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PUBLIC HEARING ON “CONVENTIONAL FOODS  
BEING MARKETED AS FUNCTIONAL FOODS”

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FOOD AND DRUG ADMINISTRATION  
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION  
HARVEY W. WILEY AUDITORIUM  
COLLEGE PARK, MARYLAND

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MR. LANDA: Well it's almost 9 on the dot. Why don't we get started. My name is Michael Landa. I'm the Deputy Director for  
5 Regulatory Affairs here at CFSAN. Let me welcome you to the Wiley Auditorium in the Wiley Building at CFSAN. While I'm on the name Wiley, let me encourage you to take a look at the historical exhibit that we have outside the auditorium, the corridor leading to it, which starts of course with Harvey Wiley as one of the, as sort of the founder of FDA.

10 Let me ask first if there's anyone in the audience who needs a sign language interpreter. No one signed up indicating that there was a need, but if there is, we have someone here who can help out. If you would signal by raising your hand, please.

15 For those just entering, there's plenty of room down towards the front. It's often a problem getting people to come all the way down to the front but we always try and today it looks like we may succeed because the back seats are taken.

20 Our subject today is conventional foods being marketed as "functional foods." And this is what's called a Part 15 hearing. It is not formal in nature. There's no direct testimony. There's no cross. The rules of evidence don't apply. We will have questions by an FDA panel which I will introduce later. The questions will be asked only by the FDA panel. The informality of the proceedings as opposed to a judicial proceeding is illustrated by our timer.

(Laughter)

5 There is actually a clock on the podium so the speakers will be able to see how much time they have left and one of us, probably, it will probably fall to me on the panel will signal when there's just a few minutes left.

The agenda for today's hearing is in your folders. I should add to that that there is no, quote, unquote, hidden agenda for this meeting.

10 Shortly after the Federal Register notice published, a number of us began to get inquiries from the private bar, from trade associations, from private advocacy groups, from consumer groups about what we were sort of up to. There really isn't anything we're up to here.

15 Given the interest in “functional foods” as evidenced by reports from GAO, citizen petitions from CSPI, a report from IFT, some work that ILSI has done and obviously interest reflected in the marketplace, we thought it would be useful both to share our view of the regulatory scheme as it applies to these foods and to hear from any and all interested persons about their, their views on “functional foods,” how we should regulate them under the statute.

20 There is, of course, no definition in the statute. There's no definition in FDA regs of “functional foods.” There's no guidance on the subject. Perhaps out of what we learn today and in the comments to the docket we will be prompted to work up a definition.

With that, let me just get to some housekeeping details.

Restrooms, the top of the stairs, if you go left and left out into the corridor, about 40 or 50 paces down on your right. Lunch, there are I guess two alternatives, one is the Wiley Café, which is in the front of this building, they'll have boxed lunches today. I think sandwiches and salads. They have some hot foods, but there's, they will have trouble serving all of you, I think. There is in your packet a list of restaurants nearby. They are about, at least some of them, are about a mile away. Walking distance, I suppose, but it's a cold day for that. Food and beverages, we'll have a couple of breaks, one in the morning, one in the afternoon, but we do ask that you not bring any food or beverages into the auditorium.

We will have two FDA speakers to present an overview of the statutory scheme as we see it. Obviously, some of you may disagree with that and we'll look forward to hearing from you. We will then have invited speakers, two invited speakers, one from CSPI and one from IFT. The panel will be asking questions of those speakers. That will conclude this morning's presentations.

This afternoon will be devoted to comments from the public. A list of folks have signed up to speak. The panel, again, will be asking questions of those speakers and that will, we will then conclude we think around 4 or 4:30 today.

All the presentations will be put in the docket. We'll be accepting comments on the docket through January 5, 2007. A transcript

of today's hearing should be available in two or three weeks. You'll be able to access the docket via the Internet site sometime in early 2007, not before then.

5 So, you will not be able to look at comments in the next few weeks that are submitted before the, well before the end of the close of the comment period.

10 Let me introduce now the FDA panel members. Starting with Louisa Nickerson who is Associate Chief Counsel for Foods, Office of General Counsel for the Food and Drug Division on my immediate right. Next to Louisa is Dr. Barbara Schneeman, who is Director of the Office of Nutritional Products, Labeling and Dietary Supplements in CFSAN. Next to Dr. Schneeman is Kathy Ellwood.

15 DR. TARANTINO: No, I'm really not.

MR. LANDA: No, what's wrong with my script. It is Dr. Laura Tarantino who is head of the Office of Food Additive Safety in CFSAN.

Next to Laura is Dr. Donna Robie who is a Science --

20 DR. ELLWOOD: No.

MR. LANDA: It is Dr. Kathy Ellwood, also from ONPLDS.

Next to Kathy is Dr. Donna Robie who is also from ONPLDS.

Got that one right.

And then Paulette Gaynor who is with the Office of Food Additive Safety. And then the last panel member Dr. Ritu Nalubola.

5 Our first speaker will be, FDA speaker, that is, will be Dr. Laura Tarantino who is currently head of the -- Director of the Office of Food Additive Safety in CFSAN. That's the office that's responsible for managing the safety evaluation of substances added to food, substances including food and color additives, substances that are generally  
10 recognized as safe, GRAS substances, and also new plant varieties developed using recombinant DNA method.

Dr. Tarantino joined FDA in 1987. At the Agency she has been involved in the development and implementation of regulatory policies pertaining to food and color additives and GRAS ingredients, food  
15 irradiation and new food varieties developed using the methods in modern biotechnology.

Before she joined CFSAN, she was on the faculty at Columbia University College of Physicians and Surgeons and at Eastern Medical, Eastern Virginia Medical School in Norfolk, Virginia. She received her  
20 Ph.D. in Biochemistry from Cornell.

Laura.

DR. TARANTINO: Thank you, Mike. Let me get the microphone down to my area and decide what I need to press to get my presentation up.

5 Okay. Well, thank you. As Mike said, we're here really to hear from you and to collect data and information concerning the regulatory regime that we use for the regulation of what are known as “functional foods.”

10 And I for one am very much looking forward to engaging in the discussion this afternoon and seeing the comments that are sent in to the docket after this meeting.

But first, it falls to me to describe as discussed the statutory and regulatory regime that we currently use in terms of evaluating the safety of ingredients added to food. This is going to be very familiar territory for many of you in this room.

15 So, I'm going to try to give kind of a 30,000 foot overview, but to highlight a few particular issues that I think are particularly relevant to the discussion this afternoon, as well as relate what we're talking about to the questions that we asked in the notice announcing this meeting.

20 As noted, I guess, what we're talking about is the regulation of ingredients intentionally added to conventional foods and as Mike said, there are no definitions of “functional foods” or “novel foods,” novel ingredients. There's also not a definition, per se, of conventional foods, except there's an allusion to what conventional foods are not.

Conventional foods are not foods that are dietary supplements. So what we really want to talk about today are the ingredients added to conventional foods.

5 Now society I guess and I think it's very reasonable through its laws have decided that the regulatory regimes and the safety standards for different what I'll call segments of the food supply are different. That is the standard of safety that apply to foods, itself, versus unavoidable contaminants versus dietary ingredients versus, in this case, substances intentionally added to foods, which is what we're, we are, what really is the issue in terms of both conventional foods, "functional foods," all of which are regulated under the same paradigm.

10 Mike already mentioned that there are no statutory or regulatory definitions of "novel foods" or "functional foods." They are regulated under the regime that covers ingredients added to food in general. And sort of the short form of the rest of the talk is in the second bullet, that is, if the intended use is in food, an ingredient must be an approved food additive unless it is GRAS for that intended use or falls under one of the other exemptions from the food additive definition.

15 Mike mentioned the photographic exhibit out in the hall. This is the centennial of the 1906 Pure Food and Drug Act. The Act that we operate under today is the 1938 Federal Food, Drug and Cosmetic Act.

If you walk down the hall, and I very much recommend it, about halfway down there are some photographs and issues that have to deal

with the passage in 1958 of the Food Additives Amendment which I think was passed in part because in the '50s and in the middle of the Century there was more and more processed food, more food prepared outside the home, more use of texturizers and anti-oxidants and classical food additives. And the Food Additives Amendment did a number of different things and among the things it did was to define food additive, said that if you had a new food additive, this was the first time it said you had to have premarket approval. It laid out a procedure for the way you did that, the formal rulemaking and petition process, it established the standard of safety.

So, this is the short form of the definition of food additive. I suspect most of you are very aware of it, but why I want to put it up here is to talk about it does mean any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food. And it goes on to include, it includes holding, transporting food, it includes sources of radiation used to treat food. Messages, it's extremely broad. Left alone it could cover just about anything. But the framers of the Food Additives Amendment then went ahead and put into effect a number of exclusions from the definition of food additives.

And first there's a whole series of these, they are really authorized by really other laws or other amendments to the Federal Food, Drug and Cosmetic Act. Pesticides would certainly fit the, pesticides that

remain in food would fit the definition of a food additive. Animal drugs that remain in food, dietary ingredients, color additives. Prior sanctioned substances are essentially the, kind of the grandfather clause that before 1958, if you got an authorization from FDA and/or FDA or USDA, this is a prior sanction, prior sanctioned foods are also exempt from the definition of food additive.

And then of course the one that's relevant today and the one we'll be talking about most, substances generally recognized as safe are exempt from the definition of a food additive.

This is also the short form of the definition -- or the GRAS exemption and the language in the Act that says that food additive means any substance, in that broad general definition we just talked about, if such substance is not generally recognized among experts qualified as having been adequately shown to be safe under the conditions of intended use.

And I've, the important issue here and the one I want to bring up right now and we'll come back to GRAS later, but the main point I want to talk about now is this only says -- this says that it is based on the view of experts. What's relevant is what it doesn't say. It doesn't say that it's based on the view of Government experts. It doesn't say that it's based on the view of FDA experts, that is, that it's explicit in the Act that a GRAS determination is not reserved to the Government.

Part of the definition of or the discussion of GRAS in the Act that I left out was the basis for a GRAS determination. This is a simplified

version of what those bases are. Scientific procedures is kind of a term of art in the Act which essentially says scientific studies that are appropriate for looking at the safety of food or if there was a substance that's been used in food before January 1, 1958, it, a substance can be GRAS either based on scientific procedures; that is, appropriate studies, or on use in food prior to that time.

I want to come back to GRAS in a minute and talk a little bit more about it and about some of the, what we do in terms of evaluating the safety of food additives and GRAS, but I want to go back to the Food Additives Amendment when we talked about one of the things it did was establish the standards of safety.

Standard of safety in this case and of course is, has been interpreted and from the legislative history and now in our regulations as reasonable certainty of no harm. This is actually quite a high standard. It's quite a high standard versus, for example, a standard to which is applied to foods themselves and there is then in the Act an affirmative obligation on the part of marketers ensure that any ingredient that is intentionally added to foods meets this standard.

And of course the standard applies absolutely equally to food additives or to GRAS food ingredients. A couple important things and, that are very relevant for today's discussion. The safety standard for foods is safety-based only. There is no explicit balancing of risks or benefits. The notion was that food ingredients should be safe, period. When we

review food ingredients, we consider safety. There is not an explicit consideration of benefits. Food, I think the, in 1958 Congress knew about the GRASE standards, but chose to leave this as a safety standard, that food is consumed by all and should be safe.

5                   And, of course, historically ingredients that we've been involved with, their technical effect has been in the food. People didn't necessarily consume a food for the texturizer or the anti-oxidant that was in the food.

10                   Now as we say in our announcement and discuss with the advent of interest in ingredients in which the effect is a putative health effect on the body, it is important to note that the way the system is set up now is that the review of the ingredient is safety only.

                  On the other hand, there is another regulatory regime in which possible health benefits can be assessed and that's what Barbara will talk about in a few minutes, the label claims and health claims system.

15                   Just to say that obviously the Food Additives Amendment, again, said that you can't market a food additive unless you have a regulation in effect which lays out the specific conditions of use under which it can be safely used. It outlined how you go about getting that regulation, outlined the kinds of information that one should have, what is it, how is it being  
20                   used and safety studies, without being specific of exactly what safety information is needed for a particular case.

                  Food additives, the regulation does lay out the conditions of safe use. Again, with GRAS, I will also say it also is that the use that is

GRAS. A substance can be GRAS for one use and perhaps not GRAS for another, but we'll talk a little bit more about that in a minute.

5 Food additives. GRAS, again, the same safety standard. What is different is that with the food additive, ordinarily at least some of the important data on which safety exists is not generally available. It's held by the person developing the food additive. They send it to the FDA. The FDA reviews it, owns the safety decision, defends it, it's our decision.

10 GRAS, important, the data and information are generally available. They have to be generally available so that those experts that are mentioned in the law can know about them and furthermore, the experts that are mentioned in the law then can also look at it and come to a conclusion that in general the data do support and come to a consensus that the data do support the safety of the ingredient.

15 And again, although manufacturers can self-determine that something is GRAS, obviously at any time that determination can be challenged by the FDA if we disagree.

20 This is just another restatement that the real difference between GRAS and the food additive is the information; what is generally available, is it widely known and is the information about the intended use, which includes things like use levels, which foods, is there consensus among experts that the data that's out there that is generally known actually does support the safety of the ingredient.

This says the same thing, but it's prettier, so I put that up, too, and thank Paulette and her colleagues for making the pretty slides as opposed to my dull ones. And again, it's pretty much the for food additives and GRAS substances, evidence of safety is exactly the same.

5 The standard of safety is exactly the same. With a food additive, there is review and approval by FDA. GRAS substance you have an extra burden to be able to say that the information is widely known and agreed upon.

10 One way that manufacturers and developers often do that is to empanel so-called GRAS panels and at the risk of offending those in the audience who make their living by sitting on GRAS panels, there is not necessary -- it's not the only way to do it, they are not required, but it is one way that developers and manufacturers can get some assurance that their determination, self-determination of GRAS is, indeed, falls under the consensus standard.

15 I'm not going to really talk about this, this is just getting a little bit further into detail of what common use in food and scientific procedures mean. Common use in food, really all I want to say is that it really does have to do with food use before 1958. Use in some other context is medicinal use or in some other context doesn't really get you to  
20 history of use. It has been interpreted in our regulation as meaning substantial history of consumption by a significant number of consumers and ordinarily it's generally available data.

Scientific procedures, pretty much what I mentioned. It talks about studies appropriate to establish the safety of a substance. What is useful to our regulations. Also say it's the same quality and quantity of evidence that is needed to approve the use of a food additive. That often is sort of misunderstood. There is a general notion that somehow GRAS substances are so safe you don't need data. It really has to do with the substance and what is known about it, whether you get an approval as a food additive, whether you come in and make a determination that it's GRAS. The information that's needed really has to do with the substance, the use, the use levels, concern levels and so forth.

So, GRAS doesn't require the involvement of the Government. You can self-determine, but obviously there was a reasonable societal interest in having the Government be involved in GRAS in the sense that manufacturers said, well, what if I guess wrong and it's -- the FDA disagrees with me, maybe it would be useful to have some assurance, but that's unlikely to happen.

And 30 odd years ago we invented a completely voluntary process by which someone could petition us to affirm that, indeed, the substance on which you have self-determined GRAS was, indeed, GRAS.

For the Government to say, for us to say that something is GRAS, it's kind of a big deal because it means that we are saying we are voluntarily giving up the right to say that we can require premarket approval for this substance or presumably others like it and people like

Mike Landa and Louisa Nickerson and General Counsel tend not to like to give up authority all that easily, just in case we need it some other time. So more recently and the process that is used right now is the GRAS notification process which I think many of you are familiar with.

5                   We proposed a rule, again, this is entirely the construct of the FDA since there's no requirement for any of this so that we proposed to say that you're making this determination of GRAS. You can notify us of your view that the use, and again, not the substance, the use of the substance is GRAS and tell us your basis, why do you believe that.

10                   And we can react, if you will, and you can get some reassurance that we are unlikely to challenge your self-determination and on the other hand, we get the ability to have a better idea of what's being put into the food supply.

15                   Although this is still a proposed rule, we said at the time that we proposed it that we would begin to entertain notices under the proposed rule and we're now up to about 225 of those. The inventory, the FDA responses are all to be found on CFSAN's Website.

20                   So, this is probably a repeat of what I've been saying. A GRAS determination and/or notifiers is, a notifier's determination that something is GRAS, it is time dependent because, after all, because what distinguishes GRAS from food additive is information, so something that may not be generally recognized as safe today may be generally recognized as safe five years from now. It's not an FDA approval. It's not

a license and perhaps to repeat again, it is the use of the substance so that other uses may be GRAS but are not necessarily true or so.

And obviously this will depend on things like use levels, technical effect, what foods you're using it in, exposure levels.

5 I went through the list of GRAS notices and pulled some out not completely at random, but not very systematically either, but just to show the range of GRAS notices that are up on the Web right now where the ingredient could conceivably be thought of as a “functional ingredient,” in some cases may be thought of as a “novel ingredient.”

10 Calcium certainly could be thought of as a “functional ingredient,” probably not terribly novel. Phytosterol esters, lutein esters, carrot fiber and salmon oil. Now in both of those cases, for example, fiber certainly can have a technical effect on the food, in fact in this case I guess they were talking about as a texturizer and bulk agent. On the other hand,  
15 it certainly can be thought of as a “functional ingredient.” Salmon oil, oils that have omega-3 fatty acids could certainly have a technical effect as being replacement for other oils as well as being “functional ingredients.” There are many others.

20 This was kind of a selection because as we think about do we want to define “functional foods,” “functional ingredients,” “novel ingredients,” “novel foods,” I'd ask that you think about the range of substances which now are all dealt with under the current regime.

This is kind of just a restatement that safety assessments, we have good, a good deal of guidance and recommendations, but really safety information is largely case by case, depending on exposure level, depending on concern level of the particular compound. And when the 1958 amendments and for probably 30 years after that were passed, many of the ingredients that came before us were really things that were used in small amounts where we had a very sort of classical method of getting to a safety decision, an EDI/ADI safety factor.

Over time that has changed with the different kinds of ingredients. For example, macro ingredients took a different kind of set of information and data and I guess one of the questions we ask in the Federal Register notice is for “functional ingredients,” are there data and information types that would be particularly appropriate for these kinds of ingredients. And if so, what would they be and what's the basis.

So, overall conclusions under the current regime, foods, substances added to food must be in compliance with the Act. The legal and regulatory framework under which we work is 50 years old, but even though it's getting a little long in the tooth, it's remarkably resilient and limber and has allowed us to deal with changes and new types of ingredients and new types of submissions that are sent to us.

But I think one of the challenges is obviously that the interest in the “functional foods” category is increasing and I think the reason we're here is to hear from you as we asked in the Federal Register notice, are

there either regulatory regimes, testing recommendations, definitions that, or guidances that would help people work their way through the current regulatory regime. Are there things that we could and should be doing in this particular area.

5                   So with that, I look very much forward to hearing from everybody and reading the comments and I wish you a fine day, thank you.

MR. LANDA: Thanks, Laura.

10                  Dr. Barbara Schneeman will now talk to us about sort of the other half of this equation which is the claims or statements half of the equation and how ONPLDS evaluates labeling claims or statements.

15                  Dr. Schneeman is head of the Office of Nutritional Products Labeling and Dietary Supplements, as I mentioned earlier. That's an office with a large portfolio. She oversees the development of policy and regulations for dietary supplements, nutrition labeling and food standards, infant formula and medical foods.

20                  Before joining FDA, she served as a member of the faculty and administration at the University of California at Davis. She held a professor appointment in the Departments of Nutrition, Food Science and Technology and Internal Medicine in the School of Medicine. She has served as Assistant Administrator for Nutrition in the Agricultural Research Service in the U.S. Department of Agriculture.

Dr. Schneeman received her BS from the University of California at Davis in Food Science and Technology and her Ph.D. in Nutrition from the University of California Berkeley. Barbara.

5 DR. SCHNEEMAN: I always appreciate it when you say that but don't give the years.

Okay, Donna, what's it called? Oh, there it is, got it.

Great, good morning everyone and thank you very much for coming to this hearing.

10 As you've heard and you will hear many times from us, we, we look forward to the comments, both at the hearing today as well as the comments that will be submitted during, to the docket for our consideration.

15 In terms of the framework for the labeling of food, FDA's authority to regulate food labeling is provided in three laws as amended to cover various labeling provisions, the Federal Food, Drug and Cosmetic Act, the Fair Packaging and Labeling Act, as well as the Public Health Service Act.

20 In my presentation today, in the short time that I have, I'm going to speak just briefly to the provisions in the law for false and misleading labeling. I want to talk about the various types of labeling claims that are used in food labeling, including nutrient content claims, health claims and structure/function claims and then I'll end with just some brief comments

on the fortification policy that FDA has in the Code of Federal Regulations.

5 So, just by way of introducing, again, you'll get sort of a similar slide from each of us. In terms of the use of the term "functional foods," we're certainly aware that in the private sector, these are foods that are developed and marketed as foods for health. I referred to what I think the the IFT definition that refers to these foods as providing a health benefit beyond basic nutrient content, however, in looking at the Act and the Code of Federal Regulations, the term is not recognized or defined as a category of food.

10 And as you've heard from Mr. Landa and from Dr. Tarantino, we do, in fact, regulate these foods under the same framework as other conventional foods and that's one of the areas that we're really interested in hearing comments about. We feel confident that that regulatory framework is appropriate for this category of foods and we're interested in the comments we hear regarding that assumption on our part.

15 So in terms of the provisions regarding false and misleading labeling, this gives the citations to the Act in the Public Health Services Act and it simply states that food is misbranded if its labeling is false or misleading in any particular. Obviously it's easier for us to deal with the issue of false labeling or something is not truthful in the labeling. It is more challenging to determine what is misleading and recent legal

decisions have suggested the Agency does need consumer studies to understand what is, in fact, truly misleading to consumers.

In determining whether the labeling is misleading, FDA and Courts take into account any representation such as by statement, word, design, device or any combination thereof. The way we talk about that in practical terms is if we're asked if a label is misleading, we have to look at the total context of the label, to look at it in terms of how, what is the total representation on the food package.

And then the other aspect of misleading is whether it fails to reveal facts that are material in light of any representations that are in the labeling or with respect to the consequence which results in the use of the article. In other words, does the consumer have the information they need to have about the use of that particular product.

So those are really where the Acts address the issue of false and misleading labeling. Now in terms of the label claims for foods, this slide illustrates the legal background. The Nutrition Labeling and Education Act was enacted in 1990. It amended the Federal Food, Drug and Cosmetics Act and one of the things that it did provide for was health claims that were based on significant scientific agreement in food. Prior to enactment of NLEA, such a claim might simply be considered an unapproved drug claim, but this, in fact, created a safe harbor for these types of statements on food products.

And then in 1994 with the Dietary Supplement Health and Education Act, this then provided for structure/function claims, claims on general well-being, nutrient deficiency claims and dietary supplement labeling and also allowed for the use of health claims if the product met the criteria for the health claims. And we'll talk a little bit more about the conditions for use of these claims.

I know most everyone in this room is familiar with the *Pearson versus Shalala* Court cases in 1999 which did indicate that there is a First Amendment protection of commercial speech and that FDA must permit claims that did not meet the significant scientific agreement specified under NLEA if they were properly qualified to prevent consumers from being misled.

And the way that FDA addressed those Court decisions was through, partially, several steps were taken, but one of the ways was through a task force report in 2003. The Consumer Health Information for Better Nutrition, and this guidance document introduced the use of qualified health claims and the process that the Agency would use for qualified health claims that could be used for both dietary supplements as well as for conventional foods.

Now to go back and look specifically then at the goals of NLEA, which is really the primary legal framework that we work with in terms of claims that are made on foods that relate to nutrition and health, those

goals were primarily four goals, to make nutrition information available to assist consumers in selecting foods that could lead to healthier diets.

The second goal was to eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent and consumers then could rely on the use of those nutrient content claims.

A third goal was to help them maintain healthy dietary practices and protect them from unfounded health claims, so that if a health claim were used on a product, it could be something that consumers could rely on to give them truthful and not misleading information.

And of course a fourth goal was to encourage product innovation through the developing and marketing of nutritionally improved food. And I think in our most recent example with the addition of the *trans* fat labeling to the nutrition facts panel, we've certainly seen a lot of innovation in the marketplace as manufacturers identify ways to lower the *trans* fat content of foods that are in the food supply. So we know that we do make progress in that fourth bullet.

So, the way the goals of the NLEA then are played out by the Agency is on the one hand the nutrition facts label which provides consumers information and gives them a context by which they can make judgments about foods, it has the information, but it also has the percent daily value, so a consumer can determine whether a particular food is high or low in a nutrient and make judgments about that food product and how it might fit into their daily diet regime.

But then the other way the goals of NLEA play out is through the authorization of health claims and nutrient content claims.

Now in terms of the types of claims related to health and nutrition that are used in labeling, I do want to mention two other categories of claims that are used and that are recognized by the Agency. The first are dietary guidance messages that might be included in food labeling. These are messages that refer to a general category of foods in health.

So a general category might be fruits and vegetables is probably the easiest category for most people to understand, that it's not referring to a specific fruit or vegetable product, but to that general category.

These claims are not reviewed by the Agency. It's the manufacturer's responsibility to make certain that any type of dietary guidance statement is, in fact, consistent with, for example, the *Dietary Guidelines for Americans*, a *Dietary Guideline* policy statement.

And these messages cannot convey an implied health claim or in any way meet the definition of a health claim.

And then with dietary supplements, we also saw a greater use of nutrition support statements which could be structure/function claims. We'll talk about the definition of those in a minute. These can also be well-being claims.

Some of these statements are also referred to classical nutrient deficiency. Usually if they make a statement about a nutrient deficiency,

they have to also point out how prevalent that deficiency is in the U.S. population so consumers would have appropriate information to make a judgment about the product.

5                   And again, the Agency doesn't take premarket action for a nutrition support statement. The manufacturer is responsible for substantiating, having the scientific evidence to substantiate those claims and if we saw claims that were false or misleading, we could take action, but generally there's not a premarket action that the Agency needs to take.

10                   Now, in terms of the types, two types of claims shown on this slide, these are the types of claims where some premarket activity is required of the Agency. The nutrient content claims which are, give reference to the nutritional profile of a product and health claims including the qualified health claims that characterize the relationship between a food or a food component and a disease or a health-related condition.

15                   So I'm going to talk a little bit about the structure/function claims, nutrient content claims and health claims just to give a little bit more detail on those types of statements.

20                   So a structure/function claim, these are claims about maintaining health. They, about how an ingredient is intended to affect the structure or function, but they're really about maintaining the health of the body. When they're used on the product, they cannot contain statements about treating, mitigating, curing, diagnosing or preventing disease. The

manufacturer's responsible for the accuracy and the truthfulness, including the substantiation of these claims.

5 A disclaimer is required when a structure/function claim is used on a dietary supplement product and the Agency must be notified 30 days after a product bearing the structure/function claim is first marketed.

And in the petition that we received from CSPI, there was some reference to the structure/function claims, so while we are not really talking about dietary supplements, it's important for you all to understand how these types of claims are managed with dietary supplements.

10 And this just simply states the disclaimer that is used on dietary supplements when a structure/function claim is included, that the statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

15 So, nutrient content claims. Again, these are claims that characterize the nutrient profile of a product. They can be statements that describe the level of a nutrient or a dietary supplement. For example, stating that something is free of a particular nutrient or it's low in a particular nutrient -- whoops -- such as saturated fat, it defines how much of that nutrient can be in the product in order to use that claim.

20 Likewise, it's used for nutrients such as vitamins and minerals where one might point out what is a good or excellent source of that nutrient or an excellent source of that nutrient. They can also be used to compare the level of a nutrient or a dietary supplement to another food, so

whenever terms such as more or reduced are used and that comparison is made, this defines the way that comparison can be made, how much does it need to be reduced in order to use this type of claim.

5 There are also implied nutrient content claims. So, for example, the use of the word healthy implies a nutrient content claim and so that also is defined in regulation of what criteria need to be met.

And then there are also certain types of claims that are specific for dietary supplements.

10 Now the kind of actions that the Agency is involved with for the use of nutrient content claims, these claims require nutritional criteria for making the claims and those criteria are based on the reference daily intakes, or the RDIs, or the daily reference values, the DRVs, and those reference values are established within regulation. So we work to establish those reference values.

15 Many of you are aware that we are in the process of looking at the dietary reference intake reports from the National Academy of Sciences to update the reference values that are used in food labeling. But it also then, we authorize the kind of descriptors that are used, for example, making a statement that a food is an excellent source of vitamin  
20 C means that the product contains at least 20 percent of the RDI for vitamin C in the serving size.

Okay. Shifting to health claims, then. The purpose of health claims is to allow foods to bear certain science-backed claims about

reducing disease risk without their having to be regulated as drugs. So again, it's that notion of creating a safe harbor and it's important to keep in mind that these are about reducing the risk of disease or a health-related condition. They are not about treating, mitigating, curing or preventing disease.

5

The elements of a health claim, there is a substance that the claim is about and that substance then is the specific food or component of food, whether it's in a conventional food or a dietary supplement form, and this is, the substance is related to its nutritive value. And I'll have, I have a slide about nutritive value. Again, these were questions that, these comments relate to questions we've raised in the Federal Register notice.

10

And then the other part, the other element of the health claim is the specific disease or health-related condition, which is defined in the CFR as you see on this slide, and nutrient deficiency diseases are not included in this definition.

15

So in terms of nutritive value, the way it's characterized in the Code of Federal Regulations is that this is a value, it has a value in sustaining human existence by such processes as promoting growth, replacing lost nutrients or providing energy. And if you look at our health claims as well as our qualified health claims, it gives you an example of the types of substances that have been considered by the Agency and so it, it, they were considered and seen as having nutritive value.

20

And so I just put in parentheses here some of the things, the items that have been considered as meeting the definition of the substance for a health claim or a qualified health claim. Calcium, soluble fiber, DHA and EPA, the omega-3 long chain fatty acids, lycopene, sodium, green tea, folic acid. There are a variety of things that have been reviewed by the Agency in terms of being a substance.

And again, just to emphasize that health claims are about reducing risk and so just to look at this diagram, if we think about increasing risk, if disease occurs, that then is treatment, that is not the purview of a health claim. Health claims are simply about the process that would help reduce risk in the population.

So, there are several ways that health claims can be approved by the Agency or allowed by the Agency. For the health claims that are based on significant scientific agreement, these are referred to as the health claims that are authorized under NLEA, the Nutrition Labeling and Education Act. The Agency goes through a rulemaking process to allow for these types of claims.

Some of our most recent actions have, in fact, been amendments to existing health claims. For example, recently we amended the soluble fiber health claim to allow barley as a part of that health claim.

Qualified health claims, in addition to characterizing the relationship between the substance and the disease or the health-related condition, also characterizes the quality and the strength of the scientific

evidence, because these claims are not based on significant scientific agreement and these claims are done through the use of enforcement discretion by the Agency. And the letters that we issue for enforcement discretion are available through our Website.

5                    Now there's a third way that health claims can be allowed in food labeling and these are claims that are based on authoritative statements and the authoritative statements would be a scientific body of the Government or of the National Academy of Sciences.

10                    These claims are done through a notification process. A notification is sent to the Agency. We have 120 days to review that notification. There may be some communication with the notifier about that claim, but once that 120 days has passed, the notifier can use the claim until the Agency takes any further action.

15                    For example, if we felt we needed to object to the claim, it's clearly going to take us longer than 120 days to issue that through rulemaking because that's the nature of the activity we would have to take.

20                    And just to remind you on the qualified health claims that the significant scientific agreement reflects a body of consistent, relevant evidence from well-designed clinical and/or epidemiological studies. Qualified health claims are categorized in various degrees of support and again, you can see not only the qualified, qualified health claims that we have reviewed and use enforcement discretion on, but you can actually

read the letters to see how we reviewed that evidence. And I'm not going to go into that because we don't have the time to cover that here.

5 Just to end, I want to have a few quick comments on the FDA policy on nutrient fortification of foods because many of the issues that have come up in the category referred to as “functional foods” might relate to fortification of different food products and within the CFR there is a policy on nutrient fortification. It's a policy statement. It recognizes the public health importance of achieving and maintaining a desirable level of nutritional quality in the food supply. The policy is intended to prevent  
10 over- or under-fortification, nutrient imbalances, any deceptive or misleading claims for certain foods. It does not encourage indiscriminate addition of nutrients, quite the opposite, and it does identify foods that are not appropriate for fortification, such as fresh produce, meat, poultry, fish products, sugars, snack foods such as candies or carbonated beverages.

15 It does give examples of where fortification might be appropriate such as correcting a dietary insufficiency, restoring nutrients lost in processing and just the last one here, compliance with other regulation such as standards for enriched products. So there's several ways that we recognize that fortification might be appropriate.

20 And then we also outlined several principles for nutrient addition to foods to ensure that they are stable under the customary conditions of storage, distribution and use, that those nutrients are physiologically available from the food. They would not result in excessive intake from

the nutrient considering all other sources of the nutrient and it is, in fact, suitable for the intended purpose and in compliance with other regulations on safety of substances in foods and certain nutrients are, in fact, regulated as food additives.

5                   And also just as a final point, in thinking about fortification of food supply and that whole process, we also are very cognizant of the *Dietary Guidelines for Americans* and as we think about our fortification policy and any adjustments that are needed to that policy, we are cognizant of the recommendations in the *Dietary Guidelines*. The *Dietary*  
10                   *Guidelines for Americans* do serve as the policy document for the Federal Government in the area of nutrition and the *Guidelines* point out that a basic premise of the *Dietary Guidelines* is that nutrient needs should be met primarily through consuming foods and in certain cases fortified foods and dietary supplements may be useful for one or more nutrients that  
15                   otherwise might be consumed in less than recommended amounts, however, supplements, while recommended in some cases, cannot replace a healthful diet and that it's important to keep the principles of the guidelines in mind.

                  So, with that, I will end and turn it back to Mike. Thank you.

20

MR. LANDA: Thanks, Barbara.

We're running a little ahead of schedule so what I want to do is take a break a little earlier but also come back a little earlier than we otherwise would have.

5 But before we do that, let me just make one announcement which is those of you who are registered to speak this afternoon but have not contacted Dr. Donna Robie, would you please do so either during the break or at lunch time, in any case, before this afternoon's session.

Why don't we reconvene at 10:25. Thank you.

(Short recess taken)

10 (Hearing Reconvened at 10:28 a.m.)

MR. LANDA: It's about 10:30. Why don't we get started.

15 Thank you. Three short announcements before we hear from our next speaker. First, there was apparently a lot of food left over from this morning, so those of you who would like to nibble for lunch instead of trying the delights of the Wiley Café or huffing it over to Route 1 are welcome to make the food and beverages, the food and, yeah, beverages from this morning serve as lunch are welcome to do so.

20 Second, we're apparently running a little tight on space. Some people I guess have had to be turned away or we've had trouble finding room for them. So, first, if you have a coat on a chair next to you and it's your coat, please remove it.

Second, for FDA attendees in the auditorium now who did not register, would you at lunchtime please report to the registration desk.

Thank you.

That's right, demerits will be handed out.

5 Our next speaker is Barbara Petersen from IFT who will be speaking about the IFT's Expert Committee Report, "Functional Foods: Opportunities and Challenges" and she'll be speaking on IFT's behalf. She's internationally recognized for her expertise in risk assessment, exposure assessment methodology, food consumption, functional food  
10 evaluations and nutrient profile modeling and applications of Monte Carlo techniques for safety evaluations.

Dr. Petersen has pioneered the technical methods for incorporating information about food composition, dietary practices, actual agricultural practices in commercial food processing technologies  
15 into regulatory and health issues.

Dr. Petersen.

DR. PETERSEN: Good morning. The Institute of Food Technologists commends FDA for holding this public hearing on  
20 functional foods as we do believe that a few changes in regulatory policies could provide some very positive benefits to society.

The functional foods already on the market represent only a small fraction of the potential for these types of foods. But that's not to

say that we believe that all of the foods for which claims are being made today are being properly represented based on science and proper regulatory policies. Some of the claims are not factual and are not based on current science.

5                    In view of current regulatory policies, some of the food labels' claims cannot be factual and do not adequately represent the science.

                  Before I start with our formal presentation, we just wanted to make three corrections to the Federal Register Notice.

10                    The first is that the IFT report focuses on health claims and qualified health claims and the IFT report does not suggest that the GRAE panel, I'll be discussing, functions as a U.S. Government scientific body for the purpose of FDAMA notified health claims.

15                    And finally, we do not address structure/function claims except with respect to the FDA policy on the nutritive value definition for such claims.

                  Today's science and technology really can provide many additional functional foods and future scientific and technological advances promise an even greater range of health benefits for our consumers.

20                    Functional foods can provide health benefits by reducing the risk of chronic disease and by enhancing the ability to manage chronic disease, thus improving the quality of life. It is in these contexts that IFT decided to develop this expert report in an effort to provide a further understanding

of future possibilities and recommendations for resolving some of the obstacles that are currently associated with the development of functional foods.

5 As the Agency has requested, I will present IFT's expert report on functional foods this morning and we really do appreciate the opportunity to share this report with all of you. It was written by a panel of distinguished experts, 18 in total, based on their scientific, medical and legal expertise. Their contributions represent their individual contributions and not the collective wisdom of IFT nor I suspect their own  
10 companies.

For the purposes of this report, and it took us a long time to get there, we defined functional food as foods and food components that provide a health benefit beyond the basic nutrition and specifically for the intended population.

15 To go a little bit further into the definition, that it provide essential nutrients often beyond quantities necessary for normal maintenance, growth and development and/or biologically active components that impart health benefits or desirable physical effects.

20 We recognize that many new scientific disciplines are driving our need for updated policies. Diet is one of the key environmental factors to which our genes are exposed. Nutrients affect gene expression and formation of various proteins at discrete points in the processes of their formation. Discoveries in genetics make it possible to understand the

effects of nutrients in processes at the molecular level and also the variable effects of dietary components on each individual.

5 The expert report recognizes disciplines such as nutrigenomics, proteomics and metabolomics or metabonomics, measuring the potential outcome of changes that are suggested by our genomics and proteomics and that these are tools that are contributing to the rapid change in the development of functional foods.

10 We also spent a great deal of time on bioinformatics, a tool that uses computer databases technology to integrate data from all of these multiple disciplines and will play increasingly an important role in development.

15 Early functional studies have focused on single genes, however, many common diseases are undoubtedly influenced by complex interactions among multiple genes combined with environmental and lifestyle factors. There's a need for researchers to simultaneously study these functional interactions, networks and pathways and we expect that this research will reveal the effects of nutrients on molecular level processes in the body and that we'll be able to document variable effects of nutrients under different conditions.

20 IFT suggests that some changes in FDA's policies will be necessary to facilitate this rapid advance in science. Also in the IFT report are summaries of the current U.S. legal standards for health-related claims and scientific standards for proposing and evaluating such claims.

I'm not going to discuss those, we've already heard quite a bit this morning and there's a great deal in our report.

I think instead I'd like to jump to what we saw as limitations of current policies. The current policies limit addressing the full scope in many cases of benefits and potential developments for functional foods. The existing terminology and regulatory framework, in particular, limits the scope and accuracy of consumer information and is likely to hinder the development and marketing of many functional foods.

I suspect everyone understands the convoluted wording of claims that is sometimes necessary to avoid the drug classification and that that often leads to an inaccurate presentation of the actual effect of the food, or result, or it can result in actual misleading statements of the underlying science.

Current FDA policy requires that health benefits attributed to a food be derived from its nutritive value in order for the food to be exempt from regulation as a drug. This policy we believe unduly restricts the health effects of foods to the limited concept of nutritive value and appears to us to be inconsistent with the Court's interpretation of the FTC Act. The FTC Act defines a drug to exclude food intended to affect the structure or function of the body of man. The Courts have held that this exclusion from the drug definition applies to food broadly and not just to the nutritive components or the nutritive value of the food. Foods are

defined in the statute as articles including their components used for food or drink for man or animals.

In a, in the case *Nutrilab, Inc, versus Schweiker*, the Court concluded that foods are articles used by people in the ordinary way that most people use food, primarily for taste, aroma or nutritive value. The Court stressed that to hold that articles used as food are articles used solely for taste, aroma or nutritive value is unduly restrictive. The Court also noted that some products such as coffee or prune juice are undoubtedly food but may be consumed for reasons other than taste, aroma or nutritive value.

Other Courts have accepted this broad interpretation of food as including articles consumed for reasons other than taste, aroma and so forth by way of the food exemption to the drug definition which precludes its regulation as a drug, notwithstanding a manufacturer's representations as to the physiological effect. The Court reasons that Congress did not want to inhibit the dissemination of useful information about a food's physiological properties by subjecting the food to drug regulation.

Thus, under the Court's interpretation of the statute, truthful and non-misleading claims about the beneficial physiological effect of a food or a food component on the structure or function of the human body need not be limited to foods that derive those benefits from the classical nutritive value.

Therefore, the IFT panel recommends that the FDA policy not require claims about health effects on normal health structure or function of the body to be based on the very limited concept that we use today for nutritive value. Rather, the panel supports basing structure/function health claims on broad-based scientific criteria that address the underlying link between health and nutrition and meet the need for the sound, scientific substantiation supporting the relationship between structure and function.

Just to continue a little bit, with regard to health claims, the FTC Act describes a health claim in terms of the relationship between a particular nutrient and disease or other health-related condition. FDA's policy requires the substance intended to be consumed at other than decreased levels to contribute to the taste, aroma, nutritive value or a technical effect to the food in order to be eligible for a health claim. And for this purpose, nutritive value is defined as value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients or providing energy.

While the Agency has acknowledged that this definition was intended to be flexible, past application of the nutritive value criterion has varied and at times has been very confining.

Therefore, as I said, we recommend that FDA not restrict the health effects of the food to this very limited concept. And in the report we note our understanding of the inner-connections between nutrition and

other scientific disciplines such as physiology, endocrinology, biochemistry and so forth and we note that it's rapidly evolving.

The concept of traditional nutritive value is too narrow to support today's comprehensive and likely advances in future research.

5                   The FTC Act provides that in general express or implied claims that a food can cure, mitigate, treat or prevent any disease are drug claims that make the food subject to regulation as a drug. Traditionally what constitutes an implied drug claim has been interpreted very broadly by FDA.

10                   For example, FDA took the position that a claim that a food lowers cholesterol would be considered a drug claim because it implies treatment of abnormal cholesterol levels, which the Agency considers to be a disease. Therefore, functional foods that affect cholesterol levels can only state that the food maintains normal cholesterol levels, which is a  
15                   permissible structure/function claim.

                  However, such a statement is potentially or in my view misleading if the food, in fact, lowers cholesterol levels. A petition for a health claim was filed linking consumption of phytostanol and phytosterol esters to a reduced risk of heart disease. After a time-consuming and  
20                   costly health claim petition was approved, then the related cholesterol lowering disease claim was allowed on the label of a spread containing these esters.

The IFT expert panel recommends that product labeling be allowed to accurately reflect the scientific evidence as long as claims are scientifically valid. Enormous public health benefits would result from consumers understanding and acting on the claimed product benefit.

5           The expert panel supports scientifically defensible, and it's clear that we are really anxious for that, that we're understood that all claims should be based on the adequate science in the marketplace and therefore we do support the use of qualified health claims.

10           However, consumers may be misled if qualified health claims are not adequately differentiated from approved health claims. To promote consumer understanding, the wording of qualified health claims should clearly indicate the degree of scientific support or certainty associated with a biological effect or modifications of disease risk.

15           And the panel recommends that FDA prohibit claims that are relied on very limited and preliminary studies and that guidelines be developed that will protect consumers from what we would term limited or meaningless scientific data to support a claim.

20           I'd like to turn now a little bit and talk about efficacy. The efficacy determination must include both the presentation and evaluation of the data and the development of the consensus of what the research says for the functional food or its ingredient or perhaps both.

          The IFT panel recommends a process that's parallel to the GRAS process that was described earlier today. We've called it the Generally

Recognized as Efficacious, or GRAE, panel to provide that evidence of consensus. The IFT panel also recommends a GRAE notification process for qualified health claims, and we would put a GRAE panel together in much the same way that is composed of independent scientific experts who are qualified in the appropriate scientific disciplines for the substance being evaluated and that the panel would be expected to use the Hill criteria as criteria for evaluating the research findings and that a GRAE panel report would be prepared and submitted to the FDA. This publicly available GRAE panel report would provide transparency, documentation and evidence for the consensus.

We believe that these recommendations, if implemented, would encourage public confidence in the labeling of functional foods and importantly would conserve Government resources by having a great deal of the work done by an independent panel.

The multi-disciplinary nature of the panel would provide a broad context for data evaluation and it would ensure that the resulting conclusions are scientifically defensible and relevant to consumer practices.

The panel of experts with appropriate scientific expertise would be fully disclosed. The report also provides a critical path forward for developing and marketing functional foods which begin with identification of the new bioactive ingredient and the second or second and third steps defined, depending on how you break them out, are to confirm safety and

efficacy. And once those have been done or perhaps a number of these steps will proceed on parallel tracks, you would identify appropriate food vehicles for the bioactive substance, evaluate the characteristics of the food and importantly determine the intended consumer.

5                   A consensus would always need to be developed regarding the interpretation of both the safety and efficacy through GRAS, GRAE, FDA notification and then the process of properly communicating with consumers so that they understand the benefits and are not misled.

10                   The final step is an ongoing surveillance in market to confirm that the findings of the premarket assessments and assumptions are, in fact, as, as predicted.

15                   In general the safety of functional foods should be based on the long-standing principal that foods are safe. Further, the safety assessment should accept the safety of components already established through the generally recognized as safe determinations and food additive approvals.

20                   That said, an objective, science-based evaluation process must establish that functional foods are safe at the projected use levels under the context of a functional food. The safety assessment must be sufficiently flexible to consider the many factors associated with consumer responses to food and food ingredients, including genetic pre-disposition, age, sex, nutritional status and lifestyle.

The safety assessment would be concluded through current procedures for establishing GRAS status or by obtaining food additive approvals.

5 The IFT panel also recognized the important role for research to disclose that functional foods currently on the market represent such a small fraction of the potential. Intensive research is needed to achieve this potential as well as to ensure both safety and efficacy. The panel identified a number of research areas that are vital to the development of functional foods.

10 Number one, understanding the mechanisms of action, dose response relationships, clinical outcomes and individual response for nutritive and bioactive substances.

Two, identification and development of additional biomarkers and surrogate markers as well as further defining acceptable ones.

15 Three, identification and tailoring food vehicles for delivery of bioactive ingredients.

Four, expansion and use of existing food composition and dietary intake databases to identify the relationships between diet and health.

20 And four, use of nutrigenomics to provide nutrient plans and products based on the interaction of genetics and diets for groups and individuals, kind of a mass customization of the diet.

It also recognized that further research is needed in the area of ethics, regulatory and legal implications of nutrigenomics.

Appropriate incentives would obviously greatly enhance the development of functional foods.

In conclusion, the IFT expert report identifies areas that need changes and further encourages the development of functional foods.

5 Overall, the IFT expert panel recommends the following, expanded research into traditional nutrients, other bioactive food components and the intersection of genetics and molecular nutrition.

Two, expanded research on biomarkers and physiological end points.

10 Three, the use of GRAE panels to evaluate claims and streamline the regulatory process.

Four, allowing structure/function and health claims in products labeling to more accurately reflect the scientific data without triggering drug status.

15 Five, modifying the current definition and application of nutritive value requirements.

Six, allowing health claims based on significant scientific agreement and qualified health claims based on the weight of scientific evidence.

20 Seven, indicating the degree of scientific certainty for approved and qualified health claims.

Eight, developing incentives for companies to invest in functional food research and development. And finally, using health

claims on food labels as a foundation for consumer education regarding dietary components for improved health.

Thank you very much.

(Applause)

5

MR. LANDA: Yes?

DR. PETERSEN: Sure, do you want me to sit there or however you want me to do it?

10

MR. LANDA: Why don't you stay there.

DR. PETERSEN: In answering questions, there are also a number of other members of the committee here, so if I can't answer it, I call on them.

15

MR. LANDA: I want to exercise the prerogative of the chair and ask the first question, which is how does this, the proposal for these panels fit into the current regulatory scheme?

20

For example, setting aside the question of nutritive value, you could have a health claim which a company would take, I suppose, to one of these panels.

DR. PETERSEN: Right.

MR. LANDA: And the panel report would then go to FDA.

What do you contemplate FDA would do with it, given the  
5 current regulatory regime?

DR. PETERSEN: We believe the practice would be very similar  
to the GRAS panel notification to FDA, that you have an opportunity to  
review the report, but it would contain all of the relevant information and  
10 to provide your, your added conclusions to that process.

DR. TARANTINO: Can I follow up?

Then do you think that that could obviate the need for a petition  
which presumably is still required under the Act, unlike GRAS?

DR. PETERSEN: We're not speaking about FDAMA clients  
15 here now, just to make it clear, so we think it would --

DR. TARANTINO: Yeah, health claim petitions also require  
20 FDA involvement.

DR. PETERSEN: Right, but we think that this could go through  
that process the same way, yes.

MS. NICKERSON: So if I understand correctly, you're saying that this would not be a notification process whereby once the GRAE panel had issued its conclusions and a certain period of time had passed, then people would automatically be able to make a claim -- but first FDA would have to make its decision?

DR. PETERSEN: I believe it would work the same way as the GRAS notification works now, is our, our recommendation at least.

MS. NICKERSON: Yeah, I think what some of the earlier questions were trying to get at is that our statute for conventional food health claims requires a petition to FDA and there are certain benchmarks for FDA issuing its decision, so it doesn't provide for a notification process where if the Agency doesn't reply, then that constitutes a decision -- actually, well it does, it says if the Agency doesn't make a decision, then the answer to the petition is no, it's automatically denied, but it doesn't provide for automatically, a claim automatically going into effect.

DR. PETERSEN: Are you distinguishing between health claims and qualified health claims in that discussion?

MS. NICKERSON: No, it's the same process.

DR. PETERSEN: Because I think we are.

MS. NICKERSON: -- for both.

5

DR. PETERSEN: But I think we're trying to separate the two here.

MS. NICKERSON: Yes, but I'm just saying --

10

DR. PETERSEN: Recognizing that the health claim -- well we see those applying to the health claims but not to qualified health claims, making that, making that distinction in what we're doing.

15

DR. ELLWOOD: So you're saying that some company would come to IFT and they would then set up the GRAE panel? I don't see your point.

20

DR. PETERSEN: No, the panel did not envision or at least did not even address who would form the GRAE panel, just as GRAS panels are formed independently. IFT is a scientific organization, we were looking at a process for ensuring that the data --

DR. ELLWOOD: Then who's going to set up the GRAE panel?

DR. PETERSEN: I think that --

5 DR. ELLWOOD: And how would they choose the scientists that  
would compose that?

10 DR. PETERSEN: I think that our vision is that the GRAS  
process has worked quite well with manufacturers identifying the need for  
a GRAS panel and identifying the issues to be evaluated and coming with  
a full panel of experts who are qualified to judge the issue at hand and we  
see a parallel process here but with different experts because we're looking  
at efficacy instead of safety.

15 DR. TARANTINO: And I think because there has been I think  
some confusion about the way the GRAE panels would function, what I  
gather, I think there is one thing to say that a manufacturer who wants to  
use a claim could assemble voluntarily a panel of experts to look at the  
evidence and write a report.

20 I think where we're differing is that unlike the GRAS process,  
which as I said doesn't require FDA involvement, a health claim or  
qualified health claims, then you could anticipate that a report could be  
part of a submission to a petition, but I'm not sure absent a change in the

law that you could have the report, itself -- or could have a system by  
which a claim could be authorized absent an objection from the Agency.

5 DR. PETERSEN: Again, distinguishing between health claims  
and qualified health claims in that process?

DR. ELLWOOD: There's no -- it's the same for both.

10 DR. PETERSEN: Diane, where are you. Diane McColl is one  
of our panel members, she's an attorney with Hyman Phelps.

MS. McCOLL: I provided the overview --

15 DR. PETERSEN: Diane.

UNIDENTIFIED FDA PANELIST: Could you step up to the  
mic so we can get the transcriber to transcribe it.

20 MS. PETERSEN: Do we have another mic?

DR. PETERSEN: I think this is really an important point and so  
I'd like to spend some time on it.

MS. McCOLL: You raise a very good question.

MR. LANDA: Just identify yourself.

5 MS. McCOLL: I'm Diane McColl from Hyman, Phelps and  
McNamara and I served on the IFT expert panel, along with my partner,  
Steve McNamara, as the lawyers on the scientific panel.

10 Done. One thing that the panel did not do was put together in the  
report a legal rationale for how you can do this and that's what you're  
asking.

15 And I think that there are two points to consider and these are  
only to put on the table as options to think about how we might bifurcate  
the qualified health claims from the qualified health claims. And I don't  
have my statement in front of me, but I believe if you look at the language  
in the statute, there are a couple of areas where there might be some, I like  
to call wiggle room.

20 One is that when you look at health claims, it speaks in terms of  
nutrients of the type that are listed in (q)1 and (q)2. Well not all that --  
and FDA when it originally undertook the rulemaking for health claims  
did disagree with the -- or did reject the argument that there are nutrients  
for which there could be health claims that are outside the statutory  
mandate for rulemaking because they'd be nutrients that are of, they may  
not, that are not of the type in (q)(1) and (q)(2).

Well, (q)(1) and (q)(2) of the statute doesn't mean each and every -- only the nutrients that are listed in those provisions. It certainly doesn't mean each and every possible nutrient in the whole human diet. That's one argument that could be made.

5                   Another argument might be the fact that the rulemaking requirement in the statute speaks to health claims. Health claims are claims that meet SSA. Qualified health claims don't meet SSA so, therefore, could you set up a separate system for processing qualified health claims.

10                   Now, without having researched and written a brief, that's about as far as I'm prepared to go at this hearing, but perhaps that might give you something to think about as options for pulling these qualified health claims out of the cumbersome notice and comment rulemaking procedure.

15                   MR. LANDA: Just one follow-up question, would this scheme contemplate FDA approval or authorization in some form of these qualified health claims or are you thinking that FDA would continue to exercise enforcement discretion with respect to such claims?

20                   MS. McCOLL: I think we were looking, thinking more along the lines of a notification system because, let's face it, the GRAS system is adequate or has proven to be adequate for the safety of food ingredients and there isn't a single manufacturer out there who's going to market their

product for use in foods if you get a we have questions, what we call a bad day letter when you submit a GRAS notification.

5 So the practical matter, if you could set up a notification system, the Agency, while not an approval, would certainly have a say in terms of their response letters to whether or not they agree with the description of the state of the research, this is emerging research that was described in the GRAE panel report.

10 But that's, like I said, that's one of several possibilities that could be considered as a way to in this day of limited resources help deal with the and keep pace with the evolving discoveries and the relationships between our foods and foods ingredients and health.

Thank you.

15 MS. NICKERSON: Before you go.

MS. McCOLL: Yes.

20 MS. NICKERSON: I promise not to ask you to go into any more detail, but I do want to ask a clarifying question just to make sure I understand.

You're suggesting that because nutrients that are not of the type required to be on nutrition labeling are not covered by the existing NLEA statutory health claim provisions, that we could set up an extra-statutory

process for those that wouldn't be limited by the health claim provisions;  
is that correct?

MS. McCOLL: I think that's something that's worth considering.

5 One of the things you'll have to look at is the overly broad definition of  
health claim in the regulation and the overly broad definition of disease.

MS. NICKERSON: Okay.

10 MS. McCOLL: Those may have to be modified somewhat to  
accommodate this system, but it's, it's just an option to consider.

MS. NICKERSON: Okay, thank you.

15 DR. PETERSEN: If I could just have one more comment, I  
think in particular one of the things we like about the GRAE panel is that  
it requires the development of a consensus and of a document that fully  
documents, if you will, what the literature says and that it's very public  
and provides essentially a path through the evaluation of the data for, for  
20 FDA's review as well and we think that that's, that's a way to look at  
conserving resources and perhaps let the burden of developing that  
document where it belongs.

DR. ROBIE: I have a question on a little bit of a different topic to change gears a bit. You mentioned briefly the issue of manufacturer incentives. They are on page 50 of the IFT report, though, there's a long list of -- or a list of recommendations that indicate that the panel, you know, discussed this issue at some length.

Can you briefly say a few words about the panel's recommendations in the area of incentives, specifically on the period of exclusive use recommendations?

DR. PETERSEN: Yes, I think the panel looked at this and recognized that you're going to get a lot more research and you're going to get a lot better research if, if when you're through you have an opportunity as the manufacturer to either have a period where you're the only person selling it or you have some, some benefit.

And so we looked at that as a possibility, whether it's a short time period, a longer time period or some other ways and I'm not -- we have some recommendations in the report for people to look at.

I'm sure there are other ways that you might also do that, but, but I think it's important that we think about it and that we be realistic that, you know, you spend money hoping to re-gain it in, in the marketplace and so.

DR. ROBIE: As a follow-up to that, the period of exclusive use recommendation, how does that, the panel reconcile that recommendation regarding the period of exclusive use with First Amendment rights for manufacturers to put information that's truthful and not misleading on their labeling?

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DR. PETERSEN: We recognize that that's an ongoing issue, but

--

(Laughter).

DR. PETERSEN: -- but it's certainly been done in other, in other areas from, from drug-related claims to pesticides to there, there are a variety of places where exclusivity is allowed.

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DR. SCHNEEMAN: Hi, I had a question about the set of recommendations you made about the concept of nutritive value and I wanted to be sure I understood. As you thought about re-defining nutritive value, what are the implications then for what the Agency might have to review in terms of health claims that would be based on a broader concept of nutrient -- nutritive value?

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DR. PETERSEN: Well, this is perhaps more of a personal opinion, but it seems to me we got to the classical list of nutrients in a very narrow context and that pretty much everyone now recognizes that there

are other ingredients out there that don't fall in the definition of a nutrient but are clearly nutrient in the classical, you know, nutrition textbook concept, but that are clearly providing a benefit and I think you don't end up with a lot more to review except that it's not a -- it's not defined as a nutrient.

It's defined as providing another benefit and that benefit is based on data and so hopefully if the data are clearly presented and summarized, you would come away with the same understanding and comfort that you would come away with for a nutrient. It just simply isn't on the master list of nutrients.

DR. SCHNEEMAN: I'm not sure I understood when you were talking about the concept because it, it sounded like you were perhaps indicating that certain things that now fall under structure/function claims should be incorporated into the way we look at health claims.

Is that correct?

DR. PETERSEN: That's probably true, yes. Right. I think if it causes, I think if it causes a physical effect, a physiological effect or whether that's through nutritive value or through perhaps another definition of what it's doing.

MR. LANDA: I just want to return for a minute to the GRAE panel idea.

What kind of public participation, if any, do you contemplate that that process would include?

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DR. PETERSEN: In addition to the individual experts?

MR. LANDA: Yes.

10

DR. PETERSEN: Yes, we certainly want the document that comes from that panel to be publicly available.

Again, I think our notification process would be very parallel to the public process for GRAS that is available now.

15

MR. LANDA: What I'm thinking of here is for our qualified health claims which I gather the GRAE process would address, we have, petitions are posted on the Web and there is an opportunity for the public to comment on them. It's not as rigorous a public participation process as informal rulemaking, but there is still an opportunity for public

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participation.

DR. PETERSEN: I would expect that that seems reasonable also for this.

DR. SCHNEEMAN: If I could just ask one more question.

I, I still am interested in terms of where IFT came out in their deliberation with respect to -- are you talking about policies that apply to all foods or do you perceive that a set of policies need to be developed by something that's going to be defined as a functional food?

Are you making a distinction between those things or how --

DR. PETERSEN: I would guess that every single meeting we had we had that initial disclaimer that all food is functional, but here we are really trying to talk about a functional ingredient that ends up in a food and by being in that food and being consumed, it becomes a functional food. So, we're trying, we're trying to develop a process for evaluating a biological measurable effect.

DR. ELLWOOD : You stated that you're only interested in claims that are weight of the evidence, so not credible?

DR. PETERSEN: No, I don't think that's what I said.

DR. ELLWOOD: Are you distinguishing --

5 DR. PETERSEN: I think what we're trying to do is stay away from the health claims that are clearly defined in a great deal of detail by the statute with the SSA process and putting the other things into a formal procedure for evaluation of efficacy and the development of a consensus that as the product will be sold and used, you will see measurable effects that a consumer could rely on.

10 So, we're trying to make a distinction between where you really have junk science or completely inadequate science to support a claim and where you have good data but that doesn't meet the SSA standard.

DR. ELLWOOD: So you would develop the claim language?

DR. PETERSEN: I --

15 DR. ELLWOOD: -- to weigh the level of science?

DR. PETERSEN: Yes, I think that would have to be a part of the process, yes, definitely.

20 DR. ELLWOOD: So would you then also be doing consumer testing?

DR. PETERSEN: To make sure they're not misled. I heard that in I guess was it yours, Barbara, the need for surveys of consumers and you'd definitely have to make sure the claim is understood, or it would be misleading, yeah.

5 We did not discuss how that would be done.

MR. LANDA: I just, I have one last question. You had a slide titled limitations of current policies and indicated that existing terminology and regulatory frameworks limit the scope and accuracy of consumer information.

10

Setting aside the question of the definition of nutritive value, which I take it is one of the limitations you see?

DR. PETERSEN: Uh-huh.

15

MR. LANDA: Are there other limitations?

DR. PETERSEN: Yes, I think I also presented the issue with the sterols and stanols of not being able to say, you know, that if you have abnormally high cholesterol, it lowers it. Sticking to that maintain wording is another place where you're dancing, in my view, on the head of a pin trying to, trying to stay away from a drug claim and yet in the process really confusing somebody who thinks they look at this and say

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well, if I have normal cholesterol, it will maintain it, but I don't have normal cholesterol, I have high cholesterol in the process and I'm sure there are other examples like that.

5 MR. LANDA: Thank you.

DR. PETERSEN: Thank you.

(Applause)

10 MR. LANDA: Our next speaker this morning is Bruce Silverglade who is the director of legal affairs for the Center for Science in the Public Interest. He's going to talk to us at least in part about CSPI's petition to FDA concerning "functional foods." CSPI is a non-profit consumer advocacy organization. It's based in Washington, D.C., with  
15 offices in Ottawa, Canada. If it's not cold enough for you here, you can head north and...

Mr. Silverglade coordinates CSPI's advocacy activities in a variety of areas involving food safety and international trade, nutrition policy, functional foods and dietary supplement regulation. In addition, he  
20 has supervised Court litigation in more than a dozen cases involving food labeling and advertising.

Before joining CSPI, Mr. Silverglade worked in the U.S. Federal Trade Commission's Bureau of Consumer Protection and Office of Policy

and Planning. He received his law degree from Boston College and his BA in political science from the University of Illinois.

Bruce.

5 MR. SILVERGLADE: Thank you. We also have an office in  
Dallas, Texas, which is a little bit warmer and a little bit more relevant to  
today's presentation because that's our litigation office. And yesterday we  
wrote the makers of this product, Inviga, which are no less than Coca-Cola  
and Nestle, and told them that we felt their burns calorie claim here on this  
10 energy drink was unfair and deceptive and that we would bring a suit  
under State law for unfair and deceptive trade practices if they didn't  
change the claim.

So, bringing the discussion kind of back down to earth again, this  
is the kind of product we're talking about and we need to decide what kind  
15 of regulatory framework we should have for those kinds of products.

Okay. Here's the outline of my formal presentation. First I'll  
look at some public policy considerations in addition to the one I just  
mentioned. Then regulatory approaches, the threshold question is do we  
regulate food products as foods or as dietary supplements or something  
20 else. And then I'll go into the details of our petition.

So, first, some food for thought. As we've heard already, all  
foods are functional foods and functional foods are not new. Vitamins and

minerals have been added to foods for decades. So what, if anything, has changed.

Well, there are foods with novel ingredients that wouldn't normally be found in the food and they can be as simple as calcium which is of course found in dairy products but put into orange juice, for example, might be novel. And of course we've heard about the margarine substitutes, Benecol, with plant stanol esters, an ingredient again that's not normally found in the food supply.

But while those two products are useful, most products currently on the market do not address chronic diseases, but rather are targeted at minor health problems. So what role can functional foods play in helping consumers address major public health problems. Most products on the market today don't address major health problems. This is a sample of products that was the subject of a 2000 complaint that we filed with the FDA before our 2002 petition.

So, the marketplace is currently bloated with dubious functional foods, so to speak. There's energy drinks, as I've shown, herbal medicines added to beverages and tonics, snacks of low nutritional value with purportedly a functional ingredient.

So we believe that FDA should use this opportunity to crack down on unauthorized ingredients in claims. We've notified Coke and Nestle yesterday of our intent as a consumer organization on behalf of our

members to bring litigation against those companies. If we can do it, FDA can do it.

5 This is, of course, the quintessential example, in addition to the product I held up at the beginning, Arizona RX energy herbal tonic. This is, you'll find this out in the hallway, I think, in the bookcase of quack foods and the Arizona is a modern example of 21st Century quackery.

10 Okay, so let's change gears and look at the regulatory approaches. Well by any definition, as I said, functional foods are foods and accordingly they must be regulated under the food safety and labeling laws and not under laws pertaining to dietary supplements.

15 If it's a food, it should comply with food law. Now there -- IFT alluded to this product before, Benecol, it was first marketed, it's a margarine substitute, it was first marketed as a dietary supplement in order to try to escape the rules that apply to food additives and health claims for foods, but the company was able to market the product correctly after FDA reviewed the safety of plant stanol esters and reviewed the health claims and FDA issued an interim final rule to speed up the process to approve the health claims.

20 And other companies like Unilever that maintain control, a competing product to this one, follow those rules from the onset and were able to market products, similar products successfully. And health claims, of course, can be made for foods with both added and natural nutrients, so Tropicana, an orange juice, has a health claim about potassium which has

been approved by the FDA and other ones with additional ingredients that have been approved as well.

5 So, in short, a new regulatory category is not needed. We are already having FDA approve ingredients, novel ingredients in foods with health claims under the current regulatory framework, but FDA regulation of these types of novel ingredients that have physiological effects can be improved, so what we're calling for is keeping the current regulatory framework but tightening it up a little bit because company's are adding ingredients with intended physiological effects and that calls for a formal regulation a little bit stronger than what we currently have.

10 So, here's our petition and of course it's broken into the two basic areas of food safety and label claims and we'll briefly go through this.

15 We are calling for premarket notification of novel ingredients and then we'll talk about how to define them. And then in label claims, of course the three basic categories of claims.

20 So, first, food safety elements. Manufacturers should be required to notify FDA of novel ingredients that are intended to have physiological effects and provide a summary of relevant data. And the rationale is because novel ingredients are specifically intended to affect health, they are more likely than other substances to cause adverse effects.

So while normally manufacturers can self-affirm as GRAS, if a manufacturer is intentionally adding a novel ingredient that has no history of use in food, knowing or intending it to have a physiological effect, we

believe the current law would allow FDA to require a notification by the company to FDA that it intends to use such ingredient. And premarket notification was recommended by the Government Accounting Office in its 2002 report.

5                   To help guide the industry, FDA should issue guidelines on categories of novel ingredients that are subject to premarket notification. We don't envision everything, of course, being subject, but just certain ingredients.

10                   So perhaps phys -- one definition might be physiologically active substances with no history of use in conventional foods would be subject to a notification and FDA could also establish guidelines for substances that are specifically exempt from notification, such as vitamins and minerals within safe upper limits.

15                   The authority would be based on those sections of the Food and Drug Act.

20                   Now, premarket notification will help ensure that all market entry decisions are made in full compliance with the law and this principal was proposed by FDA in its rule for notification of genetically engineered foods in 2001. So we have, in a sense, borrowed from FDA's idea in that area to suggest a notification scheme for novel ingredients.

                  And how should they be defined. Well, clearly they have to have nutritive value, but FDA's criteria for nutritive value are flexible. In various proceedings FDA has said in the second bullet there that a

substance can assist in the functioning of metabolic processes necessary for the normal maintenance of life. We believe that's about as far as the Agency has to go. This encompasses many different types of substances that could be added to foods.

5                   But, we, it's important to retain the nutritive value concept and we say that the ingredient must primarily provide taste, aroma or nutritive value or otherwise affect the characteristics of the food, but it could be added to food for an express or implied purpose of affecting physiology, so that's where we get into a novel ingredient that still provides nutritive  
10 value but it's novel because it's added to expressly or implicitly affect physiology.

                  We would also say that it would have to meet FDA's fortification policy.

15                   Now, IFT has presented some very different ideas. Instead of talking about novel ingredients, they're talking about functional foods. We're talking about novel ingredients and functional foods by IFT was defined as biologically active components that impart desirable physiological effects. Nutritive value would not be required and therefore the distinction between foods and drugs would be eviscerated.

20                   Now, recommendations to permit the addition of non-nutritive substances to foods and to make health-related claims for purported physiological effects would really strike at the heart of the Food, Drug and Cosmetic Act and the IFT committee was heavily influenced by industry

representatives and consultants, but the basic point I have is where would we draw the line?

5                   Would a manufacturer be allowed to add willow bark to iced tea to alleviate headaches. Willow bark contains substances that are in aspirin, over-the-counter aspirin.

                  Where would, if we allow anything with a biologically active component to affect physiology, where would we draw the line?

                  Well Congress drew a distinction between foods and drugs for a good reason.

10                   Now, let me go into the claims elements of our petition and today we've heard of course about the different types of health claims, structure/function claims and of course there's nutrient content claims as well. For the purposes of my discussion, I'm going to focus on qualified health claims and structure/function claims, there's also a few more.

15                   Now, qualified health claims, I'm going to take a step back for a second here because CSPI believes that qualified health claims are not even authorized for foods. Now we're well aware that FDA has authorized them for foods over the last couple of years, but we believe that this process is not in accordance with the law. Unlike DSHEA, Congress  
20                   provided a specific statutory standard significant scientific agreement for food health claims and *Pearson versus Shalala* was not decided in the context of foods, it was decided in the context of dietary supplements.

The NLEA legislative history provides a solid basis for stricter standards for health claims for foods. The Congress was very clear that there was a tremendous problem in 1988, '89 and that's why the NLEA set strict standards for health claims for foods. The legislative history didn't address dietary supplements, but it was very clear about the problems with the food industry and, therefore, strict standards were written into the law and we believe that FDA can play those standards administratively.

Also, I would note that foods and supplements are consumed for different reasons by different groups of consumers and in different forms. So, foods claims should not be regulated as claims for supplements.

Moreover, when FDA studied its qualified health claim program, it showed, FDA's own study showed that consumers don't understand them and in that vein, I think the First Amendment protection is very minimal if, because the First Amendment obviously doesn't protect misleading speech.

So if FDA's own studies show that qualified health claims are not understood by consumers correctly, then even if you assume *Pearson versus Shalala* applies to foods, which it doesn't, but even if you assumed it did, the First Amendment wouldn't cover this type of speech.

Now, let's move on to structure/function claims. Congress provided for structure/function claims for foods as an exemption to the definition of a drug and all products making structure/function claims, except foods, are drugs.

5 So it's an exemption and it's important to see it in that light. The purpose that Congress had in mind was to cover products like slenderizers in the drug definition even if no disease claims were made about the product. The purpose back then was not to allow drug-like claims for foods.

10 So structure/function claims, it's a narrow concept. The common sense definition of a food according to the Court in *Nutrilab v. Schweiker* is a food is primarily consumed for taste, aroma or nutritive value. Foods can have a physiological effect but that's secondary to the primary reason they're consumed. So coffee and prune juice would be foods with secondary physiological effects.

15 Claims for functional foods are intended to affect health and therefore for the same reason as we had for novel ingredients, we believe the FDA should be notified prior to marketing for structure/function claims for foods with novel ingredients, both the ingredient should be notified to the FDA, the use of the ingredient and the claim, the structure/function claim.

20 FDA could develop a list of claims it considers permissible and that do not require notification. For example, structure/function claims connecting structure/function claims having -- connecting vitamins and minerals with classic nutrient deficiencies would not have to be notified.

Legal authority again would be found in those sections of the Act listed there.

Now, one question that would come up when FDA is notified of a structure/function claim is how much evidence should the FDA require of a manufacturer. Well, consumer research shows that consumers don't distinguish between structure/function claims and health claims. Just lawyers like myself in Washington appreciate the fine distinction.

Thus, the level of evidence required for both a health claim and a structure/function claim should be significant scientific agreement.

There's really no reason to require less scientific evidence for a structure/function claim, no public health reason, that's for sure. Now the IFT report only requires that a substantial body of evidence exist for plausibility. We don't believe that's sufficient. And the IFT approach, if followed, would actually roll back current FDA enforcement standards.

We also believe that nutrient disqualifying levels and the jelly bean rule should apply to structure/function claims as they now apply to health claims.

One other labeling question that arises is do we need a disclaimer on the label that says this claim has not been reviewed by the Food and Drug Administration.

Both the 2002 GAO report and the CSPI petition in that same year discuss the issue. Since that time, though, in 2004, studies have been published showing that the disclaimer in the context of dietary supplements, at least, is ineffective and the studies showing this have been summed up in the journal of public policy and marketing.

So based on this relatively new research, we would believe a disclaimer for functional foods or foods with novel ingredients as we would prefer to call them is inappropriate and actually not needed if FDA establishes a strong substantiation standard for structure/function claims based on the significant scientific agreement standard for health claims.

So, in summary, promoting foods' ingredients on the basis of physiological effects is a serious public health matter and regulatory policy should be proportional to the seriousness of the issue.

The IFT approach would roll back food safety and label claim rules in the name of creating a new category of food products and let's stop talking less about functional foods which is really a marketing term and more about novel ingredients and how they should be regulated.

Foods with novel ingredients meeting FDA food additive and labeling rules are being successfully marketed under the existing law, so no new regulatory category is needed.

And while existing laws are adequate, the FDA needs to update its enforcement policies to keep control of the marketplace and, therefore, novel substances with physiological effects call for premarket notification of ingredients and structure/function claims.

We don't want to turn the environment into this. And I will end on a positive note. Thank you.

(Applause)

MR. LANDA: Questions?

DR. NALUBOLA: I have a question specific to something in the petition.

5                   One of the recommendations from the GAO in their 2000 report specifically about FDA's authority, the GAO report recognized the limitation of FDA's authority as provided by the statute and the differentiation between dietary supplements and conventional foods and made the recommendations for notification and disclaimer language to  
10 Congress.

                  However, in your petition you made those recommendations to FDA. Can you elaborate on that?

15                   MR. SILVERGLADE: Well, I think that's a good point. The GAO did suggest that FDA seek new legislation and we would certainly support that, so the, but the question is what can FDA do in the meantime.

                  I think the handling of genetically engineered foods indicates that the Agency at least in that context believed that it had authority for premarket notification of certain types of ingredients and I'm not sure  
20 GAO considered that at the time it issued its report.

                  But it, perhaps the Agency could start with an advanced notice of proposed rulemaking bringing these issues up and asking for public comment on whether it has the authority or needs to seek new legislation.

Frankly, I think the new Congress next year would be open to giving the Agency new legislation.

5 MS. NICKERSON: As a follow-up, in case Congress does not cooperate, in the biotech notification proposal we explained our decision to, our tentative decision to require a notification in terms of biotech ingredients posing increased safety concerns because of their novel nature and so on.

10 But here I think we're facing a statutory limitation that we didn't face there, namely, that our statute presumes that dietary ingredients and dietary supplements that have a history of use prior to October 1994 are safe.

15 So, given that fact, what would be the Agency's basis for presuming a greater likelihood of adverse events as you suggested for these same ingredients when they're used in conventional foods?

20 MR. SILVERGLADE: Well, conventional foods are used differently than dietary supplements. They're presumably safe to be consumed by anybody at any time, children and so forth. They are consumed probably we must presume in larger quantities. If one's really thirsty, they may drink the whole carton of juice where somebody would not intentionally take, you know, large doses of dietary supplements if they're thinking rationally, at least, you know. You know, they wouldn't

take a whole bottle of pills but they could conceivably drink a whole carton of juice if they're thirsty.

5 So, foods, what might be safe under DSHEA for dietary supplements is not necessarily safe as a food additive or GRAS ingredient or, you know, an additive ingredient for foods.

10 DR. TARANTINO: And if I can, I guess in your presentation you said you weren't suggesting a new regulatory category but it sounds like you're suggesting a new regulatory category in the sense of novel ingredients which would need to be defined and presumably separated away from other ingredients which can indeed be GRAS and not have to be notified, is that, am I, have I got it right?

15 MR. SILVERGLADE: There would be no new category of food products, so we wouldn't have anything called functional foods, but there would be a new category of substances that would have to be notified both for ingredients and structure/function claims.

20 DR. NALUBOLA: Follow-up to that, then, when you talked about structure/function claims, one of your requests in your decision is that FDA require --

MR. LANDA: Excuse me, could you move a little closer to the mic. Thanks.

5 DR. NALUBOLA: Okay, sorry. One of your requests in the petition was that FDA require notification for products bearing structure/function claims. It was not clear whether you're talking about products, all food products that bear structure/function claims or the products that contain these novel ingredients?

10 You tried to make that distinction when it comes to safety issues, but for labeling, I was not sure.

MR. SILVERGLADE: I intended to say that the notification for structure/function claims should be for all novel -- all claims dealing with or connecting to a novel ingredient, tying in with a novel ingredient.

15 However, FDA could issue guidance exempting certain substances from the notification requirement if it considers that there's no safety issue and that the claim is undeniably true, for example, recognized in nutrition textbooks or something of that sort, it could create an exemption. But I guess the presumption would be that all novel  
20 ingredients – structure/function claims for all novel ingredients would have to be notified, would be the general presumption.

DR. NALUBOLA: Another question about the GAO report.

The report talked a lot about health claims and the distinction between health claims and structure/function claims and made a recommendation to Congress that there should be an independent review of the question of fundamental differences between these two claims.

5

You've made a request in your petition to FDA on this same issue as it relates to "functional foods."

Do you think there are any questions that are unique and separate to "functional foods" or so-called "functional foods" that may not be applied in the broader context?

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MR. SILVERGLADE: Is the question are there issues related to functional foods that are unique and separate from conventional foods or from dietary supplements or from --

15

DR. NALUBOLA: From conventional foods?

MR. SILVERGLADE: Well yes, I think the unique element about a food with a novel ingredient or a so-called functional food is that the manufacturer has intentionally added a substance for, to achieve a physiological effect and that certainly raises my eyebrows and I think it would hopefully raise the FDA's eyebrows and it hopefully would be

20

construed as giving the Agency more authority to require notification of both the substance and a structure/function claim.

5 MS. NICKERSON: One of your recommendations is that for FDA to require post market surveillance and adverse event reporting for functional foods.

What do you envision as the legal basis for such requirements?

10 MR. SILVERGLADE: Yes, I kind of skipped over that slide but not intentionally, just to save time.

The legal basis would be to ensure safety. There are, in certain situations, not all, but in certain situations the safety of a novel ingredient could not be assured unless FDA required the manufacturer to conduct some post marketing surveillance.

15 Now as you know, it wouldn't always be the case, but it's just that the Agency should make it clear to the industry that that might be required in certain cases.

20 MS. NICKERSON: And one more legal authority question, then I'll be done. You also suggested that in certain cases FDA should institute safe packaging requirements. There was a case in the 2nd Circuit involving child resistant packaging for iron-containing supplements where we did promulgate such a requirement and the Court struck it down saying

that those sorts of requirements are under CPSC's purview and FDA did not have authority to require them.

5 Do you, did you consider that case and if so, you know, why do you think it doesn't apply here or that there's some way we can get around it?

10 MR. SILVERGLADE: No, that's an unfortunate decision and it's a law in one circuit, so it's not necessarily the law of the land and there may be some functional foods that can be consumed safely if they're consumed in certain quantities, but may become unsafe if they're consumed in larger quantities.

15 So, again, to, through the food additive law and the GRAS law, we presume FDA would have implied authority there to require a packaging size requirement, if necessary, to ensure safety. But I understand the case that you've mentioned, yeah.

MR. LANDA: I have a couple of legal authority questions.

20 The first one is you cite the proposed rule with respect to premarket notification for bioengineering foods as a precedent for the notification scheme you're advancing.

The question is are there other precedents you can think of, I put precedents in quotes because what you have is a proposed rule, there has not been a final rule, so there has not been a final Agency determination

about that proposed notification scheme, but can you think of other circumstances in which the Agency has imposed notification schemes in the absence of explicit statutory authority?

5                   MR. SILVERGLADE: I think we would have probably included them in the presentation if we had, but anyway, my colleague Ilene Heller this afternoon may have some additional examples.

                  MR. LANDA: Fair enough.

10                   Second question. You pointed out correctly that *Pearson versus Shalala* was decided in the context of dietary supplements and not foods, not conventional foods.

                  But you then seemed to say that was a basis for not applying it in the context of foods and my question is why does that matter for First Amendment purposes?

15                   If the First Amendment analysis for a dietary supplement is that there are certain rights to make -- certain free speech rights, why wouldn't those rights apply for conventional foods?

20                   MR. SILVERGLADE: Well, the Court, it depends on the facts of the case.

                  What I'm saying is that a Court may interpret the First Amendment different if the facts of the case are different.

In *Pearson versus Shalala* we're talking about dietary supplements. There was also -- which are not foods, they are not consumed in the manner that foods are consumed in.

5 The Court also assumed in its opinion that all supplements were safe, putting that question aside, I don't think we can assume that all physiologically active ingredients added to conventional foods would be safe. So the statutory framework is different, too. Congress spelled out the significant scientific agreement standard specifically for foods but left it up to others to decide the standard for dietary supplements.

10 So, there's a different statutory background and factual background.

MR. LANDA: Thank you.

15 DR. SCHNEEMAN: My interpretation of what you covered with respect to structure/function claims is that you were talking about a notification system, not a premarket review system as we currently have. And I think we heard from the IFT report also some suggestions about a system that some might interpret as a notification.

20 Do you see fundamental differences in what the two of you are reporting or do you see similarities in what you're reporting?

MR. SILVERGLADE: No, I think there's fundamental differences. IFT was talking about a notification system for qualified health claims. We believe that that is impossible under the current law, that the law requires petitions for health claims except for those based on authoritative statements. So a qualified health claim, a significant scientific agreement health claim would still be subject to requirements for a petition.

CSPI's remarks for notification of claims were limited to structure/function claims which right now have no notification at all, but we think should be required for novel ingredients with physiological effects as a general matter.

MR. LANDA: Any other questions?

MR. SILVERGLADE: Thanks.

(Applause)

MR. LANDA: We are scheduled to reconvene at 1:30 and although we've finished a little early, why don't we stick with the 1:30 time.

We'll see you back here then, thank you.

(Lunch Recess)

MR. LANDA: Silence descended more quickly this morning, so lunch must be better away from Wiley Cafe.

I want to make the same inquiry I made this morning, if there's anyone that needs the services of an interpreter, would you please let us know by raising your hand.

Thank you. I'm going to first put up on the screen and run through it very quickly the questions we posed in the FR notice just to refresh everyone's recollection and then we'll begin with the public speakers. It's five minutes per speaker followed by five minutes per questioning until we finish today, although I think we'll have a break in the middle.

The issues and the questions are broken out we think into three categories, ingredients, labeling and then there's one general one. The first issue concerns the CSPI petition which requests that we require food companies to notify us regarding the use of novel ingredients prior to marketing foods containing such ingredients.

The second really goes to whether we need a definition and a distinct or I suppose one might say new regulatory approach for evaluating ingredients added to "functional foods."

You heard this morning about the regulatory scheme as we see it now and has, and as we think it applies in this area. But there's obviously room for other ideas and it's one of the reasons we're here today.

We'd like to know what the definition would look like if you think we need one and what kind of approach is needed that isn't adequately addressed under existing law, as well as finally in this single question, some information about the scientific and legal basis for the position you're taking.

1B, should companies that market ingredients for addition to “functional foods” be required to notify FDA prior to introducing the ingredients into interstate commerce? If so, what's the scientific and legal basis for your position?

The second issue goes to food additives and the interest in them that's arisen in the context of “functional foods” with claims about health benefits. So we're asking what types of data and information would be appropriate to demonstrate that ingredients added to conventional foods, conventional foods being marketed as “functional foods,” meet the safety standard that Dr. Tarantino spoke about this morning, the standard of reasonable certainty of no harm and what is the scientific and legal basis for your position?

2B, how could we partner with interested stakeholders regarding the development of appropriate recommendations or other information regarding the safety assessment of ingredients added to “functional foods?”

Issue 3 refers again to the CSPI petition in its request that we require companies to notify us within 30 days of marketing a conventional

food bearing a structure/functional claim if the food contains a, quote,  
unquote, novel ingredient.

Assuming for a moment that our statutory authority permits,  
should we require food companies to notify us within 30 days of  
5 marketing a conventional food bearing a structure/function claim?

And what about the disclaimer that's now required for  
structure/function claims on dietary supplements, the statutory disclaimer?  
Under what authority could we require notifications of these claims? We  
discussed that a little bit this morning, but we'd certainly like to hear more  
10 this afternoon.

Let's turn for a minute to IFT. IFT, as you may recall in the  
report, recommends an expert panel approach to evaluate the effectiveness  
of the "functional food" component that's being considered. These panel  
reports would be submitted to FDA under a process that IFT proposes at  
15 least that would be similar to the notification program for GRAS  
substances.

Within our statutory authority, how if we're going to do this at  
all, should we use findings of non-Government groups such as the IFT  
recommended GRAE panels, whether that's in support of health claims,  
20 nutrient content claims and other labeling claims about the effects of a  
"functional food" or ingredient such as a structure/functional claim?  
What's the scientific and legal basis for your position?

Should we have a premarket notification process for review of the scientific evidence for structure/function claims for “functional foods” and ingredients? If so, what's the scientific basis for that position and under what legal authority, existing legal authority could we institute such a program?

There was some discussion this morning about *Nutrilab versus Schweiker* and the limitation to effects that derive from taste, aroma or nutritive value of the food or the food ingredient. The health claim regulations reflect those three characteristics, taste, aroma, nutritive value and add technical effect recognized in the food additive regs.

We think at least that we've been flexible in determining whether a substance possesses nutritive value. The definition is set out there and there was some discussion this morning of the need to broaden that.

IFT in particular, or the IFT report recommends that FDA permit a labeling claim for a “functional food” if the claim benefit is based either on nutritive value or on, quote, the provision of the physical or physiological effect that has been scientifically documented or for which a substantial body of evidence exists for plausibility.

Question five concerns whether the Agency's interpretation of or application of *Nutrilab versus Schweiker* limits structure/function claims and health claims in an appropriate manner or does it not adequately allow for claims in the labeling of functional foods.

If it is inadequate, how so and what's the scientific and legal basis for your position? If you favor a change, that is, if you think the Agency's approach is unduly limited, do you favor the IFT approach or some other alternative? And what legal rationale would support your preferred change in the approach?

IFT report talks about incentives for the food industry to do the research needed to support “functional food” claims, if you will. There isn't now any statutory provision for market exclusivity as there is, say, in the human drug and animal drug context.

But should FDA provide incentives, if so, how, what kind of incentives and again, what's the scientific basis for your position? What's the legal basis for your position?

As we discussed this morning, the statute we administered, the principal statute doesn't define or otherwise recognize the category of foods called “functional foods.” We haven't done that in regulation, we haven't done it in guidance, we haven't done it anywhere else, as far as I know. IFT suggests that we should and we should issue regulations defining, recognizing “functional foods” as a distinct category.

There's obviously increased market interest both on the part of consumers and marketers in this category and as we discussed this morning, interest in, on the parts of many organizations, Government and non-Government.

Is the current regulatory scheme adequate to regulate “functional foods;” that is, the conventional foods being marketed as “functional foods?” Food additive provisions, regulation of GRAS substances, regulation of various labeling claims, health claims, nutrient content claims, structure/function claims, are these adequate? If they're not, if they're not sufficient, why aren't they sufficient, why are they lacking scientifically and from a legal standpoint?

As I said earlier, the speakers will be limited to five minutes each. They'll be heard in the order in which they registered. As the speaker before you is about to finish, please, if you don't mind, make your way down to the front of the auditorium. I should say the finish is not only the five minutes that each speaker will have, but roughly five minutes for questions.

With that, why don't we begin with Andrew Shao from the Council for Responsible Nutrition.

DR. SHAO: The Council for Responsible Nutrition, CRN, is pleased to be able to offer its views at today's public hearing on products being marketed as functional foods.

CRN represents both manufacturers and ingredient suppliers that provide raw ingredients to both the dietary supplement and functional food industries. While the stated purpose of today's hearing is to receive comment on approaches to the regulation of conventional foods being

marketed as functional foods, CRN wishes to emphasize that the policy directions promoted today will undoubtedly impact both conventional foods and dietary supplements.

5 Given that reality, CRN's request is that all stakeholders involved in this debate proceed with care and display a full appreciation for the interrelationship between these categories.

Sorry. Yes, proceed with care.

10 A key unspoken question for this meeting is to what degree should dietary supplements and functional foods be regulated in a consistent manner. But asking this question does not presume that functional foods and dietary supplements should be regulated identically. Several facts illustrate the relevance and importance of this question.

15 The first is the increased prevalence of conventional foods being labeled and represented as dietary supplements with a supplement facts box on the label. At the same time dietary ingredients commonly found in dietary supplements are also appearing with more frequency in conventional food forms that are labeled as foods with a Nutrition Facts box.

20 For all practical purposes, certain aspects of the intended use of dietary supplements functional foods have become strikingly similar.

FDA will need to fully understand and appreciate the consumer-driven marketplace as well as the regulatory imbalances that exist between these two categories that are driving the blending of these product lines.

Now despite the similarities, many differences currently exist between the two categories, both in terms of how they're consumed and how they're regulated. For example, there are different safety standards, reasonable certainty of no harm for food additives and GRAS substances versus reasonable expectation of safety for dietary supplements. There's different manufacturing standards. Food GMPs versus the proposed dietary supplement GMPs. Differences in allowable claims. DSHEA expressly authorized the use of structure/function claims for supplements but not foods. Differences in labeling. Disclosure of amounts of all added functional ingredients for supplements but not foods, appearance of the FDA disclaimer statement for supplements but not foods.

Finally, functional foods may taste good and provide either thirst quenching or (inaudible) and, thus, may be consumed casually primarily for these purposes.

Therefore, any action taken by FDA, including no action, has the potential for significant ramifications. If the Agency attempts to streamline the regulations between dietary supplements and functional foods, they face several imposing obstacles, the most daunting of which may be the chosen standard for safety.

If the Agency proceeds with the recommendation to implement the GRAE concept being proposed or entertains the notion of providing incentives to companies to research their functional food products, surely the same would need to be considered for dietary supplements.

If the Agency decides that the current regulatory framework for functional foods is sufficient, in other words, as conventional foods, and chooses to take no action, this decision could also be met with consequences. The disparities that currently exist between dietary supplements and functional foods may become more prevalent as the market expands, perhaps leading to more confusion related to labeling, manufacturing and the representing of conventional foods as dietary supplements.

Therefore, it's the recommendation of CRN that FDA consider and review carefully all of the issues and ramifications of any decision on both conventional foods and dietary supplements before proceeding with any action.

In the end, FDA's most important concern should be assuring consumers that they receive safe products and sufficient truthful information to make informed purchase and usage decisions, regardless of which category the product is regulated under. Both consumers and industry will be well served if the outcome of today's hearing lead to a further committing to safety, more accurate and understandable information in the hands of consumers and more innovation and research in the product development process.

Thank you.

MR. LANDA: Any questions?

MR. LANDA: You referred to regulatory imbalances between conventional foods and dietary supplements, could you give some examples of what you mean by that phrase?

5

DR. SHAO: Well, you have a different standards for safety for the two, for the two products which we believe either has led to or will lead to a migration, if you will, of the marketplace towards a set of regulations that appear to be less restrictive and our concern is that that not continue, that it not continue that way. We're concerned about that migration.

10

MR. LANDA: But, well I guess you don't have to agree with this, I'll ask it as a question, are those standards a function of what Congress has given us or what we have done with what Congress has given us or something else?

15

DR. SHAO: At the moment I think it's what Congress has given you and which standard is the appropriate standard is obviously a matter of huge debate, which one is the best for consumers, which one's the best for industry and we're still evaluating that, as are you.

20

DR. SCHNEEMAN: I think you also mentioned as a disparity between dietary supplements and conventional foods the use of the structure/function claims and I was wondering if you had any more thoughts about that in terms of the implications of that imbalance and whether there's something that needs to be addressed there?

DR. SHAO: Exactly what should be done isn't clear, but I think what appears clear and I don't have research to base this on, but when you have disparities in how things are labeled, it could lead to confusion. The presence of an FDA disclaimer on one product but not another, both of which may contain the same ingredients and have a similar claim, it's possible it may lead to confusion and of course the whole idea here is to provide consumers with information they need to make informed decisions.

Now whether the use of the disclaimer is the right thing or not on both or, you know, that's a matter of opinion, of course.

MR. LANDA: Thank you.

Our next speaker is George Burdock of the Burdock Group.

DR. BURDOCK: I don't make enough to replace this if I break it, so.

All right. Thank you. Thank you for the opportunity to appear here today. Time is limited, so I'm going to read this speech and I hope you've taken an Evelyn Wood course and can follow along on the slide.

5 My name is George Burdock, I work for Burdock Group, a consulting company, with offices in Florida and Washington, D.C. And I'm not projecting. Okay, it comes out of your time.

(Laughter)

Somebody's gone out to get somebody else.

10 DR. SCHNEEMAN: It looks like the slide projector is -- oh --

DR. BURDOCK: It shut down totally. Well if somebody else would like to go, I need my slides.

15 MR. LANDA: Somebody else want to go?

DR. BURDOCK: Yeah, let's do that.

MR. LANDA: Daniel, do you have slides?

20 DR. FABRICANT: I do, but --

MR. LANDA: Our next speaker is Daniel Fabricant with the National Products Association.

5 DR. FABRICANT: First of all, I want to thank Michael and the folks at the FDA for having us here and bringing the opportunity for us to speak and encourage dialogue between all the interested parties in the natural products community, suppliers, retailers, consumers and regulatory agencies.

10 We were the artist formerly known as the NNFA, the National Nutritional Foods Association, now the Natural Products Association. Our, we have a fairly diverse membership from the smallest health food store to some of the largest manufacturers of natural products out there, including supplements, natural and organic foods, natural health and beauty aids, raw material suppliers as well as functional foods, even 15 though it has no definition as we've heard.

(Laughter)

20 With respect to the document that was released on the 25th of October, we are very happy again to comment and our experience has been that the natural products community tends to be a -- research indicates they're a little better informed than the average shopper. They're generally the first wave of buyers of innovative health products like this and the expansion and growth of functional foods to the mass market, coupled with increasing availability of health information, Internet

exposure often makes for unbalanced and provocative attention, somewhat causing undue concern regarding the appropriate regulatory checks and balances.

5           Regarding the current climate of functional foods, we would like to reiterate the point made in the docket that supplements currently do have their own detailed regulatory category as a result of DSHEA. However, in moving the discussion forward, the intent of DSHEA needs to be considered. That intent, the Congressional intent was to balance consumer protection, that's safety, not efficacy, with consumer access and  
10           that may or may not apply to functional foods in certain areas.

          With that said, the current food safety regime seems to work quite well. It's allowed the -- it's allowed Americans safe access to one of the greatest food supplies in the world, both the FDA and FTC have taken enforcement action against unsafe products, false claims and demonstrated  
15           that the current system provides these agencies enough regulatory authority to take action when and where appropriate.

          Additional regulation would most likely be, additional regulation would simply be overregulation and result in limited access to products that may provide a health benefit beyond the nutritive value. The solution  
20           isn't more regulating, but rather stronger enforcement of current food, food and safety fraud laws, FTC Section 543A and FDA misbranding provisions which Barbara brought up earlier in the day to address the problems that may exist in the current marketplace.

In addition, there are some questions that do require or need some direction or answers where possible. Guidance regarding intended use, how an intent is determined by the FDA, regarding serving size, ingredient concentration, food matrices, and what exactly, you know, a conventional food matrix may or may not be seemed really central to the discussion as well as expanding if there is going to be any expansion of *Nutrilab versus Schweiker* to apply structure/function claims to functional foods.

Commercial speech, including advertising, has been determined to be a valuable source of information to the consumer and the Courts, including the Supreme Court, have generally not upheld approaches that limit free -- that restrict free speech. The Government generally has to first consider increasing either nutritional education, self-regulation, other approaches that would make -- that may be more applicable to functional foods.

One other point, it's something that wasn't in the document was good manufacturing practices of functional food products. There are GMPs for food and it's guidance and as of this morning, there still wasn't a GMP rule for dietary supplements, as far as I know. But with that said, once the rule is in place, where do products containing I guess supplement or dietary ingredients that fall under the supplement GMPs in conventional food matrices, whether fortified or otherwise, where do they fit in with

respect to manufacturing practice. Will the Agency offer additional guidance and regulation as they do with infant formula, medical foods.

We believe GMPs are part of the answer as well offering appropriate consumer protection and lastly, again, I'd like to thank you guys for the opportunity and going forward we'd like to reiterate our interest in working with the Agency on further discussion.

DR. TARANTINO: Just a clarification I guess, one of the things you talked about was the potential use, usefulness of guidance and what I'm reading here is on intended use and how intent can be determined on an ingredient specific basis.

Can you elaborate on that, are you talking about multi-ingredient products?

DR. FABRICANT: Multi-ingredient products that this meeting primarily sprang about because of beverages, so I think that's probably where it's most applicable.

DR. TARANTINO: Thank you.

MR. LANDA: Are you suggesting that intended use would be determined from something other than statements, representations and the like made by or on behalf of a marketer?

It would be something sort of inherent in the ingredient that would indicate its intended use; are you suggesting that that's a possibility?

5 DR. FABRICANT: Well the metrics have to be considered. If you have a liquid, a liquid supplement and the serving size is an ounce and not, not per se, even though it's a liquid, you know, it obviously shouldn't be considered a beverage, so really we're looking at concentration, so if we're looking at concentration, it obviously -- can that be applied forward  
10 to a beverage and if the concentration is similar to what you find in a supplement product.

MR. LANDA: Thank you.

15 DR. SCHNEEMAN: You raised the issue of the GMPs and I'm wondering if you have given some thought as to how you would see GMPs applied and whether or not something is different?

20 DR. FABRICANT: Well, I see it, it could be, I mean it could potentially create I guess an unlevel playing field whereas if a supplement has to go through, and again, I haven't seen the final rule yet, so based on the proposed ruling if the supplement has to go through all those steps that

were offered in the proposed ruling versus the food GMPs, obviously there's some disparity there.

Thank you.

5 MR. LANDA: Thank you. Second try, right. Start the clock.

DR. BURDOCK: Well, this is the first slide.

10 Good afternoon and again, thank you for allowing me to speak today. Today there exists an impasse between the interested parties in functional foods, the FDA, industry and consumers. This impasse is the result of all the reasons cited in this slide and probably many more as well. Importantly at this point in the stalemate only FDA has the power to resolve this impasse.

15 To resolve this impasse, FDA must do four things. First, create a new regulatory category of functional claims, a category more relaxed in its requirements than those for health claims or qualified health claims, something that is more realistic and attainable.

Two, promote the use of independent expert determinations.

Three, initiate a notification system.

20 Four, provide a term of exclusivity and enable a period of return on investment for manufacturers.

Functional claims should be defined as only providing health benefit beyond basic nutrition. FDA needs to make the switch in mindset

from health to functional claims. At the present time we already have found the no-brainer nutrient such as vitamins, calcium and iodine where a deficiency was clinically obvious and for health claims those substances for which cost of clinical studies was no object.

5                    Now is the time for FDA to stretch its thinking. First, disconnect the health disease conundrum. Allow claims based on changes in biomarkers, allowable claims for a specific population subsets. For example, people who are poor absorbers of an ingredient or those who may possess a single nucleotide polymorphism that may result in a  
10                    subclinical deficiency. FDA must and most of all remain flexible.

                    Now is -- excuse me. Now is really the time to make the tough choices and allow claims for which a consensus may not be there, but for which persuasive and clinical and mechanistic data exists. We can't wait for acceptance by the majority of the so-called mainstream scientists who  
15                    for reasons of their own may not want to recognize the efficacy of a substance. For example, the beneficial, beneficial effects of folate were known long before it was accepted by the Agency and this late recognition resulted in a hit on the credibility of the Agency.

                    Now is the time to allow changes in biomarkers and persuasive  
20                    data from the new sciences of proteomics and metabolomics and to allow special subpopulations to experience a benefit.

However, let me make it clear that while a functional food may benefit only a small subset of the population, all functional foods must be safe for all consumers.

5 The second thing FDA must do is accept the input of independent expert panels and there is ample precedent for the use of outside groups.

10 Third, FDA must start a functional food notification program which will inform consumers about which products are safe and efficacious. In this scenario, experts qualified by training and experience will submit a confidential dossier on the safety and efficacy of the ingredient to the Agency. The Agency can make a determination on the credibility of the experts, the rationale supporting the claim and the credibility of the supporting data. If the decision is that the dossier is not persuasive, the dossier will be returned to the submitter without prejudice for possible resubmission.

15 If the dossier is found to be persuasive, FDA would inform consumers through a posting on the Internet with the product name, manufacturer and the safety data. The efficacy data would remain proprietary such as in a food master file or drug master file. All substances making a claim must submit their own efficacy data. There could be no piggybacking on efficacy claims.

This system would respond to the demands for consumer empowerment, demands for a commercial free speech and would relieve a potential log jam of petitions.

5 Keeping efficacy data proprietary is the essential fuel for driving this research. Without the possibility for return on investment, there is no incentive for research. Making efficacy data public has killed the value that might otherwise have been derived from health claims or qualified health claims.

10 Again, safety data and the substance should be made public but efficacy data should remain secret, at least for some period in which the investment can be recaptured. As we see in the following slides, the schematic for functional foods consists of manufacturers investing in research and upon a no objection from the Agency, the manufacturing, marketing and distribution chains can be cranked up to serve the public and profit return to the manufacturer.

15 However, if the no objection notice by the Agency also reveals the efficacy data, then pirates, for lack of a better term, can also crank up their manufacturing, marketing and distribution chains and without the cost of research, can sell the product at a much lower price.

20 Selling at a lower price has the predictable effect of bleeding off profits for the return on the investment needed to fuel more research, therefore, product innovation stops.

Now, to recap, the FDA can be the engine of resolution here to this impasse but to do so, it must take four steps.

One, change from health claims to functional claims. Two, promote the use of independent experts. Three, initiate a notification program and four, permit a term of exclusivity for return on investment.

This proposal is a win/win. The consumers, industry and FDA can all benefit and as a bonus to FDA, this will forestall increasing abuse of the medical foods category.

If anyone would like a copy of these slides, please E-mail me or get me through my Website at [www.burdockgroup.com](http://www.burdockgroup.com).

Thank you.

MR. LANDA: Thank you.

MS. NICKERSON: I was intrigued by your suggestion that FDA disconnect the health/disease conundrum.

Could you expand on that a bit?

DR. BURDOCK: Well, if you look at the legislative history, there was no requirement in the law, but it was in the legislative history or suggested in the legislative history that substance and disease not be connected. It was substance and symptomology. Substance, connected to disease, I believe is an FDA creation.

If you could connect substance to biomarker and expand the list of biomarkers you use, I think that would be a much more valid way of proceeding with functional foods.

5 DR. ELLWOOD: Can you expand on what type of biomarkers you're talking about, because obviously you're not limiting them to validated biomarkers that we currently use?

10 DR. BURDOCK: Well according to the, the list of validated biomarkers from the FDA is a very short list and in fact FDA doesn't recognize one of my favorite biomarkers, which is PSA.

15 Now this PSA biomarker is universally used by physicians across the country. It's accepted by the medical community, even insurance companies will pay for PSA. So this is an accepted medical biomarker. There are many, I can think of only one right offhand, such as cholesterol, that the FDA recognizes. There are obviously more, but there could be a whole lot more.

20 Plus, I believe we could use proteomics, metabolomics, nutrigenomics, especially with proteomics, there's a lot of good biomarkers here that we're letting slip through our fingers as a methodology for alleviating problems.

DR. SCHNEEMAN: Actually, just to follow up on that, do you have some examples from the proteomics and metabolomics that are good biomarkers that are good at predicting --

5 DR. BURDOCK: I'm not prepared to give you that list today, but I'll be glad to get back to you with a list.

DR. SCHNEEMAN: Thank you.

10 I would be interested in having you comment, I think when you used the, described the panels that you were talking about you were referring to generally recognized as safe and effective and I was wondering how you then reconcile that with a highly confidential process. So how do we get to the generally recognized piece in a confidential process?

15 DR. BURDOCK: Once the -- that takes place during the notification, the safety data should be posted. All safety data should be generally available. It's just that the efficacy data is the part that should remain confidential.

20 There, and it could be just like a food safety file, in a food safety file even some of the safety data can be held in confidence, but here we would allow all the safety data to be publicly available. There is no requirement under the regulations or the law to make any efficacy data or

technical data or manufacturing data a food ingredient to be public knowledge. That can be held as trade secret.

5 DR. SCHNEEMAN: So you're suggesting then that the safety data is generally recognized, but the efficacy data would not be generally recognized?

10 DR. BURDOCK: Efficacy data -- well, general recognition of safety doesn't mean approval by everybody and I think there's good case law to back this up. That general recognition of safety is done by a group of scientists that are recognized by the trading and experience of being experts in that area and a decision they make is considered to be, to my understanding, a consensus of legitimate experts.

15 Naturally you're not going to convince everyone, every scientist on earth that this is going to be safe, or efficacious, but if you have a legitimate panel, and that would be one of the FDA's jobs, to make sure that the panel was really qualified to do this, not some people pulled off the street, but certainly somebody with some credibility that can make this decision and you could look at their credentials and if they are credible  
20 individuals, then this could go a long way towards your decision that the dossier is persuasive.

DR. TARANTINO: So, George, let me see if I can clarify.

5                   What you're saying is that the safety decision, you're not suggesting any changes, that a new ingredient follows the food additive regulations and it is approved or is GRAS, but that efficacy data, in a separate notification process, is submitted and during the time that the notification is being looked at, that that submission and its contents are held confidential?

10                   DR. BURDOCK: That's kind of a compound question. Number one --

DR. TARANTINO.: Maybe I don't understand then.

15                   DR. BURDOCK: All safety data, since this is going into food, then the safety data must be public.

DR. TARANTINO.: Yeah, so you're not saying that there's any change to --

20                   DR. BURDOCK: There's no change to that. The efficacy data is held -- is confidential, however, you've got to have that to have a return on investment. Without that return on investment, there's no more innovation, no more research.

5 MS.NICKERSON: How do you square that idea with the First Amendment notion that if a claim is truthful and non-misleading, as it would be if efficacy had been shown by one firm, how would the First Amendment allow the Agency or, you know, the law to prohibit other manufacturers of the same ingredient from using that same claim?

10 DR. BURDOCK: Well you can look at drug law, the drug regulations. There's no First Amendment protection for drugs and their efficacy data, is there?

MS. NICKERSON: Well, it's not the First Amendment that directly protects efficacy data.

15 It's the idea of whether use of a claim based on the efficacy data can be restricted, whether the First Amendment permits that, but in the drug field, it's not, you wouldn't have people marketing the exact same product because the product is proprietary, you know, until an ANDA has been approved.

20 DR. BURDOCK: I don't see how this applies. If efficacy data can remain confidential, just like a lot of things in a food master file that can remain confidential, such as manufacturing information, efficacy data has never been placed on a label anyway.

Efficacy data supports the claim that's on a label, so there's no reason to make the efficacy data public.

5 MS.NICKERSON: Right, well the efficacy data could remain confidential, but the idea I think you're suggesting is the claim should be exclusive to the manufacturer that supplies the efficacy data; is that correct?

10 DR. BURDOCK: To the person that produces the efficacy data?

15 MS.NICKERSON: I'm saying that's where the First Amendment might limit our options in that if the claim has been shown to be truthful and non-misleading because of the efficacy data, then other manufacturers, it would seem, would be able to use that claim, even if they didn't have access to the underlying data.

DR. BURDOCK: Could you explain to me how drug efficacy data is kept confidential? Why is there a big difference here?

20 MS.NICKERSON: Well as I said, it has to do with the fact that it's not merely the claim, but also the product that is proprietary.

DR. BURDOCK: Well, could you also explain how manufacturing data can be kept confidential, for food?

5 DR. TARANTINO: Yeah, I don't think anyone is suggesting you might not be able to keep the efficacy data confidential.

What happens is then if there is a claim authorized on the basis of that, how do you keep the claim from being able to be used by whomever can use the claim?

10 DR. BURDOCK: Oh, why no piggybacking. Well, the idea is that everybody that makes a claim must submit his own efficacy data, unless he can, like a drug, buy into somebody else's master file.

MR. LANDA: Just one more question.

15 Why, the drug regime provides for what you're describing here, including market exclusivity for those folks who choose not to duplicate clinical trials if they want a full NDA or less than that if they want an abbreviated application. We don't have that kind of scheme in this statute for foods.

20 DR. BURDOCK: There's something -- there's, well getting back to what Laura doesn't believe in the congruent argument or congruent example here, that I believe if you have the power to keep manufacturing

data confidential, then you have the power to keep efficacy data confidential.

5 It's just -- well, do you require efficacy data -- if I have a new texturizer or something that makes potato chips crunchy and I ask this to go into a food master file and I can sell my ingredient as make your chips crunchy; and Frito-Lay says try our new Crunchos, all right, because the chips are more crunchy. The efficacy of that texturizer or that crunchiness stuff is in my food master file, so then how can Frito-Lay say these are crunchier chips because of cruncho and still allow that texturizer or 10 crunchy stuff be in a food master file? Why don't somebody else come along and say that?

DR. TARANTINO: But someone else who, I mean -- and it really isn't a good argument because you don't have the First Amendment 15 factor, but presumably if you used your texturizer to get a food additive regulation, that food additive regulation is not exclusive to you now, admittedly.

20 Somebody might either be able to get or not get all of the specific manufacturing data so that they would know how to make your crunchy texturizer, but that's sort of another issue. The regulation we would issue would still be a generic regulation and anyone who can make the texturizer that fits the regulation would be able to use it.

DR. BURDOCK: Sure, and they would submit their own data.

DR TARANTINO: No, not --

5 DR. BURDOCK: If they're claiming a technical effect.

DR. TARANTINO : Not if the regulation, if they met the  
regulation, but we're probably getting off the subject.

10 DR. BURDOCK: Okay, I can respond to you when I revise and  
extend my remarks for the file submission.

MR. LANDA: Thank you.

15 DR. BURDOCK: Thank you.

(Applause)

MR. LANDA: Our next speaker is Michael Ruggio with the  
American Association for Health Freedom, Alliance for Natural Health.

20 MR. RUGGIO: I want to thank you for allowing us to comment  
on the proposals.

I'm outside general counsel for the American Association for Health Freedom and its European associate, the Alliance for Natural Health.

5 These organizations represent the interests of substantial emerging innovative functional food and dietary supplement sectors, including a large number of practitioners and consumers.

10 The present blurring caused by the lack of adequate definition and clarity of scope of conventional foods, dietary supplements, functional foods and drugs is creating increasing legal uncertainty that compromises informed consumer choice and creates unnecessary risk to business operators and lack of clarity for regulatory enforcers, as well.

15 The functional food and dietary supplement industries have been, have seen rapid growth in recent years alongside scientific research which is increasingly demonstrating the pivotal role of nutrients and other dietary and natural components in disease risk reduction and the management and promotion of good health.

20 A new legislative framework for functional foods is urgently required which reduces legal uncertainty and caters for changes in the way in which scientific evidence is appraised. Accordingly, food companies can commercialize scientific findings borne out of emerging science and consumers can benefit without unnecessary delays.

The Association and the Alliance uphold that functional foods should be regarded as a subcategory of conventional foods and thereby

utilize all relevant aspects of food law, except in conditions where health claims are made. We propose that there should be two distinct levels of health claims, one involving structure/function claims that utilize the same framework presently used under DSHEA for dietary supplements, the second being more specific authorized by a relevant scientific body and involving a higher degree of scientific substantiation which would be categorized according to a three-tier world health organization system, conclusive, probable or possible.

The former structure/function claim category would require 30 days premarket notification while the second authorized health claims category would require 120 days premarket notification. Authorizations would be agreed by consumers, by a task force comprised of Government, industry, consumer and academic representatives affiliated with a recognized appropriate scientific body, the National Academy of Sciences, et cetera.

Critical to the evaluation of health claims is the consideration of the totality of the evidence. This should emphasize human studies but should not give undue weight to specific randomized control trials which may be less scientifically relevant than observational or epidemiological studies.

Functional foods provide a delivery system for functional ingredients within a food matrix and may potentially provide one of the most important tools in health management programs given their food

base. They also are very well suited to health prevention as they can be used regularly by consumers without specific advice from health professionals. We strongly support the development of Government-sponsored research programs to facilitate new research.

5                   Owing to the gray area that exists between functional foods with label claims and licensed drugs, also with distinct medicinal label claims, it is important to develop a regulatory framework that reduces legal uncertainty for functional food companies so that they are able to work using clearly delineated criteria to avoiding FDA drug classification of  
10                   their products.

                  And I'd last like to leave you with two questions, one is back in the pre-1994, people were suffering harm and there was a reason, there was a cause for a need for a change with respect to dietary supplements, et cetera. But I don't think there's any evidence that's been developed or  
15                   promoted or produced, any data which shows that people are suffering harm from functional foods and I think that is a significant issue that needs to be dealt with and responded to.

                  If there is such data, I'd like to see it and if it's being developed, I'd like to know about it, but there is none as far as I know or my  
20                   organizations know.

                  The other thing I'd like to leave as a question is there is going to be a significant disproportionate impact if we go forward with what's being suggested here because large companies can do fairly well under

extensive FDA regulations as we all know, but it's the smaller groups, the smaller companies that are going to be disproportionately affected and damaged as a result of trying to comply with a number of FDA stuff that will come out of this and I think if we look at some of the groups behind pushing this initiative, they're substantial corporations, they're substantial groups which have a history of dealing with FDA regulation and I think we have to look at that in the context of what does it mean for the groups that cannot survive under that kind of huge weight.

And thank you for taking the time to listen to me.

(Applause)

MR. LANDA: We may have some questions for you.

MS. NICKERSON: Under your two-tier system, what would be the standard of evidence for the structure/function claims?

You said that that would be lower than the three health claim type claims which are conclusive, probable or possible, so are you envisioning something below possible for structure/function claims?

MR. RUGGIO: No, I don't think I am.

If that answers your question, I don't think I am.

MS. NICKERSON: Good.

MS. NICKERSON: I'm sorry, what would be the --

5 MR. RUGGIO: No, I don't think there would be anything below  
that.

I actually think there would be an evolution, there would have to  
be a group to study what would it be and what would be the level.

10 DR. ELLWOOD: Could you elaborate what you mean by task  
force that you have comprised here with various representatives, that it  
would be affiliated with an Academy of Sciences or you have NIH?

15 MR. RUGGIO: Right, I think there would need to be a scientific  
body which would be representative from various groups, so that it would  
be basically a balanced group to be able to be advisory with respect to  
where we're going to go on this thing.

20 DR. ELLWOOD: Okay, so you're not suggesting that the  
Academy would put together this group?

MR. RUGGIO: No, I'm not, definitely not recommending that,  
no.

MR. LANDA: I just have one question about the health claims, you've got this three-tier system, conclusive, probable or possible.

5 Would you anticipate that a label claim would signal to consumers the degree of scientific support, that is, conclusive, probable or possible?

MR. RUGGIO: I think it would, it may be difficult to do that. I think it would be difficult to try and define maybe what category falls into and how do you define it and what's the extent of the definition and providing to get that out to the public, I think that might be a difficult practicality.

10 That, I don't know. Again, another area that needs to be worked on and resolved.

15 MR. LANDA: Thank you.

DR. SCHNEEMAN: I notice in your written comments you, you use the word a new legislative framework for functional foods and I just wanted to clarify if you felt that there is, in fact, needed changes in the statute or if you think the legal authority is in the current statute for what you are proposing?

20 MR. RUGGIO: I think the legal authority is already there.

Thank you very much. I appreciate it.

MR. LANDA: Thank you.

(Applause)

5

MR. LANDA: Our next speaker is Patricia Verduin with GMA and FPA.

DR. VERDUIN: Thank you, Mike. And good afternoon.

10 GMA/FPA appreciate the opportunity to testify on this important topic.

In past years we have submitted numerous comments to the FDA focusing on legal and regulatory policy issues that are the subject of today's hearing.

15 All conventional foods and beverages are functional, have functional ingredients and can bear applicable and substantiated claims, including health claims and structure and function claims. And the food industry have a shared responsibility for the safety of food, food ingredients and substantiation of claims.

20 Our members are committed to meeting those responsibilities and we are willing to further explore this area with the Agency.

GMA/FPA believes that consumers are best served by robust enforcement of existing provisions governing the safety of ingredients and the substantiation of claims. We are confident that consumers of so-

named functional foods are aware that they are, indeed, foods and not dietary supplements or drugs.

5           Regarding the need for regulatory definition of functional foods for ingredient safety and claims, we believe that the current statutory and regulatory frameworks provide the necessary requirements and guidance to address all foods. We see no need to regulate some foods versus others in a separate and distinct regulatory approach, specifically with vigorous enforcement of current regulations, consumers can be better protected regarding the safety of food and beverage ingredients and the  
10           substantiation of claims on labels.

          Regarding the safety of food ingredients, we strongly support statutory and regulatory provisions currently in place to ensure that foods and their ingredients are safe for their intended use. We recognize that ingredients used in the formulation of any food, including those that bear  
15           claims, must be approved food additives or generally recognized as safe for the intended use. These legal provisions are strong and they have operated over many decades to ensure the U.S. food supply is safe. Safety substantiation is one of the most important responsibilities of the food industry and one that we take very seriously.

20           Given the well equipped existing system to ensure safety, separate safety provisions for functional ingredients are not justified regarding notification of ingredient safety. GMA/FPA believes that there is no need for a company producing ingredients already fully subject to the

protections of the food additive and GRAS provisions of the food law to notify FDA prior to marketing these ingredients. Novel food ingredients, many botanical substances and other dietary substances are no different from other food ingredients regarding the information to establish safety for any intended use. We recognize that a voluntary notification system already exists at the FDA for GRAS use of ingredients. Many companies use this opportunity to acknowledge the thorough analysis of ingredient safety conducted. Others may not.

Nonetheless, a thorough safety analysis is performed. Should the FDA wish to review that analysis, they retain the authority to challenge the company's conclusion and review its basis.

Regarding limited structure/function claims to those based on nutritive value, we note that existing laws permit all foods to make functional claims; thus, all foods must be able to express the full breadth of these claims. Any claim used in labeling is required by law to be truthful, not misleading and substantiated. We believe that the claims that are substantiated and supported by competent and reliable evidence used to form a reasonable basis for that claim should not be restricted to a narrow and arbitrarily defined subset of foods.

Well substantiated claims about food's functional benefits play an important role in promoting public health by encouraging dietary patterns that support health and wellness and reduce the risk of certain

diseases. This applies to both FDA and FTC regulatory oversight for labels.

Regarding premarket notification or disclaimer requirements for claims, we believe that there is no legal basis to subject truthful  
5 structure/function claims of foods to any mandatory premarket notification or any disclaimer statement. Manufacturers must simply ensure that such claims are substantiated.

In summary, functional foods are conventional foods. FDA has the authority to enforce legal prohibitions against false and misleading  
10 claims, including unsubstantiated claims and FTC for advertising. Robust enforcement rather than new regulation will continue to ensure the integrity of conventional foods with functional benefits. GMA/FPA will submit written comments to the FDA, accompanied by relevant past comments.

15 Notably we will share our guidance for making structure/function claims for food with you. In addition, we are evaluating ideas as a result of rich discussions among our members along with the content of today's meeting to include in our written comments to you.

(Applause)

20 MR. LANDA: Questions?

DR. SCHNEEMAN: Hate to have you go away with no question whatsoever.

DR. VERDUIN: All right.

5

DR. SCHNEEMAN: You mentioned that consumers perceive these categories of foods as foods, not as dietary supplements or some other category and I'm just wondering do you have consumer data on that?

10

DR. VERDUIN: I don't, I'm not 100 percent sure if we have hard data. I know that there's some talk about developing that, so let's, let's talk with the Agency among that, because that would be a very useful piece of information for you I'm sure.

15

MR. LANDA: I have one question.

Have you given any thought to a notification system for other than structure/function claims, like for qualified health claims, which is, we've heard is a suggestion today?

20

DR. VERDUIN: Our members have talked about it and we are thinking through different alternatives relative to all, you know, qualified as well as structure/function claims and we'll be providing those.

MR. LANDA: Thank you.

DR. VERDUIN: Great.

5 MR. LANDA: Our next speaker is Annette Dickinson who is a  
consultant.

DR. DICKINSON: I appear today on my own behalf as a  
nutrition and regulatory affairs professional with a long history of interest  
10 in issues relating to the formulation and labeling of foods and dietary  
supplements marketed on the basis of health benefits.

In my written comments I have addressed some of the questions  
FDA raised in the notice of this meeting and I will be providing additional  
information to the docket.

15 However, as though we didn't have enough issues to talk about,  
I'd like to use my time today to raise another issue that I think is critical.  
Consumers need to be provided with material information about the  
identity and quantity of functional ingredients in all functional foods or  
other conventional foods in order to permit meaningful comparison among  
20 products.

I, therefore, urge FDA to require functional foods to include  
information on the identity and quantity of functional ingredients or  
components in the Nutrition Facts box or in an extension of the box that

would appear below it. Nutrition labeling for dietary supplements requires the supplement facts box to list the quantitative amount per serving of every dietary supplement ingredient in the product with the partial exception for proprietary blends.

5                    In contrast, nutrition labeling for conventional foods requires the statement of quantitative amounts per serving only for macronutrients. Vitamins and minerals appear only as a percent of the daily value and other functional ingredients are excluded by regulation from the Nutrition Facts box, although they may be mentioned and quantified elsewhere on  
10                    the label.

                    I believe it would better serve consumers if the name and quantity of any food ingredient that is the subject of a functional claim were listed in the Nutrition Facts box or in an extension of that box, a practice now being adopted voluntarily by some companies. This would  
15                    allow consumers to compare various functional foods as well as dietary supplements in terms of the amount of a specific ingredient or component that it contains. And I believe FDA has authority to require such labeling.

                    NLEA specifies the nutrients to be included in nutrition labeling for conventional foods, but it also gives FDA the authority to expand the  
20                    list of nutrients or other components to be included. FDA should exercise this authority to require fully informative labeling for foods making functional claims. A couple of examples will illustrate the problem faced by consumers in the current marketplace.

Energy beverages as we all know and have discussed have become enormously popular and consumers are using them sometimes without full awareness of the identity and quantity of their functional ingredients.

5 Red Bull, for example, one of the most common of these products, has a very limited Nutrition Facts panel, as specified actually in current regulations. That does not provide quantitative information on the amount of other functional ingredients in the product. More informative labels are provided by Arizona Tea and by Glasgo vitamin water on their  
10 energy formulas, which also bear the Nutrition Facts panel, but provide additional information in an extension that appears below the usual Facts box. I believe this additional information is important to consumers and should be required, not prohibited, as is done under current labeling regulations.

15 A second example relates to foods containing omega-3 fatty acids. One brand of eggs in the market where I shop highlights the fact that each egg contains 225 milligrams of omega-3 fatty acids. One brand of canned Red Sockeye Salmon, in the same store, highlights the fact that each serving provides over 700 milligrams per serving of omega-3 fatty  
20 acids. Neither label provides this information in the Nutrition Facts box and neither specifies which omega-3 fatty acids it contains.

Consumers may easily conclude that the two products provide similar benefits, but in fact the eggs provide only ALA while the salmon

provides EPA and DHA, which are more strongly related to health benefits for the heart.

I believe more specific information is material to consumers and should be provided regarding the omega- 3 fatty acids in these products and the logical place for that information is in the Nutrition Facts box.

Thank you very much for your time.

(Applause)

DR. TARANTINO: Your notion that it's the functional ingredients that need to be declared on the label, does that imply that we do need a regime to define what functional ingredients are or are you suggesting that any ingredients for which a producer makes a claim are the ingredients that need to be labeled?

DR. DICKINSON: I've given that a good deal of thought, but I think for the, I think the practical response is that it would be tied to the claim being made.

MR. LANDA: What happens if an express claim isn't made, or no claim is made, but an ingredient over time becomes associated with a certain functional effect?

DR. DICKINSON: I think there's precedent for that in previous  
FDA rules.

5 For example, at a time before nutrition labeling was mandatory,  
it was mandatory only if a nutrition claim was made, which meant that  
some products had it and some products didn't, which isn't perhaps ideal  
but I think that's, that's the kind of system we have.

MR. LANDA: Any other questions?

Thank you.

10

DR. DICKINSON: Thank you.

MR. LANDA: Our next speaker and the last one before the  
break will be Wes Siegner from Hyman, Phelps and McNamara.

15

MR. SIEGNER: How do I get to my presentation here? Exit.  
We're making progress.

MR. LANDA: It should be up there.

20

MR. SIEGNER: Okay. Thank you. Very good.

I'll leave you a tip.

I have extra copies of everything that I have, plus some other things if people are interested at the break. I'll carry them with me and you can get them during the break.

5 One of my colleagues read through my presentation and said, Wes, you're only making one point, and I said well, I only have five minutes.

So, I have confidence that in five minutes I can make one point. Two points might take ten, so be careful about what questions you ask me.

10 Basically I'm here on behalf of clients of our firm, not all clients of our firm, but some clients who make both foods and dietary supplements and generally I'd like to agree with FDA, which is maybe an unusual thing for me, but I think certainly in terms of food safety, I don't see functional foods however we define them or whether we define them, I don't think we need to define them more than what we've done, regulatory  
15 or statutorily.

Safety is assured through the food additive provisions of the law and the GRAS exemption to the food additive definition and just to point out one factor here, it is, everything here is geared into intended use, so if you have an ingredient that you want to add to a food, say, that would  
20 have an effect on cholesterol, theoretically, at least FDA could require that you have GRAS, sufficient public data to establish GRAS status for that ingredient for that use. So there are, there are aspects of the law here that I

think allow FDA to address any new or novel safety issues that might arise.

And likewise, with the labeling provisions, the, any claims that industry would like to make regarding functional foods need to have adequate substantiation. That derives from the existing provisions for labeling. The claims need to be -- cannot be false or misleading and I believe that the current regulations as interpreted by *Nutrilab*, and that's where the but comes in in my initial heading, as interpreted by *Nutrilab*, are adequate to both permit industry to make the, a wide range of functional food claims and also to allow FDA to make, to require that those claims be substantiated.

Now I just, the one point I want to make here in this presentation is to make sure that everybody gets out of here with an understanding of what was said in *Nutrilab* and I noticed several other people have talked about this, but I wanted people to be able to read it and see what the quote is from which this whole idea of limiting functional foods to functional – structure/function claims for foods to paced enrollment or nutritive value.

And this is what the Court said. When the statute defines food as articles used for food, it means that the statutory definition of food includes articles used by people in the ordinary way most people use food, primarily for taste, aroma or nutritive value.

Now the District Court had held that that was all that food was about, but the Court of Appeals, and this is a quote from the Court of

Appeals, said to hold as did the District Court that articles used as food are articles used solely for taste, aroma or nutritive value is unduly restrictive since such products, some products such as coffee or prune juice are undoubtedly food but may be consumed on occasion for reasons other than taste, aroma or nutritive value.

Now I just, Bruce Silverglade pointed out this morning that, and he pointed to this word primarily and I think maybe that's what FDA's focusing on, but I think that the exemption here or whatever, however you call this, I mean people who consume prune juice probably aren't primarily consuming it for taste, aroma or nutritive value and I'm not sure whether prune juice acts physically or chemically or both, I think maybe I used to teach biology, but my knowledge doesn't go that far, I have to be honest.

But the concepts here with prune juice and coffee I think are, if interpreted the appropriate way in accord with the IFT recommendation that structure/function claims for foods are really just as broad under the law as structure/function claims for dietary supplements. They derive from a different statutory provision, but they're really parallel.

I mean people consume coffee. Yes, you like the aroma of coffee, but let's be honest, you know, most people drink caffeine -- coffee for caffeine and the aroma is attractive because it makes you feel awake because you know you're going to get the stimulation.

Now, I just wanted to contrast what we just read about *Nutrilab v. Schweiker* from the actual Court to focus on what the FDA has said about *Nutrilab v. Schweiker*. Most recently in this Federal Register Notice for this meeting and notice that the FDA derives the interpretation of nutritive value as being restricted to taste, aroma and nutritive value from that same -- or structure/function claims deriving from, for food as deriving from taste, aroma or nutritive value from that same Court case but they don't read it to include the second sentence of the actual quote from the case.

And then further just to illustrate this point, and I'll admit that FDA and I see things in a little different light, but nutritive value, they view this as kind of a broad definition that encompasses lots of claims. But the problem I see with this definition, which is their definition from the health claim provision, is that you could read this maybe to include caffeine or under providing energy, but I don't think that's what they're getting at. I think they're getting at calories and so what they're really saying is you can't make a structure/function claim for a food unless it derives -- well nothing really derives in terms of structure/function from taste or aroma, so it's nutritive value.

I don't know what that means really particularly, but my point again is that the law, if read correctly and as interpreted correctly by *Nutrilab*, is that the same types of structure/function claims are legal for foods and functional foods as they are for dietary supplements. It's not

restricted to nutritive value. It can be also applied in the area of physical effects and physiological effects.

5 So, just my, my recommendation or conclusion is that FDA needs to abandon its current interpretation of *Nutrilab*. Leave everything else the same and allow a broad range of structure/function claims for foods.

10 The question then arises well how do you separate foods from drugs? Well, it's separated in the law according to the intended use. As long as you're not making drug claims, meaning claims to treat, cure, prevent or mitigate disease, you're not a drug. If you're making claims for food, even if they are structure/function claims, you're still a food.

Thank you.

(Applause)

15 MR. LANDA: Any questions?

MR. SIEGNER: I just had one point, they were afraid to ask the question. I'll have to make another point.

20 DR. SCHNEEMAN: Perhaps it would help clarify for me in terms of the comments of your sense that FDA is, has a limited interpretation, do you have examples that would illustrate the point that you're making?

MR. SIEGNER: Well, actually, in terms of how nutritive value limits the types of claims people can make for foods; is that, Barbara, is that what you're getting at?

5

DR. SCHNEEMAN: Right.

MR. SIEGNER: Actually, I've seen this more in the sense of the animal food area almost than in the human food area, but there is, I don't know, just one example that pops into mind on the animal food side is there are products, pH controlled products marketed for cats to help control urinary or bladder infections and that is viewed and tolerated at FDA as a discretionary drug claim whereas it is simply a pH of the food that's supplied, I view that as a structure/function claim for foods, although it's, you know, it clearly also gets into the health claim area.

10

15

But, I'm trying to think in terms of human food, I guess you could, if you're talking about effects of omega-6 fatty acids and prostaglandins and some of the functional effects in the body that prostaglandins have, I'm not sure that that derives from the nutrition provided by omega-6 fatty acids. I would think that FDA might say that that's not a permitted structure/function claim because it doesn't derive from taste, aroma or nutritive value.

20

I can't really come up with any really good examples.

Thanks.

MR. LANDA: Thank you. I'm sorry.

5 MS. NICKERSON: One more.

With regard to the Agency's reading of the *Nutrilab* case, you say  
that we read out the second sentence in the Court of Appeals opinion, but  
I'm not sure reading out that sentence is the only way to get to the  
interpretation of the case that claims need to be related to taste, aroma or  
10 nutritive value.

For example, I think one could argue that if you start to promote  
a product for a non-food related use, in other words, you know, even with  
coffee or prune juice, those are not marketed, that I've seen anyway, with  
claims on coffee, you know, keeps you awake or prune juice, you know,  
15 keeps you regular.

Have you considered the interpretation that perhaps if you start  
promoting products that would otherwise be foods for this use, they  
change what they are primarily consumed for and therefore you fall out of  
what the Court of Appeals delineated as what -- how to stay within the  
20 food category?

MR. SIEGNER: Well, I don't, I don't, I mean there, a  
structure/function claim I think pre-DSHEA used to mean something else

and I have to commend FDA in the final rule for dietary supplements in being pretty open about the breadth of structure/function claims. So, you know, I think I know what a structure/function claim is and I think that, you know, claims like supports the immune system or the laxative type claims that FDA has allowed in that, in the context of dietary supplements are accepted as structure/function claims and if you, in my view legally companies can currently make the same claims for foods, it's just that they're reluctant to do so because the food industry generally speaking tends to be more conservative than the supplement industry. A lot of people think that's probably a good thing.

But I don't really see a reason why companies could not make, food companies could not make the same structure/function claims for foods right now that they, that are permitted for supplements.

I don't think that, that doesn't take you into the drug area, it's just the only explanation I have for that on the food side in terms of the restriction is that FDA is saying you can't do that because it doesn't derive from nutritive value and I don't see, you know, I don't, I think *Nutrilab v. Schweiker* clearly recognized that foods have other effects and if that's true, how can you read *Nutrilab* and say it can't make claims about those effects.

MS. NICKERSON: Well, I was just wondering how you could reconcile that view with the Court's language about what the product is

consumed primarily for. You know, if you start to promote a product for a certain use, aren't you changing what the primary reason for consumption is? But, anyway, we don't need to get into a debate about it.

5 MR. SIEGNER: Okay, later.

(Applause).

MR. LANDA: Why don't we take a break until 5 after 3 and we'll resume then.

10 Thank you.

(Short recess taken)

MR. LANDA: If folks would please take their seats, please, thank you.

15 Our next speaker is Ilene Ringel Heller who is a senior staff attorney with the Center for Science and Public Interest. Ilene.

MS. HELLER: Okay, thanks, Mike, and good afternoon.

20 I'm going to be making three points this afternoon. First, GRAE review panels are unnecessary and unlawful, economic incentives are not needed and there's a need for great enforcement.

It's unlawful and unnecessary for companies to establish GRAE review panels to make recommendations to FDA that become law if FDA

does not respond in 90 days. Although functional foods is a common term in industry and the press, existing provisions in the Food, Drug and Cosmetic Act address the regulation of such products.

5 It's clear that Congress wanted FDA to have sole approval authority for claims with one limited exception. FDAMA, under FDAMA, FDA can only consider authoritative statements from a Government Agency with scientific expertise as support for a proposed claim. The proposed claim will become lawful if FDA does not act within 120 days, but FDA has to decide whether the statement is, in fact, 10 authoritative and whether the significant scientific agreement standard is satisfied.

And if FDA would like to consider outside opinions under the Advisory Committee Act, there are procedures for establishing advisory committees that make sure that there are no conflicts of interest and that 15 everything is out in the open for the public to see.

Okay, turning now to economic incentives, I don't know why industry is complaining so much about the need for incentive. Sales are up, they're up more than 24.3 billion. I understand that figure has even risen since 2004 without economic incentives.

20 Whoops, wrong way.

Most of the products tend to be on the energy products, although we're also seeing a lot of candy products. The beverages account for 20 percent, including soda, water, sports and energy drinks.

There have also been a number of technological advances. If you go into any store, you'll see a lot of products with omega-3 fatty acids in them ranging from eggs, as Annette said, to bread and this is the result of the fact that there are 17 companies that have come up with formulations of fish oil that doesn't taste bad, so the technology is there.

And Congress did not want exclusivity. Under the Act petitions need to be filed by individuals for food additives, health claims and nutrient content claims, but anyone can use the authorized claims and ingredients. And the market is full of products with health claims, nutrient content claims and structure/function claims.

Where we feel that there needs to be some additional effort is in the area of enforcement. Now FDA has recently been cracking down on ads on the Web. We did see, there was one effort where in one fell swoop there were letters sent to 29 cherry juice companies that made claims about treating or preventing cancer, heart disease or arthritis. But they haven't done as well when it comes to actually going into the plants or looking at labels in the abstract.

Our search of their Website found only five letters in the last few years. This CocoaVia label was one of them. CocoaVia claims to help reduce bad cholesterol and promote a healthy heart. FDA sent out a warning letter complaining on three grounds. First, the product is adulterated.

Folate cannot be added to candy. There are only a limited number of products that folate can be added to because FDA is afraid of consumers getting too much folate. FDA also said that Mars could not make healthy heart claims because it has too much artery clogging saturated fat in its product. And finally it said that claims to reduce bad cholesterol are illegal drug claims.

Well, Mars sent a response to FDA which FDA is now reviewing, but meanwhile Mars and others who have received such letters are still marketing their products. I guess a warning letter is just an invitation to be a pen pal with FDA.

Two problems arise from the lack of enforcement. One of them is illegal nutrient content claims for ingredients. We're particularly seeing this with ingredient claims for product -- for ingredients that are the subject of qualified health claims, such as green tea and omega-3 fatty acid. We believe that FDA has got to authorize health claims and nutrient content claims in tandem.

We're also seeing a lot of products that are taking advantage of the medical, medical foods loop hole. Medical foods are exempt from the NLEA requirements and are not subject to regulatory framework to ensure that they are safe and effective for their recommended uses. These foods aren't intended to be sold to the general public. They're not supposed to be available for mail order. They're intended to be used in nursing homes,

hospitals or by outpatients under the continuing and active supervision of a physician.

Look at Glucerna, I bought this in Giant. It is all over the place. It is supposed to be used for diabetics. Yes, it says on the side use under medical physician -- use under medical supervision, but there is no guarantee that consumers will consult a physician.

So, what needs to be done? We think that the approach to enforcement needs to be changed.

Each District needs to have a designated functional food inspector. That inspector needs to go into the supermarkets, look at the Web, go to the plants. FDA needs to do more than just issuing warning letters, it should bring enforcement actions that will have a deterrent effect on false and misleading claims for unlawful ingredients.

What we're seeing right now is FDA goes into a plant, it's part of a safety inspection. The inspection operations manual says that inspectors are only allowed to look at three labels and they are not allowed to conduct critical reviews unless they have specific authorization to do so. This is no way to crack down on foods.

Thank you.

MR. LANDA: Any questions?

DR. ELLWOOD: Are you suggesting then that FDA should have a definition for functional food?

5 MS. HELLER: No, what I'm suggesting is products that we all know are functional foods should get a heightened regulatory scrutiny. You can do it with all the tools that you have. Prenotification certainly would be helpful for structure/function claims and for ingredients that haven't been used for the physiological properties in foods before.

10 But, otherwise, you know, everything can be as it is, except that the nature of the inspection and the enforcement needs to change. You need to get out into the supermarkets and you need to actually go for labeling inspections, not just as, you know, an after the thought because you're in the plant anyway looking at safety.

15 MR. LANDA: I have a question about the advisory committees. You're quite right, of course, that we're allowed at least under certain circumstances if we get the appropriate permissions to create advisory committees, but I think the suggestions that we heard this morning were not that FDA create the advisory committee, but that industry would create expert committees on its own just as it now does for GRAS substances.

20 I presume that you don't think there's anything unlawful about that?

MS. HELLER: No, they can -- the part that I did think was unlawful is FDA was given a period of 90 days whether to accept or reject that. I mean they can't even do that for FDAMA, let alone an industry group.

5

MR. LANDA: Thank you.

Any other questions?

DR. ELLWOOD: Could you expand a little on FDA authorizing both health and nutrient content claims in tandem if, perhaps, the substance is not a nutrient --

10

MS. HELLER: Well --

DR. ELLWOOD: -- and it wouldn't fit our nutrient content definition?

15

MS. HELLER: It could be an issue, yes.

20

MR. LANDA: Thank you.

MS. HELLER: Thank you.

MR. LANDA: Our next speaker is Kimberly Caldeira with the Center for Substance Abuse Research.

5 MS. CALDEIRA: I just wanted to kind of turn -- but I guess I'll just leave it up.

Good afternoon, everyone, I'm with the Center for Substance Abuse Research at the University of Maryland, so not a, not a far trip for me today.

10 My comments are somewhat different from the other comments we've been getting a lot of today. We're going, I'm going to be focusing just on energy drinks and specifically the research or lack thereof regarding the effect and possible health consequences of energy drinks.

15 Okay. So energy drinks, of course, as we all know are designed to deliver a rapid burst of energy with high doses of sugar, caffeine and other stimulants such as ephedrine and guarana.

They have grown increasingly popular in recent years among adolescents and young adults, however surprisingly little is known about how these beverages are used and their possible adverse consequences.

20 Our research team at the Center for Substance Abuse Research is conducting a large longitudinal perspective study of college students and young adults entitled the college life study and it's funded by NIDA.

Preliminary data from our study has shown already that 1 in 5 college students have used energy drinks in the year prior to being

surveyed and perhaps more surprisingly that use of energy drinks was associated with higher levels of alcohol consumption, higher levels of illicit drug involvement and non-medical use of prescription drugs.

5 I will just say as a sidebar that we didn't set out in this study, it wasn't one of our, one of our primary aims at all to study energy drinks or energy drinks consumption and so it, it's very interesting to find in a study of substance abuse that there is this strong, well let me not say strong, but this significant correlation.

10 There have been limited other studies in the literature which have observed that energy drinks have been associated with lowered subjective alcohol intoxication, meaning that people, you know, are using energy drinks while they're consuming alcohol and the, it has the effect of making them feel less drunk, even though the objective effects of intoxication are still present.

15 And as others have mentioned today, concomitant use of alcohol and energy drinks is becoming more common, so despite the preliminary nature of these findings, they do point to a need we feel for more research around energy drink consumption, particularly among college students.

20 There's also a lack of data we feel regarding the possible physical consequences of energy drink consumption given what is already known about the health effects of caffeine and sugar sweetened beverages. More research on how energy drink consumption is a contributor to weight gain we believe is warranted.

Given their apparent popularity, the ways in which energy drinks are being used have important public health implications. We strongly believe that consumer trends around energy drinks need to be closely monitored through systematic research and surveillance using standard methodologies similar to those already in place to monitor use of alcohol and other drugs.

A clear understanding of the reasons why young people use energy drinks, the context in which they are used as well as the potential for adverse health effects, if any, will provide the foundation of knowledge needed to inform sound policies regarding the possible regulation of energy drinks.

Thank you.

(Applause)

DR. SCHNEEMAN: Thank you very much.

You've indicated that your results are preliminary at this point and so I think it would be helpful for us to know what the long-term plans are for your research and when do you anticipate the study would be finalized?

MS. CALDEIRA: Well we are in the process of, well we've submitted a research letter for a publication of these particular results. It's only a research letter, so it is, it's somewhat brief and it's not clear at this

stage how far we're going to go with the, with the energy drink issue in our study, given that it wasn't one of the main aims.

5 I can't say when the letter would be published, when the research letter might be published, but we were prompted to, prompted to submit it with the, by the announcement of this meeting.

10 DR. SCHNEEMAN: But the overall collection of data for the study has been done, you're just merely in an analytical phase at this point?

MS. CALDEIRA: Oh, okay, let me say a little more about the study.

15 We've been collecting data, it's a longitudinal prospective study, so we're actually following the cohort for several years and we're continuing to collect data now. We are funded to, funded to collect data through the end of 2007, basically, and we began collecting data on the cohort in 2004.

20 DR. ROBIE: In your survey have you asked any follow-up questions about energy drink consumption along the lines of what the consumers would be consuming if they weren't consuming energy drinks, what they are substituting, would it be water or milk, I mean are they substituting -- not milk for alcohol consumption?

MS. CALDEIRA: Oh, you mean if they weren't, if they weren't consuming energy drinks?

5 DR. ROBIE: Are they consuming these in addition to their regular diet or did they used to consume other drinks or is it the question that you've addressed with them?

10 MS. CALDEIRA: We haven't asked anything approximating substitution or choices. We really just asked them what forms of caffeine they consumed and that was, you know, energy drinks, they were invited to name as many products as they, as they could, you know, as they use. So it's not in context of other dietary habits at all.

Thank you. Is that all?

15

MR. LANDA: Thank you.

MS. CALDEIRA: Okay.

20

MR. LANDA: Our next speaker is Bhimu Patil who is with Texas A&M University.

DR. PATIL: Good afternoon, my name is Bhimu Patil. I'm coming from Texas A&M University. I'm happy to see some of the academicians here, three or four at least.

5 I thank the FDA for organizing this open forum. To complete the definition of open forum, I'd request the organizers to see whether they can distribute the PowerPoint presentation of this morning's session to all of the audience also, that's one of my request, if you can distribute the, what do you call, contents to the public.

10 The second question I have is are we sure that we know the definition of functional food? As we are talking and have been discussing in several forum, all foods are functional foods. Is there a need of the word functional food?

If we're not re-defining or properly defining the functional word, otherwise just take it off, if all foods are functional foods.

15 That was the first question I have. To the panel as regards to the other people involved in this, the second, of course I'm not really presenting it, I'm basically giving some of these thoughts from the academicians and what we feel is important.

20 The second thing we need to consider before any of these rules are finalized by the FDA or any other Agency, we need to understand better, as you heard from the previous speaker, the synergistic effects of this whole food. For example, if you take a functional component, it may behave as different things in different products. Sometimes, for example,

if you tried to increase calcium in all the functional food we drink or eat, what happens to the toxic effects. We know enough about the toxic effects of some of this by active compounds. We know about calcium, but what about the new functional components we have been doing research.

5 So we need to put a limit or we need to do more research on toxic limits of this.

The big question we have as a food industry is we need to understand when the FDA release a drug, I don't, I don't think this belongs to this panel, but I think we have to learn how to communicate within the  
10 FDA organization, when they release a drug, for example, Lipitor, they need to make sure that any drug they release should not interact with the food we eat or drink, because right now just an example of grapefruit drug interaction, right now as we speak, the grapefruit industry is hurting bad or the juice industry is hurting bad, but if you really think about the science  
15 behind it, some of the enzymes involved are effecting all the food we have been talking today.

Some of the functional components are effecting the enzyme which are causing the metabolism to some of the 60 percent of the drug on the market. So before the FDA approves any medical drugs, they should  
20 check whether it interacts with a food we eat or drink, we do every day.

The, when I talked about the definition, we need to reconsider or think about whether we are trying to use this functional food as health promotion or health maintaining properties because that's, I don't know

whether we are really promoting health. Maybe we are trying to maintain the health.

So we need to reconsider that point into our consideration.

5 There are other questions which I think I cannot elaborate in the four questions I have, but I think the other question is how are they categorized as additives, this particular functional food.

10 Will the amount of functional food or the quantity of the functional component will be regulated, as I mentioned earlier, before we learn about the toxic levels of some of these compounds, we need to maintain -- consider the relation, okay what is the maximum we can go for a product.

15 As you heard, even Vitamin C is becoming pro-oxidant sometimes. We've been talking about Vitamin C is good, but sometimes Vitamin C is becoming pro-oxidant in some cases. We need to be aware of that.

20 And the last question I have is we need to instead of using the industry money to fund this kind of research and in terms of more research, maybe all the industry should give the money or some ways to find the mechanisms to FDA or any other Agency to provide that money to --

(Laughter)

MR. LANDA: We want to hear more.

DR. PATIL: Of course I don't oppose it, but we need to make sure that we, the clinical research particularly on the scientific evidence is if you really looked at the findings from the clinical research and all the money you might need for the clinical research, that's very small they are spending.

On the amount of money that they are spending, I'm not saying that the research is bad, but when you take that message to the consumer, they don't trust it. Because when I say if I'm working on grapefruit, who is, what funding agency. If we say Grapefruit Growers Association, they say that research is not good.

So, if the company wants to make a scientific evidence proof concept, proved the concept based evidence, we should make a central Agency, not necessarily FDA, where the money could go and unbiasedly of distributing the money for the clinical research.

With that, I will take the questions.

MR. LANDA: I have one question for you, how would you define functional food?

MR. PATIL: I agree with the definition but I think we, what I feel is it's a definition borrowed from Japan and Canada, we are using it here.

So, we should have a panel like this and kind of discuss a lot of other aspects of the functional food and particularly we're still under the concern that all foods are functional. If it is the case, why you need to add functional there.

5

MR. LANDA: Thank you.

Our next speaker is Anthony Young with the American Herbal Products Association.

10

MR. YOUNG: Thank you, thank you, Michael.

I'm Tony Young, I'm the general counsel of the American Herbal Products Association. Our association represents manufacturers and suppliers of botanical ingredients, many of whom supply ingredients to the food and of course the dietary supplement industry.

15

Functional foods have been around for a long time. I think we agreed generally with FDA that all foods are functional. Some foods are more functional than others, but some of the great successes of functional foods, electrolyte replacements, et cetera, have occurred in the last 40 years and these all occurred under the present system of law.

20

The use of his -- of functional foods historically has varied, but it probably all fits within the IFT definition. Our view is that present law is adequate for these types of foods. The food additive amendments with GRAS self-affirmation and GRAS notification adequately address safety.

Label claims must be truthful and not misleading and not fail to reveal material information and that adequately addresses structure/function claims that might be made for such products. And if you go to the next level to a health claim, you have to clear it through FDA or notify the FDA if based on an authoritative determination and the Courts have taken care of qualified health claims so as there is now a system there if you can't reach the high standard that the law sets for health claims.

GRAS substances in food was discussed I think at length this morning. It is a system along with the food additive amendments that have worked for a long, long time, I think almost 50 years now. GRAS notifications must list the foods for which the ingredient is intended. There's 43 categories. You describe and list the proposed amounts and many food ingredients are not GRAS for all purposes.

General recognition of safety is a well-established concept here and it can certainly be applied to novel food ingredients.

GRAS self-affirmation is probably the first step before someone puts a new ingredient in food and then important risk averse food manufacturers may well not accept GRAS self-affirmation and FDA has set up a system whereby one can go to the Agency and get their ticket punched before they put something into food and that system has worked extraordinarily well.

There have been about 213 notifications, roughly 75 percent  
FDA has no question. It is a good, scientific dialogue between the  
ingredient proponent and the Agency and it seems to work well and we  
would expect that it would continue to work well as one evolves into  
perhaps more limited use ingredients.

Novel ingredients are often not intended to be added to a wide  
variety of foods, but we think and I think this was spelled out a bit in the  
CSPI petition, that limitations can be put in -- on various ingredients based  
on the intended use and whether or not there has to be any labeling that  
adequately explains how they are to be used.

And so novel ingredient reviews should probably be based on  
specific limitations of use, adults only, consumed more than a certain  
amount per day and it will require more labeling, perhaps cautions or  
warnings. And I know FDA has an aversion to cautions or warnings on  
food labels, but we do have a more educated society these days.

So, failure to carry all the material information as Annette  
Dickinson said earlier is something that can be addressed in the labeling of  
novel ingredients and in the safety review itself.

This morning I think FDA pointed out and others have pointed  
out that a touchstone here is Section 201(n) of the law. It allows FDA a  
substantial amount of power by which to determine what is necessary for  
labeling to be truthful and not misleading.

So, we recommend no functional food category. The GRAS affirmation, and ingredient notification process works well and they should work well here. Section 201(n) can be used to require any kind of labeling that might be necessary for limited food use.

5 Novel ingredients, and it's up to the manufacturer in the first instance to label their product properly and to assure that it's not false or misleading and that it does not fail to disclose material facts and for those who want a little bit more certainty, FDA could establish a voluntary food claims notification process that parallels the GRAS ingredient notification  
10 process for those who want the assurance of an FDA review.

And then we also think caffeine added to food ought to be labeled. There's a big beverage concern here. We've heard it. Caffeine is a medicinal ingredient. AHPA has made a recommendation to its own members through its code of ethics and business conduct that the amount  
15 of caffeine, if above 25 milligrams per serving, be declared on the labels of dietary supplements. AHPA recommends that labeling of added caffeine above 25 milligrams per serving in packaged form food. You can't read that Website, these Websites too well, but one of them describes caffeine amounts in beverages, the other describes the health effects of  
20 caffeine.

Medline Plus, which comes out of Bethesda there, somewhere, says it is recommended that pregnant woman consume less than 300

milligrams caffeine per day. Well how do we know that if we don't know how much caffeine is in a product?

Section 201(n), material information for moms, FDA knows how to use that provision, why not, why not require added caffeine to be  
5 labeled on food products?

In conclusion, current law, it's working. Doesn't seem to be broken. I think we would recommend more enforcement in every area that CFSAN regulates as well as other parts of the Agency and that FDA initiate rulemaking to require the amount of caffeine added to food be  
10 labeled.

Thank you very much.

MR. LANDA: Any questions?

15 MS. NICKERSON: Your statement that FDA has an aversion to warnings and caution statements was interesting. Do you base that on anything specific?

20 MR. YOUNG: My partners have told me that and I think I only see a couple of, of such cautions on foods, on food ingredients. I think Aspartame is one and I think there may be one other, I don't recall what it is. Protein -- I can't recall what it is. Protein -- yes.

MS. NICKERSON: Psyllium.

MR. YOUNG: Yes, yes.

5 DR. TARANTINO: Earlier there was a lot of discussion of various proposals for notification process for claims. You're talking about a voluntary food claims notification process.

What does that mean? I presume, are you talking about structure/function claims, okay?

10 MR. YOUNG: Yes, the claims that aren't presently covered by the existing system for either health claims or qualified health claims.

MR. LANDA: What do you mean by novel ingredient?

15 MR. YOUNG: Novel ingredients I would say are new ingredients that haven't been used in the food supply before, the kinds of ingredients I think that we're seeing in the GRAS notifications now, but perhaps some that have more functional effect. We have a lot of functional effect ingredients.

20 The number of fish oils is astounding, but there's a lot of fish out there, and they are, you know, there's not functional in the manufacturing process of food. They don't hold it together or make it crispy, they

actually make it healthier, so it's those kinds of ingredients that may be coming up from time to time.

There may be ingredients out there that have been in food for a long time that we'll find new meaning for as research goes on.

5

MS. NICKERSON: When you say in the food supply, do you mean just conventional foods or would the food supply be considered to include dietary supplements?

10

MR. YOUNG: Conventional foods. Conventional foods. I think anyone who wants to bring a dietary ingredient into a food has to go through the process that's outlined in the law in terms of either GRAS, GRAS notification or food additive approval. That's what the law requires.

15

DR. SCHNEEMAN: Just to clarify, I take from your comments that a lot of what you're encouraging us to do when we asked the question of where's the legal authority, you looked to the false and misleading section and that you feel there's probably more legal authority there than we're using, is that --

20

MR. YOUNG: Well certainly with respect to the potential for labeling because of the need for material information on, on labels.

The point Annette Dickinson made about products being marketed on the basis of the presence of a certain ingredient and yet if it's in food form, that ingredient, unless it's a nutrient, it's up in that, up in the supplement -- or the Nutrition Facts panel, we don't know how much it is and for our members it means they won't use so much. They'll just use the name.

Thank you.

(Applause)

MR. LANDA: Our next speaker is Stephen Shapiro with Ullman, Shapiro and Ullman.

MR. SHAPIRO: Hi, my name is Stephen Shapiro and I am a partner in the New York law firm of Ullman, Shapiro and Ullman.

I'm here today speaking on behalf of Hanson Natural Corporation of Corona, California.

Hanson develops, markets and sells various foods in beverage form as well as energy dietary supplements in liquid form.

Hanson believes that there is not, not a current need for regulatory definition for the term functional food, or for a new regulatory approach to evaluate the safety of ingredients. Hanson believes that the current regulatory scheme is more than adequate for this task.

If, however, the Agency decides to create a definition for functional foods and an accompanying regulatory scheme, it should be done with one purpose in mind, to find a way to allow companies to continue to better educate consumers about the benefits of the foods and the ingredients in those foods that they consume.

Hanson would object to any changes in the law or regulations with an objective of limiting the amount of information that could be provided to consumers.

Certainly in large part the reason that we are here today is that we all recognize the public's increasing demand for functional foods which we take to mean foods that in themselves or through added ingredients have a health promoting and/or disease preventing property beyond the basic function of supplying nutrients essential for life.

The public has recognized the benefits of dietary supplements and is now searching out every day foods that offer similar health benefits and well-known health benefit ingredients.

By and large these so-called functional foods primarily include common herbs including green tea, caffeine and caffeine sources and essential fatty or amino acids, all well-known ingredients with long histories of safe use and consumption.

As to any question concerning the safety of functional food ingredients, Hanson respectfully submits that current regulatory requirements applicable to conventional food ingredients, namely, food

additive in the general recognition of safety standards are more than adequate as are requirements for new dietary ingredient notifications that apply to dietary supplement products.

5 If any so-called functional food were to contain an unsafe ingredient, the FDA has more than sufficient authority to declare the product adulterated and to take enforcement action.

Among other things, a food is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health.

10 As to allowing claims for these so-called functional foods, Hanson is strongly in favor of allowing the public to receive what it clearly wants and what is in its best interest to have, more information, not less, on food products and health benefiting ingredients that they contain. There is, therefore, no rational argument to be made for restricting the ability of companies to provide consumers with truthful, non-misleading, 15 substantiated information about food products and ingredients including information about common well-known historical usage. Indeed, the principals of commercial free speech demand this.

20 For this reason, Hanson would strongly support expanding the current requirement of nutritive value for conventional food structure/function claims to include claims for the provision of physical or physiological effects that have been scientifically documented or for which a substantial body of science exists.

Here, too, the FDA has more than ample authority to regulate products and to take strong enforcement action against any misbranded food defined in part as a food where its labeling is false or misleading in any particular.

5                   In addition, the Federal Trade Commission has ample authority to take enforcement action against companies that advertise foods with false, misleading and/or unsubstantiated claims.

10                   Hanson would not, Hanson would also not oppose a requirement that notifications to the FDA for the use of structure/function claims for conventional foods be required as is currently the case for dietary supplements.

15                   Finally Hanson is concerned that this hearing may be sought to be used by some as an attempt to have the Agency promulgate regulations that will restrict the sale of functional foods or will negatively effect the sale and marketing of dietary supplements that resemble conventional foods.

                  The Federal Register Notification for this meeting stated that for the purpose of this hearing we are not considering dietary supplements to be encompassed by the term functional foods.

20                   Dietary supplements have their own detailed regulatory framework prescribed by Congress from the Dietary Supplement Health and Education Act of 1994, which I'll refer to as DSHEA.

DSHEA permits dietary supplements to be similar to conventional foods in composition and form so long as the products are identified as dietary supplements, there are Supplements Facts tables when required and are not represented for use in a conventional food use as the sole item of a meal or diet.

There are beverages such as sodas that are conventional foods that may quench the thirst and have no other purpose and there are products that are correctly labeled as dietary supplements whose purpose is not to quench thirst but are intended to provide other benefits such as providing energy by delivering dietary supplements in a convenient liquid form.

Clearly one of the purposes in DSHEA in permitting dietary supplements to outwardly resemble conventional foods was so that we would not have the arbitrary distinctions that existed before DSHEA.

It would defy logic, for example, to draw a distinction between an energy dietary supplement in powder form to be added to 16 ounces of water and a product correctly labeled as a dietary supplement but subject to a different classification and regulatory scheme merely because it is sold in the constituted form in a 16 ounce bottle with the water or other liquid already added.

Along these lines it is illogical that under the current regulatory schemes for foods and dietary supplements that the Agency's focus is

frequently on arbitrary distinctions, sometimes based on a single word on a product label, whether a product is a food or a dietary supplement.

There's nothing to suggest any real safety concern with functional foods, at least none that we are aware of.

5 Hanson submits that the FDA should be focusing its attention and limited resources on how it can create a means for companies to best be able to communicate valuable, truthful, non-misleading and substantiated health information on all products, both foods and dietary supplements to consumers, valuable information the consumers want and  
10 should be entitled to.

Thank you.

(Applause)

MR. LANDA: Any questions? I have one.

15 You indicated that Hanson would not oppose a requirement that notifications to FDA for structure/function claims for conventional foods be required.

Do you think the Agency now has the authority to require such notifications?

20

MR. SHAPIRO: I'm not certain.

MR. LANDA: Thank you.

Thank you. Our next speaker is Dennis Gordon from North Dakota State University.

DR. GORDON: Thank you. I'm professor emeritus, I'm retired.

5 Is the slide showing? We must, we do move in different circles. In my entire career, I've never heard so much about prune juice. Now I'm waiting for you to give me a structure/function claim, because I'd really like to hear it.

10 On November 13th I was given an invitation to come here and to listen to comments –

MR. LANDA: The mic --

MR. GORDON: I don't need the mic.

15 On November 14th, I submitted my application and then I offered to make comments. My colleague, Jim Kopp, agreed and these are our joint comments.

20 We have three purposes, really. The food industry has a marketing bonanza. They would like to reference and highlight functional foods. The consumer is interested in learning more about nutrition, but we as professionals need to protect our interests. And finally, the goalkeeper in all of this is the FDA, the Food and Drug Administration. Yes, safety, and then provide this information on the food label.

I read this Federal Register in preparing my comments and the big issue is what, definitions. And we're in, we're in the gray area there. The way I understand it, the FDA has a definition of foods, but they do not have a definition of conventional foods; and to me, the two terms are synonymous.

In that broad area of foods or conventional foods is something called functional foods, better for our health. There is a problem with nutritive value. I think the nutritive value needs to be separated when we're talking about a functional food ingredient, and I'll get to that in a minute.

The summary here is that foods, conventional foods and functional foods are synonymous. They all have nutritive value. Nutritive value is the 41 essential nutrients.

There is no definition, nor do I think there's a -- necessary to have a definition of functional foods at this time. It's premature. This works well for whether it's marketing, advertising or for us as professionals to talk about it. What's the real benefit of functional foods? It's teaching people to eat a variety of foods, much bigger than they do now.

What you need to do or we need to do is separate functional foods from the bioactive ingredients they contain. An example, what's healthy, what's the healthy aspect. It is whole grain or is it the dietary

fiber in the whole grain that's the active ingredient. Is it the whole food or the dietary fiber?

And in that regards, I think we don't need to define functional foods, but we need to come to grips with something called a bioactive substance. Now sometimes some people have called it ingredient. I've heard today novel ingredient, and then I get -- an explanation was asked of that, it's not there. I think it's in my next slide. I would suggest a term nutraceutical or I'm getting ahead of myself a minute, or a functional food ingredient.

There are two ways now that the food industry can promote and market functional foods. You have the ability to make quantitative statements. This product on a panel could say contains 10 to the 8 colony-forming units lactobacillus per serving, or if you had leutein, it contains 500 micrograms. That alone is one indication that it may be a food different within the category of conventional foods.

Along with that, if you have the data, provide a structure/function claim, promotes eye health, promotes a healthy intestine.

Oh, here's my nutraceutical. There are approximately 10,000 compounds in food that we are trying to investigate as having functional food properties, better for one's health, outside the 41 essential nutrients. They are not essential nutrients and until such time as any one is shown to be essential, and I think there are a couple that should be considered, they

are just either novel ingredients, functional food ingredients, nutraceuticals and that's the way they should be labeled.

If you isolate a functional food ingredient and you add it such as the big ones today are what, phenolics, if you add it to your food, then you should be, have to put added in the statement, such as added.

And then the last slide I have is that if you, if you have a functional food and you need to declare a nutraceutical ingredient, fine, you have a qualified statement. If you have data, you can make a structure/function claim. But if you extract something and you add it back, then you better prove to the consumer and to the FDA that that ingredient extracted is safe. There's a procedure in place, GRAS notification.

The other thing I'd suggest is do some homework, what's a tolerable upper limit. And then secondly, I do endorse in a broad sense the IFT's recommendation generally recognizes efficacious panels. I don't think we should overburden the FDA or the industry of having all kind of pre and post notification, but you as an industry responsible to investigate -- to organize your own panel to say, to have the data on hand that this product is efficacious as we claim on our structure/function claim.

And then finally, there needs to be better, better communications with the FDA.

Thank you.

(Applause)

MR. LANDA: Any questions?

5 DR. SCHNEEMAN: Dennis, in terms of your comments here on  
the GRAE panels, it sounds like you were suggesting this is something  
that the industry could use as a way of making some determination rather  
than something that is just for the FDA to use. Did I --

10 DR. GORDON: No, exactly right. My recommendations would  
be before an industry decides they're going to do a structure/function  
claim, they are their own panel, do a little better job than they're doing  
now. You know yourself, there's a margin between a testimonial, sort of  
marginal data, fair data, good data and I'm avoiding health claims or  
qualified, I'm just talking about functional foods.

15 It should be industry's responsibility to be prudent in what they  
say on the label and they should use that panel to their advantage. That's  
all I would suggest.

You're too burdened now, in my opinion, you, the FDA.

Yes.

20 DR. NALUBOLA: I have a question about the slide where you  
talked about added lutein. In terms of FDA's regulation of safety or

labeling of these products, are you trying to make a distinction between added versus naturally found?

5 DR. GORDON: No, the question has to do with added or naturally occurring. If you have a product with lutein and you'd like to promote it because of its lutein content, say, for, I didn't -- for a health reason dealing with the eye, but you don't have that information, but you have a product with lutein, I think it's a qualitative statement should allow you to say we contain lutein, we have lutein.

10 Now if you want to have some research to make the structure/function claim, then you have the other bullet to promote your product. So you have something in place now to promote a functional food.

Is that, did that answer your question?

15

MR. LANDA: Anything else?

Thank you.

DR. GORDON: Thank you.

20

(Applause)

MR. LANDA: Our next speaker is Evan Richards with Rejuvenative.

MR. RICHARDS: Hi, I'm Evan Richards, founder and CEO of Rejuvenative Foods. We are makers of 11 flavors of raw cultured vegetables. And the ideas I'm about to present are in conjunction with the presumed goal of getting consumers to be healthier when they eat functional foods.

So this makes me concerned that when people eat functional foods, they are not consuming ingredients that have a potential for a detrimental health effect.

So, to give you background on my perspective, I'll mention that since 1980 I've been supplying raw cultured vegetables, including raw sauerkraut and kimchi and it's easy to see that raw cultured vegetables epitomize the concept of functional foods in conjunction with a few key facts that have inspired me about 10 years ago to put my money where my mouth is rather than make health claims, so that all 11 flavors of our raw cultured vegetables led consumers -- it states on the labels that consumers can request their money back if they don't feel better or healthier after eating the raw cultured vegetables.

And I do this, the few facts that inspired me to give this money-back guarantee or all the kinds of healing practitioners and consumers and including MDs that have raved about the fact that they feel better and healthier after eating raw cultured vegetables and furthermore, that raw cultured vegetables, since they have not been heated and are a fresh, live

food that have naturally present enzymes and lactobacillus and other micro flora that are in there, that are there naturally occurring in the raw cultured vegetables and so these have a parallel.

5 Raw cultured vegetables parallel the human digestive tract when they are culturing. Since the naturally present lactobacillus that's in culture, that's in the vegetables before they're cultured are converting sugars and starches into lactic and acetic acids, that's the sugars and starches in the vegetables are being converted into lactic and acetic acids and this is a similar process to what the human digestive tract does.

10 So that raw cultured vegetables as they are being created, stored, eaten and swallowed are performing and supporting functional metabolic humanistic processes.

15 So with this said, it's easy to say that raw cultured vegetables epitomize functional food concepts. So even though this is all true, I've never marketed raw cultured vegetables as a functional food because it didn't seem appropriate to align raw cultured vegetables with the unhealthy ingredients that may be common in other functional foods.

20 So, I'm taking this opportunity to inspire a functional food definition guidelines to preclude foods that may have functional food additives. When these foods also contain less healthful ingredients such as *trans* fats like New York City recently outlawed.

In other words, if a consumer is led to believe a food is a functional food and good for them, then the food should not contain

certain ingredients that for most humans could be considered detrimental or not good.

Now I can see this idea as being wrought with potential problems and concerns and I can also see that the nature of reality may let some  
5 arguably unhealthful ingredients be in functional foods. I still think a good-faith stab at protecting consumers from foods called functional with really unhealthy ingredients such as *trans* fat is in order and creates a more appropriate and healthful to consumers' outcome.

As a method to accomplish this, it's my recommendation that you  
10 all create a scientific panel or task force to make a list on a spreadsheet that lists categories and additives in foods that may not be healthful and then from there decide what to do and see if a happy medium might be found which might simply be a very short list of prohibited ingredients in functional foods.

15 And another point is please consider how raw cultured vegetables as a food type will fit into functional food definitions in conjunction with them being a synergistic living food without additives at least to the extent that they would not be precluded but instead seen as a shining star of functional foods.

20 (Applause)

MR. LANDA: Any questions?

DR. SCHNEEMAN: I take it from your question of, just if I could clarify that, it sounds like you're suggesting that if something is marketed in this functional food because it has a certain type of claim on it, that perhaps there should be disqualifiers then and that the Agency should develop disqualifiers for when a food, and are you thinking, are you thinking of health claims or structure and function claims?

Have you thought of particular types of claims that might -- you're suggesting we should have these disqualifiers for?

MR. RICHARDS: I wasn't thinking of it in those terms as much as just thinking about if someone's going to eat *trans* fats, they would not want to be thinking they're eating a functional food, so I wasn't putting it in the terms you were. I was just seeing it as I want people to be aware if they are eating a functional food it doesn't have any really bad ingredients in it.

MR. LANDA: Anything else?

Okay.

Our next and I think final speaker is Mary Hager with the American Dietetic Association.

MS. HAGER: Good afternoon.

No, I'm not on your list, I'm one of those that showed up and said I wanted to talk. And looking at the time, I promise I won't keep you by saying anything provocative that the panel will question me about.

5 I'm Mary Hager, I'm senior manager for the American, for Regulatory Affairs for the American Dietetic Association.

The ADA represents approximately 65,000 food and nutrition professionals serving the public through the promotion of optimal nutrition, health and well-being. I'm pleased to have this opportunity to share ADA's comments about functional foods.

10 The ADA has developed principals for food product labeling, I will mention those briefly, and then we've also published position papers on functional foods and on fortification and nutritional supplements and those papers are available to the public on our Website, which is [www.eatright.org](http://www.eatright.org), O-R-G, so if you do want to see those papers, you can.

15 Now back to our labeling principals, which this is what it all boils down to, is what we're telling consumers about what's in the foods. ADA believes that label claims should be clear and understandable to consumers and some recent research suggests that that might not be the case. We also do believe that the label must be truthful and not  
20 misleading.

We believe that the content on the label should help consumers make informed decisions to build a healthy diet. Also the label content should have consistent type and format so products can be read, and as

you get older you'll understand why. And consumers can make, you know, good product comparisons.

5 All claims should include labeling of accurate, quantitative information about the dietary substance, and this is again now if we're going to make a claim, we're going to have how much of that substance is in the product and if it's appropriate, the percent of daily values in a single serving, when known, or the daily dietary intake necessary to achieve the claimed effect.

10 Consumer research is imperative before making any changes to the labels and of course this was brought up earlier today, what do the consumers think.

15 And then lastly, the label is only a source of information and thus sustained support for educational programs and individual counseling, when appropriate, by registered dietitians is very important, particularly if we are working with people who have specific disease or conditions.

20 ADA relies on an evaluation of the science in taking position on an issue such as this one, so in 2005, we had a peer reviewed evidence-based analysis which found that functional foods, including whole foods and fortified, enriched or enhanced foods have a potentially beneficial effect on health when consumed as part of a varied diet on a regular basis at effective levels.

The Association supports research to define further the health benefits and risks of individual functional foods and their physiologically active components.

5 Now there are tenets that summarize this position and I'm going to read these tenets bullet by bullet. It won't take too long.

But ADA classifies all foods as functional at some physiological level. You've heard this before from other speakers today.

The term functional food should not be used to imply that there are good foods and bad foods.

10 Next point under current regulations, functional foods or components can be placed into a number of existing regulatory categories, including conventional foods, food additives, dietary supplements, medical foods or foods for special dietary uses.

15 The category used to define a specific functional food or components depends on how the manufacturer selectively positions and markets the product for its intended use and the specific label claim associated with the food items.

The ADA supports the use of pre-authorized claims on food products, including functional foods as required by NLEA.

20 The ADA believes that health and nutrient content claims authorized for foods and dietary supplements should be based on the totality of the publicly-available scientific evidence, including results from well-designed studies conducted in a manner that is consistent with

generally-recognized scientific procedures and principles. Therefore, it should not be preliminary, nor should it be speculative.

ADA believes that structure/function claims on foods as well as dietary supplements without prior FDA authorization as allowed by DSHEA has created a legal loophole by which some companies may choose to market functional foods as dietary supplements.

Therefore, the scientific underpinning of those claims is often limited, at best, and potentially disputable.

ADA recommends cautious evaluation of clinical efficacy of individual products and dietary supplements before recommending their use to promote a specific health outcome.

ADA supports efforts for consistency in functional food labeling and strongly recommends an evaluation of the body of available scientific evidence prior to the development of consumer diet health messages.

ADA recommends that all foods and dietary supplements, including functional foods, be regulated to ensure that the products are safe, that the products have been manufactured using recognized good manufacturing practices and that all label claims, whether they're health, nutrient content or structure/function are truthful, not misleading and are based on significant scientific agreement.

And last point, current and functional, future functional foods should be labeled with specific information regarding any ingredient and whether that's a nutrient, a phytochemical, a zoochemical or a botanical

used to market the product as well as the specific amount available in an average serving.

Recent studies have shown that consumers cannot distinguish between health claims and structure/function claims. Therefore, to address the ambiguities and complexities regarding the labeling of functional foods, ADA recommends no functional food category.

Functional foods might be considered any food that is defined as a food or ingredient, including dietary supplements, with a health claim.

Second, ADA recommends that all health and structure/function claims require premarketing notification.

And ADA recommends that there's a broader interpretation of the term nutritive, because sometimes there's no clear distinction between what is nutritive and what's health promoting.

For example, a nutrient deficiency disease such as rickets, beriberi or scurvy can be considered a chronic condition if adequate levels of essential nutrients are not regularly consumed. So, consuming that nutrient is health promoting for that individual or those groups of people in other parts of the world.

Similarly, other naturally occurring food components said to be health promoting are in essence nutritive, though they don't make the list. When they are consumed in amounts typically found in the diet, they're still nutrients. And any additional health promoting effects from consuming novel food-based ingredients or nutrients at levels considered

above both naturally occurring are effects that prevent signs and symptoms of any kind of diseases are potentially marketable for specific health claims. But, they still should trigger the quantitative amount of whatever that ingredient is.

5                   And lastly, all foods and dietary substances should be evaluated as foods with uniform rules and regulations for claims requiring safety evaluations, premarketing approval and sound scientific evidence in support of the claim.

10                   We recommend FDA consider these points in exercising its authority and formulating a cogent, coherent, consistent national policy on functional foods so consumers can understand and use it in the context of the myriad of food and dietary options available in today's market.

Thank you.

(Applause)

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MR. LANDA: Any questions?

MS. HAGER: No?

20

MS. NICKERSON: Do you have any thoughts on what would be the legal basis for FDA to require the significant scientific agreement standard for structure/function claims as well as for health claims?

MS. HAGER: Currently existing? No.

MR. LANDA: Straightforward.

5 MS. HAGER: Yeah, we're thinking of an ideal world, you  
know.

10 DR. TARANTINO: When you talked about quantitative labeling  
of functional ingredients, were you talking about the same kind of  
approach that Annette did, that is, if you make a claim --

MS. HAGER: Yes.

15 DR. TARANTINO: -- then you need to put it on the label?

MS. HAGER: Yes, and then we would consider that it might be  
most helpful for consumers to understand what the amount is per serving,  
something like Annette said.

Thank you.

20 MR. LANDA: Thank you. Well, this concludes our Part 15  
hearing today.

I remind you that the docket remains open until January 5 and encourage folks to submit comments and to respond to the questions posed in the notice.

Thank you for attending and participating and we'll see you next time.

(Hearing adjourned.)

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