Selena Kremer,
USDA FSIS Moderator

Good morning and welcome, everyone. If you could please take your seats, we're going to go ahead and get started. Welcome back to the public meeting, day number two. I'd like to go over a few housekeeping items as everyone's getting settled. As a reminder, this meeting is being webcast live. Please note that this is a public meeting, it is being recorded to video and if you are publicly speaking in the auditorium today you will be part of those recordings. There is no expectation of privacy as the video recording, the presentations and the transcript of the meeting will be posted on the FSIS website shortly after the conclusion of the meeting. Wings 4 and Wings 5 in the building have restrooms for your convenience, and please note that food and drink are not permitted here in the Jefferson Auditorium. To open the meeting today, I'd like to introduce Paul Kiecker. He's the Acting Administrator of FSIS in the U.S. Department of Agriculture.

Paul Kiecker,
FSIS Acting Administrator

Good morning, everyone. My name is Paul Kiecker and I'm the Acting Administrator for the Food Safety and Inspection Service. I want to thank everyone for being here today and thank those that are participating on the web as well. I also want to thank Food and Drug Administration for working together with us on this meeting. Yesterday, we heard a lot about the regulatory framework that is in place and we heard concerns that people were bringing up that pertain to that. Today, our focus is not going to be specific to food safety, but it's going to focus more on labeling of these products to make sure that the products are identified according to customer expectations, and so that the products are labeled and don't come up with any type of advantage or a disadvantage to those that are either producing this product or other products that would be in competition with them. With that, I just want to invite everyone to really participate today and make your comments known. Yesterday was a little bit slow at times. Today we hope to keep things moving along a little bit. If we are done a little bit sooner than expected, that is fine, but we want to make sure that everyone has the opportunity to make their comments known today. With that, I want to turn it over to Susan Mayne with the Food and Drug Administration. Thank you.

Susan Mayne,
FDA CFSAN

Okay, good morning, everyone. As you heard, my name is Susan Mayne and I direct FDA's Center for Food Safety and Applied Nutrition. You heard a lot yesterday about potential safety hazards of foods and products created using cell culture technology, what comparators to use in interpreting those potential safety hazards and potential strategies for addressing them. Today focuses on another important part of our mission, which is ensuring that food products are truthfully labeled and are not misleading. This is essential for giving consumers the confidence in products developed using new technologies. It enables consumers to make informed decisions about their diet and what they feed their families. My colleagues, Dr. Douglas Balentine, who directs FDA's Office of Nutrition and Food Labeling, and Malcolm Bertoni, our Associate Commissioner for Planning, will be joining the conversation today about the labeling issues associated with the development of animal cell cultured food products. We need to be looking at how technology and transparency can go together. This is a theme we hear repeatedly. Consumers are increasingly interested in the foods they eat and

want transparent labeling. As we think about labeling of these products, what information do consumers need for transparency? We also heard about the desire for labeling that can ensure that consumers who have food allergies can identify the source of products to which they might be allergic. At both FDA and USDA, improper labeling for allergens is the leading cause of food recalls. Here we have an opportunity to hear about things we may not have considered from such a diverse group of stakeholders, and to do this right in advance of products coming to the market. Public dialogue like this is crucial to openly address both the opportunities and challenges in being transparent that are presented by emerging food technologies, such as animal cell cultured foods. In the nutrition innovation strategy announced by Commissioner Gottlieb in March, we committed to exploring how to make ingredient information on food labels easier to understand. As the food supply becomes more innovative and diverse, it's even more important that we look at how we label foods. One thing we want to hear about is how much consumers understand now about food products produced by animal cell culture technology. Do they understand the nature of the technology? Do they have a perception as to whether it is more or less healthful or nutritious than traditionally bred animals, poultry and fish? What essential elements do consumers need on a food label for cell cultured food products to truly understand what they are getting? Should the labeling address how the product is made? Would such labeling give the consumer the impression that the cell cultured product is equivalent to or significantly different from traditionally bred animals, poultry and fish? When we consider appropriate labeling, how much did nutritional composition of these foods be a consideration in labeling? How would specific label terms affect how consumers perceive the nutritional value of these products? As you will hear today, USDA and FDA work closely together on labeling and food safety issues. Where appropriate we harmonize label elements for consumer clarity. We are seeking your input today as to how labeling can be most transparent and truthful and not misleading when it comes to these innovative products. We look forward to hearing your thoughts about labeling considerations to ensure that consumers have the information they need, whether it be for nutrition or for safety. For example, with regard to allergens when food produced from animal cell culture technology come to the marketplace. And you will hear more about this today from our experts in FDA and FSIS. Thank you.

Selena Kremer,
USDA FSIS Moderator

Thank you, Mr. Kiecker and Dr. Mayne. We're going to get started with session five if you're following along in the agenda. We're going to talk about the regulatory frameworks for food labeling, the mandatory elements. Dr. Douglas Balentine, the Director of the Office of Nutrition and Food Labeling at the FDA's office, CFSAN, is going to begin with his overview of regulatory frameworks for mandatory labeling elements. Following that, Mr. Jeffery Canavan, the Deputy Director in the Office of Policy and Program Development, Labeling and Program Delivery staff at FSIS will give his presentation. Dr. Balentine.

Douglas Balentine,
FDA CFSAN

Good morning everyone. It's a pleasure on behalf of the Food and Drug Administration to be here this morning, and to share with you the regulations that we have in place that govern our food labeling. You'll find that we work quite closely with FSIS. Jeff (Canavan) and I have worked

together on food labeling and Codex, our teams talk to one another on a regular basis so, I think you'll hear what FDA does and you'll hear what USDA does and you'll see that there's quite a lot of alignment for the most part between our approaches to labeling. I think by the time you hear us both you'll have a good picture on how the labeling rules that are in place could might be applied to products produced from cell culture technology. Food labeling regulations have been around for a long time. It started in 1906 with the Pure Foods and Drug Act. It was amended in 1938 where it was renamed the Federal Food Drug and Cosmetic Act, which we still use today, and that that Act is the primary law that we follow still today that governs labeling and packaging of food products. As Dr. Mayne has said, one of the overriding principles around labeling is providing information to consumers that is truthful and not misleading, and to make it clear to consumers what the foods that they're getting are, what's in them, how much is in them, what the nutritional composition of those, what the ingredients are. I will go over how those come together. There're some other regulations in place that govern our food labeling regulations. There's the Food Additives Amendment that was added in 1958 that governed the regulatory structure for allowing food additives in food. We had the Nutrition Education and Labeling Act of 1990 that really put into place many of the Nutrition Facts labeling requirements, and a number of the other nutrient content claim requirements. There's the FDA Modernization Act of 1997 that governed additional labeling requirements. Finally, there was FALCPA in 2004, which really put the requirements in place around allergens and foods. That put the mandatory labeling of the 'Big Eight' allergens in place. Those are some of the main regulations that you can find online that govern labeling of food products. There're some other regulations as well that govern food products; there's the Fair Packaging and Labeling Act which put in place their requirements for net content statements so that consumers could accurately compare one product to another product in terms of knowing that they can know how much the weight it is, they compare price, they can compare value. That assured that consumers had an idea of what was in products. There's a number of other food labeling regulations that can be found in 21 CFR Part 101. CFSAN issued a Food Labeling Guide to help companies find their way through many of these regulations in more consumer-friendly terms, and we issue a number of food policy guides that govern food labeling. Those are really the laws and the regulations that we use to guide our compliance work in terms of food labeling, and one of the things that is a difference between FSIS and FDA is we do not do pre-market approval of food labels. We look for food labels for compliance based on our inspection post-market. Just to be clear on what constitutes labeling from an FDA point of view; labeling is all the written material that appears on a on a package, both the principal display panel and the other display panels of a package. Any wrapper or packaging material. It also can go to accompanying material, so shelf talkers or shelf tags that might be put adjacent to a product in a grocery store can be considered labeling. When a company website is put on the package, material that is then linked to the web content is also considered in many instances to be an extension of labeling of that food package. In terms of modern technology where we have a lot of e-commerce, we have a lot of information available on websites, labeling can be considered quite broad in terms of the information that might be considered web labeling as part of a food product. When we think about labeling, FDA regulates foods and beverages that you find in most grocery stores. We regulate food if it contains less than two to three percent meat; otherwise, USDA regulates those products that contain meat. It does create some confusion. For example, FDA would regulate a cheese pizza whereas USDA will regulate a pepperoni pizza. There are some differences on which one of our organizations would regulate the product depending upon how

much meat or poultry or fish would be in those products. We also regulate labeling of seafood and game meats. For some products such as catfish, which you heard yesterday we share jurisdiction with USDA, where USDA is now doing the inspection part of catfish but we still regulate a certain amount of the labeling of those particular products. As I said before, we do not pre-approve labels, but we view labels as part of inspections. As our inspectors go out and do safety inspections around the various factories that you heard about yesterday from Doug Stern, and others, we will look at the labeling materials and we will determine whether the labeling of those particular products being manufactured is in compliance with the labeling regulations. We do have quite a bit of compliance activity that we do to make sure that labeling is accurate and consistent with our regulations. One of the roles we have in terms of labeling is education. We do issue guidance documents and a variety of regulations and compliance guides to make it clear what the labeling regulations are and how they might apply to various food products. Particularly as we are seeing an emergence of many new and novel food products that are being put into place, particularly because of either consumer preference, or new ways of production, or new ways of manufacturing. An example of that would be using cell-based technology. We also work internationally on food labeling through Codex Alimentarius where we participate in the Food Labeling Committee, in addition to the Nutrition Committee. That helps us guide food labeling for international commerce so we can assure effective trade with, with partners around the world. That's another element that we work with and we work quite closely in those areas with USDA as well. When it comes to food labels that FDA regulates, there are a number of elements that are required mandatory and then there's another group of elements that are considered optional or voluntary. The mandatory elements and it came up yesterday, one of them one of the most important ones is really the regulatory name that a product must carry. We call that the statement of identity. I'll spend quite a bit a little bit more time a little later in my talk, talking about statement of identity. Statement of identity is really the regulatory name that a product must carry so that a consumer knows what that product is. There must be a statement of quantity of contents, and that needs to be present in in either pounds or ounces but also in metric, that determines the amount of material in a product. There must be an ingredient statement on the product that captures the ingredients on them. They're listed in the order of descending amounts, and they must be listed in either in a regulatory name or the common unusual name of the product. The ingredient statement would not contain for example, an incidental additive or certain process aids. For example, as they aren't alternately ingredients in the final product. Unless exempt, it must also contain the name and the address of the manufacturer or the co-packer or the importer if it's some product coming in from outside of the United States. The information must have a street address so that consumers or FDA can contact that manufacturer, and it would be considered not an acceptable label if that information is not on the product. It must have nutrition information. There are a few examples where they're exempt, but for the most part, it must have nutrition information. As I said earlier with FALCPA, if it contains any of the, the 'Big Eight' declared allergens, it must disclose the presence of those allergens on the food package.

Jeff Canavan,
FSIS OPPD

Thank you and good morning. I'd like to emphasize and reiterate what Doug mentioned. FDA and USDA have a very long history of working closely together. I think you'll will see as we talk up in the discussions today about

the mandatory elements regulatory and guideline development consistency across all food categories is an important consideration as we develop regulations and other policies. I'd like to start off today's discussion with talking a little bit about the principal display panel. It's similar to FDA's definition. It's the part of the label that is most likely to be displayed, presented or shown, or examined under customary conditions of display. Looking at the picture here on the slide, FSIS would consider the, the front of these packages as they're displayed in the retail case, the principal display panel. FSIS does have specific requirements for certain mandatory features to appear on the principal display panel. Those include, the product name, that we'll talk a little bit more in depth about, inspection legend in the USDA mark, a handling statement, and also the net weight statement in some cases. Here's just an example of a principal display panel. If you could see this product displayed in a retail case at your local grocery store, it has the required features there: the USDA mark in the lower left-hand corner, net weight, handling statement and a product name. As Doug was mentioning, there's quite a bit involved in the identity, the naming of a product. Many factors come into play. One would be if there is a standardized name. There are standardized names in the regulations, and also in informal policy standards, as well. For example, FSIS has a standard of identity for a frankfurter or a hotdog. It's pretty specific to fat limitations or combination of fat and water limitations, limitations on the certain use of ingredients, and others regulatory standards can be a little bit less prescriptive. For example, a beef stew, really the identity just specifies the minimum meat requirement, which in the case of a beef stew is 25 percent. Ground beef is one that's a little bit more prescriptive. It is very limiting in a sense. It has a maximum fat requirement of 30 percent. It actually prohibits certain ingredients such as water, binders, extenders, and phosphates; so you're limited to dry seasonings that can be added to ground beef. Within the absence of a standardized name, the next here would be is there a common or usual name that would apply. A beef ribeye steak; you'll see that's commonly used in the marketplace, referenced in various publications as a common or usual name that consumers are familiar with, for a particular cut of meat. That would be an acceptable product name. Cheese quesadilla, pepperoni pizza would also be an example. We don't have regulatory definitions, or standards of identity for these products, but they are considered acceptable common or usual names. There are also products in the marketplace that have a descriptive name in the absence of common or usual name. These could be a unique blend of various ingredients, some meat and poultry, and some ingredients under FDA, as well. A good example would be some type of mixture of chicken and vegetables with cheese and a pastry. It doesn't necessarily have a common or usual name, or standardized name, but it accurately describes the characterizing components of that product. Sometimes we also have what's called a nonspecific name, and this would be one that really can't stand alone as a product identity. It doesn't give the consumer enough information on the characterizing ingredients of that product. It's not specific to the species of meat or kind of poultry that is used. An example would be a chuck wagon patty, and so we would expect that that would be followed immediately by the ingredients statement, or possibly followed by a descriptive name. Here's an example of a chicken nugget product, whole grain, breaded, shaped chicken breasts with rib meat patties. The next FSIS requirement is a handling statement. This would be where a product requires special handling to maintain its wholesomeness. Typically, you'd see "Keep refrigerated" or "Keep frozen." There are certain situations where a product is distributed in commerce in a frozen state and then thawed prior to retail sale and sold in a refrigerated state and that would have the handling statement there about "Previously handled frozen." There's an example of the handling statement of "Keep frozen." The net

weight statement, it's required for all products sold at retail. There are some caveats to the net weight for random weight consumer sized packages that way can be applied prior to retail sale. It does not have to be applied by the federal establishment. There are certain exemptions. For example, products that are going to hotels, restaurants, and similar institutions. There's an example of a net weight of five pounds. The USDA mark of inspection is one feature that's unique to FSIS regulated products. Every establishment that has a grant of inspection has a unique number associated with that establishment. The mark of inspection that's applied; there's two marks, but talking about a meat or poultry, the one on the left there is for meat and the other is for the poultry. The establishment number is required to be displayed. It doesn't have to be in the mark of inspection, it can, but it can be placed elsewhere on the package. That helps identify the product in commerce if there's a need, say in the event of a voluntary recall, or some type of other market withdrawal. There would be an example of the poultry mark of inspection on this poultry product. Now the information panel is a particular location on the package other than the principal display panel. Many times, it's not feasible to put all the required features on the principal display panel, and also, it's not a regulatory requirement. There are certain features such as the ingredient statement, nutrition facts panel, and signature line, or address line, the name and address of the packer that can appear on the information panel. One requirement and our regulation is for one of those features are presented on the information panel, they have to be presented together in a contiguous manner. You can see this example where the nutrition is off to the left and the ingredients and the address line are to the right. However, they're all placed together. A very important labeling feature is the ingredient statement and it's required when there's two or more ingredients are used to make a product. FSIS' regulations, we also have guidance available, that further clarify ingredient labeling requirements. Going back to the regulation for a moment, there is a requirement that all ingredients be listed in descending order of predominance. Of course, with labeling there are exceptions. One would be for ingredients that are added that are considered minor in nature. There're provisions for listing them in any order, provided it's prefaced with a statement such as, "Contains 2% or less of the following," and then those ingredients can be placed in any order. We also have, I mentioned guidance, particularly clarifying some ingredient labeling requirements. We work very closely with FDA in the joint FDA and FSIS ingredient approval process. Oftentimes, we get questions for example how flavorings should be labeled. Spices such as black pepper, and white pepper, and red pepper can be listed by common or unusual name. However, they can also under our regulations be listed as spice or flavoring. That's not such the case with ingredients of animal origin. If a hydrolyzed beef protein may be used for flavoring, but we require the species of livestock or the kind of poultry to be declared. You couldn't label that as flavor and have to be labeled as hydrolyzed beef protein. There's an example of an ingredient statement. Well we won't spend a lot of time on this. It's the name and address of the manufacturer. If it's the name of the establishment, the federal establishment on the grant of inspection, it can just be the name. Also, the city, state, and zip when listed in the phone directory. It can identify the name of the company that the establishment is producing it for. Maybe it says particular grocery store chain, for example. In that case, it would have to be prefaced with a term such as "Distributed by" or "Manufactured for" to indicate that it's the name and address of that entity as opposed to the manufacturer. There's an example of the address line. Nutrition facts. We have regulations in place that's required for most products, again with labeling there are certain exemptions, one would be small business exemptions or products for hotels, restaurant institutions. They're not intended for retail products, for further

processing. An important part of these exemptions though is that the label cannot bear any nutrition information or claims that would kick it out of the exemption, and then require Nutrition Facts information. There's an example. The safe handling instructions is one feature that's unique to meat and poultry products, and it's also unique compared to other labeling features and they can appear anywhere on the label. It can be on the information panel, the principal display panel, front riser panel, and it needs to be on any meat or poultry product that's not ready to eat. Raw, raw meat, the ribeye steak, for example, would have safe handling instructions on it. It provides consumers additional information on how to handle the product, to prevent cross-contamination, cook thoroughly, and also how to properly handle leftovers. There are exemptions. For example, products going for further processing at another establishment; consumers would not see these products and there are requirements for how it needs to be displayed, such as a one-color. Finally, with the required labeling features for products that are imported into the United States; they have to identify the, the country of origin underneath the product identity on a media container. Here's an example of a product of Denmark under a canned ham product name. Here's just an example of a label for ground beef where all the product, all the labeling features I should say, are on the principle display panel. The following's an example where they're split, and you can see that the required features, the mark the name, the weight, handling statement or the PDP, the restaurant, the information panel, and that would be in compliance with emphasized regulations. As mentioned yesterday, and Doug mentioned this morning, FSIS does implement a prior label approval program. We draw our authority to regulate meat products from the Federal Meat Inspection Act, and there actually is language in the FMIA as you can see in the second bullet here where it talks about labeling and containers which are not false or misleading and which are approved by the secretary are permitted. USDA has always interpreted that as that statutory language as mandating pre-approved of all labels prior to their use and commerce offered for sale. Now we've established, based on that authority, we've established regulations related to the prior label approval system, which we'll talk about here in a moment, and then also about other labeling requirements. They talk they tie back to the misbranding provisions of the Act we have certainly other types of labeling requirements such as product name qualifiers than our regulations that we've conducted rulemaking for. It's all related to making sure that the consumer has the appropriate information at the time of purchase to make an informed purchasing decision, and also to make sure that that label is truthful, accurate and not misleading. I will talk a little bit about the types of label approval, and types of labels that you'll see on products. Generic labeling; we talked about how all labels are approved by the agency. There is a subset that are approved by the agency; they're just not physically submitted to the agency for approval. They're generally more basic in nature and have the required features. A sketch approval, whether it's a sketch label which is really the concept of a label. We do require certain sketch labels to be submitted to the agency for evaluation and approval and will ultimately give those sketch approval or sketch modified, which we'll discuss more in a moment. We also have final labels. Those are the labels that are actually applied to the finished product, as they go out into commerce. We also have labels that are considered temporary which are used in certain situations. For the labels that need to be submitted to FSIS for evaluation under this prior label approval program, we mentioned our regulations in 2013 effective 2014 to require four categories. These include labels for temporary approval. If you're not familiar with temporary approval, if a label is deficient in some particular, maybe an ingredient is listed out of order, but it doesn't create a health or safety situation and does not provide the company and economic advantage,

we can grant temporary approval to use that label while changes are made. Just a couple of examples. If a company was making a claim such as grass made meatball, made with grass-fed beef and they had some issues with their supplier and they wanted to use beef that was not grass-raised, we would not grant that temporary approval. Clearly, a granting that temporary would provide that that company economic advantage, so we would not do that. Relating to ingredients, I mentioned minor changes, but for example, if salt was tenth in the order of predominance and now, they wanted to adjust it to be second and it significantly changed the nutritional profile of that product, so the amount of sodium was greater than 20 percent of the declared value on the label. That's another situation where we would not grant temporary approval because it would be of concern to some individuals particularly on a low sodium diet, for example. We evaluate those on a case-by-case basis labels for products produced under religious exemptions, is a very small category essentially, they may deviate from some part of a regulations such as head on, feet on poultry labels for products with export of labeling deviations. We've been talking today, and we'll talk later today, about domestic labeling requirements we do allow deviations from those domestic labeling requirements if they're for export only and if they're in compliance with the importing countries labeling requirements. When we conduct our label approval, we're looking for information to support that the label is in compliance with the importing countries labeling requirements. Finally, the largest category of labels that we see fall into this special statements and claims, and we publish guidance that identifies not only the examples of label claims that are commonly used on meat and poultry products, but also in some cases the documentation that needs to be submitted to support the label claim for label approval. The reason why FSIS requires these four categories is because it felt that these four categories were more likely to present significant policy issues relating to health or economic factors. We're going to transition into a little bit here about the labeling records. We do have requirements. We actually updated them in the 2013 rulemaking, as well. The final label again that's the label is applied to the product needs to be included in the labeling record, product formulation process and procedures, and anything to support other claims that may be made on the label to support that they are truthful and not misleading. These labeling records are important because our inspection program personnel that are in the plants are conducting label verification activities, which we'll discuss in a little bit greater detail in just a moment, and so they need to have that information available to not only verify label approval in some cases but also to conduct that verification activity. In one such activity, [verification activity] falls under directive. Directives provide permanent instructions to our inspection program personal personnel and unless they're deleted, modified or amended. We have permanent instructions in place for the ongoing formulation verification task. As mentioned yesterday in a presentation, there's been a sustained number of recalls for undeclared allergens, many of which were the result of in plant inspection activities. This directive is targeting particularly products that are multi ingredient products, contain other ingredients, such as purchased seasoning mixes or other purchased foods. If you're making a meatball and it's formulated with bread, that's going to be a purchase component. The inspectors are looking at what's actually going into the formulation, comparing it to the product formula and the labeling record, also comparing it to what's declared on the label, and our specific instructions on how to document a non-compliance, and also to prioritize the highest risk products, essentially, when conducting that label verification activity. Again, we're targeting these multi-ingredient products that may contain one of the big eight allergens. Then there's a general label of verification activity and this is republished in 2014 when we updated our prior label approval. It provides

instructions to inspection program personnel on how to conduct a label verification activity. Essentially, what features [they] should be looking for, the mark of inspection, the handling statement, are they in compliance with the regulations, and it's focused again on the final label. A sketch is an important part if you're if you need to get your label approved by the staff, but really what we're verifying is that the label on the product: Is it consistent with the product formula, and what's in the record to protect public health? When labeling is not compliant, there are some corrective actions that an establishment can take. They could submit for temporary label approval, and we would evaluate on a case-by-case basis whether temporary approval is appropriate. Again, ensuring that there's no public health or safety issues or providing the company economic advantage. In other cases, the label can be brought into compliance with pressure sensitive stickers, essentially to cover a feature that may not be compliant to bring it into compliance. Finally, I wanted to talk today about procedures for rescinding or refusing approval and our regulations for the rules of practice. We do have the authority if a label is found and [the] Agency [found that] label on a product in commerce that's not in compliance, they would bring that to the attention the labeling staff. Alternatively, maybe from a competitor that might find a product in commerce that they don't think is in compliance. We'll evaluate those on a case-by-case basis and determine whether they're in compliance with FSIS regulations. In the case they're not, we can reduce a label to temporary approval if there's no health or safety issue. Or, we could resend the label to prevent its future use. There's a lot of ongoing working with our inspection program personnel as you can see with the verification activities and also, in some cases, resetting or refusing approval. We're working closely to get more information about the products and then how to, and then what actions may be taken if they're found to be not in compliance. That concludes my presentation. Thank you.

Selena Kremer,
USDA FSIS Moderator

Thank you, Jeff [Canavan] and thank you, Doug [Balentine]. I think that was a lot of helpful information and you can certainly tell they're both experts in their field. Next, we want to talk about the current landscape for food labeling. We're going to start off with Matthew Michael. He is the Director of the Issuances Staff in the Office of Policy and Program Development at FSIS, followed by Dr. Douglas Ballantine, the Director of the Office of Nutrition and Food Labeling at CFSAN. Matthew.

Matthew Michael,
FSIS OPPD

Good morning. As Selena said, the topic of this session is the current landscape for food labeling. I'm going to get there by telling you about a petition that USDA received back in February. This petition is one of several catalysts behind not only the current ongoing examination of animal cell culture technology by USDA and FDA, but also a catalyst for this meeting. As Selena said, I am the Director of the Issuance Staff in the Office of Policy and Program Development at FSIS. Not surprisingly, the Issuance staff and the Office of Policy manages the development of policy issuances. These would include *Federal Register* publications, such as notices, proposed rules and final rules, which could pertain the labeling. Guidance to industry, which also could pertain to labeling. Instructions to our inspectors, which many of you will know as emphasize directives and notices, which could pertain to the verification of the truthfulness of labeling and FSIS responses to petitions.

Let's talk about petitions. A petition for rulemaking, which is what we typically call it, is a written request to FSIS to issue, amend, or repeal a regulation or policy. Anyone can file a petition with FSIS. We have regulations governing the petition process in volume nine of the Code of Federal Regulations in part 392. The regulations contain instructions on how to submit a petition, describe the type of information that may help FSIS to review a petition in a more efficient manner, and they also permit interested parties to comment on the petition while we're reviewing it. After a petition has been filed, FSIS evaluates the requested action to determine whether we should grant or deny the petition. We consider the supporting information included with the petition, as well as any comments we receive after we complete our review. We inform the petitioner in writing of whether or not we will grant or deny the petition, what action we'll take, and we post our response on our web page, as well. All of our petitions comments and responses to comments are available to the public both in our docket room here in the South building, and online. In the event where we have a petition that generates a lot of public interest and a lot of public comment, we often also put it on regulations.gov. That's the case in the petition in question I'll be talking about today. This is a screenshot of regulations.gov if you've never seen it. You can get there for our petitions often by a link on the FSIS website petition page, but you could also go directly here, and they have a number of ways you can search for our regulations or petitions, comments and those of other federal agencies. The petition in question. This is a petition, followed by the U.S. Cattlemen's Association, or USCA as I'll call them, concerns the labeling of cell cultured meat products and other products that may be marketed like meat but are not meat necessarily. It was submitted to USDA on February 9. We've received over 6,000 public comments, all of which are on regulations.gov. I looked yesterday and there's 6,159 right now. It's still under consideration. We continue to examine the petition and the supplementary material that was provided with it. It was a lengthy petition, a lot of attachments. We're looking at all the comments on the petition, and we'll be considering the comments made at this meeting and submitted in writing in response to this meeting. What did USCA request? First, they asked us to limit the definition of beef to products from cattle born raised and harvested in a traditional manner. Second, they asked us to limit the definition of meat to the tissue or flesh of animals that have been harvested in the traditional manner. Notably, they made a point in their petition that they wanted these definitions to distinguish traditionally produced meat, not only from products cultured from animal cells, but also from products made from plants or insects that are labeled or marketed like meat. Also, interestingly, the petition does not request that we change our regulations; they don't request that we go through rulemaking to affect these definitions. Instead, they ask that we amend what's known as the FSIS Standards and Labeling Policy book. The policy book is guidance. It's intended to help industry produce labels that aren't, that are neither false or misleading. Also, you can use the guidance to create what are called generically approved labels, labels that would not have to go through prior approval. The policy book is incorporated by reference into our regulations, but it's not a regulation in itself. It's guidance you can use. That's an interesting facet of this petition. Our response to this petition in light of the development of cultured cell products will obviously be an example of how we respond to the labeling of new meat and poultry products. Again, we'll be considering all the comments we received, the supplementary information, before we respond. FSIS has a lot of experience in regard to the labeling of new meat and poultry products because it being developed all the time, as well as novel processes to treat those products. I'll give you a few examples. We have irradiated products. We published regulations in 1999, so we actually have regulatory requirements for their

labeling, which include the inclusion of the redura, it's the radiation symbol on the label, as well as a statement that the product was irradiated or the way use of the word irradiated as part of the product name. We also have advanced meat recovery products. We have labeling requirements that are determined by the constituents of the final product of advance meat recovery. It determines whether it can be called pork, for example, or mechanically separated pork, instead. We also have high-pressure processing; we don't have positive labeling requirements for those. You don't have to state that on the label, but we have reviewed a number of claims regarding high-pressure products, high-pressure treated products on the labels of those products. Then, a final example is products with modified atmosphere packaging. We have labeling requirements for those products depending on the gas that is used for the modified atmosphere in the package. For all of these products, and for future products such as cell culture products, we would apply the same statutory and regulatory standards ensuring that the labeling is neither false nor misleading and to make sure that consumers are given enough information to make an informed purchase. I hope this discussion by getting there by way of talking about the petition was helpful in in showing how FSIS reviews the labeling of new and novel products. Thank you.

Douglas Balentine,
FDA CFSAN

This time I wasn't planning to have slides, so we're, we're in a little better shape. I'm just [going to] make some brief comments about the current landscape. I think as well, where the food marketplace is rapidly changing and innovating as new technologies are being matured and become economically viable to use to produce new products in novel ways. For example, the topic of this particular public meeting is looking at how cell culture technology is being developed for the applications of producing new food products, bringing unique products into the marketplace. We've seen rapid advances in agricultural changes. For example, we've gone to greenhouses, to now we are entering the age of vertical farming where we have large warehouses growing fresh produce that are across from large distribution centers that are rapidly allowing fresh products into the marketplace. That's changing the dynamics of how we get agricultural products. We see the emergence of insect proteins being explored as a way of cheap, inexpensive, high-quality proteins to assure that there's sufficient protein available for meeting the needs of the growing population. Through biotechnology and bioengineering, we're seeing the evolution of typically food ingredients that would only appear in from animal sources are now being produced from plant-based sources, so we have hemoglobins being produced in plants that can be used in production of plant-based patties. We're seeing dairy proteins being put into a variety of plant sources that will allow those proteins to be produced from yeasts and other plant sources. The landscape is rapidly changing. We're looking at that landscape and looking at how we need to add our view of our regulations to take into account the rapidly changing landscape. Clearly, we'll continue to always focus on the principles that clear, truthful and not misleading labeling will be critical foundations to make sure that consumers are understanding the products that are coming into the marketplace, and can understand how they are either similar or different from more traditional products in the marketplace, with a focus on making sure that these products are both safe, and keeping track of whether or not these new products are nutritionally adequate or how they're nutritionally different from more traditional products. We do believe that that truthful and not transparent and transparent labeling is critical so that consumers can build diet patterns that

are consistent with our national guidelines, because those diet patterns are essential to public health. In doing this, we do maintain very strong partnerships we work closely with USDA and this meeting is an example of one of those partnerships. We also work closely with USDA, CDC and NIH in order to make sure that all of our work is based on sound science. We really do you that this is a critical time for us to be looking at the emerging landscape of how the food landscape is changing. That we think we can really make sure that we can advance public health as a public health agency by empowering consumers with the right information to facilitate building healthy diet patterns, and at the same time enabling industry to innovate into the changing landscape and marketplace. As you might all be aware of, Commissioner Gottlieb who spoke yesterday announced earlier this year our nutrition innovation strategy, which is looking ahead at how FDA can begin to take a fresh look at how its regulations can be applied in part to this changing food landscape, in order to help build healthier diet patterns. While the strategy is still in in its earliest stages of development, we are looking at how we might amend our food standards principles to take into account the rapidly changing food landscape, to make sure that it has the flexibility to do what it needs to do but also allow product innovation. We're going to update the regulatory definition of healthy and we hope to be coming forward with the proposed rule on what that new definition might look for. We're looking at how we approach our health claims, which I'll talk about this afternoon. We did have a public meeting earlier this year on July 26 to begin the public dialog, similar to this meeting, around how the nutrition innovation strategy might be developed and evolved, and we had an open docket that closed on October 11, just a couple weeks ago. We received over 5,000 comments from the public into that docket and are currently looking at reviewing those dockets, as that that public comment period is really critical to inform us in part on the way forward. I would encourage you all to also take advantage of the opportunity to provide comments into the docket that will be open for this particular meeting because public comments are critical. Regarding the petition process that you heard from USDA, FDA has a similar petition process where citizens or groups can petition the FDA asking us to consider changes in our policies or regulatory actions. As USDA had received a petition around labeling of these cell-based products, we've received a citizen's petition from the Good Foods Institute, who you heard speak yesterday, asking us to consider a naming framework on how standardized terms, such as milk or meat, might be used in the naming of plant-based alternative foods. We've received that petition. It's up in the docket. People can also look at it and comment to that docket, and similar to USDA we are currently looking at a petition and considering how we might respond to that petition. Public comment, again, is critical to helping us make sure that all can have an informed and voice in how we might move forward in reviewing that petition that would set that the basis for how we might name a variety of plant-based alternative or alternative food products that will be emerging in the marketplace in the future. In closing, I'd really like to say that this morning we did share with you some thoughts on food labeling, and you can see that that there is a lot of consistency between the labeling approaches of both USDA and FDA. We really look forward to continuing the dialogue today and hearing your views and your input on, on food labeling because your input is critical. Thank you.

Selena Kremer,
USDA FSIS Moderator

Okay, well we're running a little early this morning. We're running ahead of schedule, so we're going to take a break a little bit early. Let's reconvene back here in 15 minutes, so that'll be five minutes to the hour. We'll see you then.

[Chattering]

If you'll go ahead and take your seat, we'll get started in one minute. Okay, welcome back. I hope everyone got a chance to stretch your legs. We're going to go ahead and move on to our next session, which is open public comment. I want to introduce Malcolm Buitoni, who is the Associate Commissioner for Planning at FDA.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Welcome back everyone, and good morning. My name is Malcolm Bertoni and I'm the Associate Commissioner for Planning at FDA, and I'll be your moderator for this next session. From yesterday, if you were here or if you haven't, I'll just explain that one of the important purposes of today's meeting is to gather input and commentary from the public. This session here is an open comment period, so you do not have to have signed up if you have some particular thoughts that you would like to share. We very much want to hear them. We are soliciting comments on the labeling aspects of the discussion that we've had, so we would appreciate it if you have comments that you do share them on labeling. If we have time, we can perhaps entertain some other comments, as well. We have two microphones down here near the front of the stage here, and we have some ushers who can help maintain orderly lines, and we ask that you just come down and the ushers will direct you to one of the two microphones. Now in order to make sure that we allow everyone to have an opportunity to speak today, we do have a three-minute time limit for each comment. There's a screen where you can monitor your time available. Also, we very much would like for you to state your name and your affiliation. Without any further ado, let us start the session and begin with our first speaker.

Liz Holtz,
Animal Legal Defense Fund

Hello, my name is Liz Holtz, and I'm speaking today on behalf of the Animal Legal Defense Fund. I'm set to give formal comments later this afternoon, but I'd like to offer the following comments about the issue of safety addressed yesterday. I want to first thank the USDA and FDA for the opportunity to participate in this public meeting. The Animal Legal Defense Fund commends the agency's forgiving this critical issue of animal agriculture technology such careful consideration. The potential for animal cell culture technology to transform how we produce meat and other animal products cannot be overstated. Conventional production and slaughter practices are inhumane, unsafe and environmentally destructive. More and more consumers want alternatives. In light of the enormous benefits this technology offers, we urge USDA and FDA to employ an efficient and transparent regulatory pathway that spurs innovation, while ensuring product safety, instilling consumer confidence and preventing deceptive labeling for all animal products. Whether made from slaughtering animals or culturing cells. On the question of safety, innovation in the meat industry is urgently needed conventional methods rely on the intensive confinement of animals in unsanitary and inhumane facilities. These unnatural conditions require extensive use of antibiotics to address diseases that proliferate among the crowded, stressed animals, contributing to the spread of drug-resistant superbugs. Animal slaughter further involves broad potential for adulteration, as meat comes into contact with fecal matter and other contaminants. These adulteration risks are compounded by overly fast slaughtering speeds that make detection of contaminants and disease more difficult, and the turning over to ill-trained slaughterhouse workers of critical food safety inspection tasks, a program USDA is at this moment poised to expand to pig slaughterhouses nationwide. In contrast to slaughtering live animals, meat produced using animal cell culturing can be produced in aseptic controlled environments that present significantly fewer and different food safety threats. The vast differences between these production methods show that USDA would not be the appropriate agency to regulate their safety, even if it had jurisdiction over their production. Instead, FDA should build on its significant experience regulating other cell-culture technology applications to develop a process that ensures food safety for these new animal products. Thank you.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you for your comments. I know we have some technology to help us with the time line, but it does require a manual step so we need someone to help me on the clock. Great, thank you.

Jessica Almly,
The Good Food Institute

Thank you for the opportunity to submit these comments. I'm Jessica Almy. I'm the Policy Director from the Good Food Institute. We appreciate the Agencies thinking through these issues to ensure that adequate information is provided to consumers and bright lines are created for producers. Thinking about labeling cell-based products, consumers are enthusiastic about these products. We did a poll with the confirmed analytics and we found that two-

thirds of Americans are willing to try meat grown from cells without slaughtering animals, and 40 percent said they would pay a premium for these products. The expectations are that these products are healthy, safe and environmentally sustainable, while looking and tasting the same as conventional meat. As to the FDA's specific questions, yes, the source of the cells the species from which the cells come should be required information on the label. This is important to protect consumers from potential allergens, as Dr. Balantine pointed out earlier. We also think that there needs to be flexibility for labeling requirements. Standards of identity have shown that they have limited utility in light of other disclosures on labels, and it's difficult if not impossible for federal agencies to keep up with the growing choices in the marketplace. Fundamentally, statements of identity must follow to the two principles that Dr. Mayne enumerated in her remarks this morning, for all aspects of the label - that they be truthful and not misleading. Plant-based products regularly reference meat counterparts to convey information on their flavor profiles and how they're used. They also use modifiers, like plant-based or vegan on their labels, so long as consumers are not misled these products are not mislabeled. We, of course, urge FDA to grant GFI's petition, which was mentioned before the break. We have every expectation that cultured meat companies will have incentives to set their products apart when they're first introduced into the marketplace. Initially, the products will be clearly communicated the way that their products have been produced because it's important to consumers. They will command a price premium. Over time, we think it's important to see whether the production process is material to consumers. As Mr. Canavan said, labels should provide consumers the information they need to make purchase decisions in the supermarket; moreover, they should not advantage some producers over others. We look forward to providing formal and written comments on this topic and thank the FDA and USDA for this opportunity.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you for your comments.

Barbara Kowalcyk,
The Ohio State University

Good morning. My name is Barbara Kowalcyk. I'm from the Ohio State University, and please forgive me; I have a bad cold. I'd like to make a couple of comments on labeling and risk communication, which has been basically talked about this morning. I would like to preface this by saying I'm an epidemiologist and statistician by training. My Ph.D. is in environmental health and I would love to see food products that can be developed and produced in environmentally and friendly, and sustainable ways. That said I have some significant concerns about some of the claims that are being made about these products. These products have been put out in the public purview as being clean meat, which may give consumers the misrepresentation that these project products are sterile. They will not be sterile. As a member of the FDA science board, although I do not speak on behalf of the FDA science board, and I encourage everyone to read the transcripts from Monday's discussion, which we had in depth. The product, the environment in which cell-based products are grown, in cell culture medium, is very conducive to the growth of all pathogens. If that becomes contaminated, there will be contamination in the ultimate product. In

addition, the scaffolding elements, the elements used in scaffolding these new products may have hazardous effects on the public, and that needs to be clearly labeled and considered during the labeling process. How do we available what has gone into growing the product, and then in the cell culture medium? For example, in some cases based on the research that I read, human growth hormones are being used to produce in the culture medium. How is that going to go into the labeling process? The other thing that I think, and I see my time's running out, the other thing that I think that is important for the agencies to consider is these products are being touted as being more environmentally friendly and sustainable than traditional meat and poultry products. I have no idea. I do understand that there are significant environmental impacts through traditional production, but I want to understand how is this going to differ? I think that the impacts would be different, but I still think there will be impacts. At the FDA science board meeting on Monday, it was stated that it will take five thousand liters of fluid to produce one to two kilograms of product. That's half of a milk tanker. What happens when we have contaminated product that that cannot be put out onto the marketplace? Where is that recalled product going to go? Where are the byproducts of this process going to go? If companies start marketing this as being environmentally sustainable, do we have a definition of that for the labeling process? That's something that I think, my times up, so I will stop there. Thank you.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you very much. Please state your name and affiliation.

Michael Hansen,
Consumers Union

Hi, my name is Michael Hansen. I'm a senior scientist at Consumers Union, the Advocacy Division of Consumer Reports, an independent nonprofit organization with 7 million members nationwide that works side-by-side with consumers for truth, transparency and fairness in the marketplace. I'd like to talk about is we did a survey - a nationally representative phone survey - using random digit dialing of 1,018 U.S. adults this June. The data were statistically waited so that respondents in the survey are demographically and geographically representative of the U.S. population. The first question we basically asked is how Americans think the packages should be labeled. The first question we asked is if you were to see a package for purchase at a grocery store or other location containing food that is produced in a laboratory from animal cells to look and taste like meat, how do you think the package should be labeled? Only five percent said it should be called meat without any further explanation. A little over half, 52 percent, said it should be meat but accompanied with an explanation as to how it was a produced. Forty-three percent said it should be labeled something other than meat. We then asked people for what actually it actually say on the label. We gave them seven choices and we actually randomized those choices in terms of how we ordered them. Those seven were lab-grown meat, artificial or synthetic meat, something without the words meat, beef, pork. Third, was animal free meat such as no pig pork, cowless beef, beef cultured meat, clean meat and *in vitro* meat? The two that were at the top, lab-grown meat, 35 percent said that it should be labeled. At 34 percent, said it should be labeled artificial or synthetic meat and at the bottom were clean meat at nine percent, *in vitro* meat 8 percent, then, a little above that, at 11 percent, was cultured meat. We think

consumers have made it clear how they would like to see this product labeled, is number one, it should make very clear how it was produced, and number two, they should use terms that consumers understand. From our sampling, that clearly shows it's either lab-grown meat or artificial meat because those collectively got almost 70 percent of the samples. Again, at the bottom where *in vitro* meat, clean meat, and cultured meat. We think this should be labeled as either lab-grown meat, artificial, or synthetic meat because that's what consumers have said. The one potential problem with cultured meat or even cell cultured, is some consumers might think might not realize what culture means. They could think that - does cultured meat is a cultured meat product one that for example likes opera and all these other things, which is a different form of culture. I think we have to use terms that consumers understand. We'll submit this. We'll also make detailed comments and submit this survey to the docket.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you very much.

Perry Ames,
Food Resource LLC

My name is Ames Perry. I'm the Director of Food Resource, which is a regulatory consulting group to the food industry. Yesterday during session two, which was the potential hazards for cell culture of technology products derived from livestock and poultry, Dr. Fasano of FDA mentioned the nutritional manipulation of cultured meat and poultry products, the possibility to do that, which of course will impact nutrition claims. I think there are a lot of other claims that could be made about the altered nutrition that need to be considered when we're looking at who needs to regulate this. I think because FDA does not do prior label approval, I would also make the case that those considerations would make it more natural fit for FSIS. Thanks.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you very much.

Mike Selden,
Finless Foods

Thank you all for joining today's conference. The conference has

Hello. Mike Selden, co-founder and CEO Finless Foods. In terms of labeling, I just want to make one quick point. Lab-grown meat as a name is not just wrong; it's just incredibly inaccurate. We are not going to be producing anything at scale in a lab. A lab is, by its nature, single, like small experiments. It's the same way that beer is prototyped. Like in any brewery that you go to. You will find like a white room, lab coats, science type benches, black tabletops and that's where they'll be prototyping and designing new types of beer, which is then produced in a brewery. To use the word lab-grown meat, and to even suggest if that as an option in this case, is intentionally misleading. Also, not setting up a fair playing field. If we are lab-grown meat, then beer is lab-grown beer. If you're going to change our label, then change that one, too. Thank you.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you.

Eric Schulze,
Memphis Meats

Good morning. My name is Eric Schulze. I am the Vice President of product and regulation at Memphis Meats. As Secretary Purdue noted yesterday, in the next 50 years the world will demand as much protein as has been produced in all of human history to this point. To feed the growing planet, protein production must increase and become more efficient. This will require many innovative partners, including traditional food producers large and small, as well as cell-based meat, poultry, and seafood companies. To meet this challenge, this pursuit of innovation must occur not only in industry, but also within government. Appropriate existing regulation allows for such innovation, while ensuring safety through sound risk-based policies. No one company, industry, or government agency can address this alone. Memphis Meats strongly believes and has stated previously that cell-based products and technology are and, not an or solution. Recognizing our shared desire to support innovation and feed the growing world, Memphis Meats uses the term cell-based meat and poultry to describe the products that are result of animal cell culture. We know that a wide array of terms have been used to describe our products and technology. In this room. In the media. By stakeholders. Even within our nascent industry. I'd like to take a moment to explain why we believe that cell-based meat, poultry and seafood is the right term to describe our products and technology. Some terms like fake, synthetic, or artificial meat are intended to not only cast our products in a negative light but are also simply false and misleading. We're making real meat and seafood, and that's the whole point. The term lab-grownhas an accuracy problem, as well. As with many familiar and currently marketed food products, the early development of our products happens in food labs, but the products that we bring to consumers will be produced in food production facilities. Not labs. We also no longer believe the term clean is the right term. While we've used it in the past, primary intent was to highlight the sustainability aspect and controlled production environment we are developing. Since then we've heard feedback from many stakeholders and we've learned that the term clean can be confusing, is perceived as disparaging and does not fully convey our process and product to consumers, and we value that feedback. That's why Memphis Meats has begun using the term cell-based meat, poultry, and seafood. This term is clear, factual, and inclusive. It organizes products into categories that will help consumers. It is distinct from plant-based proteins in animal-based meats. It differentiates our products, while also clearly convey that Memphis Meat,that cell-based meat, is in fact real meat. We are encouraged by the fact that others are beginning to use this term cell-based, as well. Now we know that determining the appropriate terminology for food labeling depends on certain factors including the characteristics of the finished product and applicable standards of identity, or other regulations. As we continue to continue to answer these regulatory questions, we hope that using the term cell based open the door for a broader conversation and commitment from all stakeholders to describe the products of animal cell culture in a clear, accurate and transparent way moving forward. We look forward to working with stakeholders as well as USDA and FDA to clarify the appropriate labeling terminology and regulatory framework for cell-based

meat, poultry, and seafood ingredients. We think the agencies for convening this important meeting and for the opportunity to comment. Thank you.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you. It looks like the line has died down, so I'd encourage people who are thinking to come on up and offer your, your comments.

Alain Rostain,
Simple Foods Collaborative
Company

Hi, everybody my name is Alain Rostain. I'm the CEO of Simple Foods Collaborative, or just Simple, a new research and development company intending to one day commercialize blended cell-based lean fish products. Along with Memphis Meats, we've been calling the products we hope to commercialize one day at cell-base since Julyfor all those reasons. I am very lucky.My mother passed away two years ago at 90 in love and in peace, completely healthy. Mom used to say there were two kinds of people in the world: those who ate to live, and those who live to eat. She was one who lived to eat, and Cornish hens, lamb chops and ground beef were her protein staples. Therefore, I'd like to start by thanking the USDA and FDA for your organizations important work in keeping us all safe, fed and healthy, past, present and future. I'd like to then extend my thanks to all of meat and poultry and seafood, if you're here. I will never forget my gratitude for helping to give my mother such a long healthy life. We have an extraordinarily safe food system in the USA. I'd like to circle back to the conversation about allergens and build on what Mike Selden brought up yesterday around allergies to fish, and also build on what Susan Mayne raised here earlier today around how improper listing of allergens is the leading cause of recalls. Quick poll: how many, a quick poll, how many of you know what yellow perch is, or wahoo? They’re species of commercial fish. It is estimated at 0.4 percent of the U.S. population is allergic to fish. That's 1.3 million Americans who are allergic to fish. That's not shellfish, which is another two percent of the population that overlaps. I believe the right thing to do for cell-based fish for maximum consumer safety is that the ingredients label an “allergy contains” label must not only make it clear that the food product in question contains a specific species, but also make it clear that it's fish. Fish is one of eight allergens with specific labeling requirements of the Food Allergen Labeling and Consumer Protection Act of 2004. Under that law, manufacturers of packaged food products sold in the U.S. containing fish or a fish product as an ingredient must identify on the ingredient label, in clear language, the specific type of fish used. As I understand it, it must list the species, but because we don't know what these things are, wahoo, people who are allergic to one fish are generally advised to avoid all species of fish, unless they specifically know they are not allergic to that fish. Unless we learn, otherwise, it's safe to assume that the proteins responsible for fish allergies will be present in the cell-based fish protein we intend to one day grow and harvest. That's why it's not enough to list the species name. To minimize serious allergy reactions for 1.3 million Americans, the ingredients label and contains label need to make it perfectly clear, without ambiguity, that by consuming this product the consumer is consuming fish and is

consuming wahoo. It's also why we can't call it artificial, because then people will wonder if they're going to be allergic to it or not. In conclusion, to avoid serious dangers to those with fish allergies, all cell-based seafood will need to include labeling this has both fish and wahoo, both the word fish and the name of the species. In closing, I'd like to remind us that everyone here wants to feed people safe, healthy, and clean food. We share the same interest. Thank you, again to the USDA, FDA, and everyone here for embracing a rational, thoughtful, collaborative, and empathetic science-based approach to regulating cell-based meat, poultry, and seafood. Thank you.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you. And let us know if those are going to be your formal comments, or… They are. Okay, great. Thank you. The line has died down again. I'm going to display the second set of questions on the other slide, just in case that inspires some additional thoughts that folks may want to share. Would anyone, there we go. Thank you for sharing your name and affiliation.

Danielle Beck,
National Cattlemen's
Association

Danny Beck the US Cattlemen's Association. I just want to start by thanking all of USDA and FDA for having this. I know it was the answer to our petition that that brought this up, and certainly appreciate your collaboration on this. The questions that you guys have asked, I would say yes to all these questions. We should have standards of identity to identify these products as different than beef and meat. We feel that meat has already been defined. Consumers, when I travel tell me all the time that when they purchase product at the grocery store, they think of what we're doing as families on the land, taking care of the land, taking care of those cattle every day. They don't think about somebody putting a group of cells together and growing a new product. That's not beef. Should the methods by which animal cell culture proteins are produced be communicated, as well? Yes, it should be. I truly think people know how beef is produced historically. This is a new method. It needs to be explained, explicitly. Should the source of the animal cells be put on the label? Yes. How should products containing both animal cells and cultured products, or traditional meat, be labeled? I really think they shouldn't be combined. That's my opinion. If they do, I think you need to label that as such, and probably they need their own identification and inspection system altogether. I don't think it should be the same beef inspection system at all. Thank you.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you.

Brian Spears,

New Age Meats

Hello. I'm Brian Spears, Co-Founder and CEO of New Age Meats. We make pork. Pork from animal cells instead of animal slaughter. I have the distinct and rare privilege of being able to taste our cell-based meat. I remember the first time I did taste it, which was about a month and a half ago, we were making it for the first time and we had several containers of meat. Some of which we had bought in the store. We ground it up because it was similar to what we were producing, and then we have the stuff that we made. We had them in different concentrations and we had a chef there that was cooking up our meat, and we tried one sample and I ate it and said, “Ok, that's bacon, I recognize bacon.” “So, what's next?” Our chef said, “No, no that's, that's your meat.” I said, “Wait that's, it's not like…” When I ate it, it’s not like it was, or was like meat, it was meat. It was perfectly mistakable for meat because it is meat. In fact, we then fed it to 40 people who came and had our cell-based pork sausage, including a reporter from Business Insider. To quote her, “It tasted like meat.” Then again, it is meat. I wasn't sure I would have been able to tell the difference between this pork sausage and any other.” When we go to market. It will be simply dishonest to label it as anything other than meat. Thank you.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you. If there are any other folks who are planning to give their formal public comments, or anyone who would like to provide some additional comments, you may come forward.

Barbara Kowalcyk,
The Ohio State University

Barbara Kowalcyk. The Ohio State University. I don't have any formal comments, this is just an additional comment. I think it's very clear from the good discussion this morning that there's a lot of debate about how to label these, and I think that this is something that the agencies are going to have to look at very carefully. Involve social and behavioral scientists in determining how to label this. One thing that always strikes me when I come to these meetings, and other scientific meetings, is we get into these discussions as should it be cell-based or cultured? Every person in this room is not normal, okay? We know things that most of the American public does not understand, and so what we think it should be labeled in some ways is irrelevant. We need to engage normal, average consumers in in-depth studies and that's going to require a lot of engagement of social behavioral scientists in figuring out how to label this appropriately so that the average American consumer who may not know what a culture is, and may not remember what a cell is – as sad as that may sound – to adequately describe this risk to them. There are going to be risks with this product. It's not going to be risk-free and we have a hard time explaining the risks with traditional food products to the American public. For those of you that don't know me, and I want to also comment and I have my grandstand here I've heard a lot of people talk about how safe our food supply is, and it is it is one of the safest in the world, and I do want to commend the agencies for the work that they do.But there have been a large number of recalls from both agencies just in the last week and someone made the comment earlier that most people understand how our food is produced. No, they do not. Most

Americans are out of touch with how products are produced in this country, and so I want to caution us in making a lot of assumptions about what people do and do not understand about these risks. And that's going to require the agencies to do a lot of work, which is actually pretty difficult for them to do given some of the, the Data Reduction Act, and things like that. Doing the kind of social and behavioral research that we need to do around these products is difficult, so it's going to require partnerships from academia and from industry to get that done before we can have a full-vetted conversation about how these products should be labeled and I'm going to make it, a stab, a play, I'm going to also request, again, that we think about how these are going to be really labeled in terms of environmentally sustainable and clean. I know I'm at my limit, but one of the things that I've heard is, repeatedly on Monday, yesterday and today is the fact that antibiotics are not going to be used in these products. That is not true and microbials will be used in these products if they are produced in an aseptic environment. They have to use antimicrobials to get there, and so these are things that consumers are aware of their environment. They're concerned about the environment; they're concerned about antibiotic stewardship. if these products are not labeled properly, so that consumers have the information they need to make informed decisions, it's going to be misleading. I'm not saying I have the solution. I'm just saying that there's a lot of work that needs to be done to figure this out. Thank you.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you. Next Speaker.

Sharon Natanblut,
Natanblut Strategies

Hello. I'm Sharon Natanblut. For many years, I worked at FDA doing communications and stakeholder engagement. I am now a private consultant and I monitor a number of these issues, and I'd like to make a comment. One about communications, and two, about stakeholder engagement. The one about Communications builds on what Barbara just said. I am aware of the consumer research that both sides have done and I do not think anyone is surprised by the findings that both sides have come out with, based on who they are. I would urge that for anyone truly interested in this issue, now is the time to get it right. Spend the money; take the time to do real consumer research. Not just surveying simply what, oh here's five names, what do you think of them? What does this mean to you? That’s an important step. It's not the first step; it's not the key step. This is a new technology. It has to do with food. You have to put your communications and thinking of the naming in the context of how people eat. What they think about their food. Why they want to consider a different type of meat. Why they love the meat that they eat. How does this fit all together? Really listen to them. It’s not a quick survey of here are the five names, what do you think. They don't know enough about it. Rather than just asking them for the names, probe deeply to understand how they think about it and how it will fit. What the context is. I think from that, everyone will be able to come out with something that will be far superior. I also think that it's wonderful, I heard Memphis Meats and some others talking about

the stakeholder engagement, and that it actually moved them away from the term clean. I think that's remarkable and wonderful. I think it's completely understandable that the industry hated the term clean for obvious reasons and that was very good that they spoke up about that. It's very good that, that there are those who are considering what other alternatives are. If there's that kind of reasonableness, if there's a true willingness to have USDA involved and FDA involved in their respective complementary manners, I think that we can do a lot better than what happened with GMOs. I would hope that maybe some of the lessons of what FDA did on FSMA, collaborative forums that were hosted by, in that case, it was Pew, look for some groups who have not staked out such a strong position but can be the true mediators and bring together. I think there's much that everyone in this room can come out with something. It's ultimately all about consumer confidence and the more that they're seen as being two sides who are battling each other the more that that raises concerns among consumers about eating meat and eating this cell-based meat, or whatever the term is, that ultimately is decided. Thanks very much.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you. Next Speaker.

Brett Kenzy,
South Dakota Farmers
Union

Hello. I'm Brett Kenzy. I'm a cattle rancher from South Dakota. I'm here as an individual and this is not my official statement. I do have a couple of impromptu statements that I've come up with as I listen to this, and I've gained a tremendous appreciation for what USDA and FDA do. I appreciate what they do and I appreciate the task that they have ahead of them. Statement two, again unofficial: In the last two years, live cattle supply chain ranchers have dramatically changed their use of antibiotics. People made the call and we answered. Now, a vet prescription is required for all antibiotic use. Label directions have been changed for antibiotic use. We've always had withdrawal times for antibiotic use. Then one more thing I thought of well I came up here is, antibiotics are expensive, people. We only use them when we need them. I'd like to finish with a question: How will antibiotic use be regulated in cell culture technology? Will they have prescriptions to get? Will they have withdrawal times to respect? Thank you.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you very much. Do we have another commenter?

Jack Bobo,
Intrexon

My name is Jack Bobo. I'm with Intrexon. Just a couple of comments. The first is that I think a lot of the challenges with labeling that have been raised this morning apply to our entire food system. I think that consumers really

don't understand. Many consumers don't understand whether or not a cow was involved in producing low-fat milk. I think we need to recognize the starting point that we have for the entire food system. There are definitely challenges. I think people have never cared more nor known less how their food is produced. That's a challenge for all of us. People care passionately and they're asking for things and changes to our policies and yet they have very little understanding what our food system is all about today. There are broader goals that we need to achieve in terms of educating the public about what our food system is. I don't really see a huge amount of difference in this room on the labeling question. I think that on one hand, we have the companies producing cell-based products that passionately want to convey to the consumer that their product is different. If they want to convey that information, then the question is how to convey that information. I think we need to go through the process of making sure that we convey it in the best way possible. I think that on both sides of this conversation everybody wants that to be the case. Hopefully we'll focus on the things that we have in common. I think it's also worth pointing out that people love innovation almost as much as they despise change. There's no place they despise change more than in the food they eat. Food is what brings us together as family, as friends, and if you mess with my food, you're messing with my family. But, if we don't change how we produce food, everything will change. We need to recognize that the agriculture industry has changed dramatically over the last thirty years. It uses 50 percent less water to produce a kilogram of beef from the livestock industry; they've done amazing things. This is just one more change. We need to produce 50 percent more protein by 2050. If a hundred percent of that was cell-based, it wouldn't impact a single livestock producer on the planet. I think that there are opportunities here and that we're going to achieve that in multiple ways. I'd like to close by saying that we have the best food system in the history of the world, but it's also the worst food system we'll ever have, because it's going to get better as we go forward. Thank you.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you very much. We have some additional time. It’s not Sunday, so we can't break for brunch. If you're thinking about a particular comment or perspective that you'd like to be considered, now is a great time to come on up. You might be on the edge. Can I nudge you toward the microphone? There we go. Thank you.

Nigel Barrella,
Law Office of Nigel
Barrella

Hi, I'm Nigel Barrella. I'm an attorney. I'm speaking on my behalf here. On the question of labeling and kind of a statement of identity for these products, I don't think at this stage we should be prescribing a standard or prescribed nomenclature. I think putting a bunch of people in a room and asking them whether, they're linguists, or scientists, or marketers, asking them to kind of come up with a new word that people are actually going to use is pretty much impossible. Whatever these products end up being called, I am sure it is probably going to be something that no one has thought of in this room, no one suggested at this meeting. As a starting point, I would look at the kind of appropriately descriptive term, branch of common or unusual

names, for these products. Describe perhaps, different companies will describe differently what the product is as long as consumers are aware of the basic nature of these products that should be fine as a starting point. Then as consumers become familiar with them and perhaps adopt their own term, or perhaps like the Oreo, a certain branded term will kind of take over the entire category as kind of a shorthand for these products, like, Xerox or Kleenex, or in some quarters even Coke is kind of shorthand for any soft drink. That could very well happen here. Long story short, I think that developing standard prematurely for what to call the products is not the way agency should go. That is my comment on the labeling issue. I have formal comments that I'll give later. Thank you.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you very much. I think this is a point where we say that no specific mention of a particular brand constitutes an endorsement by the FDA or the USDA. If you are sitting there thinking that, “You know, I have a perspective that's a little different from any of those that have been expressed to-date,” you might seriously consider coming up and offering that perspective. It's important that we hear from a broad range of viewpoints, and we have the time. Or, if you're thinking that you might want to get out a little early and give your formal comments this morning instead of this afternoon, that would be fine as well. Great, we have a taker.

Eric Sumption,
South Dakota Farmers
Union

Eric Sumption from South Dakota Farmers Union. Cattle producer. Just one quick comment. Our industry's taken a lot of heat over hormones, antibiotics, things like that. It comes down to an educational issue with me. Nobody is ever educating me how this process works and what it involves. We talk about consumers. Consumers are very important. If we don't educate them so they understand this product. No matter what we label it, are they really going to interpret what it is. Me as a cattle producer, we've worked a long time to build trust between consumers, that's why I urge these companies or individuals that are doing this technology to maybe step back and educate us so we understand it. It might help us be more accepting to what you want to accomplish. Thank you.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you very much.

Rocky Forman,
South Dakota Farmers
Union

My name is Rocky Forman from South Dakota. I believe that the definition of meat should be restricted to the tissue of animals that are born, raised, and

harvested in the traditional manner. I bring two perspectives to the conversation. The first is that as someone who grew up on a ranch in South Dakota and who has worked with family farmers and ranchers throughout my adult career, I've seen firsthand the time and sacrifices producers make to raisesafe, high-quality meat for their families andconsumers around the world. With each with each successive generation, these ranching families have worked to improve the stainability of their operations and the quality and safety of their products. I also bring a unique consumer perspective. As a father, I became increasingly aware of food labeling when my four-year-old daughter, Mellie was diagnosed with celiac disease. If became clear to me how important clear straightforward and honest food labels are for the health of health and safety. Why proteins produced using animal cell culture technology does not pose the same immediate threat to Mellie's health, there are still many questions about the safety and nutrition of these products. I am confident in the quality safety nutritional value in meat products that derive from the tissue of animals born, raised, and harvested in a traditional manner. I do not have the same confidence in cell culture products and have a right to know the difference when purchasing a product labeled as meat. By law, FDA and the FSIS have a responsibility to implement this standard; the Federal Meat Inspection Act requires FSIS to deem a meat or meat food misbranded if it, if it's labeling is false or misleading in any particular. The Federal Food Drug and Cosmetic Act requires FDA to deem of food misbranded if it is an imitation of another food and is not clearly labeled as such. Family farmers and ranchers take great pride in providing a sustainable, safe, nutritious food supply. With this and any food label, they want to be able to take credit for their hard work. At this time, consumers want to know they are purchasing an authentic, safe, and nutritious product. The bottom line is, consumers want to know, and producers want to tell them. Thank you.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you, and was that your formal comment? Great, thank you very much.

Sarah Sorcher, CSPI

Hi, this is Sarah Sorcher from CSPI. I had talked enough yesterday. I was not planning to give comments today but, the discussion over standards of identity has been interesting for me and I wanted to comment on that. First of all, I say CSPI does think that there should be clarity around so that consumers will know whether or not they're eating cell cultured meat or traditional meat, because some consumers will be seeking this product out and others really would want to avoid it and they should be able to make that choice. We had always thought of this as something that could be done under the general authority over misleading labeling by either FDA or USDA, but it is interesting to think about applying standards of identity to this. Traditionally, these standards were developed to prevent food fraud, right. It was about making sure someone could not call something butter when it was actually margarine. In here, you want the rule to accomplish both things. You want it to make sure that people who want to avoid this product can avoid it, but also people who are seeking out can seek it out. I don't what that standard would look like. Would you have a minimum threshold for the percent of the product that had to have cell-cultured meat in it? Or,

would you have a maximum and say that it had to be called cell-based meat if it had any of this product in it? I think in a way, this is a clunky tool for addressing the problem. Also, what would you do about existing standards? Could you call it beef stew if it was cell-based beef stew? I think maybe USDA needs to look, or FDA if it ends up being FDA, it needs to look beyond the standards and develop something that's more comprehensive to address these issues.

Malcom Buitoni,
FDA Moderator
Associate Commissioner
for Planning

Thank you very much. Again, if there's anyone who has not recognized their point of view being expressed, we're quite happy to entertain additional comments here in this open public forum. Or, if you would like to share your formal comments early, we're happy to accommodate that as well. Not seeing much energy here. Like I say, we are a little bit short on brunch opportunities here. We may make a little change in the program and move the first afternoon set of presentations up to here. Unless hearing that inspires someone to come forward with their comments; otherwise, we are going to continue the session here, but we will have some additional presentations that were originally scheduled for after lunch. Okay, thank you very much.

Selena Kremer,
USDA FSIS Moderator

Thank You, Malcolm, and thank you to all our commenters. Certainly, this time is for you and so we do not want to take any of that time away, so I just want everyone to be aware that there are additional opportunities to comment later this afternoon. However, let us go ahead and move with a, move ahead with the program. I'm going to ask Jeff Canavan and Dr. Douglas Balentine to come back up and we're going to move on to the presentations on the regulatory frameworks for food labeling claims. Jeff Canavan is the Deputy Director for Labeling and Program Delivery Staff in the Office of Policy and Program Development at FSIS. Dr. Balentine, he is the Director of the Office of Nutrition and Food Labeling at CFSAN. We'll go ahead and get started with Jeff's presentation first.

Jeff Canavan,
FSIS OPPD

Thank you. One of the objectives today that I wanted to highlight is some of the differences between claims, whether to their regulatory or maybe the subject of a policy, and then provide some examples of areas where FSIS has developed some regulations, and some policies, for the use of various claims. Some claims are defined in FSIS regulations, and the big one that I think of right off the bat are nutrition-related. We have a number of nutrient content claims defined in our regulations relating to the good source of nutrients, good source of protein, high-fiber, more claims, light, low-fat, low-cholesterol; these all have very specific regulatory requirements that were established through public notice, comment, and rulemaking. There are also claims that are not defined in regulations, and that does not automatically mean that they cannot be used. It just means that they cannot be misleading. Again, I think you have heard this a number of times today that

all information, especially claims on labeling, needs to be truthful not misleading. In addition, there are specific regulations that address that. There is the opportunity, Matthew provided an overview of the petitions process; interested parties can petition the agency to make regulatory changes which can include the development of new claims regarding not only nutrition, but anything related to the meat and poultry. I've mentioned that FSIS, in the absence of a regulation, may publish labeling guidelines, which we have done in the past, and I'll go over a few specifically as examples. However, it is important to note that the agencies really work closely together. You will see in the development of certain guidelines, we work closely with FDA; we work closely with Agriculture Marketing Service on animal production raising claims and the Center for Nutrition Policy and Promotion. We don't develop these guidelines or policies in a vacuum. We're certainly collaborating with other organizations, government agencies. Again, I want to emphasize the consistency with food labeling policies and regulations across all food categories is a very important consideration for the agency. Here is an example of a policy guide that we developed. We were presented with some labels through a prior label approval system that wanted to make statements about the amount of omega-3 fatty acids in a product. This is not a nutrient that is in the nutrition facts panel, that omega-3s are not specifically called out. We developed a guideline that explained if the omega-3 fatty acids occurring in the meat were increased through the feed the animal was given, you could make a statement. We would need data that would be submitted with that label application that supports a specific level that you're declaring. We also felt that it was important if the omega-3s are being introduced in a different manner, say through a particular ingredient, that it was important that the consumer know where the source of the omega-3s are coming from. That would be a different type of claims such as x milligrams, omega-3, and fatty acids from the fish oil and the breading. Here's an example of a beef patty product that had a claim, and similarly we had a guidance document relating to whole grains. We were presented with some labels where a company wanted to make, or highlight the fact, that the breading in the product had a certain amount of whole grains. Through the policy development looking at potential claims, we felt that it could potentially be false and misleading if there was not a significant amount of whole grains in the product; the consumer would could potentially be misled into thinking it was a there significant amount of that product. We worked with FDA and CNPP, and in our guideline, we established that to make a statement of this type it should have a significant amount that should be at least eight grams per serving. Here is an example of a chicken nugget product making such a claim about 10 grams of whole wheat per serving. With these compliance policy guides the agencies typically will put the guidelines out for 60 days for public comment, so they'll go out on a draft form and then ultimately be published in a final form. Moving onto other types of claims that are not defined in our regulations, there's those called negative claims. It might sound kind of not right. How can you make a claim that's negative? However, they are negative in the sense that you are highlighting the absence of a particular substance, ingredient or class of substance, as if no preservatives would be a class or no MSG or no soy. Through a prior label approval system, we are seeing a significant number of those types of claims on meat and poultry products. Next slide, please. We have also approved statements relating to non-genetically engineered claims. It’s another example of a compliance guideline we've published. It’s currently in the draft form; we’re evaluating the comments. However, it establishes the criteria for which FSIS will approve labels for claims of this type. They are required to be under a third-party certification program, and so the claim would consist of the absence of genetically engineered feed and an animal's diet or the absence of

genetically engineered ingredients in a product. The claim would also be expected to identify the certifying entity, as well as provide a website so the consumers could obtain additional information on the specific standards that are being applied under the third-party certification program. Here is an example. A label has multiple claims raised without antibiotics and added hormones, but it also has an example of a claim about the no GMO feed ingredients, and in this case is using the USDA Organic Program as the third-party certifying entity. We also have approved statements about the presence of genetically engineered ingredients can be specific to a particular ingredient or more general in cases where one or more genetically engineered ingredients may be used. It may also describe the purpose of use. Another good, very recent example is animal raising claims. We've seen a growth in this area and claims over the last 25 years, recently published a guideline that described the types of information that would need to be submitted with the label application to support a particular claim, such as a breed claims, such as Angus raised without antibiotics, grass fed or also under an AMS process verification program. For most animal production claims, the required documentation, I think it is important to emphasize as we talk about the types of documentation that FSIS' jurisdiction starts at the slaughterhouse. These claims are encompassing a number of raising practices that have occurred outside of our jurisdiction on the farms. This is why we needed additional information such as detailed written protocol explaining the controls in place for assuring the production from birth to harvest, and we will have some examples here in minute, signed affidavits declaring the specifics of the animal production claim, how they were, for example, raised without antibiotics, and also tracing the segregation mechanism. If you are making a "raised without antibiotics" claim and you have to treat the animal and event of illness, how are you going to segregate those animals from the from the herds to maintain the validity of the labeling claim of for the rest of the animals once they're slaughtered? A protocol for the identification controls segregation and non-conforming animals, that I was just talking about. Feed formulations in the case of feed claims, and certainly a third-party certifying verification claims, we are going to need to see a copy of the certificate. On this compliance policy guideline, we received a lot of feedback from industry requesting clarification on the types of documentation. It was published in 2016, and we are currently going through those comments to publish that in final. One of the years that I really wanted to discuss today is the new labeling focus on claims or evocation. If we rewind to 2010 where we conducted rule base require nutrition labeling on ground single ingredient products and ground or chopped meat, in that final rule it talked about how FSIS was going to collect samples of raw ground beef for nutrient analysis in order to verify compliance with what's being declared on the label. The project goal for FSIS was to do this surveillance sampling to get an idea if are the products we are sampling are in compliance, and determine whether the information is accurate or whether further testing is going to be needed. One of the criteria for this sampling with our labs is that there had to be consumer ready packaging, so they could do the analysis and then also compare to what is on the product label of how the product is would being marketed in commerce. Again, this is based on there was there was ongoing concern about whether the claims being presented. Make sure we have a prior label approval process, but also it helps to have this post-market surveillance activities to determine if these claims are truthful, not misleading, or in the case of nutrition labeling of what's being stated on the label accurately represents the product. In 2018, we also expanded the raw ground, we started sampling, and we expanded the raw ground beef sampling, doubling the number of sample samples analyzed in the laboratory. As I mentioned earlier, we have seen a growth of the use of certain claims through a prior

label approval systems, such as no soy, negative claims, such as no or raised without antibiotics. In 2018, we also expanded as part of this laboratory surveillance sampling program to look at raw ground beef products with negative no hormone claims, raw chicken parts with negative no antibiotics claim, and ready to eat products with negative and no soy claims. We'd be looking at doing continue with our nutritional analysis but then also looking at other types of claims on these products as well. Again, this was to verify, used as a surveillance mechanism to verify industry's compliance with, with information on the labeling being truthful not misleading, and also to determine whether the claims were also truthful and not misleading. Thank you. [Clapping]

Douglas Balentine,
FDA CFSAN

Good. I think I stand between you guys and lunch, so I will do my best to talk about claims. I think you'll see, there's a lot of commonality between how FDA views claims and FSIS has reviewed some sorts of claims, but there are differences in that FDA doesn't regulate meat, so we don't deal with organic and we don't deal with hormone free and that sort of thing. But we have a whole variety of other claims, including health claims, that that we have to deal with, so I'll spend a little bit of time going over claims from the FDA perspective. The basis of most of the current claims are, were established in in 1990 when the Nutrition Labeling and Education Act was revised. That gave us authority over what we call nutrient content claims and health claims, informal health claims, and , I'll come to it in, then because of court litigations, we've also then developed the alternative of what are now called qualified health claims, and I'll discuss each of those. There are other truthful and not misleading claims that we look at on food labeling; it could be made with sea salt, it could be something like made with real maple syrup, it could be something like vegetables only grown by American farmers, and we would look at each one of those to make sure that in fact it was truthful and not misleading and that a company manufacturing the product could substantiate that that claim was, in fact, backed up by fact in science. I will start with nutrient content claims and these are this have been quite popular on packaged food products. They would be something like low in fat, low in saturated fat, low in sodium, sugar-free, high in oat bran, those sorts of nutrient content claims that are "high in" and "low in." They're based predominately on having a daily value or reference amount that claim would be based on. It also there also could be terms including free, high, and low. Well comparative claims such as more reduced light, or nutrient content claims, the regulated term "healthy" is a nutrient content claim. Alternatively, you could have simple amount of percent claims, which would be factual statements that captured the amount of a particular component. Think when we looked at simple amount of percent claims a little bit like FSIS, we would be looking to make sure that that that the percents were that were declared were meaningful in terms of the nutritional and public health context. These are just all of the regulations that provide the detailed regulations that describe these various claims, and I will not go through them. However, you can see them in the 21 CFR. There's an additional claim that was established in NALA which will call FDAMA notifications and that was a basis that said in some circumstances when an authoritative body like a Dietary Guidelines Committee, or a DOI panel makes a certain statement, that there is considered to be scientific consensus around those particular statements. Rather than petitioning FDA for the use of those particular claims, we can be informed that based on that authoritative statement that

a particular claim, health claim, or nutrient content claim, could be justified because there already is general scientific agreement around that particular claim. One comment, and Jeff [Canavan] alluded to it in labeling this morning, is that some products do not require nutritional labeling, but when you begin to make a health claim or a content claim, nutrition labeling is then required to go along with it. One of the requirements of doing nutrition-based claims is nutrition facts information must then be provided with it. The general requirements of nutrient content claims, they're generally based on nutrient levels. They're generally based on what we call racks or serving sizes from an FDA perspective, or reasonable amounts customarily consumed. That's the typical amount that consumers use and that will be the serving size information that is on nutrition packages today. One of the policy discussions that we've been recently discussing with FSIS is that with dual column labeling what would be the basis of those nutrient content claims on packages and whether it would be on the larger serving size or the traditional rack. I think we believe it should stay with the traditional rack of those particular products. When there's a nutrient content claim, let's say a good or excellent source of vitamin D, vitamin C, iron, or protein, for example, if that particular product contains excessive amounts of sodium, added sugars, or saturated fat, for example, you'll see a disclosure statement that refers the consumer to the nutrition facts panel to make sure that they don't think that a product just because it has a nutrient content claim on it is, is also healthy in all aspects, and to make sure that they're referred to the nutrition facts where they can refer to the content of saturated fat or sodium. For example, in order to make sure that consumer has full information about how fit those products into their diets. Nutrient content claim “healthy” has been quite popular on food labels. The original nutrient content claim describing “healthy” was put into regulation in 1994. It was based on the nutrient content of foods, of providing a meaningful amount of some of the key nutrients in shortfall but not an excessive amount of sodium, cholesterol, saturated fat or total fat, for example. As you are aware, we've been revisiting that definition - we held a public meeting last year to get, get input around redefining the definition of “healthy.” We also received a citizen's petition that asked us to consider a definition. We're currently working on, on how we might modernize that that definition. This just provides some of the background about the comments we got in the public docket. I think it shows that the value of public comment. I think it shows clearly the value of public comments, one of the things that came out of the public comment is a desire for somehow that we take food groups into account and not just nutrients as we consider a modernized or updated definition of “healthy,” and we're looking at how that may or may not be able to be accomplished within the regulatory framework. However, I think those types of comments are quite helpful to us as a regulatory agency as we strive to do that. The other aspect we're looking at is how could we better make sure that modern definition of “healthy” is aligned and consistent with Dietary Guidelines and USDA does a lot of work in terms of education on Dietary Guidelines. It's another place where we collaborate with USDA and in terms of how can we best make sure that our labeling requirements are also helpful in fostering the goal of getting Americans to build diet patterns that are consistent with our guidelines. Another group of claims that come out of NALA that we as an agency spend a lot of time reviewing because we have statutory authority to approve are what are called formal health claims. These are relationships between a substance in a fluid or a food and reduce risk of a disease relationship. That may be in the general population or it could be in a sub population. These are risk reduction claims and they're not claims that I'll talk about the ability of any substance to reduce the risk of a disease, but not to treat, prevent, cure or mitigate an illness; those are drug territory not food territories. Like I said, FDA must review and authorize the

use of both significant scientific agreement claims and qualified health claims. The general requirements for these health claims, and the petitions that would ask us to consider health claims, are in 21 CFR and it's under 101.14 for those that want to and we generally spend quite a bit of time consulting with firms - submit health claim petitions to make sure that the petitions are robust and based on the best science possible. As I said, there are three types of health claims that, that can appear on food packages. The strongest ones are significant scientific agreement claims. These are claims where we believe that the science is the strongest that really is robust, in that there is general agreement among scientific experts that the relationship between the substance and the disease is supported by strong science. In some cases rather, as I said, rather than us reviewing the claim, if there is an authoritative statement about a similar relationship, it is called FDAMA, that is another path to having those claims authorized. There are some claims that have been authorized through FDAMA, but they are not common now. Then, we have what are known as qualified health claims and that is response to First Amendment considerations in the United States and that the view that we can't prevent expression of claims that are substantiated by some science, but that we issue enforcement discretion around that. Those claims and we make sure that we provide appropriate qualification as to the strength of the science that might support that relationship when it does not meet a significant scientific agreement level of scientific evidence. All health claims that appear, have to have some basic facts they have to have a substance that the claim is based on that might be a nutrient, it might be a food, but that there clearly is a substance. It must be a disease or health-related condition and the discussion of the relationship between those particular things. For example, we have claims on the relationship between oat bran and reduced risk of cardiovascular disease based on cholesterol reduction. It's an example of a type of health claim. A labeled health message that could be health messages. For example, dietary guidance statements, or other messages on packages that might be related to health that would be a truthful and not misleading claim on packages but those sorts of messages cannot relate between a diet and disease relationships. For example, talking about the importance of whole grains in healthy diet patterns would be a health-type message but it would not be a health claim. As with nutrient content claims, there are disqualifying levels for a variety of nutrients, where if you exceed those you are not able to make a health claim, and that's the amount of saturated fat, cholesterol, sodium, and total fat, are all factors that we take into account and because of the relationship between those dietary components and increased risks to public health. We put those the regulation does allow us to, to give exceptions to some of those claims. For example, we have a claim on the relationship between eating certain nuts or olive oil and reduce risk of cardiovascular disease, and those particular nuts and seeds or oils do contain meaningful amounts of saturated fat. Because saturated fat is naturally occurring in those foods, we give an exclusion to the saturated fat content of those and they can still be authorized to use the claim, and those are examples of that. I've already talked about significant scientific agreement claims. I won't go over all of them, but currently there are 12 significant scientific agreement claims that we've, we've authorized for use in foods. An example of another one is, "Diets low in saturated fat and cholesterol may reduce the risk of heart disease," that's another example of a significant scientific agreement claim. Another one is, "Low fat diets rich in fiber containing grain products, fruits, and vegetables may reduce the risk of some types of cancer." However, it gets a little bit qualified because we say a disease is associated with many factors. That's another example of a type of significant scientific agreement claim. Again, disqualifying nutrients apply. I have already talked about FDAMA claims in saying that they are based on

authoritative statement. An example of one of those is, “Diets containing foods that are a good source of potassium and low in sodium may reduce the risk of high blood pressure and stroke.” That is an example of one of the authorized claims that came from FDAMA. Then I'll come to qualified health claims. In addition, these are the more typical claims that we as an agency are authorizing the enforcement discretion rather than significant scientific agreement claims simply because the level of evidence for a significant scientific agreement is a very high threshold. Qualified health claims must be supported by scientific evidence, but they're below significant scientific agreement. We authorize them through enforcement discretion letters where we specify specific claim language, and we also qualify the level of scientific support for the relationship of the claim. An example of one would be, “Supportive but not conclusive evidence, or research shows that eating 1.5 ounces per day of walnuts, as part of a diet low in saturated fat and low in cholesterol not resulting an increase in caloric intake, may reduce the risk of coronary heart disease,” and then we say, “See nutrition information for fat and calorie content.” It is quite a mouthful, but, but those are the types of claims that we will consider authorizing under qualified health claim requirements. Other claims and statements can be put on packages, so long as they are truthful and not misleading. I think we heard some comments this morning about production methods. You see claims on packages now that talk about not made with bioengineered foods, so you see some of those particular claims that are used on packages. We have claims around gluten-free, grown on a family-owned farm, for example. There are varieties of those sorts of claims that can be put on packages that marketers can do on a voluntary basis and we judge them based on whether they are truthful and not misleading. For food, for further information, we have a food-labeling guide that that really provides a lot more information about claims, so thank you. [Clapping]

Selena Kremer,
USDA FSIS Moderator

Thank you so much. That does conclude our presentation portion for today, but we will have an opportunity this afternoon to hear from you again as you can make open public comment and we will round out the day with a formal public comment session. Right now, I think we're going to break for lunch. Let's meet back here at 12:30 and we'll begin the next open public comment session. As a reminder, the USDA cafeteria is in a Wing 3 and they do have quite a lunch selection there so please enjoy yourselves. Thank you.