are claimed to affect the structure or function of the body.

This common sense meaning was defined as the ordinary way food is used primarily for taste, aroma, or nutritive value. The Nutrilab case continues to form the basis for allowable structure-function claims for conventional human and animal foods and CVM references this case in the guide. However, the guide does not reflect current understanding of substances that can meet the common sense meaning of food for use in animals.

ETA recommends looking to CSFAN policies and regulations for guidance on how CVM's guide can be updated, particularly as it concerns the term nutritive value. When CSFAN promulgated general requirements for health claims in accord with the Nutrition, Labeling, and Education Act, it developed a clarifying definition of nutritive value. CSFAN turns, turned first to the dictionary meaning of nutrient and nourish, which led it to define nutritive value as a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy. FDA states that the definition provides flexibility in evaluating an array of substance that could logically ~~a~~ supply nutritive value in the daily diet. As an example, the Agency stated that a food component that supports cellular and functions by providing catalytic support for protective reactions could be viewed as providing nutritive value. In a subsequent related final rule, FDA added that nutritive value includes assisting in the efficient functioning of classical, nutritional processes and other metabolic processes necessary for the normal maintenance of human existence. And in 2000, FDA authorized a health claim concerning the relationship between plant sterols and the reduction of heart disease. And in determining that these substances were food substances, FDA stated that they provide nutritive value because they achieved their cholesterol lowering effect through their effect on digestive processes, a nutritional process necessary for the normal maintenance of human existence.

While a CSFAN regulatory definition of nutritive value is limited to human food based upon CSFAN's jurisdictional limitations, ETA cannot find a reason why the term should have a different meaning for

animal foods. Thus, ETA recommends that CVM adopt the CSFAN definition of nutritive value as well as its statements and policies further clarifying the terms meaning in updating CVM's own current definition of nutritional ingredient in the guide. Adopting CSFAN's nutrient value definition will immediately improve the guide by enabling animal food products and nutritional ingredients meeting the nutritive value definition to bear appropriately substantiated production claims. For example, a feed ingredient proven to enhance milk production by providing energy through improving feed digestibility clearly has nutritive value because it achieves its milk production effect through the feed's ingredients effect on digestive processes. ETA will provide additional detail on how enzyme feed ingredients provide nutritive value in its written comments, however, in the interest of time we provide short comments on two additional topics.

First, the policy of regulating all products with production claims as drug claims is a barrier to US innovation in the animal food industry and limits product availability for US livestock producers. Most firms will not take the new animal drug regulatory pathway for nutritional ingredients because of the high cost to develop and produce an animal drug in the US. Thus, ETA supports an update to the guide that would align the US with other major world geographies, including Canada, the European Union, the United Kingdom, and Brazil. For example, the EU permits claims for ingredients that favorably affect animal production or performance, the environmental consequences of animal production and animal welfare. Gaining access to production claims that are permitted in most geographies will not only enable US food producers to provide farmers with animal food and nutritional ingredients responsible for more efficiently produced high quality food, but it will also spur environmental benefits from farm animal production. This is especially critical in a time when FDA and other US Federal agencies seek to meet the objectives of the One Health initiative which recognizes the interconnectedness of human health, animal health and ecosystem health, and strives to promote, improve, and defend the health and well-being of all species.

Second and finally, the good news is that FDA can adopt the proposed changes to the guide without legislative changes or any need to introduce the prior review program. The Act's current misbranding provisions adequately address the manufacturer's responsibility to ensure that structure-function claims are truthful and not misleading before such products are introduced into commerce. In other words, the manufacturer must fully substantiate such claims, assure that they do not overstate a structure or function benefit, and that the claims are not otherwise false or misleading. As FDA knows, failure to comply with these statutory requirements could expose the violator to FDA enforcement action including, but not limited to, criminal prosecution.

With that the ETA thanks CVM for the opportunity to provide its comments on this important matter today, and looks forward to submitting additional written comments. Thank you.

[01:23:46] Dr. Walter Ellenberg (Moderator): Thank you. And our next speaker will be Dr. Jamie Jonker, and that will be followed by Kristi Smedley.

Dr. Jonker, please unmute and begin.

[01:24:07] Dr. Jamie Jonker: Great. Thank you for having me, and just confirming that you can hear me, Dr. Ellenberg.

[01:24:13] Dr. Walter Ellenberg (Moderator): Yes, I can. You may move forward.

[01:24:16] Dr. Jamie Jonker: Great, thank you. Um, I'm happy to be here today. My name is Jamie Jonker. I'm the Chief Science Officer of the National Milk Producers Federation. We are a trade association that represents dairy cooperatives and their dairy farm owners in the legislative and regulatory processes in Washington, DC.

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Just a little bit about the US dairy industry. We have almost 9.5 million dairy cows on our nearly 30,000 licensed dairy farms in all 50 states and Puerto Rico. Ninety-four percent of those farms are family owned and they produce 226 billion pounds of milk annually from an average of 316 cows per herd.

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We view US dairy as an environmental solution. In 2020, we released ambitious environmental goals that by 2050, the US dairy industry collectively commits to achieve greenhouse gas neutrality, optimize water use while maximizing recycling, and improving water quality by optimizing utilization of manure in its nutrients.

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While we came out with those ambitious goals two years ago, they actually built upon what has been a long-term process of becoming a greener, and more sustainable US dairy industry. Producing a gallon of milk has been getting greener. In this paper published in the Journal of Animal Sciences in January 2020 looking at the effects of improved performance in the dairy US industry on environmental impacts over a ten-year period from 2007 to 2017, they found that producing a gallon of milk required 19 percent less greenhouse gas emissions, required 21 percent less land use, and 30 percent less water use. So we're well on our way to meeting our 2050 goals, but there is more for us to do.

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In order to reach our 2050 goals, we have a variety of working streams in our processing sector and in our field and farm sector. Going to focus here on our field and farm sector because of the topic that we're talking about today. Our US dairy Net Zero Initiative is a collaboration across dairy organizations to advance research on farm violence and new market development opportunities to make sustainability practices more accessible and affordable to farms of all sizes. The central first phase to help accelerate our progress towards our 2050 goals, and we have work streams in the feed production at the field level and enteric methane from our animals, manure management, and energy generation.

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Here we see where the greenhouse gas emissions occur in our dairy farm structure. And I want to focus specifically on enteric methane being greater than one-third of our total greenhouse gas footprint on US dairy farms. There are a variety of things that we can do today to help reduce enteric methane emissions per gallon of milk produced, but there are other things that need additional research, and frankly, the ability to have a regulatory approval pathway that is not prohibitive. That's where we get into the idea of feed additives and what they may be able to do, for enteric methane emissions from our US dairy cows.

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Concentrating on feed additives. And you've heard from a number of speakers today about the potential already in this area. Research has demonstrated that several feed additives can reduce enteric methane from dairy cows by 30 percent or more. Roughly 95 percent of the methane from our dairy cows comes out the front end. There is about five percent that comes out of the back end, but these feed additives, not only have they shown a potential promise, they've already been approved some in other places, such as the European Union, Brazil, Australia, and Chile. As was previously mentioned, the EU regulates the use of zootechnical feed additives in animal diets and allows for claims for environmental animal welfare and production purposes, something that right now in the US is regulated through the new animal drug application process, which is stymying the development and availability of these important feed additives for US dairy farmers.

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This gets us to the current FDA's Center for Veterinary Medicine Program Policy and Procedural Manual Guide 1240.3605, which was last updated more than 24 years ago, it refers to animal feeds and foods to feed for livestock, poultry, and other animals, and pet food. These articles may ordinarily be thought of foods as defined by section 201(f) of the Food, Drug, and Cosmetic Act, and also in some cases as food additives under section 201(s) of the Act. However, in 1998, the last time that the FDA CVM Program Policy Procedures Manual Guide 1240.3605 was updated, FDA chose the regulatory pathway for animal feeds and foods and feed additives which may have environmental benefit claims, production claims or claims about the effects on animal well-being and preharvest food safety as animal drugs, a decision that has not been revisited since 1998.

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And this is where we are today where the US dairy industry is looking for a modernized FDA CVM Program Policy and Procedures Manual Guide 1240.3605 and we believe that using existing statutory authority where FDA can relegate products with data-backed claims of acting on or in the digestive tract that have environmental benefit claims, production claims, and claims about the effects on animal well-being and pre-harvest food safety can be done as animal feeds and foods, and as feed additives. We support FDA in a process to modernize this Program Policy and Procedures Manual Guide so that there is a pre-market process for ah efficacy of the products, safety to the animal, safety to the animal products, and safety to humans.

We believe that FDA has that existing authority, and we hope that FDA will modernize this process so that our US dairy farmers, which are already exporting 20 percent of their dairy production worldwide, will be able to catch up to the ability of their competitors in such places as a European Union, South America and Oceana.

With that I thank you for the opportunity to speak here today. We will have more extensive written comments submitted to FDA by the deadline in November. Thank you.

[01:31:46] Dr. Walter Ellenberg (Moderator): Thank you. And our next speaker is ah Kristi Smedley. Ms. Smedley, please ah unmute, and you may begin.

[01:32:04] Kristi Smedley: Hello! Can you hear me?

[01:32:07] Dr. Walter Ellenberg (Moderator): Yes, I can. Thank you.

[01:32:09] Kristi Smedley: Great! Thank you.

Good morning again. I am Kristi Smedley. I am the Owner and the Principal of the Center for Regulatory Services. I have worked almost 35 years in the area of animal feed regulation, 10 years with the Center for Veterinary Medicine, and 25 years as a consultant in the regulation of products for animals. For years I have considered the changes needed to the Policy and Procedure Mannual, that's generally every time the policy is used as a barrier for innovative new food substances. Simple corrections and clarifications to the policy would allow regulated food ingredients that would permit animal feed to be used more efficiently, animals to be healthier, human food to be safer, and to provide a positive impact on the environment. These changes would are all can be all completed within the confines of the existing Federal Food, Drug, and Cosmetic Act, and in the implementing regulations.

I am pleased that FDA is considering changes in their policy and procedure document as it is ah outdated, in some cases inconsistent with the Act. It does not cover the the current animal food products that are being developed. It is not consistent with important trading countries, causing difficult hurdles for the feed industry, and as Jamie indicated puts us behind. And the scheduling of this listening session suggests that CVM is open to making these important changes.

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I will not spend much time discussing the change that I am asking in this first on this first change, I'm requesting that a modification of policy matrix line 3 and the accompanying footnote remove the word “excluding production claims.” There's no legal basis for this. It is the simplest and the most straightforward of my request. The there is no legal basis for the exclusion of production claims from permitted structure or function claims for animal food as there is no specific prohibition under the Act. The policy is only found in this matrix and has never been legally supported in case law that I'm aware of, however, it does reflect the long-standing operating policy of the center. Scientifically, it is well established that nutrition in the basis of it is the basis of animal growth and production. Hence, the exclusion of a claim from structure/function for this is insupportable. If you can suggest the calcium, build strong bones, why can you not claim that an increase in enamel production of meat, milk, or eggs?

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The second modification I am requesting is for the policy and procedure guide to consider the regulatory status specifically of food substances whose intent is to modify the digesta, hence the impact is within the lumen of the gastrointestinal tract and that would include the microbiome. Although the current policy and procedure guide does not cover these products directly, the center has determined that the changes in the intestinal digesta and the microbiome affect the structure or function of the body, and will be regulated as drugs regardless if they are feed ingredients or pharmaceutical products. There are two considerations that support this request. Scientifically the microbiome is not a part of the animal's body, hence suggesting the products that modify the microbiome to affect the structure or function of the body is really not supportable. The microbiome is a part of the digesta found in the lumen of the gastrointestinal tract, which is external to the body, and such claims should not be considered to be structure or function claims of the body.

The second is the regulation of such products appear to be arbitrarily applied. There are many ingredients that FDA has authorized based on their effect on the digesta and the microbiome, but, however, the center has singled out specific products to be regulated as drugs.

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Examples of substances that FDA's consider to be regulated as food ingredients include enzymes, which are intended to to increase the digestion of feeds, direct-fed microbials, live microorganisms, and feed acidifiers, just to mention a few. According to the AAFCO listing for a number of the carbohydrates, the given supported use is tied to digestive viscosity, and so, therefore, requiring a measurement of the digesta in the the digestive tract. It just seems to be confusing. Examples of claims that FDA prohibits for feed ingredients, including our include competitive exclusion in the gut lumen, decreases in enteric methane release, digestibility of food resulting in the production increases, and reduction of potentially pathogenic bacteria solely intended to reduce the risk of contamination of human food. CVM has determined that products with these claims will be regulated as animal drugs based on their interpretation of the current policy and procedure manual.

The policy and procedure manual needs to be clear on the status of claims for feed ingredients that modify the digesta or the microbiome, and it must be consistently applied. These products in my mind should be regulated as food. I recommend, as others have also, that CVM consider the gut modifier guidance as recently issued by the Canadian Food Inspection Agency as a workable model for FDA.

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In order to provide transparency and general understanding, I'm requesting that the policy and procedure manual include definitions of two terms: 'structure or function claims for the body', and the term 'food'. There is no legal definition of structure or function, with the exception of DSHEA that i'm aware of, but this definition, as provided in DSHEA, may inform CVM's thoughts for animal products. I've provided that definition here. The role of a nutrient or dietary ingredient intended to affect the structure or function in humans characterizes the documented mechanism by which the nutrient or dietary ingredient acts to maintain such structure or function, and describes general well-being from consumption of the nutrient or dietary ingredient.

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Hence, we are requesting a definition of structure or function be a part of the policy and procedure guide manual, and how it would be applied to food so it is clear to all. Specific to the definition of food, I note that beyond the Federal Food, Drug and Cosmetic Act, which defines food as articles used for food or drink from man or other animals, DSHEA further defines food as nutrient or dietary ingredient. I suggest CVM consider these congressional thoughts. I um am in heartened by the ETA um discussion, and I hope that we do end up with a definition of food that is workable, understandable, and able to be applied in this policy and procedure guide.

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The current policy and, and the interpretation of the policy results in obstructioning obstructing the marketing of food ingredients that would increase the safety of our food supply, permit efficient use of resources to produce human foods, and provide direct benefits to the environment.

I appreciate that FDA is considering changes to the policy and procedure guide which will remedy these obstructions. Thank you very much.

[01:41:33] Dr. Walter Ellenberg (Moderator): Thank you.

And that brings us to our lunch break. And although we're a few minutes early, I'm going to go ahead and try to resume the normal schedule on the agenda and so we will break for lunch until 12:20. at which time, at 12:20 Joan Salwen will give her presentation. We look forward to ah talking with you at ah 12:20. Thank you.

LUNCH BREAK, 11:45 AM to 12:20 PM EDT (~ 35 minutes)

[02:16:19] **Dr. Walter Ellenberg (Moderator)**: Check check.

Folks will be getting started in about two minutes. Two minutes.

[02:18:00] Dr. Walter Ellenberg (Moderator): Well, good afternoon and ah welcome back to the FDA virtual listening session on the regulation of animal foods with certain types of claims. We hope everybody was able to have a nice lunch, and now what we will do is continue with public presentations. Ah and our first speaker is Joan Salwen of Blue Ocean Barns. Excuse me.

And uh Ms. Salwen. When you begin, just make sure you're unmute, and we'll begin when you begin your presentation.

[02:18:40] Joan Salwen: Hello, Dr. Ellenberg, can you hear me clearly?

[02:18:43] Dr. Walter Ellenberg (Moderator): I can. Thank you very much.

[02:18:45] Joan Salwen: Great. Alright.

[02:18:46] Dr. Walter Ellenberg (Moderator): Please begin.

[02:18:47] Joan Salwen: Alright. My name is Joan Salwen and I am the CEO of Blue Ocean Barns. We're a startup that's based in California and Hawaii that has been in conversation with CVM, AAFCO and state regulators since 2019 regarding an algal feed additive. Like dozens of algal feed additives currently approved and in use by dairy families and beef producers in the US, the dried seaweed meal that we produce is an animal food with a well-rounded nutritional profile evidenced by 20 percent or more crude protein, which is about the same as young cut alfalfa plus fat, minerals, and carbohydrates. The algae is known to be rich in biologically active compounds, including antioxidants and flavonoids and it contains brominated compounds as does nearly all currently approved algae. And, like all those that do, our algae acts naturally to interrupt methanogenesis in the rumen. This interruption in methanogenesis allows hydrogen and carbon that otherwise would be eruptated to remain in the digestive tract, making additional valuable nutrients from feed available to the animal.

I really appreciate the opportunity to provide feedback today on CVM’s application of policy for the regulation of products like ours, especially since we've been in this process for a number of years.

Under its current operating policy, CVM regulates most products that impact the gastrointestinal tract microbiome as feed. These include direct-fed microbial products, which populate portions of the microbiome, prebiotics, which increase the population of certain microorganisms in the microbiome, enzymes, which are intended to act on food, pH modifiers, and others. However, the center has suggested that some other substances that impact the gut or digesta, even if they are not intended to diagnose, cure, mitigate, treat, or prevent disease are drugs. The regulations are purported to be different for substances that have nutritional value as food than for non-nutritive substances. However, the center was, in the case of the algae, disinclined to regulate a nutritive substance with active compounds as food if the nutritive substance is included as a small portion of the diet. As a start-up company seeking to bring an innovation and a product to market, we found the process for classifying substances as feed or drugs, even considering published guidelines, inconsistent and perhaps even arbitrary. Even the boundaries of the phrase “impacting the structure or function of the body” are unclear. As defined in the FDA statute, animal foods which result in an environmental benefits should not be categorically regulated as animal drugs.

The place and the mode of action of the product should be considered not simply the claim. In the case of algae, this impact is solely within the GI tract, and its effect on digesta, which is not dissimilar to enzymes, acidifiers and probiotics, should be regulated as a food substance.

Modernizing of existing FDA policy can allow animal foods which act solely on or in the digestive tract to use marketing claims that are truthful and non-misleading and to communicate actions that promote a sustainable climate. Products like ours are demanded by US food companies seeking to meet science-based target initiatives, SBTI goals for greenhouse gas emissions, as well as federal and international goals for emissions reductions. Because of the food industry's sense of urgency, as well as the resolve of certain States to reduce the climate pollution of industries that operate within them, these products will find paths to market. We hope that through expeditious modernization of its policy guide 1240.3605, the FDA will be a part of that process rather than confounding or delaying it and we appreciate this listening session as a step towards clarifying and modernizing policy and practice. Again, thank you for the opportunity to speak.

[02:23:26] Dr. Walter Ellenberg (Moderator): Thank you. And now our next presentation will be from Bill Collins of the Cascadia Seaweed Corporation. Mr. Collins, you may begin.

[02:23:45] Bill Collins: Thank you very much. And I am assuming you can hear me well.

[02:23:26] Dr. Walter Ellenberg (Moderator): I can. Loud and clear.

[02:23:58] Bill Collins: Thank you very much. My name is Bill Collins, I'm Chairman of Cascadia at Seaweed Corporation. We are one of the largest cultivators of seaweed in the ocean with a view towards providing a proper pathway to new and Ah new and innovative organisms and natural occurring seaweeds into our ah our, into our market system for agriculture
and crop products. I'd like to say, first of all, acknowledge the traditional territories. Cascadia operates in the coastal British Columbia, and so thank you to our partners in territorial first nations.

Next slide, please.

So I might add a little bit of a different dimension to the discussion today. ah we've heard ah um folks talk about ah important issues regarding claims made on the effects of seaweed on animal rumen, particularly on productivity. I want to talk a little bit about claims made for cultivation.

One thing is clear to us. It's really important that in order to improve agriculture and sustainable technologies, we need to look at it as a more of a circular approach. So this adds the dimension, perhaps a little bit outside of the scope of FDA, but it really demands innovation of all government regulators, and working closely with industry to make sure that what we do bring to market is is protects the integrity of our food systems and security. So, for example, claims made under the auspices of cultivation. We hear terms like sustainable, regenerative, climate positive, carbon carbon-negative. There is much discussion in the science world today about the value to, for example, to ecosystem services from ocean kelp cultivation. These claims need to be led by science. We have an opportunity to deliver vast quantities of important organic solutions into agriculture, but we must do it effectively within the bounds of scientific integrity.

We also see claims made of the product, and typically these kinds of claims discuss ethically sourced or certified product. Now product certification and origin of products is particularly important when we're discussing fraud and an injection of unregulated foodstuffs into our systems in North America and and the Western world in general. So now this may not be directly in the purview of the FDA, and probably runs into bounds of other statutory requirements, such as advertising. But I think it's important for all of us to recognize that the the importance of the food system doesn't start or end with just the regulation of animal feed in it as an isolation.

And third, we've heard product claims today and will will be important in-in understanding the um the level of authority authority in claims, methane reduction, for example, and animal productivity improvement, the prebiotics effect, and even when it comes down to better quality of meat and milk, or healthier meat and milk for the individuals, for individuals that consume, these are claims that will have to be supported in some way or other.

And if I can have the next slide, please.

So what we're doing is seeking food security in a climate emergency. Food security means knowing the source and ensuring the supply. So, for example, claims of North American supply should be facilitated with complete traceability rewarded. If we are going to claim supply comes from an organic solution or a sustainable aquaculture or agriculture, we must ensure that we are able to validate that.
So my question to the to the FDA and the veterinarians is, is the FDA in the best possible position to validate claims of climate emergency mitigation?

Next slide, please.

We, as primary producers of algae have a tremendous opportunity to improve agricultural sustainability, and indeed, food source sustainability for the globe. To support this rapid innovation and investment in this industry, a framework, a clear framework for evaluating the effectiveness of climate positive feed additives must be developed. This should be of no surprise to anybody and it's why we're here today. From the perspective of ocean-grown seaweed, which has the opportunity to provide vast tonnages at scale in a very regenerative manner. There I go. I'm making a claim, which by the way, is supported by science, but it just goes to show we won't be alone in making these claims as industry is really important, that they they are brought into there with the with science as as leading the ah the claims. So

for us, clear methodologies for GHG reduction claims that use an independent third party. So, for example, claims in certain jurisdictions have to be validated by a protocol if they are available for carbon credits, for example.

So the question I posed earlier, is the FDA in a position to validate those claims or should that be done by a third party? Secondly, any productivity, prebiotic, or product quality improvement claims should also be independently validated by certified testing organizations. This is one way when we when it comes to product labeling, and indeed safety. Maybe the third-party independent validation is the way to go.

For us as primary producers, it's key that we understand government and regulators demand innovation and industry. Industry asks for innovation from government to make sure that we are addressing food security in this climate emergency.

That's what I have to say today.

Last slide, please.

Thank you very much.

[02:31:05] Dr. Walter Ellenberg (Moderator): Thank you. And that brings us to our next presenter, Meghan Dicks, who will be uh joining us. Ms. Dicks, if you will uh pull yourself off of mute, you may begin.

[02:31:33] Meghan Dicks: Are you able to hear me?

[02:31:37] Dr. Walter Ellenberg (Moderator): Yes, I can. Thank you.

[02:31:38] Meghan Dicks: Okay, Great.

Hello, everyone. My name is Meghan Dicks. I lead the Animal and Pet Nutrition Regulatory and Scientific Affairs Team in North America for ADM. ADM can trace our animal nutrition origins in the United States back to the late 1800s when we are committed to providing science-backed products to animal producers. We would like to thank FDA for holding this listening session, and for this opportunity to contribute.

Next slide, please.

We are here today to advocate for changes to FDA's policy for regulating animal foods with certain types of claims, allowing animal food companies to make environmental benefit claims, production claims, and claims about animal well-being and pre-harvest food safety will provide valuable information to animal food producers, incentivize innovation, and align US industry with international norms and markets.

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Unfortunately, there are many challenges presented by FDA's current policy, and we strongly support the need for change. FDA’s current policy describes US animal producers of science-backed products

that address a myriad of benefits because FDA's current position that any substance fed to animals for production purposes is a drug. This interpretation is not aligned with the definition of a drug and the Federal Food, Drug, and Cosmetic Act, and it's incredibly limiting because an ingredient consumed by the animal for nutritional purposes can also have production and public health benefits, and some ingredients can indirectly improve food safety or reduce the environmental impact of the animal's digestive processes. Unfortunately though, today the FDA says that these are drug claims that are therefore not allowed for animals food ingredients.

The United States prides itself in being the world leader in science and technology. However, the US actually lags behind most of the developed world for access to animal food ingredients with data-backed claims, which stifles innovation and limits our ability to be with global competitors.

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How can the FDA modernize or improve this policy? We believe that the answer is simple.
The FDA should change their policy to allow all substantiated claims for animal foods as long as the claim is not for the diagnosis, cure, mitigation, treatment, or prevention of disease. Doing so will encourage innovation because animal food companies will be able to promote ingredients with substantiated claims in a truthful, non-misleading matter manner without subjecting our products to the animal drug regulations.

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In closing, the reason that we are here today is that we're developing products that limit environmental emissions that support the microbiome, that promote immunity, that promote general wellness and support production efficiency within the normal biological range, but we can only utilize these animal food products in the United States if the FDA revises our policy to allow animal companies to make these claims. We are not asking for a new approval pathway. We are simply asking for a change to FDA's policy that will allow responsible companies to make truthful, non-misleading science-backed claims for animal food products so long as that claim is not for the diagnosis, cure, mitigation, treatment, or prevention of disease. With that we thank the FDA for this opportunity, and we look forward to providing our written comments. Thank you.

[02:35:31] Dr. Walter Ellenberg (Moderator): Thank you. And that brings us to our next presentation from Kevin Korth. Mr. Korth, ah you may unmute and begin.

[02:35:49] Kevin Korth: Hi! Can you hear me?

[02:35:51] Dr. Walter Ellenberg (Moderator): Yes, I can.

[02:35:54] Kevin Korth: Alright, alright. If we could jump to the first slide.

I'd like to thank the FDA for this opportunity and would like to add my voice to others already given. My name is Kevin Korth, and I'm the director of Regulatory Affairs at Native Microbials in San Diego, California. We are a company exploring and developing probiotic ah well products based on beneficial native microorganisms for animals. I'll be addressing opinions from a narrow scope that of direct-fed microbials, casually referred to as animal probiotics.

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The close to 50 organisms currently listed in AAFCO under direct-fed microbials were approved over a couple of years in the late 80s, and the list has remained virtually without any change except for updated naming since then. During the first 30 years or so, it was known and communicated that no claims could be made for direct-fed microbials other than that they were live microorganisms. Over the recent years, that requirement is softened, and some minor claims can be made related to digestibility, but there are are still few claims, if any, allowed, making it very difficult to communicate what the microbes may be doing for the animal.

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Most agree that across both human and animal nutrition the use of the term microbiome has expanded exponentially over the last several years. Science has exploded in this important area of human and animal wellness driven largely by the ability to quickly and relatively cheaply sequence microbiome, and in some cases whole metagenomes and metatranscriptomes and study these systems and organisms at the genetic level. Animal microbiome research has lagged a little behind human microbiome work, yet both are now well understood to be critical systems in the overall well-being and health of the species.

As part of that research, science has discovered that there are there is a critical relationship between these gut microbes and performing important biochemical functions, providing digestive capabilities, and promoting resilience against pathogenic intrusion of the host. If these relationships are thrown out of balance it can affect the health of the host. Science has also shown that the role of the microbiome goes beyond the well-known probiotic functions of competitive exclusion or increased energy from food, neither of which can be claimed for animals. Few of us have gone to our doctor with digestive issues and not been recommended to take probiotics or eat live ah ah culture-rich foods like yogurt for a while especially after a round of antibiotics. Our cells would get it, but for animals they are forbidden drug claims.

One point about the microphone that should be made is that it's not technically internal, like a heart or the lungs, and therefore changes to the microbiome are not actually the same as a drug, a drug modifying organ. The microbiome is part of the digestive found the lumen of the GI tract, which, though it sounds odd to say, is external to the body, as mentioned earlier by Kristi. Because of that, in essence, drug claims should not be able to be made for microbiome as it is external to the body. It is known that foods that are clearly foods can act as prebiotics and can positively affect the microbiome without providing nutrition.

Similarly, DFMs are food. The direct nutrition they would provide, for example, as if they were dead, being just tiny bags of proteins, carbohydrates, fats, and salts, is monumentally small, but indirectly by the live metabolism, the microbiome, say in cattle, provides the major source of nutrition. They take food of very low quality and convert it to quality nutrients. There's little doubt then that the microbiome micro that microbes are actually an important part of the food, which leads to my next slide, going back to the definition of food.

So next slide.

And you've you've heard this report many times so i'm not going to read it all. As previously stated by earlier presenters, the original section 321(f) definition of from the Food and Drug Cosmetics Acts states that food is to find as articles used for food or drink for man or other animals. And then it continues on.

And then under the drug definition in (g)(1), I'm not going to read the whole thing, just part of it., foods are given license for claims without making them drugs stating that food or dietary supplements for which a claim is made according to the requirements of this section are not solely drugs because the claim the label has a claim. Foods can have truthful and non-misleading statements, and still comply to this section. Now, animals don't have a dietary supplement equivalent of DSHEA like on the human side to give structure and guidance and definitions for dietary supplements and structure/function, but the allowance for such claims in food for animals is still codified as food is defined as articles for both man and other animals. Further, in 321 in (w), which hasn't been mentioned so far today, the additional and I say additional as it does not claim to replace the definition in that it is a subset of food known as animal feed, that definition is just for animals, and animal feed is clearly intended to be a substantial source of nutrients in the diet, but ends that definition by saying it is not limited to a mixture intended to be the sole ration. We submit that the additional definition of animal feed in (w) could not indicate the original definition of food applying also to animals, and therefore, should not limit claims to nutritional.

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We know that structure/function claims are allowed for food. That's why it's so important to go back to the principal definitions of food being articles of food for man and animals. We also want to point out that we have noted a general tendency in the animal industry to interchange the word food for nutrition, as food can still be food and not provide direct information. They are not always the same.

We contend that the legal definition of food includes mic live microbes, direct fed microbials, even though they don't provide much in the way of nutrition. We therefore contend that truthful structure/function claims that can be made for food should also be able to be made for DFMs.

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I won't be going through and reading this list nor am I making any claims toward anything we as a company produce, but we all recognize that these microbials are not drugs, and should not be allowed, and and should be allowed a bit more freedom as far as their claims. Not mentioned on this list, and talked about quite a bit in earlier presentations, and are clearly being studied right now are microbes that reduce enteric methane in ruminants, a topic of particular interest these days in climate science. It's not nutrition, not even necessarily providing a benefit to the animal yet highly desirable in today's work.

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Next slide, please.

I'd like to thank the FDA for holding this session and the other presenters for reflecting a lot of the things I was able to say today. It was an honor to be able to speak with you. And would that I'll end and turn the time back to the facilitator. Thank you.

[02:43:36] Dr. Walter Ellenberg (Moderator): Thank you. And that brings us to our next presenter, Dr. Elizabeth Lewis. Dr. Lewis, you may begin.

[02:43:58] Elizabeth Lewis: Thank you very much.

So thank you. I'm Elizabeth Lewis. And for this presentation I'm representing my company for NutraSteward. We're a scientific and regulatory consulting company that work with a wide scope of companies from startups, small medium enterprises, and to larger companies. And so I wanted to give a more general perspective in this presentation, and again thank you for the opportunity to present. So I would like to take each of the the questions that were posed in the virtual listening event in terms of policy considerations.

Next slide, please.

And so if we look at the rationale for modernization of the policy, feed ingredients are developed for a global market, which we've very much seen today already with the presentations that have been given. Harmonization on the distinction between food or feed and drugs is therefore critical to innovation, and in this respect the US is currently an outlier in limiting the placing on the market to feed ingredients based on that interpretation of meeting the nutritional requirements of livestock, and much as Kristi mentioned earlier, there are other regulatory frameworks that have grappled with this, and found different ways to look at that link between nutritional effects or gut health, and maintaining the health of an animal within the context of food. And I would like to re-emphasize two of those that I think do bear relevance because they do consider the definition of food. The European Union, which has a definition for zootechnical additives, which is given as any additive used to favorably or affect favorably the performance of animals in good health, or used to favorably affect the environment, e.g. production claims based on increased digestibility of the feed or favorable effects on gut health, and equally Canada. And I know Kristi mentioned earlier the gut modifiers, and within this we have the animal performance claims supported by a nutritional purpose or mode of action. So it's recognized the role that food is playing to good health again by increased egg production, increased litter sizes. So while those regulations are structured slightly differently, they all come back to this interpretation of food. So in that sense I think it is critical to remove the outlier and become more harmonized globally.

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So today we've heard many examples of enteric methane reduction, but I did actually want to give more examples of ingredients and claims that can fall within the scope of this policy and in within the scope of the discussion, and I think it's really important to remember just how many additives we are referring to, and just how established they are as human food or animal food/feed ingredients. So, for example, obviously the examples we heard earlier about environmental benefits, they can be a range from the seaweed, the algal or the chemically defined substances. We can have the quality of animal products i.e. by reducing microbial load. Again, that can be a range of substances, botanical extracts, bacteria phages.

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And we can see improved growth or reproductive performance from a variety of substances again that we would consider to be food ingredients, direct-fed microbials, fermentation products such as

enzymes, etcetera, botanical extract, chemically-defined substances, and then improved production of milk or eggs. We get the same similar ingredients and equally organic acids or medium chain fatty acids, and again some improved physiological stress type resistance that doesn't fall within drugs. And again, fermentable fibers, bacteria, phages. DFMs. The key here and you'll have seen there were two columns I could have included a third for Canada, but the EU and the US. I just wanted to highlight the outliers there again and again, and again. Not only do you recognize those ingredients as food, but you see that in the EU, for example of one framework they have found that connection with feed and call them the zootechnical feed additives or feed materials which are nutrient sources of secondary effects, whereas in the US we see again and again, it's animal drugs, animal drugs, animal drugs.

So we see that discrepancy is significant, and I think some harmonization to reduce that is essential.

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So in terms of policy and challenges. Return on investment was mentioned earlier, and it is critical for the development of innovative products. If people cannot see a return for the investment on the extensive number of studies that they undertake for safety and utility, then it becomes very difficult to enter a market, and also it's important, of course for transparency and consistency, because when you're entering a market without being able to make all of the claims, then you can't be consistent with your safety under the conditions of intended use. You can't then establish good strong frameworks for how utility is demonstrated in a way that can give consumer confidence and livestock industry, confidence. So, therefore, there is a challenge, but there is advantage to being able to bring these things into the food framework, and being able to establish these clear guidelines, and to allow that return on investment that allows innovation, and it improves livestock, health, and nutrition in the future.
But it is important to remember that the current US system doesn't allow for any company-specific protection, and therefore, we do need to think about the studies people are doing, and how they get some reward. And so, anyway, thank you very much for your time again today, and for the opportunity to contribute, and that is the end of my presentation.

[02:50:32] Dr. Walter Ellenberg (Moderator): Thank you. And that brings us to a break in the agenda. We will have a short break, and we will return promptly at one o'clock and so until then, uh, I'm going to mute your phones, and I will join back in at one o'clock. Our next speaker is scheduled to be Cathryn McCandless.

BREAK
12:53 PM to 1:00 PM (7 min)

[02:57:33] Dr. Walter Ellenberg (Moderator): And we are back. I'd like to thank everybody for joining us for this final session of the this virtual meeting this afternoon. We have four more speakers that we will go through, and the first one scheduled to begin just about thirty seconds is Cathryn McCandless. Miss McCandless, you may go ahead and unmute your phone and the computer, and you may begin.

[02:58:05] Cathryn McCandless: Thank you. My name is Cathryn McCandless and I'm the senior environmental scientist with the Safe Animal Feed Education program. We are a division of the California's Department of Food and Agriculture within the commercial feed regulatory program.

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Why enteric methane reducing non-nutritive products are a challenge and an opportunity in California. Senate Bill 1383, a California Senate Bill 1383 established rules that promulgated short-lived climate food reduction strategies. This strategy has explained how the State would meet goals published by SB 1383 including a forty percent reduction in total methane emissions from the dairy and livestock sector.

The California Air Resources Board published a scoping plan in 2022. They are the State agency that is responsible for promulgating regulations to reach this goal. The State is expected to achieve roughly half of the SB 1383 targeted emission reduction by 2030 through strategies currently in place, as directed by the legislature. Under SB 1383, State agencies focused on voluntary, incentive-based mechanisms to reduce the short-lived climate pollutant emissions in the early years of implementation to overcome technical and market barriers. According to the California Air Resources Board, under this carrot, then, stick strategy incentives are replaced with requirements as the solutions become increasingly feasible and cost-effective to meet the legislated legislated targets, more aggressive action needed.

What that means for California livestock producers is that they are searching for ways to reduce methane at the farm level. There are two main forms of methane emissions from the livestock sector. Twenty-five percent of all California methane emissions came from dairy and livestock manure, and twenty-nine percent of all California livestock emissions in 2019 came from enteric methane production of livestock animals. Now, what this has left us with producers in California needing to reduce methane from livestock on farms, from animals, and they are being inundated with new products with claims to reduce methane emissions on animals. The challenges, the safety and efficacy of these products have not been established in many of the products, and also many of the products are not evaluated by the FDA. This leads California in a position where we are required, we will soon be required to reduce methane through enteric strategies, however, they are not products that are currently approved. So what we are seeing in California is that methane reducing claims are being placed on novel, undefined feed ingredients on both labels and marketing. We are also seeing methane reducing claims on currently defined products that have already been approved as feed products with an AAFCO, State or FDA definition. The challenges, the potential food and feed safety concerns ~~are~~ that are associated with undefined feeds, or if it's a drug, if the methane reduction claim turns out to be a drug, the challenge is there are potential carcinogens, heavy metal concerns, nitrates, vitamin and mineral levels toxicity concerns, and in one case, we've even heard of an adulterated feed that's reportedly claiming to reduce methane emissions.

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The claims the FDA should consider in review of their current policy 1240.3605 have to do with defining a product with methane reduction claims as a food or a drug. The challenge is that there is currently no guidance at the Federal level to establish whether these products are foods and/or drugs. Is this something that FDA should be considering or do we need to partner with other agencies, such as the EPA to evaluate these emission reduction claims?

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As mentioned earlier, California has been inundated with products that have methane reduction claims associated with them. The ingredients that the FDA should consider in review of their current policy 1240.3605 include the following list. The bolded ingredients are the products we have directly seen in California. The other ingredients on the list are products that we know that are available to some

producers or are working toward being available with some producers with methane reduction claims. These products do not have trade names associated with them. We have seen in California red seaweed (Asparagopsis Taxiformis), 3-NOP, an essential oil flavoring product that is FDA GRAS for human consumption but not for animals. Biochar and Camelina Meal. The other products again, have not yet approached our agency, but we recognize that they exist with methane reduction claims.

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So our current plan in California to meet our legislated mandates.

The commercial feed regulatory program in California is tasked with evaluating the safety of feed products for livestock and in livestock products, such as milk, meat, and eggs. We need to evaluate the safety of these methane reducing seed products that are undefined. We've come up with a plan to work with our sister agency, the California Air Resources Board, who will approve the greenhouse gas emissions reduction claims.

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What we are really calling for today is a collaboration with FDA. We do not want to be evaluating these ingredients in a vacuum without collaboration from our Federal partners. We are offering resources. We are offering time. And we are really calling for a national advisory work group which we, like FDA, the American Association of Feed Control Officials, the National Association of State departments of Agriculture and other relevant State agencies to be a part of this national advisory work group.

We would like to collaborate with other national and State environmental agencies as well. We would like FDA to know that California is in full support of working together and collaborating with our Federal partners. Thank you for this opportunity, and I yield the rest of my time.

[03:04:26] Dr. Walter Ellenberg (Moderator): Thank you. And now our next presentation is from Miss Mollie Morrissette. Miss Morrissette, please unmute, and you may begin your oral presentation. I would also like to state that the following. From this point forward there are no slide presentations; they are all oral presentations. Miss Morrissette, you may begin.

[03:05:07] Mollie Morrissette: Where is it? Can you hear me?

[03:05:10] Dr. Walter Ellenberg (Moderator): Miss Morrissette, You may want to. Okay, you're there.

[03:05:15] Mollie Morrissette: Okay? So yeah.

[03:05:16] Dr. Walter Ellenberg (Moderator): You may begin.

[03:05:17] Mollie Morrissette: So um. My presentation is is very short. It's just a statement in general. Um. So I think we can all agree that we're facing a climate crisis of catastrophic proportions, and as many of the people who have already spoken, we um need to address these issues of products that can reduce methane emissions in cattle. And the question is, how can the FDA um regulate a product which improves the climate positive modes of actions because there's no regulatory pathway for a feed ingredient with an environmental benefit that um environmental benefit additives that favorably affect the environmental consequences of animal production. Um, climate change and methane reduction are

not claims that are structure/functions, but claims in essence that aim to reduce methane, which brings us to the quandary of how to regulate seaweed, for example, and products like Bovaer that can make claims that benefit to the environment. If a seaweed product made claims that solely address environmental claims, could it circumvent the problem of making a structure function claim? And I think we should look to the EU for guidance on how to regulate feed additives that reduce methane emissions from cattle. Um the EU. Excuse me. The EU regulatory system has a special category for feed additives that offer an environmental benefit. The European Union and an approved use of feed additives that can reduce methane emissions from cattle by thirty to forty percent or more. So what I'm saying in essence is perhaps that um I think a way to circumvent the issue of is it a drug or an additive or a feed ingredient would be to um would be to make claim solely that it reduced that it benefits the environment. Um. Otherwise, we're stuck in this environmental or sorry in this quandary of is it a feed or is it a drug. So that's all I have to say. And thank you very much for this opportunity to speak.

[**03:07:58] Dr. Walter Ellenberg (Moderator)**: Thank you very much.

[03:08:00] Mollie Morrissette: Mhm Yeah. Thank you.

[03:08:01] Dr. Walter Ellenberg (Moderator): Our next speaker is Jessica Sleater. Miss Sleater, you may unmute and begin your presentation.

[03:08:22] Jessica Sleater: Can you all hear me?

[03:08:24] Dr. Walter Ellenberg (Moderator): Yes, I can. Thank you.

[03:08:26] Jessica Sleater: Okay. I would just like to note that um actually my ah law firm name. Okay. Well, there you go. As I say it was misspelled, but you have it right on this this slide.

Um. My name is Jessica Sleater. Ah. And I am here as in my personal capacity as a consumer, and also as an attorney um who represents consumers and lawsuits that involve pet food products, including pet foods and my law firm name is Andersen Sleater Sianni and by means of disclosure, I am not ah representing any consumers on the topic that I'm about to speak about, which involves the prescription pet food quandary. Um.

As a consumer and an attorney, I've observed the confusion that claims on pet foods can cause and the area that I wanted to highlight for the FDA today is the area of prescription pet food, and the problem that I have seen with this, and there's also several lawsuits um that are currently pending um involving the same issue is that prescription pet foods require a veterinarian's prescription, but are not approved as an animal drug by the FDA, and just to kind of explain why this is such a problem. It's as if, as humans, we're told by our doctor that you might be pre-diabetic, or need to lose weight, and your doctor might tell you to cut out salt or sugar or fat from your diet and these foods are not prescribed to you as a drug, and likewise, if you're found to be anemic, low in iron, or low in calcium, your doctor might tell you to purchase vitamin supplements at your local drugstore, which again do not require a prescription. However, in the pet food world, a veterinarian may determine that your dog is obese and needs to lose weight and prescribe a diet food that has a lower fat content and unfortunately, because these pet foods require a prescription even though they shouldn't, consumers feel required to purchase them, and they're charged a premium for them, and it also eliminates consumer choices, selection, and price.

And consistent, I think, with a lot of the presentations today, um., the biggest issue that I think that the FDA needs to address is this problem between what is a pet food and what is the drug; and this is where the prescription pet food kind of crosses both. Um. And, as I mentioned, there are several lawsuits, um consumer class actions that are pending against companies that make prescription pet food and those claims are actually based on misleading statements, false advertising, and deceptive practices that these pet foods are drugs that the FDA has approved even though they are not, and as a result they require a veterinarian's prescription which is in violation of the Food, Drug, Cosmetics Act and the the State consumer protection laws. And the damages that are alleged in these cases ah surround that ah consumers pay a premium, as I mentioned, for pet foods that they wouldn't have purchased at all or paid as much for if they knew that it wasn't actually a drug approved by the FDA that would require a veterinarian's prescription. Interestingly, several of these cases have actually gone up on appeal through different circuit courts, Federal circuit courts, and in one such case the Vanzant versus Hill's, the Seventh Circuit reversed the lower court's dismissal of the case, and in the Seventh Circuit found that although the manufacturer tried to argue that the FDA allows them to make these claims that the pet foods are in fact are you know drugs that are require prescription. The Seventh Circuit found it says that the FDA doesn't allow this, and that it's part of the FDA's discretion that it might not choose to enforce this law against these prescription pet food companies, but that they are not drugs. And so the cases are has been reinstated, and it's still proceeding, and I found that many people, many um consumers that I've spoken to are very surprised to learn that even if it's illegal for a company to do something such as a violation of the Food, Drug, Cosmetics Act. Government agencies still have discretion, and whether they seek to enforce the laws against these companies, and this has created the problem with the prescription pet food industry. These companies are left to self-regulation, which has caused them to make these claims and create basically a monopoly um of pet food, where where veterinarians are prescribing it to their clients.

The bottom line, I find, is that I encourage the FDA to address this issue involving prescription pet food in order to be truthful as to what these products are, namely, that they are not drugs, and to avoid consumer confusion. These products should instead be described as a diet or a vitamin supplement pet food, and they should not require a vet veterinarian's visit, or a prescription that creates its premium and exclusivity of availability only through vet's offices and certain retailer that function as pharmacies for pet products. It's unfair pressure that's put on consumers to purchase these products as they are required prescriptions from their veterinarians. Thank you so much for this opportunity.

[03:14:20] Dr. Walter Ellenberg (Moderator): Thank you.

And our next speaker and final speaker is Louise Calderwood. Miss Calderwood, if you would unmute your microphone, you may begin.

Miss Calderwood, you're still on mute if you if you're speaking.

[03:15:10] Louise Calderwood: Hello, I'm Louise Calderwood, Director of Regulatory Affairs for the American Feed Industry Association and the world's largest organization devoted exclusively to representing the business, legislative, and regulatory interests of the US animal food industry and its suppliers. Thank you to the Food and Drug Administration for providing this opportunity to present our thoughts on the regulation of animal foods with certain types of claims.

Founded in 1909, the AFIA serves as the voice for everyone involved in the manufacture of commercial and integrated feed and pet food from ingredient suppliers to equipment manufacturers. We are also

founding members of the International Feed Industry Federation, where we strive for global harmonization and science-based regulation of our industry.

I'm here today to explain how the animal food industry in the US lags behind most of the world, including as you heard the EU and Canada, and even Brazil, Chili, Columbia, Australia, and Thailand, in approving, safe and effective feed ingredients with animal production, environmental, and other benefits, and how that delay is not only preventing farmers and pet owners from accessing these technologies, but is limiting the United States in making progress on its climate and food security goals. We believe our country does not have time to waste. Our farmers and ranchers are prepared to do their part, and it's time for the Food and Drug Administration to recalibrate the clock and move ahead with long needed changes to its policy.

As mentioned by several speakers, animal nutrition plays a vital role in improving and promoting the health of our livestock, poultry, pets, and fish. Our members are continuously researching how existing ingredients can further support animal production and health. In addition to public and environmental health and animal well-being, they are regularly developing new animal food ingredients that go beyond the typical taste, aroma, and nutritive value historically associated with animal food, and they are developing game changing solutions that act solely on or in the digestive tract of animals. These gut-based technologies are proven to support the gastrointestinal tract function and enhance the GI microbiome to address animal well-being. They reduce environmental emissions from cattle, hogs, and poultry thereby reducing the release of greenhouse and other gases from livestock. They promote greater immunity to diseases in livestock and pets. They provide animals with resilience to food contaminants such as mycotoxin. They promote the general wellness of livestock and support our aging pets by addressing mobility and cognitive issues. They increase the safety of food for the human consumer, and many of these ingredients are known to support efficient production of meat, milk, and eggs from healthy animals. By harnessing the power of the GI tract, animal food additives can help producers and pet owners boost their animal's quality of life. In countries where they are approved, these technologies help farmers be more efficient in the use of land and water and feed. Therefore, supporting sustainability efforts to feed a growing global population.

Unfortunately, in the United States the animal food industry, and our customers cannot use these technologies due to the policy interpretation laid out by the FDA Center for Veterinary Medicine in their Program Policy and Procedures Manual Guide 1240.3605. This policy requires that these products be regulated as animal drugs instead of feed ingredients. Sure these ingredients could be put through the regulatory review process as a new animal drug, but they should not have to. They are clearly feed ingredients, and, has been stated numerous times today, should be regulated as such. Our members tell us they have products approved in dozens of other countries, but they can't even submit these products for review by the FDA because of policy limitations. The AFIA urges the CVM to to address this limitation by modernizing its guide to keep pace with scientific advances in animal nutrition, paving the way for animal food ingredients with production, animal safety, food safety, and environmental claims to be regulated as foods, not as animal drugs.

Legally, animal foods with such claims may be considered either as a food in Title 21 of the US Code, as you've heard, section 321(f) or as a drug in section 321(g). We urge the agency to adopt a science-based approach to allow these game-changing innovations to be used safely and with accurate, compliant, labeling. We believe the science surrounding the functionality of new animal food ingredients has advanced to the point that production claims can be properly substantiated, they can be truthful and not misleading, and that the CVM should recognize substantiated structure, function, and other well-

being and resiliency claims for animal foods and animal food ingredients. This modern approach and transparent policy would promote industry innovation and provide a clear direction to state-controlled officials who are currently reluctant to register or provide certificates of free sale for animal feeds and ingredients bearing certain claims.

As you've heard today, you will likely hear even more clearly during the written comment period, we are not alone in this request for needing these changes. The Secretary of Agriculture Tom Vilsack has spoken numerous times about the role of feed ingredients can play in reducing greenhouse gas emissions, and has urged the FDA to modernize an approach. He believes the FDA is now open to conversations about needed changes, and he's expressed hope that the agency is ready to think differently and broadly. We have confidence that he is correct, and this is indeed the case. Even Congress in its fiscal 2022 appropriations bill directed the CVM to study this old policy on animal food claims and make this change.

The AFIA is not asking the FDA to create a new regulatory pathway. Rather we're asking it to update its policy to support industry innovation in safe animal food ingredients that address current and emerging issues in animal food production, using the existing ingredient review pathways, the food, additive petition, the generally recognize the safe or GRAS process, and the ingredient review process through the Association of American Feed Control Officials or AAFCO. All review ingredients for safety to the animal being fed the product, safety of the resulting meat, milk, or eggs being consumed by humans, and the utility of the product, that is that the product does what its label claims it does. We believe these requested actions are in the interest of public and environmental health and animal well-being, and can be implemented without amending the Federal Food, Drug, and Cosmetic Act or FDA regulations. Moreover, we believe that the Federal Food, Drug, and Cosmetic Act and the First Amendment allows manufacturers and sellers to assert truthful, substantiated structure/function, and other well-being and resiliency claims pertaining to animal food. By making this change the agency will strengthen its mandate of ensuring public health through animal and human health by giving these products a regulatory review pathway that will be utilized by our industry. The CVM will also be helping the United States get closer to meeting its climate and food security goals.

It is often said that time is our enemy, and with the challenges before all of us ensuring that all Americans can breathe easier and have access to safe food, we do not have time to race. Let's make this moment count, and not let another day go by without recognizing the important role the FDA can play in solving this challenge. As a responsible stakeholder, we appreciate this opportunity to encourage CVM to explore potential solutions to its current policy. Thank you for considering this important industry issue. Our industry stands ready to work with you in the future.

CLOSING REMARKS

[03:23:55] Dr. Walter Ellenberg (Moderator): Thank you. And that concludes our list of presenters for this afternoon. And at this point in time, I will go through and just make a couple of minor closing remarks.

First, I would like to ah remind all the presenters who had slide preparations, if you would present. Ah! Excuse me. If you would submit your slides to the docket. For all other comments that you may have come up during the meeting or you feel that should be added, please submit them to the docket which

closes on November 17th. And with that said, I will conclude the meeting. Thank you very much and have a nice day.

[03:24:47] MEETING ENDS