Capital Reporting Company

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FDA PUBLIC HEARING SEPTEMBER 11, 2007

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FDA Hearing Day 2.txt
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                    MICHAEL LANDA: It's 9:00, if we could
      please take our seats, we could get started.
                    But before we get started today, if
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      there is anyone in the audience who needs the
      services of a sign language interpreter, would you please raise_your hand.
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                    Thank you.
We're going to begin today by continuing
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      with panels on the U.S. experience.
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                                                  Our speakers
      today are, or this morning, I should say, for the
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      first panel this morning are Ann Marie Krautheim
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      from the National Dairy Council, Cinthya Harriman
      from Oldways Whole Grain Council, Jan Ritter from Columbus Children's Hospital and David Katz, M.D.
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                    I begin by asking Ann Marie Krautheim to
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      start.
               Thank you.
                    ANN MARIE KRAUTHEIM: Good morning.
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      name's Ann Marie Krautheim, I'm a senior vice
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      president for nutrition affairs for the National
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      Dairy Council
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                    In 1915, American's dairy farmers
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      founded National Dairy Council as an investment to
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      look at how nutrition or \operatorname{\mathsf{--}} how dairy products and
      learn more about dairy products and their role in nutrition and health in the American diet.
                    For almost a century the men and women
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      milking dairy cows here in the United States have
      invested nutrition research and education to help
      educate Americans about the role of dairy in a
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      heal thy diet.
     I'd like to commend the Food and Drug
Administration for holding this hearing and looking
at this important issue of utilizing nutrition
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      symbols on pack as a way to educate and communicate
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      about nutrition information to the consumer.
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                    And I'd like to extend a thank you to
      the FDA as well for the opportunity to share
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      insights that we have learned through the
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      implementation of the three a day of dairy program
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      which includes a logo.
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                    After the presentations yesterday, what
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      I thought I'd do today is focus on four key areas
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      that I believe are unique and distinct for the three
      a day of dairy program compared to most of the
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      approaches that were presented yesterday and share
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      learnings from those elements that will be
      applicable to the discussion today.
     First and foremost, three a day of dairy is a program with a logo. It's not a logo alone. The logo is one component of a multi-faceted
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approach to help educate the American public about

a day which is consistent with the dietary

the importance of consuming three servings of dairy

FDA Hearing Day 2.txt This program involves elements such as 12 the one you see in front of you which is an 13 educational ad that we ran both in health professional journals as well as consumer publications, but it's complimented by a collaboration with brands and industry who utilize 14 15 16 17 the logo on pack, utilize the information and messaging in marketing and advertising materials and 18 in addition to that it involves health professional 19 20 organizations and patient education tools, in addition to grants that are given to State Level 21 22 organizations to implement nutrition education 0007 program in the local communities. 2 So again, the logo is a part of the It's a symbol, it's a, it's an icon, but 3 program. the program is much broader in nature. We also developed this program to 6 7 address the public health issue of a deficit. think a lot of the programs yesterday focused on 8 9 elements that consumers are getting in excess, which is a very important component in education with nutrition. This program, however, was intended to help people to recognize and understand and 10 11 ultimately change behavior to close the gap between 12 current dietary recommendations for three servings a 13 14 day of dairy versus what's actually consumed. 15 Our consumer research shows that Americans believe they're getting enough calcium and dairy in their diet when, in fact, Anne Heins data, we know that only about half of the recommended three servings of dairy daily are being consumed.

So we felt that this program would 16 17 18 19 20 provide a call to action to the American public and 21 integrate that with industry, brand and health 22 8000 1 professional efforts to bring this call to action to life and achieve a behavior change. 2 3 4 5 Another piece or element of this program that is unique and distinct is that it is implemented and it's really overseen and approved by the United States Department of Agriculture. As 6 7 part of the dairy check-off program, our programs are required to be reviewed and approved by USDA. 8 ŏ In addition to that, the three a day of dairy program has, has benefitted from really solid partnerships from leading health professional 10 11 organizations and on the slide in front of you what 12 we wanted to show here is that the program, the bottom tier shows the different public health and nutrition policies, whether they're through Government organizations or health professional 13 14 15 16 17 organizations that recommend three daily servings of 18 dairy, including from the far left the National 19 Medical Association report on the role of dairy in 20 the diets of African-Americans, the Surgeon General report on osteoporosis and bone health.
I know you'll recognize the next two, 21 0009 the dietary guidelines and My Pyramid, as well as two recent statements from the American Academy of Pediatrics, one on the role of calcium and bone-building nutrients and developing strong bones Page 3

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among children and then the other on lactose intolerance.

So all of those reports and/or policy documents do support the recommendations that we carry forth through the three a day program. And then we've partnered with, since 2003, the American Dietetic Association, the American Academy of Pediatrics, the National Medical Association, the American Academy of Family Physicians and most recently the National Hispanic Medical Association has signed on in support of the program and its messages.

And what does this mean that we're partnering with these organizations? They have agreed to work with us in the development of the program, to help maintain the integrity of the program and then collaborate with us to develop tools to help educate the public, whether it be in

the marketing environments or communications environment or directly through the health professional directly to the patient.

professional directly to the patient.

It's been a very positive relationship and this is the area of the program that I work most closely with and we have a representative from each of these organizations that sits on an advisory panel that provides counsel, guidance and we have a lot of very good discussions in ways to enhance the program and make it stronger.

These organizations then also help to take this message out to their members and help their members to put this message into practice in their environments with their patients and the public. So it's been, you know, a really critical piece.

We've also worked with WebMD. I know yesterday that was some -- there was some discussions about the importance of Web communications and Websites. On WebMD health and nutrition is the most frequently searched topic and they, they have the top, you know, Website for

health and nutrition information, so our collaboration with them has been very critical in helping to reach the public with health and nutrition messages related to this program. And then we also are working with the National Institute of Child Health and Development as it correlates with their milk matters campaign and we have a lot of consistencies and similar goals that we're working to maximize and coordinate as well.

Last, but not least, the fourth element that's somewhat different than those that were presented yesterday is the message. It's simple, it's easy to understand and it was developed through consumer research and also complimented with some of the knowledge we've gained from EUFIC over the years that consumers are really looking for context in terms of health and nutrition messages. They want to know how much, how often and what's in it for me. What's the health benefit and that's what drove the development of this program.

We tell them they need three servings, Page 4

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22 three times a day for bone-building benefits and 0012

we've found that moms, and I'll share a little bit more about that with you in a few minutes, have really appreciated this message, they understand it and they utilize it and it's making an impact.

So ultimately the three a day program is

So ultimately the three a day program is innovative in its approach and we actually were recognized through the American Dietetic Association recently in 2006 as a recipient of the Anita Owen award for innovation in nutrition education and in 2004 received the President's Circle award for nutrition education from the American Dietetic Association.

And it's really about, again, helping Americans focusing on the dairy group, but bringing those dietary guidelines to life and putting forth a call to action to the American public so that they know how many servings they need and how often and provide the motivation for them to do so.

Here's some specific reasons that the program we believe is working. It's now more, on more than 2.7 billion packages in the marketplace. It's been embraced by more than 70 retailers across

the country and this is really a critical component for the program.

At National Dairy Council, we do not own a product, we do not manufacture a product and we do not sell a product, so we needed to work in collaboration with brands and with industries to help them understand that this is an important message and how to utilize the program and really help them to be motivated to invest their dollars to help make the program come to life through their brands and their execution.

In addition to that, through consumer research we know that in 2003 only one out of five moms knew that they should be getting three servings of dairy daily. This was before the program launched. In 2004, that program had doubled where 44 percent of moms could state that they knew they needed three servings of dairy daily and by 2006, this was up to 52 percent of moms recognizing that they need three servings of dairy in their diet daily.

In addition to that, they, moms who are

aware of the logo, we talked to moms who said yes, I know that logo, I've seen that logo and other moms who were not familiar with the logo to try to gauge differences in knowledge among those two groups.

And what we found is that from moms who were familiar with the logo, they obviously were aware, more aware of the need for three, they had a higher intent to consume three themselves and to help their family consume three servings. They also were more likely to want to get their nutrients from food as opposed to supplements and they also could recognize the nutrients in dairy beyond calcium, they could name other nutrients in addition to calcium that are in milk and milk products and they

could associate dairy with its bone-building

6 benefits.

moms did tell us that they believed that an on pack logo such as the three a day logo is a good reminder for them. It's a daily reminder to them about the need for themselves and the need for their family to consume three servings of dairy daily.

I think the real test of effectiveness of this program, and I'm sure you would agree, is what is this doing to consumer behavior, are they actually consuming more dairy.

And we are waiting anxiously for the next round of the Anne Heins data to be released to help assess that. The 2004 data is available, however the campaign was launched in 2003 and that data is really too close to make a difference -- or to see a change, a significant change, so we're anticipating with the next round of Anne Heins data that we'll be able to better track that and gauge that

However, we do at this time have sales data and that's the best indicator of the effectiveness of this program. And we have seen since the launch of the program an increase in low fat and non-fat milk sales. While there's been a decline in whole milk sales or full fat milk sales, overall there's been a net increase in overall milk sales. We've also seen an increase in yogurt sales. The majority of the yogurt in the marketplace is low

fat and fat free and those yogurt sales are continuing to grow steadily.

And in addition to that, we're seeing growth in the cheese category and interestingly the low fat and non-fat cheeses are growing at a rate of sales three times the rate of traditional regular fat cheeses and in fact in 2007, in the natural cheese category, low fat or lower fat cheeses are the driver of sales in the cheese category in 2007.

So based on the sales figures and the

So based on the sales figures and the attitudes and awareness and intent to purchase, it's our belief that the program is making a difference and we'll be able to validate that further with the next round of Anne Hines data that's released.

Overall while the program seems to be working, our work is not done. We still have more room to help the public to not only recognize their need but working collaboratively with industry to help make sure that dairy products, milk and milk products are available in the form that consumers want them, in the places that consumers want them and ultimately helping consumers to have that

product and fulfill their demand for the dairy products that they want and need.

You also had asked about the criteria for the logo so I wanted to spend a few moments on that. The criteria, this logo may only be used on milk, cheese or yogurt. They need to provide an excellent source of calcium, specifically 20 percent of the DV for calcium. We do require, and which is consistent with FDA regulations, that if products

FDA Hearing Day 2.txt 10 exceed levels for total fat, saturated fat, 11 cholesterol or sodium, that a disclosure statement 12 be depicted in proximity to the logo that refers the 13 consumer to the nutrition facts panel for more information on the specific nutrient or nutrients 14 15 that may be relevant. The log -- low fat logo is available for 16 17 manufacturers to use and in all of our marketing and 18 communication tools and health professional outreach 19 and education, we do place emphasis on low fat, fat free varieties of dairy. And in addition to that, 20 three a day of dairy recipes have been developed 21 22 that also have set criteria limiting the amount of 0018 fats, total fats and sodium in those recipes. 2 3 So ultimately our challenge and our goal is to help consumers to meet their dietary guideline 4 recommendations for three servings of dairy daily. 5 With the concerns about overweight and 6 obesity in the U.S., we feel that it's very 7 important that consumers get the most nutrition they can for their calories. We need to maximize the can for their calories. We need to maximize the choices that they're making to make sure that they're not only, you know, minimizing nutrients that are of concern, the fats, the sugars, the 8 9 10 11 sodium, et cetera, but at the same time not 12 13 overlooking the fact that we have an undernourished 14 population at the same time and we need to provide education to remind people about what builds a good dietary pattern and which foods and food groups need to be a part of that. 15 16 17 18 So we look forward to continued dialogue 19 on this issue. 20 We, again, thank the FDA for taking the 21 time to have this discussion and look forward to 22 continuing to be a part of the dialogue and we'll 0019 1 plan to submit additional public comments in a 2 written form, as well. Thank you very much. 4 (Appl ause) 5 MICHAEL LÁNDA: Our next presenter is 6 7 Cinthya Harriman with Oldways, the Whole Grain Counci I. 8 CINTHYA HARRIMAN: Good morning 9 I, it's a good act to follow the dairy everybody. group because our presentation is also in the same 10 direction, we're talking about things we're trying to get more of in the diet and one of those is whole 11 12 13 grains. 14 Let me make sure I've got the system Did it, okay. 15 down here. I'm going to talk today about what the 16 17 whole grain stamp is, why it's needed, how it was created, the education and outreach that supports 18 19 I think we've all agreed that the education component is a big part of any program, how consumers use the whole grain stamp and how it nudges industry in a healthier direction. 20 21 22 0020 First of all, just a few words about who 1 we are and who our parent organization is. Whole Grains Council has been around for a little Page 7

FDA Hearing Day 2.txt over four years now, we're a non-profit consumer advocacy group working to promote more whole grain consumption for better health and we do things that fall into three groups, all of which you'll see a little bit about in this presentation. We encourage manufacturers to create more whole grain products and assist them in doing so, we support consumers in educating them about what a whole grain is, how to find it, how to cook it, how to enjoy it and we help the media to write compelling and accurate stories about whole grains. And we're part of Oldways, I have to apologize for some of the graphics, that would be a transparent background but it's kind of interesting in a Mandaean sense. Looked a little boring on the Macintosh when I created it, but the PC says why don't we have some shapes in here. Anyway, we're probably best known as creators of the Mediterrean diet pyramid about a 0021 decade and a half ago and we are working with consumers, scientists, food companies. We are of the belief at Oldways that it's important to work on both parts of the equation and I see a lot of that in this audience this week. I think it is important if we talked about whole grains until we were blue in the face and got consumers to the store and they all said, boy, those Whole Grains Council people are right, we ought to eat more whole grains and they get there and there aren't any products or they can't find them, we have wasted our time.

Similarly, if we cajole and nudge industry into doing the right thing and they put out all these great products and they get in the store and nobody buys them and they lose their shirt, they're not going to continue to do that, so you have to work on both sides at the same time and that's what we're doing. So, let me just show it to you, it actually has a sort of perforated edge, this is another kind of liberty that the computer has taken. 0022 I have some little hand-outs that will show you the stamp a little more accurately. But, anyway, these are the elements of the stamp. Yeah, there's the pointer. It has the grain chief on it which is sort of our logo that we're carrying into all of our information materials, it's a, it's not a wheat sheaf, it's an universal grain sheaf. It has our Website for more information. We have a very comprehensive Website information. We have a very comprehensive Website and it has the words whole grain on it and then we call out the number of grams of whole grain per labeled serving. And on the bottom -- on the top if the product has, where all the grain is whole grain, then it will also have an added 100 percent on top of the sheaf and all of the stamps have eat 48 grams or more of whole grains daily, we think it's really important to have the context on there. Americans don't understand grams naturally. They do become accustomed in a certain

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FDA Hearing Day 2. txt category, like they know that one gram of fiber 22 isn't much, but in another area like Omega 3s, one 0023 gram might be a lot so you need to put the context on there so they do understand and the 48 grams is the minimum prescribed in the, in the dietary guidelines so we put that on there for a reference. 5 Šo someone can look at this stamp and say oh, gee, 6 7 this gives me about half of what I needed to and get that context which we think is important. So, in summary, the whole grain stamp is a nutrient-specific symbol and not a summary symbol. 8 9 We've seen both types. It does not make a health claim, it just says here's what's in it. It is only used on products that have a minimum of at least 10 11 12 eight grams of whole grain, minimum half serving amount and we don't think it is a good idea to be 13 14 calling out whole grain content of anything less 15 than a significant amount, which is in our opinion 16 17 and in the opinion of many others a half serving, eight grams, and the number of grams is stated 18 19 clearly on the stamp. And if all the grain is whole grain, 100 percent can be added and we have the Website to 20 21 22 lead consumers to info on the health benefits of 0024 whole grain. 2 3 Again, some kind of creative graphics, but the basic stamp, just to get you a sense of what it looks like and to remind people it comes in all 4 different numbers and the 100 percent stamp.

We started with this, just to go back and give you the context now that you've seen our baby here, the context is that this statement really 5 6 7 8 9 shows where we were in 2003 when we started the 10 Whole Grains Council. 11 It cannot be hoped to successfully 12 educate market and increase whole grain consumption until consumers can identify whole grain. Study after study have showed people don't know what they 13 14 are, they think if the bread is brown, it's whole grain and they don't know it's just caramel colored. 15 16 17 All of these confusions about what ingredients are what and so forth, something was -- definitely 18 19 needed to get whole grains off the ground. 20 We had the whole grain health claim which was a very good start since 1999, but it can only be used on foods where 51 percent or more of 21 22 0025 the weight of the food is whole grain and there's 2 3 some problems with that. As with anything that generally works well, there are a few unintended 4 5 consequences. The whole grain health claim kind of 6 7 gave us an all or nothing choice, especially in the bread area. You pretty much have to make that out of 100 percent whole grain because most of the, close to half of the weight of bread is moisture weight so you don't have a lot of room for fiddling 8 9 10 around and getting consumers to move their pallets over. You've got to make it 100 percent whole grain

and too often when we give consumers a choice

between all or nothing, going all the way to

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FDA Hearing Day 2.txt 15 healthy, healthy ultimate from where they 16 are now, they just don't budge from where they are. 17 So, we need to move them gradually as 18 we've done with the whole milk to skim milk movement and there wasn't any way with the whole grain health claim being the only way you could call out on a package to actually do that. 19 20 21 22 One other, one other small problem, 0026 lower fiber grains are not included because there is a fiber proxy, fiber marker in the whole grain health claim. So rice, for instance, brown rice, you can't put the whole grain health claim on a package of brown rice because it's too low in fiber. So there's some other little unintended consequences 2 5 6 7 of this. It's a great start, but we need to go 8 further. 9 The other issue is we need to support 10 the dietary guidelines and I think we, this is a thought I want to leave everybody with on the bottom 11 of this screen, as we move forward, let's think of 12 ways that we can integrate the message that our consumers get from the Government and that they're hearing about the dietary guidelines and then there are things on the package that re-enforce and help 13 14 15 16 people move forward with the dietary guidelines. 17 18 So after the health claim, the 19 consumption hadn't really budged in terms of whole grain consumption. Then dietary guidelines came out in 2005 and we came out with the whole grain stamp a 20 21 22 week after the dietary guidelines came out. 0027 rule was out there and now consumers needed a tool. The other problem and the other need that we saw in introducing this in tandem with the dietary guidelines is that the dietary guidelines in 3 4 5 6 7 talking about the ounce equivalents really only help consumers in finding the right amount of 100 percent whole grain foods. When you say here's how you get your whole grains, a slice of bread, a half a cup of cooked grain, cereal, a cup of cereal, that sort of 8 9 10 thing, you're talking about 100 percent whole grain products and you aren't giving them a tool to move 11 12 their pallet up with these partially refined, 13 partially whole grain products as they get used to the nuttier, fuller taste of whole grains so we wanted to fill that gap, also.

So developing the stamp, we started development in July of 2003. We introduced it in January of 2005, as I mentioned, and along the way we consulted with a scientific advisory committee. 14 15 16 17 18 19 we consulted with a scientific advisory committee 20 21 that we have very eminent grain and nutrition 22 scientists who work with the Whole Grains Council, 0028 working with FDA and USDA along the way with 1 2 3 4 consumers, with health professionals, with manufacturers because a tool needs to meet everyone's needs in order to be successful.

something that the consumer doesn't trust or Page 10

won't become universal. If you come out with

the manufacturers hate it, they won't pick it up, it

Again, if you come out with a tool and

FDA Hearing Day 2.txt understand, then it's wasted. So you really have to work with everybody. But we all have seen that here.

So then we started our media campaign. Our goal in the beginning of the whole grain stamp was to talk to, through the trades, the first year, to get more manufacturers aware of it so it was on enough products before we said hey, consumers, look for the stamp. But Oprah called us and said I've heard about this stamp thing, can I have it on the program? And when Oprah calls, you don't say oh, no, we aren't ready to do consumer outreach until this Fall, sorry. You just say yes, ma'am. So we did and that was kind of cool. And she is a big

believer in whole grains and that's cool.

We did, in the Fall we did start our media outreach campaign. We were reaching millions of readers in things like Cooking Light, in Parade and that sort of thing, so, and in the last year we've included information from the stamp or about whole grains in over 200 publications.

We also do education programs, one of the cool ones we're doing now is we're supporting dietitians with materials. We have these cool little just ask for whole grains buttons and anybody who asks me can get one here if they want one and we give them out to dietitians if they can tell us about what programs they're doing to promote whole grains, kind of a little carrot thing.

grains, kind of a little carrot thing.

And this was a diabetes Summer camp in
North Carolina and these kids here, you can't see it
too well from way back there, but all these kids are
wearing their just ask for whole grains buttons and
they have this special program where they tasted
different grains and different whole grain products
and this a typical the thing we're doing with whole

grains.

We're also getting a lot of feedback from consumers that the whole grain stamp is making a difference in their lives. This is somebody who just E-mailed us and said having the whole grain stamp has made it much easier for me to find these products. She's pregnant, she's trying to eat better. She didn't eat whole grains before, it's a long E-mail, the other part of it says I bought What to Expect When You're Expecting and it said eat whole grains, but I didn't know what to do and then I found your stamp and we thought that was pretty cool.

Here's another guy who is pre-diabetic

who appreciates the stamp.

And then we're increasingly getting, I'm not going to name names here and embarrass anybody, I did not see any of company name products, did I miss them or does their whole grain bread somehow not qualify.

So, we are reaching a lot of different companies who are working with us, but consumers are

actually starting to expect the stamp now and getting a little dubious when they don't see it,

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like the stars that Hannaford was talking about
yesterday.

So we have done some surveys, this was
early on in the life of the stamp in the first year
when it was only on something like 300 products,
even then a Harris interactive pole, 51 percent of
consumers said the whole grain stamps increased the
likelihood that they would choose a product, but
rightfully another 28 percent said they need to know

I think this is something that has come up over and over and we're humble about this.

We need to continue to do education because people need to understand the source of a symbol and understand the system and know that it's

who the heck this Whole Grains Council is anyway and

something they can trust.

Another set of focus groups that one of our sponsor members did, questioning shoppers in the Midwest about the whole grain stamp, the majority of the adults associated the whole grain stamp with

being healthy, thought it carried helpful and meaningful information, I believe the stamp was reason to at least make me pick it up and look at it and that it would be a difference maker when they were trying to decide between two similar products.

So now the stamp is getting quite a consistent standard, it's now on about 1,400 products across all segments of grain products and 170 companies now are supporting our work.

These are all the different segments

that we're using the stamp in. As you can see, most of it is bread and cereals, but then that's the bulk of the whole grain products out there. But we're seeing a lot of growth in other categories. Everything up to sweet treats, like cookies and muffins we put together in that category, soups, all kinds of interesting products are going in the whole grain route.

We have, as I said, 170 members. I put Cosco and Whole Foods in red because they're new members in the last couple months and I think this is a trend to grocery stores adopting this on a

 store-wide basis, and wanting to use it on their in-store bakery products in addition to the branded products. They've seen the success of it on the branded products they bring in and then they want to use it on their in-house so that they join our effort.

 We also have among our members, our 170 members, we have companies that are based in Canada, Germany, Ireland, Norway, Finland and Italy. They're not using it on their products in those countries, but on the ones they sell in the United States, but that's getting them interested in this whole issue and the conference we're having in November, we are having an international session because a lot of these folks want to come here and say, gee, whether it's the stamp or not, how can we do similar successful promotional efforts around the health benefits of whole grains in our country.

So we're nudging industry to do better

FDA Hearing Day 2.txt and I think this is an important part of our work. 21 We recently had someone who said oh, yeah, I want to 22 join, I want to use the stamp on my products and 0034 when they put their products for our system for registering them and certifying them we said, um, 2 but your products really don't have any whole grain in them and they go oh, but that's our wheat bagel, of course it has. No, it doesn't, actually. 3 5 And it's amazing some of these big 6 7 companies really don't know what they ve got in 8 their products and when you give them some 9 benchmarks and some things to reach for and a goal, they get educated and that particular company said, well, we're going to fiddle with that, we'll come 10 11 back to you or they find out that they just miss our minimum and they're going to tweak that formulation 12 13 14 and bump it up. And this is all getting more whole 15 grains into the American public and that's a good 16 thi ng. So, we're seeing re-formulation. We're not seeing people that are just meeting the minimum, though. Of the products that are currently using the stamp, three-quarters of them offer a full serving of whole grain or more, not just the minimum 17 18 19 20 21 22 half a serving. 0035 So, we're really seeing the stamp is meaningful in that way and it's at a time when the 2 3 latest Anne Hines data, which as we all know is a couple years behind, is showing that we're still kind of stuck at one serving, to have that many products that are over another serving or more to 5 6 7 people, that's really going to make a difference in 8 consumpti on. 9 It is a completely voluntary program 10 with minimal costs to manufacturers and large 11 benefits to consumers. Just as a side thing, this has nothing to do with retail packaging, but we are branching out. We're also trying to nudge food service to do better, this is part of our campaigns this year. 12 13 14 15 16 We are using this related menu symbol on restaurants and food service and a couple operations 17 18 have started using it already, but our goal is to 19 get at least one whole grain choice everywhere where 20 Āmericans eat. So in summary, the whole grain stamp is a consistent standard that is widely supported 21 22 0036 across different segments of grain food products. It's backed by science. It has the third-party endorsement of a non-profit organization, it's not a manufacturer scheme. It makes the dietary 5 guidelines actionable and I really can't stress this 6 7 enough, you really need to figure out ways to get people to follow the guidelines. It replaces a company's specific patchwork of symbols that might exist otherwise and it is another positive good 8 9 10 stuff message trusted by consumers, easy to use and

Thank you very much. (Appl ause)

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MI CHAEL LANDA: Our next speaker is Jan 15 Ritter with Columbus Children's Hospital. JAN RITTER: All right, good morning, everyone. First off, I want to thank you for inviting Columbus Children's Hospital to talk about and present information on a tool that we developed, 16 17 18 19 20 Snack Wise, that assesses the nutritional value of 21 snack foods. 22 The first thing I'll do is give you a 0037 little bit of history as to why we decided to do 1 such a tool. Secondly, some of the rationale behind it and then third, looking at Ohio, how it's been 2 4 implemented in Ohio and other States around the 5 country. The first thing that, the history behind it, in 2002, the Surgeons General report came out 6 7 8 and really looked at the problem of overweight and 9 obesity in the United States. 10 When that report came out, one of the things that it talked about was one place that we 11 could create change would be within the school environment. And so looking at the school environment, team nutrition, USDA began to do some 12 13 14 things where they were having schools really assess 15 the nutritional quality of their environment. 16 From that point we had a lot of schools 17 18 that were asking us what is a healthy vetted food 19 item. So, we began to look at that approach by looking at the science. We know that many changes have occurred over the past 30 years that have 20 21 22 0038 1 created some of the imbalances that we see in children's diets and among them one of the most 3 4 5 important I think is the use of energy dense, nutrient poor foods. Those foods are, children have ready access to them, whether they are in the home, 6 7 whether from vending, a la cart in the school or in the community. 8 The other thing that we know is despite 9 being cautioned to use them sparingly, we know that children consume them in excess. And, in fact, 10 11 about 30 percent of their calories come in the form 12 of these energy dense, nutrient poor foods. So not 13 only does that increase the risk for excess energy 14 intake, but also it contributes to an array of micro 15 nutrient deficiencies that we see broadly within the United States, a problem that was cited in the 2005 dietary guidelines. 17 Another slide that just kind of looks at 18 the Anne Hines data and the continuing food survey 19 20 of individual intake, which shows that micro 21 nutrient deficiencies occur broadly throughout the 22 United States in the population of children, and 0039 with that we see these problem nutrients becoming increasingly a problem -- problematic around school 1 2 age where kids are beginning to express their 4 5 independence through eating behavior. Oops. Did I stop it? 6 On the other hand, we know that the 2005 dietary guidelines recommends a nutrient density Page 14

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FDA Hearing Day 2. txt approach where individuals consume a variety of 9 nutrient dense foods and beverages within and among the basic five food groups, while choosing those foods also that limit the amount of fat, saturated 10 11 fat, sugars, added sugars, trans fat and sodium. So we know that the first choice is to 12 13 14 meet nutrient needs through the five food groups, 15 however, we also know that the reality is it may 16 take a combination of naturally nutrient dense, five food groups along with some fortified foods to help Americans meet nutrient needs. 17 18 19 So both types of foods may play a role 20 in assisting Americans to achieve nutrient adequacy 21 and that is sustainable and accommodates 22 ever-changing lifestyles. 0040 1 You're probably all well aware in 2004 the Child Nutrition and Re-authorization Act 3 required that all schools actually implement 4 nutrition standards for all foods that are available 5 on their campus. And as this began, we really saw a 6 7 role in developing this tool to help schools really understand how they can provide more nutrient dense 8 foods. 9 Most schools were adopting standards 10 that were prescriptive, limiting calories, fat, 11 saturated and trans fat, sugars and sodium. That 12 approach, in fact, can restrict certain foods that may offer better nutritional profile despite the 13 fact that it could contain more fat or sugar.

For instance, one of the things that we saw were restrictions on sugar limits, some of your vendor flavored milks and yogurts which are popular among kids and also offer substantial nutritional 14 15 17 18 19 profile. 20 So another approach that we began to 21 look at is using the dietary guidelines, the daily 22 values within the dietary guidelines as well and 0041 looking at a nutrient density approach to the food labeling and that's where we developed Snack Wise. It's basically a simple algorithm to identify nutrient density of snack foods commonly found in 5 a la cart vending school stores and fundraisers. It's based on the current dietary guideline 7 recommendation and percent daily values on the food label and one other thing I want to make clear, it's 8 9 not static, it can be changed with current nutrition 10 sci ence. In fact, we already are in our second version because when they first developed the tool, 11 12 it was before the dietary guidelines were released, 13 so after that we made some changes. 14 15 This is the algorithm or the parameters 16 or criteria that we use to develop the program and basically you can see it's based on 10 components 17 commonly found on the food label. And it does evaluate the overall nutritional value of a snack 18 19 20 It either, what happens is you either add or subtract points and that's based on whether the 21 22 nutrient has either a positive or a negative impact

on the total nutritional value of that snack item.

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So it basically weights the nutritional

quality of the food.

This is just an example of how the food is entered in, we just use, again, the back of the food label or the back of the package and this is the screen, it is a computer-based software program and we are actually going Web based within the next couple weeks, but what happens is they just enter in the nutrition components off of the back of the food label, press a button and then the information is displayed as either a green, yellow or red choice and then it will tell you whether it's met the nutrition target.

You can see over here -- whoops, I'm not pointing, there's the nutrition target, so it will tell the user whether they've met the nutrition

target for each of the components.

At this point we have over 200 schools in Ohio, districts in Ohio, so that encompasses a lot more schools that are actually using Snack Wise. We're in Ohio State University now. There's quite a

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few hospitals that are using it, businesses, after school programs, so there's many. Vendors are actually taking it on and in the southern part of the United States there's a large vending company that's implemented it in all of their schools.

So one of the things that we look at is then it just uses that simple method at a glance you can identify a better choice within processed snack foods.

What it does is it emphasizes that all foods can fit within a reasonable and balanced diet and it does teach a concept that some snack food choices are better than others. And of course we always want to emphasize the fact that nutrient density, first we want them from whole foods, so fruits and vegetables of course would always be a

green if you're looking at a snack.

These are some of the components that come along in the package of Snack Wise. For vendors, one of the things that we have found that works real well is that they have this poster art where they can just actually list what foods within

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8 9 their vending machine meet the best choice, choose

occasionally or choose rarely.

The validation of Snack Wise, what we did is we used the algorithm for Snack Wise and we evaluated it against, with 64 snack foods. This was then compared with the evaluation to the overall subjective opinions of 19 experienced dietitians and what we found, the software was able to offer a similar assessment of the food item's total nutritional value.

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This is what the, basically the results, the evaluation model clearly segmented snack foods as least healthy, moderately healthy and then most healthy. So, the food ratings really represent a continuum of nutrient density ranging from lower to moderate to higher nutritional value.

One of the things I will say is the cut-off points that differentiate your red from your Page 16

FDA Hearing Day 2.txt yellow, your yellow from green are arbitrary. point values are within a range for each of the 20 21 categories, so some foods may be a better choice 22 than others within a green category, for instance, 0045 or a yellow or a red. This is just an example of a food that if you put that through Snack Wise, because of the nutrient contribution with protein is a good source 4 5 6 7 of protein as well as Vitamin A and iron and it is low in fat, saturated fat and sugar, this would be a green choice. 8 So, one of the things that we did find 9 is that you can help schools rate their machines or their a la cart, but you also need to give them 10 11 guidelines. And so because of the availability of 12 different types of foods as manufacturers begin to 13 develop things, we saw that the ratio we could use would be 15 -- no more than 15 percent of their 14 foods as red, 55 percent yellow and 30 percent 15 16 green. 17 We have schools that have dedicated machines or a la cart that are all green and yellow and that's really what our goal is, as we see manufacturers begin to respond and to produce foods 18 19 20 that meet those categories, you can pretty much 21 22 eliminate red foods. 0046 Recently Ohio introduced legislation and if that is passed, it will apply the Snack Wise algorithm and ratio of the snack foods sold in a la cart vending in school stores.

The other thing we did is just a little pilot study. We don't have a lot of money to actually do some further studies, would like to do 2 5 6 7 actually do some further studies, would like to do 8 some bigger studies but this was done in Bolling 9 Green, it's a high school and what the DECCA class, 10 which is a marketing class, basically went in and they decided that they were interested in changing some of the options within their school because of 11 12 the overweight and obesity problem. So, their objective was basically to 13 14 15 change the nutritional profile of foods within their vending machines and they wanted to see if kids 16 17 would choose those healthier options and also could it be done without losing revenue. 18 So what you can see, the intervention 19 was actually, at the beginning of the school year there was, most of the foods that they had were red. 20 21 22 The intervention was actually made in December and 0047 1 you can see that from that point on, the sales of red items really decreased as we began to see the 2 3 4 sale of yellow and green increase just because of actually product.

The interesting thing, though, is that revenue neutral. They did not have any 5 it remained revenue neutral. They did not have loss in sales. That's what schools are really 6 7 8 worried about and we see that time and time again, if you implement healthier choices, you do not lose 9 10 revenue, kids adjust to what you have in the 11 machines or on a la cart.

Okay. All right.

The other thing that

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FDA Hearing Day 2.txt 13 we asked, did, you'll notice the promotions. the things that we looked at, these kids actually 14 15 did the stickers on the merchandise, 64 percent of them noticed the stickers on merchandise. 16 When asked why they purchased the healthier snack, many of the students indicated that they either did that because they liked the snack, 17 18 19 20 that was actually the number one reason why they purchase snacks and so taste is of great value, then 21 also the other reason was because they liked, they 22 0048 1 wanted a better choice nutritionally. 2 So our conclusion really is that you can use symbols used in Snack Wise. They're a simple method to educate, guide and help shape students behavior and snack choices. The tools broaden 5 6 7 criteria. Using nutrition information on the facts label and adding in the balance of red, yellow and 8 greens are a guide that can help shape snack choices 9 for children. 10 As we have, that was our actually 11 primary audience was to go into schools, but as we have seen in Ohio, we're seeing it used at the University level, businesses and industry are also interested in it, so it is a thing that, you know, 12 13 14 basically it does follow the dietary guidelines so 15 anyone over the age of 5 can, you know, it's that's a healthy individual can use Snack Wise as rating 16 17 the individual's snack item. 18 19 The other thing that we did is go, we went into schools just recently and did a little educational intervention at the middle school 20 21 22 helping them to look at snack options within their, 0049 within the education and they were able to get on 2 3 4 the computer software program and actually look at those kinds of things and were able to determine what was a healthier snack. 5 6 7 So, I want to thank you and thank you for your time. (Appl ause) 8 MICHAEL LÁNDA: Our final presenter for 9 this morning's first session is David Katz, M.D. 10 DR. DAVID KATZ: Good morning. sincere thanks to FDA for this opportunity. 11 thanks as well to all of you for your kind attention as we discuss the overall nutritional quality index. 12 13 In July of 2003, then Secretary of Health Tommy Thompson convened a group of thought leaders addressing the topic of epidemic obesity. To meet with him, then FDA Commissioner Mark 14 15 16 17 McClellan, the heads of the NIH and the CDC, gather 18 19 around a table and share our perspectives in 20 particular on what the FDA might do to combat the 21 obesity epidemic. I was privileged to be among them and when my turn came, I said a food supply for 22

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We should translate the ability of leading nutrition experts to discriminate among the choices available to them on the basis of nutrition into a tool every consumer could use, whether that's green, yellow, red, stars, hearts, moons, clovers,

FDA Hearing Day 2.txt letters, numbers, doesn't matter, but at a glance

nutrition guidance on every bag, box, bottle, jar

and can in the food supply.

There was a certain amount of head nodding, but not a great deal else happened. We did have some follow-up discussion, I wrote an op ed which the Hartford Current published, New York Newsday published and it traveled to some newspapers around the country arguing that you shouldn't require a Ph.D. in nutrition or biochemistry to go grocery shopping.

In February of 2006, an opportunity came along to actually put this concept into action and by that time, my patience in faith had run a little bit thin, so I decided to go for it. And the mission of the ONQI development project was to

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> develop an algorithm that could stratify foods on the basis of overall nutritional quality both universally across all categories, but also to guide choice in particular within categories because after all, that's how people choose food. They don't choose bread or spinach, they choose a particular variety of bread or breakfast cereal or pasta sauce or salad dressing.

> We also set out to develop an algorithm that would entirely avoid the good food, bad food conundrum and essentially the mission, again, was to place the discriminating capacity of top nutrition

experts into the hands of every consumer.

Please note, perfect is the enemy of good. There is no nutrition expert who has perfect knowledge of nutritional composition of any food. All that is required is the ability to discriminate on the basis of what we do know to make better choices within every category. If you sum up those better choices across all food categories, the aggregate impact on dietary quality can be quite substantial.

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 $\label{thm:commended} \mbox{The process we used was, in essence,} \\ \mbox{which recommended then to Secretary Thompson, the} \\$ FDA or the IOM might convene a panel of independent nutrition experts, sequester them, if required, support them, as necessary, and give them the time they need to develop a consensus opinion on a metric that will translate their collective judgment and knowledge into a tool every consumer could use. That was the process I recommended.

That was the process we used. great deal of canvassing. There was an iterative selection process. Ultimately 17 invitations were extended to form a panel of experts, 10 to 15 strong. 15 of 17 accepted. Of the two who didn't, one is actually in the room or was yesterday, Linda Myer (sic), and Harvey Fineberg at IOM because they're precluded from their bylaws from getting involved in this sort of thing. The other ăctually was Adam Jenalski who has intellectual property in this space and was on sabbatical, two good reasons

Everyone else said yes. We did lose a

FDA Hearing Day 2.txt few to attrition and one to conflict of interest,

that was Bob Eckel, President of the American Heart Association who joined for a while, felt there was a

conflict and stepped down.

But our group includes past Presidents of the American Dietetic Association, the American Diabetes Association, the current President of the American Cancer Society, the inventor of the glycemic index and the originator of the traffic light diet, Len Epstein, as well as a number of other notables, Walt Willet at Harvard, Barbara Rolls at Penn State. Familiar names I trust.

I chaired that group and will chair an Advisory Board selected from within those ranks with an addition, Dr. David Ludwig from Harvard, but this is a group that will engage in ongoing oversight of

the ONQI as it is commercialized.

We reviewed the literature extensively, did not want to re-invent the wheel. We obviously looked at prior initiatives, many of the things being discussed over these two days. In light of the prior literature and invoking of course all of

the nutrition guidance we've heard so much about dietary guidelines, what's on the nutrition facts panel, the DRIs from the Institute of Medicine, we developed a basic working formula in February of 2006 and it took the better part of 18 months to refine it.

That process was iterative based on the consensus of the panel, with multiple meetings largely being conference calls, list serve exchanges, revisions to the formula were made and each time tested.

The initial validation process after passing phase validity criterion was to actually have these experts score and rank foods. We did dozens, then we did over 100 and we ran correlation analyses between the performance of the ONQI and the pooled independent rankings of this group of experts. The correlation we achieved before that process concluded was 0.92.

The algorithm was finalized in July of

'07, so very recently.

The numerator nutrients in the ONQL are

listed here. You'll note they include everything on the nutrition facts panel, but additional information as well.

I will note that what is not in the ONQI is as important as what is. There are a number of nutrients of considerable interest. We were very interested in Chromium and Celenium, they're not routinely available in any nutrient database as of yet. The USDA doesn't routinely include them, nor do others. If that changes, they might very well warrant consideration. We talked about Choline, we talked about a number of other things.

We have a list of nutrients to revisit

We have a list of nutrients to revisit if and when the evidence base will allow for their inclusion, but this was an evidence-based process. If the science wasn't strong and we couldn't quantify our judgment, we had to leave some

18 nutrients out.

> The denominator nutrients we've heard about from just about everybody, sat fat, trans fat, sodium, sugar, both total and added distinguished between the two and cholesterol.

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Other algorithm components because it's not just about the summative effects of micro nutrients, we looked at the quality of the macro So we have an entry for the biological quality of protein, obviously looking at composition of essential amino acids, we look at the biological quality of fat, the ratio of unsaturated to total fat.

We apply universal adjustors that ask questions about the overall profile of the food, energy density and its glycemic load. And I should note, and forgive me, this is a brisk presentation for the sake of expedition on a limited timeline, many details will be glossed over. We made a number of categorical adjustments. The algorithm is universal, but the playing field of food categories

is not entirely level.

I'll give you just one brief example. Cooking oils. I suspect everyone in the room would agree, olive oil is a nutritious food, Canola oil is a nutritious food. But you don't eat those foods in the quantities you would eat fruits and vegetables.

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19 20 21 If you apply a level energy density coefficient, it is unkind to cooking oils. We made a suitable is unkind to cooking oils. We made a suitable adjustment so that olive oil and Canola oil and their likes received the credit they deserved relative to the respect they got from the nutrition Other categorical adjustments were made as well, one of which precludes manipulating the ONQL score of a food by high level fortification, but again, I'll leave out the details.

The novel core concepts, the intellectual backbone of the understanding key, if you will, derives from threshold values based on the ĎRIs, primarily, but other sources when required, a trajectory score and then weighting of that traj ectory score. Let me quickly define the trajectory score.

The recommended prototypical diet of 2,000 calories advises no more than 2,400 milligrams of sodium intake for the day. That threshold value then is 1.2 milligrams of sodium per calorie over the course of the day; of the foods with more sodium than that will influence your trajectory for the day

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10 11 so that it's less likely you'll stay under the recommended upper limit. Foods with less will make it easier for to you hit that target.

So, the trajectory score says the sodium in a food divided by the calories in the food divided by 1.2 create a ratio of the density of sodium in that food to the average density of sodium in all foods over the course of the day if you want to meet the recommended daily intake level.

For calcium, if we're supposed to get at least 1,000 milligrams in a 2,000 calorie diet, that

FDA Hearing Day 2.txt means on average our foods must provide at least half a milligram of calcium per calorie. Foods providing more will help us hit the target. Foods providing less will contribute less. That is the trajectory score concept. It looks at all nutrients in the food relative to the targets for the day and asks are they more or less concentrated than the diet should be overall. How will they influence the trajectory toward daily targets and consequently weekly targets. 0059

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That wasn't enough, though. One of the questions that has not been asked nor answered so far in these proceedings is what do we mean by nutritious. Very difficult term to define. W might say nutritiousness of a food relates to its influence on health. Of course that doesn't help

much because defining health is also difficult. What we chose to do was say that is what nutritiousness means, it means the influence, the favorable influence of a food on health and health is defined both in terms of vitality and the avoidance of disease. We, therefore, looked at the $\,$ condition specific nutrients most impact for good or for bad and we asked additional questions based on epidemiology and we used a great deal of literature to back these up. What is the prevalence of these conditions, how significant are they and what is the strength of association between the nutrient and the condi ti on.

I'll give you an example. We talk about dietary trans fat, the primary concern is cardi ovascul ar di sease. It has other adverse

effects, but that tops the list. What is the prevalence of cardiovascular disease, it's hyperendemic. What is its severity? It is threat to life and limb, high severity. What is the strength of association between each incremental addition of trans fat in the diet and the risk of heart disease, strong. And, therefore, we used an ordinal scale, again validated using correlation analysis for these weights.

And let me compare that to cholesterol, the primary concern there for dietary cholesterol, again, heart disease. Prevalence of heart disease, the same. Severity of heart disease, the same. But the strength of association between each milligram of dietary cholesterol and heart disease, substantially less than that for trans fat. weighting coefficients are different and, therefore, account for that as well.

There are a number of other mathematical elements in the algorithm that we needn't bog down with today, we did not use strictly dichotomous threshold values. Again, consider sodium. The dash

sodium diet indicates to us that 1,200 milligrams of sodium is distinctly advantageous for blood pressure reduction, between 1,200 and 2,400 milligrams per day is acceptable, more than 2,400 disadvantageous.

You can break these threshold values down as

FDA Hearing Day 2.txt indicated into ordinal ranges that indicate optimal 7 versus acceptable versus less acceptable. 8 So, we use those ordinal scales, there's 9 a fair amount of log transformation built into the algorithm simply to compress ranges and improve splay. As noted, a number of category specific 10 11 12 adjustments. Just as a for instance, we capped the credit we will give to extrinsic nutrients added to processed food, we respect every nutrient in natural 13 14 foods. And that way you can't put an awful lot of folate or Vitamin C into a processed food and 15 16 17 inflate the ONQI score beyond that of fruits and Just can't happen. 18 vegetables. Here's a quick glimpse at the formula. Never mind. The SAS program is considerably uglier 19 20 21 than that available for your edification. At this 22 point that requires a non-disclosure agreement, we 0062 1 also have the rank list of over 1,000 foods 2 available for review. 3 Now when I flashed it at you, there is no denying that the ONQI formula is complex. In fact, at one point along the way in our deliberations, Walter Willet said I think this is 4 5 6 7 getting too complicated. And I asked him, Walter, could you build the engine of your car, I said, because it's got a lot of moving parts, and I can't 8 9 10 build mine, you can't build yours but you get in, turn the key and it goes vroom. 11 That's how the ONQI works. The 12 sophistication under the hood is advantageous because it allows for flexibility, it encompasses a 13 14 wide array of nutritional considerations, it's a 15 turn-key system. It's a score, it's a ranking, 16 translatable into any set of symbols you like, 17 18 again, hearts, moons, stars, clovers, colors, 19 letters, numbers. 20 Personally I like a 1 to 10 scale, the Olympic scoring system, bananas get a 9.2 from the Russian judge, that sort of thing, but we'll see. 21 22 0063 But it's a turn-key system at the user interface. 1 One of the great challenges we 2 3 4 encountered and had not fully anticipated is that when you build an engine like this, it burns high 5 performance fuel, namely, a great deal of nutrient 6 7 That database does not exist. USDA can't input. provide it. Nobody can. We had to build it.

Working with the University of Minnesota
and the NDSR database, we now have a method in place
to score 125,000 foods, essentially, and with little 8 9 10 help from our manufacturer friends we can use 11 12 methods analogous to those being used by NDSR and 13 the USDA to populate their nutrient database to score everything. And of course this is applicable to meals, to all recipes, as well, but in terms of packaged foods, we have access to 125,000.

We had to develop ONOI specific And of course this is applicable 14 15 16 17 functional food categories. I believe we heard from 18 Kraft that they had 49 food categories, My Pyramid gives us many fewer. Let me just briefly note what a functional food category is. It's a category 19 20 21 within which a consumer makes alternative choices. Page 23

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Breakfast cereal, we could say breakfast cereal is a grain, but people may not choose between breakfast cereal and pasta, they'll choose between one breakfast cereal and another, one bread and another.

So functional food categories are based

partly on composition, i.e., derived from grains, but also prioritized functional considerations again at the user interface where the rubber hits the road and choices are being made.

Consideration of placement in more than one category is particularly important for Web use. Consider, for example, a mom interested in selecting a healthy snack for a child's lunch. She may not be thinking of baby carrots as a vegetable and not interested in comparing it to other vegetables, maybe it should come up on the snack list and there should be immediate evidence of the relative nutritiousness of baby carrots as a snack in a lunch box compared to other potential snack items. built that functionality in.

Some of the unique attributes of the It's objective, it was born of pure science. ONQI.

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There was no commercial interest. Again, we tried to do what IOM or FDA itself might have done, just science until we were done. It's universal, it scores any food across all food categories and can be used to score the entire diet with appropriate weighting for balance and variety. It's highly sophisticated, admittedly complex, but at the user interface it's a turn-key system. It avoids the good bad, bad food conundrum.

Again, the question we asked was different, how does the distribution of all of the nutrients, good or bad in a food, influence the daily trajectory toward guideline levels. If helps, that's good. If it hurts, that's bad. food can be both good and bad or neither, depending on how you look at the universe. Personally I think there may be bad foods, I'm not so sure about cheese doodles, for example, but I digress. The ONQI is not influenced by that bias that I may have.

And one of the things I'd like to point out given all the industry input here, a system like this, or perhaps this system, could be used to

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validate others. We might take an industry metric that's better for you or not better for you, use ONQI scores and say do they, in fact, differentiate. We could score all of the industry's different systems and say objectively can we corroborate your claim that your better for you products are indeed better for you. If yes, you can say powered by the If no, we can consult with you to talk about re-formulations that would help us get there from here, but it might be a normative standard on the basis of which these more specific health claims could be made.

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There is a need for this kind of guidance, let me make the case with apologies to anybody who has a product shown on the screen. Popular potato chips, box of breakfast cereal, corn

FDA Hearing Day 2.txt 17 chips and a chocolate drink. Here matched for 18 calories shown in descending order is the sodium 19 content of these products. Highest for the breakfast cereal, next for the chocolate drink, then the salty snacks. Consumers wouldn't even know that 20 21 22 salt is a consideration in these food categories, 0067 1 but indeed it is. We must have cross-cutting qui dance. 3 4 Here we have a popular pasta sauce and chocolate ice cream topping, matching for calories, yet again more added sugar in the pasta sauce. People would not routinely pour packets of sugar over their spaghetti, but frankly in processed food that's exactly what they're doing. They have no clue. They need to be informed to be empowered. 5 6 7 8 9 10 We must overcome the current Tower of 11 Babel problem. Too much information is every bit as disempowering as none and that's the scenario we 12 13 have at present. There clearly is, and with all due respect to everybody in the room, a potential for conflict of interest in a system that is built in 14 15 response to a product portfolio. The science really should come first and the products re-formulated to 16 17 18 match that. 19 Single nutrient claims or banner ads can 20 be confusing. Let me give you one example and again, with apologies for the specificity of this, 21 22 there are many other examples, but we recently in a 0068 run of the ONQL scored one-third less sugar Kelloggs 2 Sugar Frosted Flakes and regular Kellogg Sugar The one-third less sugar brand Frosted Flakes. scored less well. We thought maybe the ONQI had run amuck, 5 6 7 dug into the details. Here's what we found in the one-third less sugar variety, more sodium, less fiber, higher energy density, higher glycemic load. One thing was fixed, four things were broken. The banner ad on the front of the package would not convey that to the consumer, however. 8 9 10 11 12 There is intellectual property here. There are patents pending. The intellectual property is owned by Griffin Hospital, a Vale-affiliated community hospital. The development 13 14 15 project was run out of Yale's Prevention Research 16 17 Center housed at Griffin Hospital. We will be developing a company separate from the science for commercialization of this. 18 19 Our retail partner is Topco, nation's second largest grocer, 4,000 supermarkets 20 21 nationwide, they routinely service 60 million 22 0069 consumers, reach up to 100 million. Our Web partner 2 3 is being finalized. Seems promising that it will be Revolution Health which is not yet as big as WebMD, 4 5 but is pretty committed to getting there as fast as possi bl e. 6 We'll be doing validation testing over time, the ultimate test is to see whether or not the 7 aggregate ONQI scores for foods across the diet are 8 predictive of health outcomes. We're developing 10 ongoing validation studies to assess just that and Page 25

FDA Hearing Day 2.txt we see applications obviously on supermarket shelves, we'd like to work with manufacturers to get it on the package.

We will have a large online presence where you can score and rank any food also in print and we do have school-based applications in mind. Those will be philanthropic. The algorithm is done, the supply line has been developed. The Advisory We'll have 20,000 foods scored by Board convened. the end of this month, approximately 50,000 before our launch in April of '08 and then we'll continue to score until 125,000 are done.

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> We plan a scientific and press conference here in D.C. or nearby D.C. November 30th, many of you will be hearing about that, national roll-out in Topco supermarkets nationwide April of '08 and again, we're actively seeking partnerships with food manufacturers and others.

With that, I thank you very much for your time and attention.

(Appl ause)

MICHAEL LANDA: We'll start with the questions from Kathleen Ellwood. Can you get closer to it?

> KATHLEEN ELLWOOD: Now you can hear, now

it's on.

The presenter for whole grains, and I wanted some clarification there, you have the stamp and you're running an education program, but in doing so are you also talking in conjunction with the food label and how you would use the food label in conjunction with the stamp?

Is any of that, and then my second

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question is, and I couldn't tell when you were going through the slides rapidly, is I assume you're putting this on snack foods because a lot of snack foods now have whole grain and if so, are you using other criteria which I didn't hear like fat and sodium, would that, you know, play a role in some of the products that you would want to see your stamp

CINTHYA HARRIMAN: Those are both good questions and to answer your first one, the complementarity of the whole grain stamp with other things on the label, first of all, the whole grain stamp, even though it's on 1,400 products, is still on -- not on all products that are grain products or whole grain products and we are primarily an educational organization trying to promote increased consumption of whole grains, not a sticker of stamps.

And so there's a lot of information on our Website and we answer questions every day about how you would figure out if a product is a good choice if it isn't using the stamp. Even answering

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that question with the blacked-out company name, we answered that user and said, you know, there's a lot of very good whole grain products out here and here's how you might look for it and just because a

FDA Hearing Day 2.txt product doesn't have the stamp doesn't mean it might 6 not be a good choice, it just means we can't tell 7 you if it is. And so there's a lot of education that we are doing that's complimentary to that and a lot 8 9 of that is explaining packaging choices and what different ingredients mean and so forth and we do 10 11 that primarily through our Website. 12 To answer your second question about any 13 other threshold requirements for the stamp, we've 14 kept the stamp purposely very simple because we think the big issue is it would be great if whole 15 16 17 grains were listed on the nutrition facts panel, but 18 you can't. 19 How do -- we just put the number of 20 grams on there and then consumers do have to make some choices, but yes, to answer David's thing, 21 22 there are now cheese doodles with 20 grams of whole 0073 grain in them. Are we making a choice, a judgment 1 about what else is in those cheese puffs; no, we are KATHLEEN ELLWOOD: I mean you will see 4 5 whole wheat, I think manufacturers are trying to put on their label if they have a whole grain product 6 and they will pick that up if they read the 7 8 ingredients lists, especially if it's one of the 9 first ingredients, which it would be. So I was just wondering, then, are, are 10 you -- and I realize you're doing a lot of education, that this would be a good opportunity to educate the consumer about how to read the facts panel and ingredients list. 11 12 13 14 15 ČINTHYA HARRIMAN: And I totally agree and that's something we take advantage of, but in 16 that 2 seconds, 5 seconds, 14 seconds, depending on which speaker you go with, there's not a lot of 17 18 19 nutrient facts panel reading that can happen and one of the interesting things, Kathy, that we find is 20 when our, our member companies that are using this stamp submit products to us for registration, they 21 22 0074 very often have ingredients on there like they just 1 list barley and we have to go back to them and we 3 have to say, is that whole grain barley, is it pearl barley, what kind of barley is it, can you prove it to us, because very often the manufacturers are, in 5 fact, missing the opportunity to tout their whole grain ingredients. They do pretty well on the wheat versus whole wheat, but on other things they drop the ball and that causes further consumer confusion. 6 7 8 9 10 And so we do a lot of education with the 11 manufacturer side also saying this is the way you 12 should describe this ingredient so that consumers get it. So it's part of teaching the consumer how to read the ingredient, it's part of teaching the 13 14 manufacturer how to write the ingredient list.
MICHAEL LANDA: David Zorn has a 15 16 17 questi on. 18 DAVID ZORN: My question's for 19 Ms. Harriman, also. You showed at the very end something, I 20

thought it was interesting, I don't think we've

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FDA Hearing Day 2.txt heard too much about it until this morning, was 0075 displaying symbols at food service, also. 1 But your stamp looks extremely different from the one that you're putting on packages. Could you tell us why it's so different? It would seem to 4 5 6 7 be nice to have a similar conjunction between the CINTHYA HARRIMAN: No, that's another 8 very good question. There are a couple reasons why we have purposely chosen to have a slightly different symbol for the food service campaign that 9 10 11 we're just starting now. One is that, first of all, on a menu, you're only going to see this very small, you can picture the little, you know, heart healthy check, V for vegetarian, things that you see on menus, 13 14 15 16 they're all very small and the entire stamp would 17 not reproduce well. But perhaps even more important, we're 18 19 very careful about the credibility of the stamp on retail products and when someone submits a product to us and we look at all the ingredients and ask them questions and look into it carefully, we know 20 21 22 0076 what's in that product and the product isn't apt to 1 change. 3 Now on the fast food chain level, that's 4 You could totally vet a product. also true. But if 5 someone's walking into a fine dining restaurant, today the chef makes the quinoa pilaf one way, tomorrow a little different, we cannot re-certify 6 7 8 that product every single day, so we have to work 9 with the restaurants and educate them on broad guidelines of what constitutes that eight grams of 10 11 whole grain, it's putting so much brown rice in a 12 dish, it's putting so much this in a dish, but 13 because we cannot be as sure of that. We're, we're touting that as an indication to consumers that there is whole grain in this product and we don't want to take away from the reputation that we've worked hard to build for the 14 15 16 17 18 whole grain stamp by the fact that it might not be 19 quite as 100 percent certified in the restaurant area just because of the impossibilities of the 20 21 logistics. 22 DAVID ZORN: Thank you. 0077 MI CHAEL LANDA: Barbara Schneeman has a 2 questi on. 3 BARBARA SCHNEEMAN: Thank you, I actually want to direct separate questions to three 5 of the panelists. For the National Dairy Council, I'm 7

curious about the criteria, other criteria that you use for the food. The dietary guideline message with regard to dairy products is for low fat and fat free and I had the implication -- or I took the implication from what you said that you don't restrict products to be low fat or fat free. I'd like you to address that issue.

For Ms. Ritter, for the Snack Wise program, I would be interested to hear how you Page 28

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handle fortification issues if the nutrients are being fortified and also whether or not your system includes beverages.

And for Dr. Katz, I, I wanted to come back and understand the system a little bit better given the examples that you used. The examples focused on a single nutrient and comparing across

categories, but one could take an odd message from the comparisons that you set up.

So I'm wondering if the intent here then is to focus on a single nutrient that a consumer might be looking for or a manufacturer is highlighting or if, indeed, you're trying to come back and make a statement about a food in a broader context.

So.

ANN MARIE KRAUTHEIM: Okay. In regards to the criteria for the logo, we have based the criteria, when the program was launched, it was driven behind the bone health benefit and for that reason we have developed the criteria solely based on FDA serving size and the excellent source criteria for calcium within that product.

Being consistent with FDA regulations we do, as I mentioned, utilize the disclosure statements where necessary for products that exceed levels of saturated fat, total fat, sodium, et cetera, so that we draw the consumer's attention to the nutrition facts panel where that information

is visibly apparent for the consumer.

We have made, you know, I think increasingly, increased our efforts to place emphasis beyond the on pack symbol on low fat and fat free products through the marketing and education tools, the consumer recipes and another key part of that we believe is educating the consumer about portion size and making sure that the consumer understands what a portion of dairy is so that they're obviously meeting the needs for three servings, but on the flip side, you know, helping consumers understand and not promote the overconsumption, as well.

BARBARA SCHNEEMAN: I guess you get emphasizing the dietary guidelines and that's why I was asking the question because the dietary guidelines specifically draw attention to low fat and fat free. So it seemed like there may be a gap there, that --

ANN MARIE KRAUTHEIM: Yeah, and we, you know, we've talked about that and we've had a lot of discussion in how to best address that and with,

with the marketplace, we know that consumers are looking for foods, obviously, number one, that meet their taste needs, but also looking at the nutrition needs.

We also believe that the approach that we're taking is consistent with current FDA regs and then knowing that some of the discretionary calories in the diet can be used to help cover the calories that people may have with the purchase or choice of

FDA Hearing Day 2.txt a fuller fat cheese, for example, if that's a choice 10 11 that they choose to make. 0kay. JAN RITTER: I will answer your 12 second question first. 13 We decided not to attack 14 beverages because you would need -- we were looking 15 at basically nutrients that are found in foods. think in the beverage you would also need to qualify 16 things like added sugars, sweeteners, caffeine and we did not address that, so that's why we did not 17 18 19 consider beverages. 20 The first question as far as 21 fortification of foods, I think that, I'm not sure 22 exactly what you're asking, but I, but as we look at 0081 the market, the market -- the re-formulation of 2 3 product, we are seeing more fortification of foods and so therefore those type of snack foods would fall into the green category 5 BAŘBARA SCHNĚEMÁN: I think the question 6 was so if, if a manufacturer -- could a manufacturer 7 fortify a product with vitamins, minerals, in your 8 system it would be limited to the ones on the 9 nutrition fact label, could they fortify and improve 10 their score? 11 JAN RITTER: Yes, you are limited by the nutrition facts label, but they can fortify and 12 13 that, in that process you're going to have a 14 healthier, you know, a better choice as far as a 15 snack food. DR. DAVID KATZ: Just to follow up on 16 that, I'll note that our system of course does score beverages and fortification will improve a score if 17 18 the food is relatively dilute in those nutrients, but we box in how much improvement so there isn't 19 20 significant categorical change and the overall 21 22 composition of the food is reflected. 0082 You noted the odd examples I showed, 1 salty breakfast cereal, perhaps, and sugary pasta sauce. The intent there was to demonstrate that the nutritional liabilities that populate the modern food landscape are not necessarily even those most 4 5 6 people anticipate. Those are there, too, but there 7 are the unanticipated ones. For that very reason, the ONQI measures every nutrient in every food 8 9 So it is not at all nutrient specific. When we evaluate the quality of a 10 breakfast cereal, its whole grain composition is very much reflected in the assessment of both fiber, glycemic load. We also look at added sugar and 11 12 13 maybe noting, as we think and I very much appreciate the presentations along with mine, but a good 14 15 healthy heart is good for bones, and so food that is potentially good for bones but has nutrients that 16 17 18 are not quite so good for your arteries has certain 19 liabilities. I favor a holistic view of health, a healthy vital body is firing on all cylinders. 20 21 22 the algorithm we put together looked across a wide 0083 array of conditions and a wide array of nutrients 1 and evaluates all foods on their merits. A

breakfast cereal that is rich in fiber, a good

FDA Hearing Day 2.txt source of whole grain but has added trans fat, for 5 example, will have its score dragged down by the 6 7 trans fat. If it's highly concentrated in sodium, which might not be expected in a breakfast cereal, but in fact is common practice, the sodium density in that cereal will affect its score but it will get 8 9 credit for its fiber and its whole grain, so we, we look at all of these nutrients in every food 10 11 12 category. 13 BARBARA SCHNEEMAN: Perhaps to help understand the system, then, for those examples that you gave, perhaps what we need to know is what the 14 15 total score was for the product, because you drew 16 our attention to a single nutrient that was maybe not consistent with a consumer perception. So it, 17 18 19 maybe if you told us what the total score was, that 20 would help. 21 DR. DAVID KATZ: I don't have it handy, 22 but I can tell you, for example, that in the Ragu 0084 Super Chunky Mushroom Marinara sauce, which is surprisingly high in sugar, it scored less well than 1 other marinara sauces which had a comparable serving of total carotinoids which we measured and other 5 nutrients in them, but did not have the added sugar. 6 7 On the other hand, the Super Chunky Mushroom Marinara sauce got full credit for its 8 content of carotinoids and so forth. 9 So, there is both interest in the absolute score which looks at the total universe of foods, but in particular it's the relative rankings. 10 11 Again, if you're choosing a pasta sauce, the competitors for your interest are the other pasta sauces and so this one would, received 12 13 14 demerits for a copious addition of added sugar, but 15 the total score would reflect the other elements of 16 that product. I don't recall it offhand, we've 17 18 scored at this point thousands of foods, I don't 19 remember all the scores, but they get the credit 20 they deserve. 21 The Chex breakfast cereal, for example, will get credit for all the nutrients added to it as 22 0085 well as its content of fiber, but the high concentration of sodium will influence that. And what determines the relative impact 4 of any given nutrient on the total ONQI score is both how far from threshold values that nutrient is, so if there's a lot of trans fat or a lot of saturated fat it has a bigger impact and then the 5 7 weighting coefficients, how important is the condition that nutrient influences, how strong is 8 10 the association between that nutrient and that 11 condition. MI CHAEL LANDA: 12 Steve Bradbard has a 13 questi on. Yeah, hi, David. Hi, Steve. It's hard to listen to STEVE BRADBARD: DR. DAVID KATZ: 14 15 STEVE BRADBARD: 16 17 your description of ONQI without thinking some about Hannaford which we heard about yesterday and the 18 19 summary score that you talked about, the ONQI, said that you prefer to think about it yourself as a 20 Page 31

FDA Hearing Day 2.txt zero to 10 type of score. Hannaford uses no stars, one stars, two stars, three stars. 0086 I guess what I'm wondering is in terms of convergence from what you know about the way in which the algorithms work, would you anticipate that if you took your ONQI system and represented it in terms of no stars, one star, two stars, three stars, you could pretty much overlay the two systems and there would be very, very little difference between them? DR. DAVID KATZ: Caren and I have started discussing the fact that we are members of the mutual admiration society and would like to begin looking at how to reconcile the two systems. We're doing focus groups and consumer testing now consulting with others who are very good at this to determine what are the range of good contenders for the translation of this system into symbols. Note that on the Internet we anticipate that the highly motivated health conscious shopper can type in the name of any food, get its ranking and a list of similar foods and look at its raw score and then click on it and find out what 0087 nutrients are driving the score. We also anticipate functionality where you can do that with a recipe, drag and drop in different ingredients and see how ingredients substitutions modify the overall nutritional profile of a recipe. So in some settings I think the raw score, the full range of values will be of use but yes, I do see value in a simple set of symbols, we're exploring that. I would, with respect to others who have argued in defense of it, say there's a potential liability in the no star realm. Bear in mind that right now 70 to 80 percent of the foods in the Hannaford star -- store have no star, consequently the system does not enhance the consumer's discriminating ability among all those foods.

So, you know, if that is a proportional representation of choices made in the supermarket, 8 times out of 10 the system isn't telling you how to do better. Frankly, there is a range of nutritional value even in the candy aisle. I think we're all increasingly aware of demerits, for 8800 example, of dark chocolate in its Flavonoid content. We can discriminate there. I do. And to some extent we asked the very practical question among our panel of experts, do you think about your choices when you want a salty Do you think about your choices when you want a frozen dessert or when you want a candy or a cookie, and the answer was yes, we choose selectively even there. So the no star category concerns me if it leaves out a lot of foods. If it is a category in its own right and we leave out relatively few, I think it would be fine. There is a balance between the simplicity, the at a glance usability of the

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FDA Hearing Day 2.txt 15 system and the degree to which it enhances 16 discriminating ability across all food categories. We're looking for the sweet spot.
STEVE BRADBARD: I guess as a follow-up 17 18 to that, you mentioned then about 70 percent of the foods in the Hannaford system receive no stars. 19 20 Using the ONOI, would 70 percent of the 21 22 foods receive a grade of one or one or two, which 0089 would be equivalent in many peoples minds to a very, 2 3 very poor score? DR. DAVID KATZ: If you're talking about the 1 to 10 system, I don't think it would be that many, but I think I'll probably just have to take the Fifth here and say we're still looking at the 5 6 7 best way to translate the raw scores into enhanced 8 discriminating ability across the widest array of 9 foods. 10 Let me give you a for instance, a 1 to 10 range compresses raw scores that spans four 11 orders of magnitude. If we just let the algorithm 12 do its thing, it turns out scores in the tens of thousands all the way down to less than one. 13 14 Clearly that's not useful in retail space or on the 15 16 package. 17 But if you compress that to one to ten, you lose an awful lot of the detail. 18 19 So, you know, maybe, maybe a better system, and I know you've thought a lot about these 20 things, but maybe a better would be, you know, 21 22 there's a green box for the best foods and they have 0090 a one to 10 range, even within the produce aisle there's the best of the best, the superstars like spinach and broccoli and lentils and maybe you have a color scheme that takes you down to the lower end 5 of the nutrition range and a range of numbers there. 6 7 We're working that out. Thank you. STEVE BRADBARD: 8 MI CHAEL LANDA: Question from Alan Levy. 9 ALAN LEVY: Thank you. This is a good panel I think to ask this question of. One of the 10 11 things that's illustrated is that currently there's 12 a lot of signage systems out there and they're not necessarily all consistent. 13 14 What do you think the consequences of 15 that are for consumer understanding of any given signage system and what remedies do you foresee to address if that's a problem, how would we address 16 17 18 it? 19 ANN MARIE KRAUTHEIM: You know, we've been looking at that pretty, you know, closely. 20 What we don't know and I would recommend 21 22 be done is that we really look at it from the 0091 consumer perspective. I think ultimately for any system to work it has to be meaningful and motivating to the public to make a behavior change 1

and I don't believe, you know, with all the presentations we've seen, we don't totally understand what, what the consumer is looking for and what's going to help them to make that decision most effectively and we'd be interested in looking Page 33

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FDA Hearing Day 2.txt at that more closely, really what are those needs 10 state for the consumer. We can put all the 11 information, all the messaging on the package, but if it's not going to resonate with the public in a 12 meaningful way, motivate them to change behavior, I 13 don't think it matters, you know, what we do or what 14 15 we say. 16 So, I think we really have to start with 17 that consumer and get a better understanding of the 18 consumer needs state around health and wellness and 19 how we can speak to them in a way that's motivating 20 and meaningful. 21 DR. DAVID KATZ: I'm notorious for 22 playing talking and although I make my living 0092 1 running clinical trials and studies in the community, I think some things are common sense. 2 3 4 5 6 7 If my foot were to catch on fire, I wouldn't need a clinical trial to fetch a pail of water. I think too much information is disempowering when it conflicts. I think that's just obvious. I think common sense indicates that You hear conflicting things from different sources and eventually you stop listening, you stop 8 I think common sense indicates that. 9 10 trusting, you just don't pay attention. 11 there's a real hazard there. 12 13 On the other hand, there may be room for 14 more than one kind of system. The systems that were discussed on this panel that are specific to food 15 groups and that are an endorsement of goodness within that category may not conflict with universal nutrition scoring, but I think we need universal 16 17 18 19 nutrition scoring. 20 I think we need to know which product is 21 better for me and my family because I don't think 22 even a scrupulous attention to the nutrition facts 0093 panel at present answers that question. You'd have to really figure it out. Well it's high in fiber, 1 You'd have but it's also high in sugar and high in salt and it has some trans fat, does the benefit of the fiber 5 outweigh the harm of the trans fat, is there a 6 7 I think that's what people want to better product. know. We haven't really put that to the test Maybe the closest is the Hannaford's $\,$ 8 9 very much. example and I think the one year results indicate that consumers like it and that it changes the way that they eat. 10 11 12 13 We clearly need to do the validation testing to ascertain that. How do we get there from 14 here. This is a really good start. You knothink action begins with dialogue and mutual 15 You know, I 16 understanding, but again, to float a proposition, 17 18 what about using an objective standard system as a 19 common denominator, a validator of some of the 20 different claims. 21 Are we putting seals of approval among 22 all these different systems on foods that truly are 0094 more nutritious when we use a common metric? And rather than imposing a common metric from the start

FDA Hearing Day 2.txt or asking that everybody adopt one, maybe we could 4 use it as a leveler, as a validator and then proceed incrementally to streamline and simplifying.
CINTHYA HARRIMAN: I'll answer just 5 6 7 briefly, I don't think we would be doing what we're doing with the whole grain stamp if there were some 8 9 kind of official universal system or Government mandated or Government developed system for doing 10 11 that, but the fact is that as NGOs and as 12 manufacturers, those of us in this room can 13 sometimes move a little bit more nimbly. You have processes and regulations that 14 in, in a way get to a more universal system that is 15 great, but at the same time makes things take a while. And we wanted something that came out right with the dietary guidelines and we could move 16 17 18 19 quickly and the result of that ability, I think it's 20 wonderful that there are so many things going on 21 Do I think it's good in the long run; 22 0095 no, we have to be moving towards something that is more consistent, but I think we're doing all the experimenting out here and learning about all of this so that as you work through your careful procedures, you're going to get all of this input from us and I think we're right where we should be 5 6 7 right now working toward a very good result.
MICHAEL LANDA: Louisa Nickerson. 8 9 LOUISA NICKERSON: My question is for 10 Dr. Katz and has to do with transparency for both 11 industry and consumers. Obviously there are a lot of advantages to having an overall scoring system that allows fine 12 13 distinctions between products both across categories 14 15 and within categories, but in contrast to, for 16 example, a whole grains stamp or a dairy stamp where 17 it's fairly obvious what a manufacturer has to do to earn that stamp and if it's not obvious, the 18 19 organization will work with the manufacturer as the 20 whole grains folks have done. 21 Since your algorithm is highly complex 22 and involves weighting and I believe is not public, 0096 how would a manufacturer who wants to earn a better 2 3 score achieve that goal and from the consumer perspective, I can look at different foods and see which one is nutritionally better overall, but suppose I have a particular interest, for example, I'm not concerned about fat because my cholesterol 4 5 6 7 is very low and no one in my family has ever had 8 heart disease, but I am very concerned about calcium 9 because all the women in my family have had 10 osteoporosis, so I'm not -- you know, I want to know specifically is this a good choice for me given my 11 12 risk factors, so how does that play out? DR. DAVID KATZ: Those are really two questions and if you didn't mind, I'll take them in 13 14 15 reverse order. 16 In terms of condition specificity, the dietary guidelines of course are a one size fits all 17 18 metric based on nutritiousness, but then there are 19 tools associated with that to personalize, My Page 35

FDA Hearing Day 2.txt Pyramid being an example. And of course at the 21 extreme we have medicalized diets, people with 22 glutin enteropathy, other food intolerances, renal 0097 insufficiency, congestive heart failure who simply can't eat the way the rest of us do.

Because of the sophistication of the algorithm, and I would argue this really is the 2 3 4 5 justification for building in that complexity, we 6 7 can medicalize and personalize the ONQi any which way. We can take the ONQI score and say what we want is the highest sum of the ONQI score and 8 calcium in a food because calcium is my priority.
Now you can't do all of this at point of purchase because if you gum up the supermarket, your friends in retail start to get annoyed. 9 10 11 12 13 You can do all of this on the Web, you can do this in print, so, you know, you could publish scores for people with glutin enteropathy 14 15 where any food containing glutin has its score 16 You could publish scores for people 17 zeroed out. concerned about their blood pressure where you increase the weight assigned to sodium content. You could publish scores and place them on the Internet 18 19 20 21 for people concerned about osteoporosis and very easiÌy. 22 0098 And again, this is a discussion I'm 2 3 having with our potential Web partner this afternoon as we explore functionality, a drop-down box, which condition concerns you, which runs in your family, you enter your profile and you tailor the score to suit you. Again, not at, not at point of purchase. 5 6 7 With regard to transparency, first I 8 would argue that all transparency is relative. 9 all of these educational outreach programs, there is limited understanding in the public at large of what we're talking about. You know, we see this on TV 10 11 from time to time where people are asked how many 12 calories are in a double cheeseburger and they say two, so, you know, a great deal of failing educational effort with regard to nutrition. 13 14 15 16 But we're committed to making our algorithm fully transparent. We're publishing in the peer reviewed literature, have not done that yet 17 18 19 but will, we will share the algorithm with any food 20 manufacturer now under terms of an NDA. We're not 21 putting the whole algorithm out there just yet, but 22 hope ultimately once intellectual property 0099 protection is in place to be able to do that as 2 well. 3 4 And I also think it can be explained in fairly simple terms, you know, essentially we're 5 looking at how concentrated are the nutrients in a 6 7

to be in your diet overall. That's, you know, that's the one line explanation of the ONQI in lay terms. So the concept is simple. There is a lot of sophistication behind it, but I will share the full algorithm with anybody that needs to see it. With regard to relationships with manufacturers, what we hope is to enter working Page 36

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food relative to how concentrated they're supposed

FDA Hearing Day 2.txt relationships with them where they get to see the algorithm and we work collaboratively to 15 16 re-formulate products to improve their scores. 17 The advantage I see in that is they're not just saying this is better for you because we say so, but they're using an objective metric that disinterested third party, a group of scientists 18 19 20 developed this, we improved our nutrition and 21 22 they're saying so because we scored to prove it. 0100 I see a really win/win by working together. The ultimate winner we're all interested in, of course, 1 2 is the American consumer. MI CHAEL LANDA: Our last question for this morning's first panel goes to Rob Post.

ROBERT POST: Thanks. My question's for Dr. Katz, but the others on the panel could probably 5 6 7 8 address it to the extent it involves them. 9 $$\operatorname{\text{Not}}$ all the presenters that we've heard from have addressed the issue of fortification and 10 it's a very real thing these days. There are an awful lot of -- there's a trend, perhaps, in 11 12 13 fortifying foods. 14 So, how important is the issue of foods, 15 of fortification to enhance nutrient value in either setting some thresholds and adjusting, as we've 16 heard, or disregarding it altogether as just a fact and a factor in today's market? DR. DAVID KATZ: I think it's extremely 17 18 19 20 important. 21 Now I should note before taking the question head on, there, there are considerations in 22 0101 1 nutrition that nobody's metric will get at and we're just talking about the sophistication of the ONQL 3 4 but let's look at the ways in which it's incredibly simplistic. Bioavailability, differences in 5 absorption, nutrient, nutrient interaction. Nobody could build a metric if we really considered all of 6 7 the different influences on how a nutrient in a food 8 influences what goes on in the body. 9 We don't make a distinction between the 10 quality of a nutrient in terms of its intrinsic 11 placement in a food or its extrinsic addition to a 12 The concern about fortification, however, is 13 you could highly fortify a food -- this is common practice with breakfast cereals, you know, I watch 14 15 Sponge Bob occasionally with my 8-year-old son and see all those commercials and at the end the sonorous voice of the announcer comes on to tell you fortified with 11 essential vitamins and minerals, 17 18 part of a complete breakfast. But my son and I are 19 20 looking at one another thinking would we eat that; 21 no, it's loaded with sugar and artificial colorings and so forth. 22 0102 You would not want the admission of a multi-vitamin to a bowl of highly-processed, forgive 3

multi-vitamin to a bowl of highly-processed, forgive me, junk, to produce a meritorious score. On the other hand, those nutrients have to count for something. We address that by capping the value we would assign to extrinsically-added nutrients while not capping the value of nutrients that are found Page 37

FDA Hearing Day 2.txt intrinsically in food. So we respect fortification. 9 And again, what is the ultimate 10 We don't have a gold standard. barometer here. Those of us who are interested in scientific validation must work towards one, but in the interim we were asking the question does the ONQI stratify 11 12 13 14 foods in accord with the collective judgment of this 15 group of people who's very knowledgeable about 16 making food choice, in essence, would the ONQI guide people to eat this stuff that we would eat. And if 17 the answer was yes, it was performing well and we 18 would not eat highly-fortified junk food. We would, however, eat food that has good nutritional property overall with the added benefit of being a functional 19 20 21 food enhanced by the addition of shortfall 22 0103 1 nutri ents. So I think there is a need to respect 3 4 fortification, but not to let it become the tail that wags the dog. 5 MICHAEL LANDA: Anyone else on the panel 6 7 respond? ANN MARIE KRAUTHEIM: Just to add to 8 that, we, with the three a day logo, we have looked at fortification and how that plays into meeting the 9 10 calcium criteria for the logo and we do require that 11 at least 10 percent of the calcium in the product needs to be naturally occurring. 12 There can be additional, above that that's fortified, but it has 13 to be, we feel really strongly that from a nutrition standpoint it's important to educate the public 14 15 about naturally-occurring nutrients and when we think about the food pyramid and why we even have 17 food groups. It's because those food groups deliver 18 key nutrients naturally into the food supply that 19 20 are important for good health. 21 So I would encourage, you know, the 22 approaches that are taken to, you know, consider 0104 that and how we can help best educate the public about those naturally-occurring nutrients and using 3 the food grouping system as a core premise for a healthy diet. Obviously there's a place for 5 fortification and maybe it's for those nutrients 6 that are underconsumed or there's a shortage of in 7 the food supply. 8 We don't have the absolute answer, but I think it's an important question and it really gets back to the core of what's the foundation of a healthy diet and those food groups that provide those key naturally-occurring nutrients is a place 9 10 11 12 of emphasis for us. 13 DR. DAVID KATZ: Just in order not for my answer to seem unbalanced, I just want to add at 14 15 the end we have compelling examples of the value of 16 17 fortification. Foliate added to foods, to grains in particular, is more bioavailable, better absorbed 18 19 and is the difference between most people approximating the recommended intake or not. 20 you know, again, I think we have to judicially weigh the influence of fortification on overall 21 22 0105 nutritional quality, but it can be a very important Page 38

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         public health venture and that needs to be
         respected.
        JAN RITTER: And I would just add, as well, that in the educational process, that's one of the things that we want to get across clearly, that you would, your first choice, and I think we do need to separate that tier of foods, that you're looking at naturally nutrient dense foods first and then from within that then when you get into those
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         from within that, then when you get into these
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         subcategories like snack foods that, you know, we know the people like to choose a snack from a
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        vending machine or wherever, then they --
fortification can play a part in supplementing.
CINTHYA HARRIMAN: Not an issue for us
because we're only calling out the presence of whole
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         grai n.
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                               MI CHAEL LANDA:
                                                          That concludes our first
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         panel this morning and our question and answer
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         sessi on.
                               Let's re-convene at 10 after 11.
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                               (Appl ause)
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                               SECOND MORNING SESSION SPEAKERS
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 MICHAEL LANDA: If we could all take our seats, please, we can get started. We're running a little late today, although we have some time in the afternoon to catch up.

Thank you. Our next panel is a continuation of U.S. experience, research and other perspectives. Our presenters are Michael Jacobson from the Center for Science in the public interest, Sue Borra from the International Food Information Council, Sheila Weiss from the National Restaurant Association and Regina Hildwine from the Grocery Manufacturers Association, back slash, Food Products Association.

We'll start with Mike Jacobson.

MICHAEL JACOBSON: Thank you very much, Michael, and to the audience I'm going to give you a break from Power Point slides and miscues.

I'm really excited that the FDA's exploring the use of these front label nutrition icons and greatly appreciate the opportunity to participate in this public hearing.

I think that front label nutrition icons

 could be the biggest labeling break-through, at least through, at least since the 1938 food drug, food and drug amendments that required ingredient labels, and it could be a highly effective way to improve diets and reduce the rates of diet-related diseases.

That's kind of my bottom line, I could end it now, but I won't because I've been given 15 minutes. But in a way, the rest is details and we've heard all these conflicting systems. There's nothing, there's no perfect system, although some systems are obviously flawed.

systems are obviously flawed.

I've been interested in rating the nutritional values of foods for over 30 years. Back in 1973 with the help of an intern, all of you know what that is, and a slide rule, many of you don't know what that is, developed a complicated algorithm called nutrition scoreboard to rate the nutritional values of food. So, for instance, in the protein group, broiled cod had a score of plus 50 and hotdogs did not have a score of zero, they had a score of minus 20.

And in the late 1980s, CSPI began advocating nutrition labeling front of the package information that would have every package bear a nutrition square divided into four quadrants, very much along the lines of what the FSA has done in the UK, each quadrant representing a key nutrient and color-coded red, yellow or green. Alan Levy shot that one down, and his consumer surveys, if you believe them.

Finally, last November 30th, CSPI filed a formal petition calling on the FDA to open a rule-making to explore a national system of front Page 40

label icons. This is all separate -- she wants me to stop drinking this and drink -- I know it's early

in the morning.

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Front, we have nutrition facts labels in this country which are extraordinarily valuable, especially to consumers who are, who have high blood pressure or osteoporosis who are looking for one or two nutrients and can make easy comparisons.

And all of this stuff about nutrition --

front label icons I think does nothing -- says 22 0111

almost nothing about the nutrition facts labels, although there may be ways to integrate these, these two approaches.

The nutrition labels can make your head go dizzy trying to compare holding up two packages in the same category, some of which -- one of which has more Vitamin A and Vitamin C but also more saturated fat and half a gram of trans fat.

you weight these different elements?

The front label icons could cut through that and reach people who don't know about nutrition, who haven't had a heart attack and are really, really motivated to look at the nutrition There, they would be understandable to a kid. You can hand your kid a 20 dollar bill and say Johnny, buy anything you want in the grocery store, but it has to have a green dot or a smilely face or whatever.

As we've heard various manufacturers, trade associations and others have developed simplified, but inconsistent labeling systems. The fact that they're using these systems indicates the

value of the systems, but the proliferation of inconsistent systems I think is really leading to confusion. So if you go into Hannaford and you pick up a package of something or other and it has a logo from one of the current systems but it doesn't have any stars from Hannaford, what's the customer to bel i eve?

In developing a system of front label nutrition symbols, basic decisions need to be made at some point and I'd like to address a few of them, and sometimes I'll give my opinion, other times just raise the point.

One key decision is whether every food or only healthy foods or only better for you foods should bear a symbol and several major manufacturers, Kraft and PepsiCo, Unilever and the American Heart Association and the Swedish Government have gone in this direction, highlight to consumers some of the healthier foods in the supermarket.

In contrast, the British Government, Hannaford Brothers supermarkets, CSPI and some

others have put foods or nutrients, in the case of Britain, on a scale from better to worse and give either red, yellow or green type ratings or stars or numerical scores.

My own gut feeling is that having a symbol on every food rating every food is the better Page 41

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FDA Hearing Day 2. txt approach, better than just the green ratings, because you have to pull of the green attracting you 8 9 to the heal thier foods and you have the push of the red ratings discouraging you, not -- still permitting you obviously to buy a food, but 10 11 discouraging you, at least.

I think yesterday Mike Rayner suggested having one big red, yellow or green dot to attract you to or repel you from certain foods, 12 13 14 15 supplemented, though, with four smaller dots or 16 17 particular nutrients of interest and that's one way 18 to tie things together. 19 Bruce Silverglade in my office has suggested just having a red, yellow or green dot on the front but on the nutrition facts label 20 21 22 highlighting the key nutrients in red, yellow or 0114 green, choose whichever nutrients you want, but that would be a way to build the nutrition label into 3 thi s. 4 Now for Mike Rayner's I guess expanded five dot system, one big and four small or three small or two small, whatever, I don't know if that's the best approach for the United States or not. I 5 6 7 8 don't know if the gradated approach is better than the just the good foods symbol or not, but I do know 10 what's missing; and that is research, good consumer 11 behavior research, perhaps in a mock grocery store with packages with first one label, then another 12 label, then another label to see which motivates 13 14 consumers to choose the healthier foods most, most 15 often. 16 In either case, though, either having just, say, a green dot or red, yellow or green system gives cut-off points and those are valuable 17 18 19 in encouraging companies to improve the nutritional 20 quality of their products to jump up a grade, to get a, go from green -- go from yellow to green or from one star to two stars. And if you have more cut-off 21 22 0115 points, you have more opportunities. You could 2 3 make, encourage improvements through a broader range of foods. That's one benefit of a gradated system. Another matter that may be significant 5 and I don't know how significant is what should the symbol, what should a good food symbol look like, is the keyhole the right symbol, is it a smiley face, is it anything else, how big should it be, where 6 7 8 ŏ should it be on the package. Some supermarket display cases have lips, so you don't want it at the very bottom of the package, so you have to think 10 11 12 about that. And, ditto, if you have a gradated 13 14 system, what should the symbols look like and if you 15 do have a gradated system, should, as in Britain, the least healthy foods bear a symbol or as at 16 Hannaford the least healthy foods not bear a symbol or something in between, like at Hannaford maybe it would be the outline of a star to remind you that maybe it could have had a star but it didn't. 17 18 19 20 So some of that's amenable to research. 21

Other issues are more policy related, judgment

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FDA Hearing Day 2.txt dependent and one such matter is whether labeling should be mandatory. When you just have a good food 2 3 symbol, you might not need it to be mandatory, but I think that it would help because some companies just may not want to do it and there would be relatively few foods in the supermarket that would have such symbols. And if a food didn't have a symbol -- the 5 6 7 good food symbol, does that mean it's not good or 8 9 does it mean the company just hasn't gotten around 10 to it or isn't interested in it for some reason. On the other hand, if you had a good, 11 12 medium and bad approach, that would have to be mandatory because not many producers of, oh, picking a food at random, Cheddar cheese would want to put a red dot on their label because of all the saturated 13 14 15 16 fat and the sodium. 17 So that, that will have to be a 18 political call, a judgment call. 19 And then getting on to the algorithm, 20 boy, have we heard about different algorithms, stretching from single nutrient to several nutrients to a whole bunch of them. What should the algorithm 21 22 0117 include and how should those different elements be weighted. And I think nutrition experts in general would agree that the nutrients highlighted in dietary guidelines for Americans and the nutrition 5 label and perhaps some other nutrients are key 6 7 nutrients that should be considered for inclusion. You know, in a way you want the least number of nutrients that give you the right answer, but you -- if you should add extra nutrients, if that adds value, then add some extra nutrients.

And another very important consideration is whether the retires should be 8 9 10 11 is whether the algo -- whether the ratings should be 12 based on a basis of per 100 grams or per serving or 13 per 100 calories. In some cases you get rather different results using those different approaches 14 15 and there may not be any one right answer. 16 It may be that a whole bunch of systems 17 would end up giving you pretty much the same result, but when you run foods through a system and see the 18 19 20 answers and you come up with inexplicable results, 21 it suggests that something needs to be changed. 22 So, Mike Rayner showed a slide yesterday 0118 that had whole milk and skim milk getting the same rating; that doesn't make sense. The American Heart Association has its logo on sugary breakfast cereals 4 because it does not consider refined sugars in its 5 To me that doesn't make sense. system. 6 7 In some systems, added nutrients can em. We heard of the, and with the UK's pose a problem. 8 traffic light system, I would question whether we should have a traffic -- whether one of the dots should be for total fat. There's already a dot for saturated and maybe trans is included, I'm not sure, so that's a, you know, could be in the U.S. we'd want to chop down that one. And the Dairy 9 10 11 12 13 Association's three a day as Barbara Schneeman was 14 alluding to doesn't maké sense if that logo appears 15 on, oh, hard Cheddar cheese -- Cheddar cheese, for 16 17 instance, because of all the saturated fat and hard Page 43

FDA Hearing Day 2.txt 18 cheeses are specifically discouraged in the dietary 19 qui del i nes. 20 And should a food that isn't one-third 21 whole grain, two-thirds refined grain get a whole 22 grain logo on it saying 8 grams of whole grain? 0119 People might be misled into thinking there's more 1 2 whole grain than there really is. 3 There's some other questions, whether 4 high levels of good nutrients should be able to 5 counterbalance a high level of a bad nutrient. you have 485 milligrams of sodium, should that disqualify a food from a good food symbol or should that be counter-balanced because the food is a whole grained food, tons of fiber, lots of certain other nutrients and no saturated fat, let's say.

Should the cut-off points vary from one 6 7 8 9 10 11 12 category to another? Sweden's keyhole system requires breads to be 100 percent whole grain to get 13 the symbol, the keyhole symbol. Pasta, though, only 14 15 50 percent whole grains because the rationale is 16 it's hard to find whole grain pastas, so it's loosening up the criteria.
So there are a lot of judgments when you 17 18 go from category to category. 19 20 And David Katz was suggesting that maybe 21 certain candies or other similar snack foods should 22 have, might deserve a red dot -- I'm sorry, a green 0120 dot or at least a yellow dot because they're the 1 best of the worst. And then we talked a little about the 4 issue of, or you talked about the issue of added, or 5 fortified nutrients and should they get full credit 6 7 or should they get no credit or something halfway in I think David Katz had a, suggested a good 8 compromise of discounting the addition of them.

One minute? And let me get to two final 9 10 points, one is should a national system coexist with these individual systems? And in general, I would say not. The purpose of a national system, like nutrition facts label, is to clear up the 11 12 13 14 marketplace confusion and have one standard system 15 replace the others. And I was very pleased to hear, 16 I think the Heart Association and maybe Unilever or Kraft say that they'd be willing to have their system be replaced by a national system. 17 18 So, stepping back from all these details, how do you get from here to there, and one way would be through FDA's regulatory approach. 19 20 21 That clearly would take 10 to 15 years, between 22 0121 proposals, funding, consumer behavior studies, economic analyses, OMB approvals and the like, 3 proposals, re-proposals, all the public comment periods. It's -- from 19 -- we petitioned the FDA 4 in 1994 for trans fat labeling, it got on the packages in 2006. A dozen years, nine and a half years until the final regulation. 5 6 7 What I propose is something different, 8 which is the FDA perhaps could start some consumer 9 10 research, but we really need legislation to 11 jump-start this process. Congress should pass a law Page 44

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      that would do two things.
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                     First, it would commission the Institute
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      of Medicine to conduct research evaluating all the
      existing systems and conducting consumer behavior
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      research and recommending one or two best systems, either an existing system or one of its own devising
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      within 18 months or two years and then the
legislation would give FDA another 18 months or some
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      fixed period of time by which it had to propose a
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      regulation.
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                     And then there would be another year or
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      a couple of years until final regulation, but I
      think if we want to see consistent -- a national, clear, consistent consumer-oriented, not
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      industry-oriented system, we need that kind of
      l egi sl ati on.
                     So thank you very much and it's going to
      be interesting to see how things proceed.
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                     (Appl ause)
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                     MICHAEL LANDA: Our next speaker is Sue
      Borra with the International Food Information
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      Counci I.
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                     SUE BORRA:
                                  Thank you.
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      Mi chael's.
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                     Good morning everybody, thank you for
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      the opportunity to share with you some of the
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      insights that we've been able to glean from some of
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      the work that we've done and actually, Michael, I
     thank you for setting the stage for me because you talked about the importance of research and I'm certainly going to share that, as well.

Though I do have to tell a little funny story, I was passing Michael in the hallway
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      yesterday and commenting on our, doing our panel
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      presentation, I said so, Michael, do you plan to use
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      slides today, he turns to me and goes nope, I'm
      doing it naked. So I want you to know your presentation was quite different than what I was
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      expecting, Michael, as a result of that.
MICHAEL JACOBSON: I hate to disappoint
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      you.
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                     SUE BORRA: I know, next time.
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                     To understand the perspective that I'm
      coming from from EUFIC, I think I'm doing -- did I just do the pointer, I just pointed to somebody's
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      head there.
                      Which one, the bottom one.
      There we go.
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                     To understand the perspective I'm coming
      from, the work I do at EUFIC, we are a non-profit
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      organization that sees as our mission is to
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      effectively communicate science-based information on
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      nutrition, health and food safety for the public
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      good.
                     So in that communication mapped date we
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      have, it is critically important for us to not only
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      understand the science that's going into it, but
      even more importantly understand the consumer
      insights that take place as you're doing this
      communication.
                     The work we do is supported by,
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FDA Hearing Day 2.txt primarily by the food, beverage and ag industries and actually I do want to thank you for inviting my 7 colleague, Joe Wills, from MUFIC which is our European counterpart. We work very collaboratively 8 9 together and bringing her here gave us an opportunity to discuss some of our next projects on 10 11 12 consumer information with nutrition labeling. 13 So for this morning what I would like to 14 share with you is some of open the lens a little We've been kind of narrowly focusing in on 15 this whole subject of, you know, looking at a food 16 pack and seeing a symbol, but I do want to open it 17 up because these food decisions, as you well know, are made in a huge other environment of activities 18 19 20 going on. 21 So to share where this context comes in 22 and how consumers are somewhat looking at these 0125 decisions as they're trying to make them, what else is having an influence. What are, where are their information sources that they tell us that they're getting this from and what do they say about some of 4 5 the nutrition information on packages. We have not exactly studied quantitatively front of pack or this 6 7 labeling at EUFIC, we certainly are looking at that 8 opportunity in the future, but some of the research 9 we have done has touched upon this so I'll share 10 some of the findings of that with you. These are a variety of consumer research 11 projects we've undertaken over the years, anywhere 12 from qualified health claims to food label and 13 14 calories and how consumers perceive that. 15 of our research reports are published on our EUFIC.org Websites, so I encourage you to go see them. A couple of them I'm presenting today. We're 16 17 still in the process of finishing an entire project, 18 19 so it will be, it will come in the near future. 20 So, to open that lens, the role food and 21 nutrition play on health and this is a question we 22 asked in a research we just conducted earlier this 0126 And the question is to what extent does each 1 factor play a role in maintaining or improving overall health; and we gave them choices of food nutrition, exercise or family health industry -health history, well you can see consumers think that nutrition plays a huge role in what impacts their health, closely followed by exercise and further down by family history. 5 6 8 9 So we've gotten the message through to consumers that nutrition and food are important 10 health -- or components of a healthy lifestyle. 11 12 Then we asked in a food and health 13 survey that we conducted this year how would you rate the overall healthfulness of your diet and you can see that, what is it, 46 and 8 percent said somewhat or extremely healthful in 2006, got a 14 15 16 couple higher percentage points in 2007.

So that they're thinking they're doing kind of sort of okay, but for most consumers, and I 17 18 19 20 think one of the supermarkets showed that 40 percent of their shoppers are saying, you know, I'm, I'm trying to eat more healthfully, but I really know I 21

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need some help so what can you do to help me. This was an interesting one, we asked this in 2006 in our food and health survey, and we asked that question about where do you get information a little different way. We said what sources of information make you change what you do about nutrition, food and health. Health professionals came up number one at 42 percent, family and friends, 42 percent.

Interestingly, the food label came up as the third highest factor in that particular list of questions which I had not seen it come up this high before, but I think in the way we phrased that question it kind of led them to a nutrition facts of

food product label being that source.

So as you drill down into what are they using on a nutrition facts -- or a food label, all the things they might see on a food label, what is it, we saw an increase over 2006 to 2007, 66 percent of the folks said they were using nutrition facts panel as a part of that, those elements on a food label that were helping to make their choices. A

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I did want to point down that you see there a statement about nutrition benefits was also one of the things, one of the elements and I don't have an arrow, but below brand name was statements about health benefits also making an impact on them as well.

Now some ethnographic research, and I'll show the design in just a little bit for you, we actually followed consumers around in a supermarket to see how they were making some food decisions. This, and this was the kind of research that they knew we were following them around. At first they thought we were just trying to figure out like from a store perspective how they were doing their shopping, they didn't know we were trying to figure out if they were using nutrition information in

making their purchases.
So, as they were picking up items and looking at things and putting things in their cart and making decisions, we'd kind of walk up and say, okay, what impacted your decision to put that product into your cart. So we drilled down to find

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out, okay, when in that shopping experience were they looking at nutrition facts panels and another -- just back up real quickly, these shoppers told us, we screened for shoppers who said they were relatively high users of nutrition facts information, that was a criteria that went into this.

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As we went through them with their supermarket shopping experience, they didn't use it very often in most of their shopping experiences. It's a point to note, they think, in their minds, though, they thought that that was an important factor for them to consider. So when they looked at nutrition facts panels, it was a new item, it was something they hadn't seen before, so that was one of the things that they would look at. If there was

FDA Hearing Day 2.txt a claim on the front of the package, they would look 17 18 to the back to see what that panel said in reference 19 to it. If they were looking at two different items in comparison and had similar front claims, 20 21 22 they would turn around and look. Price points would 0130 1 be another thing they would look at, same price, what's maybe the better choice in health. 3 4 Interesting, items requested by another adult with a health concern, so somebody in their family said can you look for some such product. 5 6 7 If their kids requested it, they might have looked at the nutrition facts panel, so that was interesting for those of us interested in childhood nutrition. And then those items that said 8 9 they were changing their recipe. 10 11 When they, we saw they definitely didn't 12 use it at all which was obviously more often in 13 their shopping experience, it was a routine item, they always put it in their cart, they've seen this stuff, they're going to continue to use it.

If they were simple ingredient products, things like milk or eggs, they tend not to look at that, that information. If a, this was interesting, and the import of friends and foreign which 14 15 16 17 18 19 and the impact of friends and family which you saw 20 in my other one, if another healthy adult had 21 recommended this product or said this was good to buy, they didn't need to look at the nutrition facts 22 0131 panel, their friend knew the answer to it so they didn't need to look any further. And then things that, price may weigh more importantly than nutrition in some of these decisions as well. As you all know, this is not new data, 5 6 7 that consumers more frequently use this information when they make first-time purchases and we see that 8 play out in the marketplace as well as in what they tell us when they use it. And when given the list of all the things that they can look at on a nutrition facts panel and what do they look at most, this is a busy slide, but interestingly they do tell 9 10 11 12 13 us they look at calories most often and that 14 certainly has been a change over 10 years ago collecting this data where fat was always number 15 one, though you can see fat is second highest. 16 can see the trans fat impact from 2006 to 2007 from 17 18 49 percent in 2006 to 63 percent in 2007 looking at 19 trans fat. 20 But with calories being the thing they look at most all, we actually in our food and health 21 survey asked a question about well how many calories 22 0132 do you think you need in a day. Well, and this was 2 3 an open-ended question, they could, it's a Web-based survey so they can answer in, just put in a number.

Let's see, in 2007, we had 11 percent
get it correctly, 15 percent order and 21 percent didn't over 5 6 43 percent underestimated and 31 percent didn't even 7 venture to guess how many calories that they had. The only good news from 2006 to 2007, though, in 8 terms of getting it correct, more folks tried to 10 guess at an answer, how's that, was the difference

between the two years and the year before.

So you can see if we're going to use calorie information, we've got a huge education component ahead of us to put this in the context of how folks are going to deal with this in their daily lives.

I mentioned to you we did, this was some of the most fun research we've done, the ethnographic research, and we did it in three places in the country. We had 26 families, they went and met with the family at home, kind of asked them a variety of questions about how they approached their

grocery shopping. It was really fun, they got to look at their cabinets and see all the things that were in there, there were some great photographs out of that. Then they followed them to the store and their shopping experience and walked through and while they knew the ethnographers were there to talk with them, they weren't quite sure the direction of it. And then we went back to their home and said okay, so now you've got all this, what are you going to do with it and had a final wrap-up so that we got some more information.

We used the directions from this ethnographic then to go into a qualitative phase to say consumers said this, so let's try with this information to see what we can come up with here and I'll share with you just a little bit of those findings.

Our goal is to take this into a third phase and do some quantitative research to really test this to see if these things hold true, when you work with consumers, can they really use this to make information.

So these are some of the things that our ethnographic research, they told us to improve readability, things like font size, they didn't like paragraph styles with nutrition facts panels, they thought the information on the footnote should be up closer to the other information. Serving size they thought should be bolded, it was something that they suggested. Things like usability, serving sizes attention across some more products, providing information that's easy to interpret for a single serve, maintain consistent terminology.

Listening -- linking to information that consumers know like the food guide pyramid was a good suggestion that they had and in fact we went into the focus group and tested a variety of mock-ups of having information that connected this food to a food group information and that was really well received by consumers. We didn't explore it to a great degree, we just started this conversation and dialogue, but this was highly well-received.

The other thing they really liked was having a link to a Website for more information.

Having the My Pyramid.gov there was really helpful to them and said oh, this is a place I can go to and get more information, so FDA may want to consider

FDA. gov on a future paragraph, how's that.

Then some other things we found to improve clarity, the whole thing about fats, there was lots of confusion about dietary fats and issues with calories and calories from fats were very confusing.

Percent daily value, I think this is a, I have done a tremendous number and been to, behind the glass in a tremendous number of focus groups on reading the nutrition facts panel. I've decided the best way to educate the consuming public is to have 350 million focus group participants go in, look at the nutrition facts label, explain DV and they go out going oh, I get it.

So, and in fact the learnings we have when we do these focus groups, by the end they're DV converts and they're ready, you know, to go out and tell the world and they like to use it in things like that. It's a very interesting process.

One of the recommendations to improve visibility, this is a big area we're talking about here, is moving key information to a small panel on the front of the package and we just took into our focus groups some of the thumbnail information that was already out there and available, presented a variety of mock-ups to them and in fact this was the one that was chosen, the one with the most information was chosen by this group as being most helpful.

And, in fact, by, as I said, by that time they, they totally understood the DV so they wanted to have that information there as well, in this particular case.

Just one real short fact about unintended consequences, I know we've talked about this but I think this is one of the classic cases of trying to provide good information and sometimes it doesn't get the necessary return on what you're trying to say.

As you all know, a couple years ago there was a recommendation that possibly to add a

 footnote on trans fat, that intake of trans fat should be low as possible. We set up a lot of tests with consumers to have them look at different food labels and you can see the first food label that says 70 percent should be label A has total fat 11, 7 grams of sat fat, zero grams of trans and the next one total fat 11, sat fat 2 and trans fat 2. And we asked which one would be most healthy and with the trans fat label there and 70 percent of the folks picked the one with higher saturated fat because that footnote scared them totally away from trans fat. So those are the things we have to look at as we're looking at these labels.

And I would be remiss not to include and people have alluded to it here, but the number one reason people choose foods is because the taste, price comes next and things like healthfulness are behind in that stack of things.

So, in summary, as we're thinking about best ways and approaches to this in the future in using a consumer-centered focus, when we look at the Page 50

FDA Hearing Day 2.txt food label, we know that there's lots of differences 0138 between what they say they are doing and using and what they really are doing, so we need to understand 1 that and take that into consideration.

We need to, we need to take into account 5 all the factors that are packed in consumers food choices. Nutrition is and health is just one of the 6 7 small components that play into that. Look at, be 8 aware of potential unintended consequences and test 9 for them. I think we couldn't agree more and 10 everybody's in agreement here that consumer research 11 is essential to ensure that all these new approaches really help consumers achieve a healthful diet and I 12 13 14 would be remiss also to say anything that we do has 15 to have appropriate investment in consumer education 16 or we're going to be in the DV situation 10 years 17 from now that we're here today. So, thank you for the opportunity to 18 19 make this presentation. I also want to thank, by the way, my colleagues at the Consumer Studies Group at FDA. They've been very helpful to us in looking at some of our research and being a consultant to us 20 21 22 0139 and I really want to thank you for doing that for 1 2 3 4 many of these research projects. Thank you very much. (Appl ause) 5 MICHAEL LANDA: Our next speaker is 6 7 Sheila Weiss with the National Restaurant Association. 8 SHEILA WEISS: Thank you very much. 9 name is Sheila Weiss. I'm the director of nutrition policy at the National Restaurant Association. 10 l would like to thank FDA for inviting us to 11 12 participate in this meeting and talk about some of the research and perspectives that have come out of 13 some of the activities in the restaurant industry.
Together with the National Restaurant 14 15 Association, Educational Foundation, the Association's mission is to represent, educate and 16 17 18 promote a rapidly growing industry that is comprised of 935,000 restaurant and food service outlets and we employ 12.8 million employees. We serve as the 19 20 leading business association for the restaurant 21 industry. 22 0140 And as you can see from this slide, we 2 represent everything from quick service to your 3 small mom and pop around the corner, we also represent manager services and contractors at 5 6 7 schools and universities, industrial plants, hospitals and nursing homes. Now it's estimated that in the year 8 2000 (sic), the sales for the restaurant industry 9 will be about 537 billion dollars and with 935,000 restaurant locations, we expect to serve 70 billion meals in this country this year. The average American eats 4.2 meals per week that are prepared 10

their food dollar away from home. Now one of the first programs I'm going Page 51

outside of the home, spending about 47.9 percent of

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FDA Hearing Day 2.txt to talk about that is taking place in the restaurant 17 industry is HealthyDiningFinder.com. This was started as healthy dining in the State of California, working with the restaurants in various local areas throughout the State to help them identify foods that fit into their criteria of 18 19 20 21 smarter choices and then about five years ago, 22 0141 healthy dining approached us to help them support a 2 grant that they were, they were, they were writing for a grant to CDC so that they could take this 4 program national on a Website. And just this past year they collaborated with the CDC, National Restaurant Association and five to nine a day to create 5 6 7 8 HealthyDiningFinder.com, which essentially is sort 9 of a Yellow Pages for restaurants. A person can go 10 on to Healthy Dining Finder and type in a zip code 11 and find participating restaurants in their area. They can also search by type of food, price range 12 13 and obviously location. At this point, this program was launched officially in, just this past March and already there are over 60,000 participating locations 14 15 16 17 through the country Now, while any restaurant can 18 19 participate in the healthy dining program, featured 20 menu items -- feature menu items must fall within 21 certain limits for calories and fat, both total and 22 saturated. And the nutrition criteria also 0142 encouraged the use of lean proteins, fruits and vegetables, whole grains, and trans fat free and non-fried items. The criteria are based on many of 3 4 5 the recommendations of the leading health organizations and for entrees the specific criteria 6 are 75 -- 750 calories or less, 25 grams of fat or less and 8 grams of saturated fat or less. And for appetizers, sides and desserts, that criteria is 250 calories or less, 8 grams of fat or less and 3 grams of saturated fat or less.

And all this information is explained on 8 ĕ 10 11 12 their Website at HealthyDiningFinder.com and then when, also whenever possible menu items that are 13 lower in sodium and cholesterol are also featured. 14 15 These are highlighted on their menu with a symbol also with substantiated -- with explanatory 16 17 information on the criteria and what is included. 18 Now when we asked our members what sorts of symbols they were using on their menus, as you can imagine and what has been discussed over the 19 20 21 last two days is that this use of symbols varies 22 greatly throughout the industry. Some are 0143 developing programs for their retail items that meet 1 2 a following criteria, whether it's looking at 3 4 specific calories or fat or a conglomerate of nutri ents. 5 Some restaurants, for example, Dennis, has a fit fare item where the criteria is 15 grams 6 7 of fat or below per serving and they have a box on 8 their menu explaining the definition of their fit fare and then with some contract, one of our

FDA Hearing Day 2.txt contract services members that we heard from, that they use a nutrient-based icon that is based on multiple nutrients, calories, total fat, saturated and trans fats, as well as cholesterol and sodium and the nutrient criteria may vary by food category, entree or whole meal, side dish and snacks and for snacks they have an added sugar threshold added for that.

And then for this program there's also a brief description with a symbol and more detailed information on pocket guides, Websites, posters, plasma stations, signs, depending on which area they're located in.

Now the second part of the Federal Register, I had my finger, sorry about that, talked -- asked for information on specific research on using symbols and in January -- and I'm going to talk about one company's examination of using symbols to represent nutrients.

In January 2007, McDonald's and ENLASO Corporation, which is a provider of translation and localization solutions, released a case study on how icons designed to represent nutritional information were culturally evaluated for worldwide use. And while this case study does not show how consumers have used the information or how it has affected purchasing decision, it shows the vast amount of consideration that needs to go into creating such icons.

And the main challenge for them was developing icons or images that would work with or without language in over 109 locales. And team members analyzed over 13,000 comments from cultural image experts and tested dozens of variations of the nutrient visuals. And this is, this is a, this is

just an image of the package in the U.S. showing the symbols.

Now their look at this focused on five main nutrient visuals, calories, fat, carbohydrates, protein and sodium that would be used globally on packaging and also designed and evaluated half a dozen supplemental visuals that might be needed in some locales.

They discovered there were no established standards for language-free nutrient visuals that could be copied or modified, so they looked to create their own. And as I mentioned, over 13,000 comments were received that they had to distill and assess.

Now some of the key findings include the importance of the role of color, as I think was discussed earlier. Red signaled, red can signal danger or caution in many cultures and they also found that universally the combination of black and yellow, black images on a yellow background is associated with traffic signs.

Now the design and evaluation phase for

most of the five primary nutrient visuals went smoothly, but supplemental nutrients proved to be more troublesome. For example, when they were Page 53

FDA Hearing Day 2.txt looking to create a symbol for calcium, they thought 5 a bone would be a great idea, but it's, it seemed 6 7 logical for westerners, but had negative and sometimes insulting connotations for others. And then also a smile for teeth also seemed like a great idea at the time, but was a 8 9 10 mystery to some countries. And milk containers, cartons and bottles were not recognized in many 11 12 Asian countries and sometimes were associated with 13 poison, which would not necessarily be a good symbol 14 to include. 15 Now, there is very little information as I said about how customers are actually using this 16 information and McDonald's, in speaking with McDonald's, they do plan to do some quantitative 17 18 customer research to evaluate the use of these 19 20 They also intend to promote the 21 understanding of these images through supporting 22 materials globally from Websites to images explained 0147 1 on tray liners and in-store displays. Now, this shows one company's experience 3 in exploring the use of symbols to communicate nutrition information. As I said, it doesn't 4 5 explore how they're utilized, but as, as the FDA 6 7 looks into this issue, we encourage you to consider a standard approach that would not further confuse 8 customers on the issue of nutrition, but help them 9 to make wiser choices. 10 Thank you very much. 11 (Appl ause) MICHAEL LANDA: Our next speaker for 12 this panel is Regina Hildwine with Grocery 13 14 Manufacturers Association, Food Products 15 Association. 16 REGINA HILDWINE: Thank you. 17 morning everyone. Still morning. 18 My name's Regina Hildwine, I work with 19 the Grocery Manufacturers, Food Products Association. We'd like to thank you FDA for the 20 21 invitation to participate in this, in this hearing 22 and to give us an opportunity to present our 0148 perspectives on the use of symbols to communicate 1 2 nutrition information on food labels and in 3 I abel i ng. 4 We, incidentally, also are intending to 5 file written comments. Just by way of background, a little clarification, too, the Grocery Manufacturers, Food Products Association, or GMA/FPA, represents the world's leading food, beverage and consumer product 6 7 8 9 10 Our association promotes sound public 11 policy, champions initiatives that increase productivity and growth and help to protect the safety and security of the food supply through 12 13 scientific excellence. We used to be two different associations, GMA, and NFPA, which changed its name to FPA, so it's very confusing. Just remember us 14 15 16 today as GMA/FPA, very simple. 17 You've heard from our members who have 18 19 made presentations at this meeting. Our members 20 make private label products for supermarket Page 54

FDA Hearing Day 2.txt compani es. Our members participate in just about all of the private logo systems described, so of

course we have a very deep interest in this subject.

The subject of symbols on food labels and labeling has certainly drawn a lot of focus in the food industry, in Governments and in other interested parties in recent years, but symbols and similar graphic elements are not new features on food labels and in labeling. And I think it's useful to remind ourselves of some history through some examples of the types of symbols and related graphic designs that have been used for many years lawfully and effectively on food labels and in labeling to communicate to consumers.

Food companies for many years have established their corporate identities on the label and labeling of their products through trademark company logos and brand icons. These symbols are very powerful in supporting consumer's confidence in a company's products, so much so that battles literally have been pitched over logos and the symbols travel with products when product lines are required by other firms.

Many packaged food products also display

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> product vignettes on their labels, pictorial depictions of the food that's contained in the package.

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Now FDA rules recognize that vignettes are an important, are important label features that, for example, can establish the characterizing flavor of a food or connote the presence of juice in a beverage, so there -- but they are, in fact, very important images.

Symbols used on labels can also signify that a product was made with a particular ingredient, such as some sweeteners. Symbols can signify that the food was made in accordance with certain religious dietary criteria or that the food fits with certain cultural themes. Think about holiday designs that are used on labels at certain times of the year. Even the Government has contributed to the lexicon of labeled symbols, with such examples as the USDA mark of inspection on the labels of meat and poultry products or the recent addition of the organic logo to signify products made according to that quality standard.

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Nearly all of these examples of symbols and graphic designs are voluntary label elements. The USDA mark of inspection being the exception. Since they are label features, these logos, icons and symbols are all required by law to be truthful and non-misleading in every respect, as are all printed and graphic elements on food labels and in I abel i ng.

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Food companies are adhering to the law. As a rule, these symbols have been and now are used on food labels and labeling in a manner that is truthful and non-misleading.

The use of symbols to communicate nutrition information fits within this context.

FDA Hearing Day 2.txt 15 They are now used in a manner that is truthful and non-misleading. Furthermore, they are consistent with the regulatory framework that FDA has 16 17 established for making representations about 18 nutrition. They are voluntary label elements and GMA/FPA believes that they should continue to be 19 20 21 vol untary. 22 Several years ago FDA challenged the 0152 food industry to start to compete by using the 2 healthy nutrition characteristics of the food. Thi s challenge prompted many food companies to re-formulate their products. GMA/FPA has collected 5 data that indicates thousands of food products have 6 7 been re-formulated to improve their nutrient profiles in recent years. 8 FDA also encouraged food companies to 9 experiment with labeling presentations on calories and serving sizes. Food companies have taken this 10 encouragement seriously and many are using label 11 surfaces and labeling techniques such as symbols and 12 related graphic designs that supplement nutrition facts in order to communicate nutrition information and food and dietary guidance to consumers.

Food companies are proceeding with their 13 14 15 16 17 efforts mindful of their responsibilities to make 18 truthful and non-misleading statements on labels and in labeling and to present novel labeling options 19 20 within the regulatory framework that FDA has established for communicating nutrition information. 21 22 The chief purpose of many nutrition 0153 symbols used on labels and in labeling is to provide positive dietary guidance messages to consumers. order to be effective, symbols focus on positive nutrition messages to consumers and do not demonize 5 food products or categories. We knew through a lot 6 7 of consumer studies that consumers feel empowered to take control of their diets when they are provided 8 options. Prohibition does not work, certainly not 9 in the long-term. 10 Because improving dietary patterns is a 11 long-term exercise, consumers are best served by 12 learning the food choices that they can turn to 13 again and again to improve their diets over time. 14 Consistent with this view, the intent behind the nutrition symbols and use on U.S. food packages 15 today is to help consumers to meet the dietary guidelines for Americans and to implement the food guidance in My Pyramid. 16 17 18 GMA/FPA right now, along with the Food 19 Marketing Institute, we're sponsoring take a peak in 20 21 My Pyramid. This is an in-store campaign that's 22 built around My Pyramid. In itself, a powerful 0154 nutrition symbol. This program is designed to help provide consumers in a retail setting with the tools 1 they need to make healthful and informed food choices. Through clear and simple in-store 5 messaging, take a peak provides easy to follow

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guidance, it shows consumers how small, progressive changes in their purchasing habits and diets can

improve their health with the selection of foods and

beverages in the five food groups and oils.

My Pyramid is often represented on the labels and labeling of food products including those that use additional symbols to communicate nutrition. Many food industry nutrition symbol programs reference the dietary guidelines for Americans or My Pyramid or both in the materials that explain the nutrition symbols.

This linkage with the dietary guidelines for Americans and My Pyramid, with this linkage the nutrition symbol programs are grounded in sound science and are consistent with the policies set forth by the Federal Government on communicating dietary guidance and similar representations about

the food.

 As FDA, itself, emphasized earlier this year in a letter to manufacturers, dietary guidance statements tend to focus on general dietary patterns, practices and recommendations to promote health. The nutrition symbol programs encourage consumers to select food and beverage product options in a company's array of products that will help support the small incremental steps that can improve dietary patterns in health.

Nutrition symbols used on labels and labeling of foods are designed to send positive and helpful messages to consumers. It's important that consumers understand the meanings of the symbols. Companies that are using these symbols provide a great deal of information, both on labels and in labeling and through educational and explanatory materials, including those on Websites to help consumers understand the helpful role of the symbols in improving nutrition.

The educational materials also remind consumers that detailed information about the

nutrients in the food presented in the nutrition facts panel. The context for the nutrition symbols is important so that consumers learn that they're focused on positive options for nutrition and so that consumers do not misperceive their meaning as signifying some other factor such as overall product quality.

Many nutrition symbols on food labels and in labeling, many in the U.S. that we've heard about yesterday and today typically are utilized with at least one statement of dietary or food guidance, relative or absolute nutrient content claim, health claim, structure, function claim or statement of quantity on the label or labeling of the product. All these types of statements are addressed in FDAs regulations and policies.

Claims may be represented on the principal display panel or on other panels of the label. Some nutrition symbols used on food labels or labeling may, themselves, constitute a claim and are consistent with FDA's regulations and policies governing such claims. For example, it's well

articulated in FDA rules that label symbols such as a heart would constitute a health claim when used to Page 57

imply a substance/disease relationship and heart symbols are used on labels consistent with that

policy.

Some uses of nutrition symbols may simply provide an illustration of the defined and stated claim, in other words, the graphic user interface to the text message. Those symbols are nutrition message corollaries to product vignettes which illustrate the identity of the food. Since nutrition symbols on labels and labeling are truthful and non-misleading and are consistent with the framework set forth by the Government for communicating dietary and food guidance and other nutrition information, they should continue to be permitted as voluntary graphic elements on food labels and labeling.

GMA/FPĂ believes that the FDA policies and guidance around nutrition communication on labels and in labeling are very clear and are being followed by the industry. Consequently, GMA/FPA

believes that additional regulations focused on nutrition symbols are unnecessary.

Thank you and we'll be providing further

written comments.

(Applause)
MICHAEL LANDA: First question from

Barbara Schneeman.

BARBARA SCHNEEMAN: Thank you and thank

you to the panel.

I would be interested in hearing the panel comment from the various perspectives about the potential for halo effects with symbols that are used in different marketing. And I think I'm particularly interested in the consumer research and the consumer focus that when something appears on a package, do consumers make other assumptions about that food; in other words, does it carry with it the notion of, gee, there must be something beneficial about this food.

And so I'm, I'm just interested in the degree to which what you've done so far with consumers helps understand that and I'm also very

interested from the perspective of the food service organization where there's less complete information provided to consumers and what assumptions consumers

make about products when they see symbols.

SUE BORRA: As a quick answer, because I'd want to think about that a little bit more, when we did the research on qualified health claims, I think we found, so you put a health claim on a front of a package and you're trying to use wording to discriminate whether or not it's a high level or low level of science, consumers really couldn't discriminate between all those types of things, so they thought every wording in the health claim all sound the same to them. They would look at it as this is all the same information, they're just saying it a little bit differently.

And there is, it does translate into some other attributes of the food potentially, like when the A, B, C and D were used, consumers judged

FDA Hearing Day 2.txt that to be it's either an A food, a B food or a C 21 food in terms of quality, not judgment of science. So that, that's how that was interpreted with 22 0160 consumers. 2 So you have to look at I think of asking the question in a way that you can study that one a little bit more specifically I think to get some of 3 5 If they make the answers that you're looking for. 6 7 one claim of it, do they not think about the other parts of the food. 8 Anybody else have research? 9 MI CHAEL LANDA: Anyone else want to 10 respond? 11 REGINA HILDWINE: I want to respond a 12 little bit. Barbara, FDA, itself, did some research 13 some time ago, probably before you got to the Agency, which talked about the halo effect with 14 15 regard to health claims and observed that consumers are bringing to their food experience everything 16 17 they know. So, the, the issue really is, you know, 18 19 what do consumers know and what kind of assistance are they going to need to help them in that short 20 time they have in the marketplace to sort of focus 21 their attention on the products that they're going 22 0161 to buy. 2 MICHAEL JACOBSON: Well, I have gut feelings, not research. But I think when there are claims, certain claims on the fronts of packages like zero grams trans fat or Smart Spot or Heart Check, people take those positive claims of healthfulness to reflect the overall healthfulness 5 6 7 of the food and clearly that's very dangerous. SHEILA WEISS: And I don't, we don 8 9 And I don't, we don't 10 have hard and fast research showing how consumers use a lot of these symbols, but when I asked, when, 11 in speaking with various food service locations 12 about how they use these and how, how these menu, how these menu items do in sales, responses have 13 14 been positive, that people -- that their customers 15 16 are happy to see them, but also we've heard 17 anecdotally that sometimes using, using the symbols, 18 people, people steer clear of those items deemed as 19 healthy when dining out because sometimes they, they 20 aren't necessarily looking for the healthiest 21 opti on. 22 But, so, it goes, it goes across the 0162 board, really. 1 About it. That's my response. 2 MICHAEL LANDA: A question from Rob 3 4 Post. ROBERT POST: Thank you. Obviously this 5 is, these past two days are for an important issue 6 7 and that deals or focuses on nutrition, but in my experience, there is a lot of complexity to food labels and there's a lot of information there and 8 9 that's come up. 10 And Regina had a comment about other symbols and the history of using other symbols, so 11 12 in that context to what extent and perhaps, Sue, 13 perhaps this is something EUFIC has dealt with, to

FDA Hearing Day 2.txt what extent are these peripheral issues like no 15 allergins or MSG free or animal product claims, to what extent do they interact with the view of the 16 overall healthfulness of a food and perhaps competing for the importance of nutrition and health information and are there data that you're aware of 17 18 19 and, in fact, were these studies performed in the 20 context of a complete label? 21 22 My experience shows that thousands of 0163 1 labels are out there with multiple messages, you know, and it's just not isolated to nutrition information, but there's a lot of other things, organic was mentioned, fresh, I don't want to say the word natural, but I will, and so these are all perhaps part of the competition.

SUE BORRA: Yeah, I would agree. I 5 6 7 8 don't know that I've seen something that's looked at the, that kind of totality of information you see, 9 kind of focusing in on different parts of it, but I 10 think that would be an important part of an overall so to say how do all these things, if we're going to understand consumer motivators, I think that's part of understanding all the motivators that go into 11 12 13 14 consumers making these decisions. 15 Though I think it's important to point 16 17 out that in, and someone mentioned earlier, that 18 each individual comes to that food with a 19 preconceived notion and that information's got to meet that individual's needs at that time to make a difference in terms of their decision-making and what their knowledge is about the food, what their 20 21 22 0164 1 knowledge is about the environment -- I mean all these things come into play, so it makes making 2 3 4 5 systems quite difficult to meet all those kinds of needs. MICHAEL LANDA: A question from David 6 7 Zorn. DAVID ZORN: My question is I think mainly for Ms. Hildwine. We all agree that it's important to do consumer research on how consumers 8 9 10 would respond under different labeling regimes, 11 under different scenarios and different criteria. 12 It seems to me that, that it would be 13 important to do research on how producers will respond under different labeling regimes. 14 There's -- it's one thing to, to communicate a message to people and find out how they would react 15 under -- when they see this or when they see that. As we learned with certainly the trans fat labeling, there's a lot of labels that people will never see 17 18 19 20 because producers decided to run for the nearest 21 trans fat exit and totally remove that from their 22 product. 0165 So, and then that's something that people didn't expect, those of us who did research 1 3 I was just asking for your suggestions. First of all, I guess would you agree if, that that 5 6 kind of research is needed and if so, how would it be done or, and if you can point to any research Page 60

FDA Hearing Day 2.txt that has been done or ways that we could explore that. REGINA HILDWINE: Well, as we're talking about this current subject of the use of symbols to communicate nutrition information, it would seem to me that it's the food companies that are in the lead and certainly availing themselves of, you know, innovative concepts. I, you know, there, there has been some research, I think it was published by the Federal Trade Commission, that observed that the ability of the food industry to innovate and novel ideas where, were explored more freely before the Nutrition Labeling and Education Act and the natural constraining effect that that's going to have 0166 because it set different kinds of limits and the, the idea of, you know, whether we would study how, how the industry would respond, I would just say be sure you're asking the right questions. And as early as 1998, which is when the trans fat nutrition labeling proposed rules were, were published, the proposals, we began to hear indications from the industry that they were looking for trans fat solutions, so it didn't happen in 2003 when the rule was published. It happened sometime before that. The industry really is on the leading edge, not the following edge on all of these concepts. MICHAEL LANDA: We have a question from Loui sa Ni ckerson. LOUISA NICKERSON: This question is for Ms. Hildwine. You said a couple times that nutrition symbols and food labeling are truthful and non-mi sl eadi ng. Do you have any research supporting that 0167 concl usi on? REGINA HILDWINE: The evidence that I have that they are truthful and non-misleading is that they are in existence in the marketplace. Ya'll have the enforcement authority in case they're not. So, so, in fact, I think this is an area where the general law covers, covers the territory just fine and we haven't really particularly studied those effects. MICHAEL LANDA: Question from Leslye Fraser. LESLYE FRASER: It's a general question and maybe I'll, it starts with comments also that Ms. Hildwine made, but I'll defer to anyone on the panel. When, in ${\sf GMA/FPA's}$ conclusion that nothing further is needed because the current marketplace is fine, I guess my first question is when you reflect back on NLEA and one of the comments was to avoid a Tower of Babel situation, do you see us on that trend or do you see the market 0168

correcting itself in that regard with the use of

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FDA Hearing Day 2.txt various different symbols out there; and then the second might be a reflection for those companies that are marketing both in the U.S. and in countries in the EU which may have voluntary systems in place that are more standardized, do you see any differences or pros and cons between what's in the U.S. now versus what's in perhaps the UK or Sweden where there are those voluntary systems, but they are more standardized to get at the point of we're fine, but how do you, how do you square those two or just see them as different? REGINA HILDWINE: My recollection of the

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Tower of Babel speech, which was of course introduced by Secretary of Health and Human Services Louis Sullivan in the Reagan administration, Reagan, yeah, it, it in part related to different meanings behind expressions on food labels.

What I think we're seeing with all of the current systems in place is that there is a consistent meaning behind the messages. If you listen closely during all the presentations,

nutrient content claims, health claims, dietary guidance, statements of quantity were mentioned consistently as a framework for all of these, all of these systems. So I don't think there's a Tower of Babel.

And as to consumers ability to understand graphic images, just think what happens when you turn on your cell phone or your computer in the morning and the number of graphic images that you automatically understand. Human beings have been communicating with graphics for over 40,000 years and I think we understand how it's done.

MICHAEL JACOBSON: I'd like to address

that briefly.

I think there is confusion in the marketplace where different symbols mean different things but they might be taken, they might all be taken to mean healthy food and, and that's one impetus to try to clear away these inconsistencies among the systems, but I think a much bigger consideration is America's health.

Obesity rates going through the roof, half a million people dying every year prematurely because of heart attacks, high sodium levels contributing very significantly to strokes and heart attacks.

So, we have some real, you know, human health considerations that should be upper most in mind and Government has an opportunity, companies voluntarily have an opportunity and Government has an opportunity to guide people towards healthier You know, clearly nutrition facts labels have not been sufficient. My Pyramid is, has severe limitations. Dietary guidelines is, you know, invisible to the general public.

So, a good, clear, national system of front label icons could be a very influential approach and as we heard from, especially from Tesco and Sainsbury has found the same and Hannaford

FDA Hearing Day 2.txt probably to a lesser extent, these, information on the fronts of packages can be very powerful in guiding people towards the healthiest food and away from the least healthy foods.

MICHAEL LANDA: Barbara Schneeman has a question.

BARBARA SCHNEEMAN: Actually I would like to address one question to Sue Borra from EUFIC.

In some of the presentations you gave, you referred to linkages to the Web and consumer interest in that link to the Web and I would be interested in knowing more about the demographic that was responding in that way and how generally applicable that would be across the population or your sense.

And then I would like NRA to address as they've, as you've developed programs where you're trying to convey more information to consumers about foods in food service sector, it seemed like sodium was getting kind of short-shriffed in some of the kind symbols or programs that you've developed and I would be interested in hearing more about the role of sodium in the kind of communication systems that you're developing.

And also, I think many of us are, have

1 seen on menus, you know, either a heart symbol or
2 other kinds of symbols trying to lead consumers to a
3 choice that might be lower in calories or some other
4 modification and I would be interested to know
5 whether or not there are general criteria that have

whether or not there are general criteria that have been developed for those or is that really on an organization-by-organization basis for doing that. SUE BORRA: To start off with your Web

SUE BORRA: To start off with your Web question, we, the research that I shared so far went from ethnographic to the qualitative phase, so this is just very preliminarily directional, you'd have to do some further testing on it. But it was very interesting in the fact especially in that ethnographic research.

They were using nutrition facts panel information sometimes to make purchase decisions. When we went home, we talked to them about, okay, what are you going to use now that you're at home. If they looked at the nutrition facts panel at home, it was more for educational purpose. They've made the decision to purchase that food, bring it in their home, they were going to eat it. But then

they're looking at it for more education kind of information.

I think that's where the Website became very valuable. It's a place I can go, it's somewhere beyond just this little box on the label to find out some more information and I think because of most of the regulation we're under now was way before the days of Web, I don't think we've even begun to explore what our opportunities are to communicate through that venue with a lot of this complicated information that's being, trying to be presented in one shop in a label environment and I

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think that's worth exploring.
So we will take that on in terms of our
next phase of experiment, however, I have to admit
we're doing more quantitative analyses now in a
Web-based environment, so it's going to be hard to
tease out, you know, who are going to benefit from
that the most, so that's something to consider, too.
SHEILA WEISS: There are two parts, so

I'm going to address the first part first. In terms of the role of sodium in this nutrition information,

now certainly in a lot of these criteria the sodium is included in a general criteria, in our food service -- in our contract service that use the lighter fare, they, they highlighted sodium more so in their elder -- their elder hostile -- not hostiles, their, I'm sorry, their retirement communities and those food service establishments to look at their audience.

Now as sodium is becoming more of an issue, a highlight for our industry as well as for the packaged food industry, our members are certainly moving to reduce sodium in various ways and one of the most successful ways they've found to do this is more, is more stealthier, to do it gradually and make changes with their suppliers, make changes in some of their other menu items and going more towards fresher ingredients and different spices and different flavors, but certainly this is something that's being done gradually in the industry.

In terms of the symbols, there isn't necessarily a general criteria because there are so

many symbols out there. When I, when we talked to our members, they had different symbols with different criteria, certainly some uses a carrot to represent vegetarian items, some use, some use, look at fat and calories, depending on, on their consumers. So, it certainly varies and there is not a general criteria.

Now obviously something like Healthy Dining Finder which is a program that we are working to promote through the industry, there is a, there is a specific and general criteria for that.

MICHAEL JACOBSON: I'm, regarding the Internet, I'm not sure what's behind your question, but I think we should pretty much ignore the Internet as a source, as a useful source of information for consumers.

Look at it this way, what percentage of people read a food label? 5 percent, 50 percent, you know the numbers vary, but it's in that, somewhere around that order of magnitude.

Fast food companies have been saying they put nutrition information on the Internet, it's

there for every consumer, people can go to the Internet, see what a Big Mac has or whatever and what percentage of consumers, of McDonald's consumers in that instance go to the Internet and use that. And I would guess it's on the order of .0001 percent and we shouldn't -- nutrition labeling

FDA Hearing Day 2.txt is extremely important, food labeling is extremely important because that's where, you know, people 8 9 have it in their hand. 10 Consumers shouldn't be forced to go to the Internet to get a nutrition facts label, 11 say, 12 which some people might have argued for back in 1990 if the Internet had been around then. 13 14 It, good information should be on the 15 I abel. MICHAEL LANDA: Any other questions from 16 the FDA panelists? 17 18 That concludes our session for this 19 Let's reconvene at 1:30, please. morni ng. 20 Thank you. 21 22 0177 AFTERNOON FIRST SESSION SPEAKERS: 1 2 3 4 Mary Hager Victor Fulgoni Mary K. Young 5 6 7 Helen Falco 8 Marty Ordman 9 10 11 12 13 14 15 16 17 18 19 20 21 22 0178 MICHAEL LANDA: If we could begin to re-assemble, that would be helpful. Thank you. 2 3 Why don't we get started on this afternoon's sessions. We have scheduled, we're 5 scheduled to hear from our registered public 6 7 commentors that's not on the program, but we're also going to have panel one from yesterday come up again to take some more questions, it was the first panel 8 9 yesterday. I was a little nervous about letting questions run on too long and consequently lots of questions that people had were not asked because 10 11 there wasn't time to ask them, so we'll remedy that 12 13 today. 14 With that, our registered commentors are Mary Hager from the American Dietetic Association, 15 Victor Fulgoni from Nutrient Rich Foods Coalition, 16 Mary K. Young from the National Cattlemen's Beef Association, Helen Falco from the Coca-Cola Company, Marty Ordman from the Dole Food Company is listed, 17 18 19 it's unclear whether he has made it here or will be 20 able to. We'll see when his time comes. 21 22 Let's start with Mary Hager from the 0179

American Dietetic Association.

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Good afternoon. I wish to MARY HAGER: begin by thanking the FDA for the opportunity to provide comments on behalf of the American Dietetic Association. The ADA represents 67,000 food and nutrition professionals serving the public through the promotion of optimal nutrition, health and well-being.

ADA does not endorse or certify food products and thus does not have a proprietary symbol or icon. ADA, however, has long been an active participant in nutrition public policy process and thus it has developed principles for food product I abel i ng.

ADA has six public policy priority areas and they readily address many of the labeling issues we've heard discussed over the two days. It's ADA's long-standing position that food and nutrition misinformation can have harmful affects on the health, well-being and economic status of consumers. Over these two days we have heard many

concerns on how labeling affects these areas,

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particularly when it comes to child nutrition, literacy and overweight and obesity.

Members of ADA are nationally credentialed food and nutrition specialists working in health care, academia, public health, the media, Government and the food industry. They are uniquely qualified to advocate for and promote science-based nutrition information to the public. They also function as primary nutrition educators of professionals and actually correct food and nutrition misinformation.

Who are ADA's 67,000 members? The majority are registered dietitians, greater than 50 percent have graduate degrees including professional degrees in laws and medicine and members also include nutritionists who are not RDs and several other groups of members.

ADA members practice primarily in clinical settings, that would be hospitals and unrelated facilities. Next to that they also practice in community settings where they have a lot of influence as well with the public and the

consumers. Again, they have several other practice

areas including academia and research.

ADA has built a reputation of relying on sound science and because of that its members are sought after scientific advisors in a large variety of venues, a lot of them Government based. Also, it produces a peer review journal and has developed an evidence analysis library which contains more than 20,000 graded scientific peer reviewed papers that have been graded for the strength of the science.

Generally specific questions are asked and then the literature is collected, rated and ranked for its science. Consequently, as you see at the bottom, we are a global leader in evidence-based practice because of that library and this is a slide which shows that we have inquiries to our online evidence analysis library by more than 120 different

countries worldwide.

 Again, we recognize that all science is not equal, so we evaluate it. And this is a member service, we also, people subscribe to our evidence analysis library for practice guidance and for other

issues related to the science.

ADA members also translate the science and they are invited in a variety of settings. They are a source of information to Government, again, professionals, other professionals and consumer education.

ADA supports FDA's efforts and its decision to explore this issue and urges it to consider the effectiveness of food and beverage product labeling symbols. These labeling symbols are designed to market certain positive nutritional attributes of specific food products in order to theoretically enable consumers to make more informed and healthier food choices. In many cases they also consider the negative nutrition attributes of a food product.

ADA has adopted its own set of principles for the labeling of foods, beverages and other dietary products that are consumed by the public and it uses those principles to guide its consideration of proposed labeling rules.

While our principles, which I'll share

with you, are not exclusive, they represent a foundation that together with the science can be uniformly applied to a wide variety of food product labels.

ADA's member task force on labeling has analyzed and advised ADA in developing its responses to a variety of agencies and you'll see the SISAN, Alcohol and Tobacco Tax and Trade, USDA and the FTC are listed.

The Association has agreed on the following set of principles supported by sound science. Label claims must be clear and understandable to consumers. The label must be truthful and not misleading. That's not our original idea, but we do ascribe to it fully.

Content of the label should help consumers make informed decisions to build a healthy diet. Label content should have consistent type and format so products can be read and consumers can make product comparisons. And this number four we consider very important and we ask a lot of the executive branch agencies to get together and make

sure that they are being consistent in how they present label information.

All claims should include labeling of accurate quantitative information about the dietary substance including the DVs and how much is needed to be consumed to meet their daily requirements.

Consumer research is imperative before

making any changes to the label. And lastly, the label's only a source of information, I'm not the first person to say that today and, or even today, sustained support for educational programs and

FDA Hearing Day 2.txt 12 individual counseling by registered dietitians are 13 essential. 14 While front of package symbols are 15 frequently promoted as helping consumers make better food purchase selections more quickly, it is unclear as to how well the current plethora of symbols 16 17 actually facilitates or form purchase decisions and improve diets. Haven't seen those data yet. 18 19 20 ADA recommends that the FDA consider 21 these principles in exercising its authority to 22 formulate a cogent, coherent and consistent national 0185 policy on symbols and icons that consumers can 1 2 understand and use within the context of the myriad of food and dietary options available in today's 4 market. 5 Furthermore, ADA believes that consumers 6 7 are benefitted when they consume a healthful diet from a variety of foods. We believe it's the total 8 diet, not any single food product, which is an 9 essential element for good nutrition and better 10 heal th. If asked which of our principles are the 11 most important for FDA to apply and considering the 12 appropriateness of icons and symbols to convey the 13 nutritional value of food, our answers would include 14 Again, they must be clear and 15 these four. 16 understandable to consumers and consequently, they 17 must be consumer tested. It should help them make informed decisions to build a healthy diet and there 18 19 should be an ongoing educational effort. We also believe that when consumer 20 research is conducted, it should not just be on the 21 primary shoppers, but it should also be on 22 0186 influencers such as the registered dietitians who 2 spend a lot of one-on-one time with individuals and who are doing public health programs because if they don't believe the icon is meaningful, they will undermine it, I'll be frank with you. They'll say it really doesn't mean anything, it's just another marketing tool. So if you take your consumer research, it should be to key health professionals. 3 4 5 6 7 8 9 And of course you heard mentioned yesterday, 10 chi I dren. 11 So, final words, labeling should help Americans make informed decisions to build a better 12 13 di et. 14 Thank you. 15 (Appl ause) MICHAEL LÁNDA: Our next public 16 commenter is Victor Fulgoni from Nutrient Rich Foods 17 18 Coalition. 19 VICTOR FULGONI: Thank you and good 20 afternoon. 21 I also want to thank FDA for holding 22 this public hearing on on pack nutrition labeling 0187

and the use of symbols. My name is Victor Fulgoni, I'm from the Food and Nutrition Consulting Company called Nutrition Impact. For the last several years I have been working with Adam Jenalski and a small group of scientific advisors to develop the nutrient Page 68

FDA Hearing Day 2.txt rich foods index and today I'm here to talk on

behalf of the Nutrient Rich Foods Coalition.

Our comments are going to address three key questions that FDA put forward in the Federal Register Notice and those are dealing with what nutritional criteria should be included in a symbol system and how should those criteria be selected, what nutrient thresholds or algorithms should be used and develop a display nutrient specific or summary symbol and do symbols affect nutrient quality of total diet of consumers who use these symbols.

We actually will probably be one of the first to show that the index can be used to actually correlate with an objective measure of diet quality, something I've heard over the last two days we direly need to see.

Our approach is based on nutrient density. We believe that nutrient density should be the basis for any nutritional criteria that's being used for on pack symbols. We believe that the, that this could help address, you know, the public health crisis about obesity and overweight and still at the same time address some of the micro nutrient issues that are still concerns about certain, consumption of certain micro nutrients in certain population groups.

The idea of nutrient density is not new. It's been around a long time. It's highlighted in the FDA -- FDA obesity report, it's highlighted in the dietary guidelines. It's really an accepted dietary principle. The problem is we haven't had very good ways of measuring it and that's what we're boning to do with the nutrient foods rich index

hoping to do with the nutrient foods rich index.

We think that the nutrient density is
the best way to actually help tell the story about
the total nutrient value of a food.

The core principles of our approach, it's science based and consumer tested. We haven't

quite completed the consumer testing, but it's going to be by the time it gets implemented. We believe it should be simple, objective and transparent so that everybody can see where the algorithm, how the algorithm works and how their products would fit into that particular algorithm.

We believe any approach should be validated against diet quality measures and hopefully even health outcomes, if that's possible. And we should emphasize the total nutrient value of the foods within and among the food groups, should be able to compare within a food group as well as across a food group.

Our approach is really looking at going across the whole food supply, being able to apply an index for all foods, not a particular category of foods, all foods, whether they are in packaged goods or in restaurants, doesn't really matter.

The algorithm should work for all of

those groups and the goal is to help people enjoy healthier diets by getting more nutrition from their calories.

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The approach doesn't, doesn't focus specifically on nutrients to avoid, nor does it focus specifically on nutrients to increase. It really looks at using the total nutrition package that we have for foods. The approach, the scientific steps we take are four, the first is really looking at the nutritional criteria, then we create the algorithm, do the testing and validation and eventually do the comprehensive consumer research.

There are a lot of questions that we had to go through as we went through the nutritional What nutrients to include, criteria selection. what, what's the reference amount for each of those nutrients, where is the dietary standard that we should have for that nutrient. What serving size, is it based on RACC, is it based on 100 calories, is it based on 2,000 calories, is it based on What is the basis for doing this. 100 grams.

Is it just positive nutrients, is it just negative nutrients or is it a combination of both. And then is it food group specific.

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know, we actually looked at an algorithm that took advantage of the fact that, you know, food groups have been developed to provide certain nutrients, could we create an algorithm just based off those particular nutrients from each specific food group.

On the algorithm there's several questions, do you do just a sum of the daily value percentages, do you create a mean, do you create a ratio, do you weight, do you cap, I mean there's a variety of iterations that we've gone to to kind of evaluate where we're going to go.

So I'll just go ahead and take you through some of the decisions that we've made based

on the validation approach we've used.

We started with the nutrients that are needed to be increased in the diet by primarily looking at the USDA what we eat in American usual intake report, looking at the nutrients that were, you know, needed to be increased in most people and also added in nutrients that were needed for some subpopulation groups; however, just adding more nutrients is not simply the solution to this.

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We found that there were several nutrients that are highly correlated, they travel together and they didn't help us in trying to explain more variation in total diet, so we actually removed some of those. Some nutrients are ubiquitous so we weren't able to use it to help differentiate among food products, so they were dropped as well.

The key focus was to actually be able to have an index that would allow us to distinguish among most foods and allow for healthier choices, consumers that saw these scores.

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> This is a list of some of the algorithms that we've actually tested, shows you the nutrients that are actually included. We actually did look at some preexisting indices that are out there.

focusing right about now on 11 nutrients seems to be an ideal number, this includes protein, fiber, four vitamins and five minerals and you can see the list there. We've added in the negative nutrients, we've actually concluded saturated fat total or added sugars and sodium are about the best group of

negative nutrients to add.

We've, we've decided to combine both positive and negative. After looking at several of our iterations, we think this provides a broader approach, it's more comprehensive and actually did enhance, as you'll see, some of our explanation of variation in total diet.

We linked the reference amounts to well-accepted standards, those of FDA's DRVs, daily reference values and RDI values. We didn't insert new evolving concepts, we stayed to the true, tried We currently look like and true consensus science. the base -- to base the calculations on 100 K cals or RACC seems to be the best.

There are other options you could use, but those two seem to be, continually to be the front runner. And regarding food groups, you saw some algorithms were actually adding in food groups, mixing food groups and nutrients. We don't think that that's a good way to create an algorithm, but we do think you can use the algorithm across the food groups and then if you want to apply it

specifically within food groups.

All of our calculations were based on USDA nutrient composition data and the national health and nutrition examination surveys. of you outside the United States, we are very fortunate in the U.S. to have extensive nutrient composition data as well as health and nutrition intake data that's available every couple of years from the National Center of Health Statistics and Center for Disease Control

On the algorithm, itself, you saw some that created a point system, you could be continuous, you could be weighted, you could be unweighted, you can use the sum, you could use the mean, you can do a ratio. We looked at all of those options and basically, we also did look at capping when we had a 2,000 calorie option. You know, 2,000 calories of peppers provided an awful lot of Vitamin C, so we had to end up capping, capping that.

We are capping now at 100 percent, but we think a continuous unweighted mean or sum would

be the best approach and I'll show you some of that. This is just an example of what you could show, this is actually looking at one of the models that included 15 nutrients, you see pretty much the same thing with the lower numbers, but showing you can differentiate foods, your vegetables and actually your organ meats are over here because of the nutrients they have.

This is energy density, just to show you the energy density related to the index.

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see that candy and soda end up over on one side and you have a continuum of where milk, fish, cheese and

other products are available.

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So that just gives you a picture of what the index looks like. On validation, and this is where we've spent a lot of our effort, if you go through the literature you'll see various approaches to trying to validate an index. Some are basically it looks right, it feels right, I've seen the data, it looks right.

Others are just, you know, certain foods that we think should be higher are higher, then

there are others that are just correlating with expert opinion. We think the best and frankly the only valid way to do it is to link to some measure of diet quality. And in our case, what we link to is a healthy eating index developed by USDA.

We've used the 2005 healthy eating index which factors in fruits, whole fruits, grains, whole grains, vegetables, vibrantly colored vegetables and goes all the way down to have saturated fat, sodium, and then the new concept of SFASA, which is the calories from saturated fat, added sugars and alcohol, so that's really the basis of how we validated our index.

All right. So we, we actually have used the, and actually the Anne Heins data and developed a regression analyses based on diet quality, body mass index, both systolic and diastolic blood pressure and cholesterol levels.

What we did, we took the Anne Heins data, calculated the nutrient index for every food that was consumed by the subjects in the study and then created an overall diet score based on the

index for those subjects and then correlated that information to diet quality as well as the health outcome variables.

This is a very data rich slide which is getting into a format for a publication and I just want to highlight on this case we're showing, we can explain about 40 percent of the variation. you're using 100 K cal as your basis, and 11 minus 3, those 11 nutrients I showed you plus the 3 negatives we talked about were about 32 percent of the variation in healthy eating index with the nutrient index. This is our, if you just looked at what a baseline would be adjusting for gender, age and race ethnicity, it's about 7 percent, so we're seeing a very significant increase in, in the explanation of variation. So showing that diet, the nutrient index can predict diet quality as measured by a healthy eating index.

We show the same thing with -- yep, yep, I'm going to go right through. We show the same thing with blood pressure and with LDL cholesterol. We can show significant relationships, however the

R-squares are significantly lower and so we, we now have a family of indices that have been tested and this is the only approach that I've seen that has actually been validated against objective measures

FDA Hearing Day 2.txt of diet quality and health outcomes and I think the 6 key next step is translation of this science to the 7 consumer. 8 There's another team that is actually 9 working on that and then as we've developed the science, they're starting to work that, you have the activities to bring that science to life, messages, 10 11 12 on pack tools, et cetera. 13 So, you know, our approach is science-based, consumer driven, objective and transparent. We believe that it's relevant, you 14 15 16 know, to the dietary needs to distinguish among the food groups, the reference amounts are linked to food labeling, we think it's important to link to the food labels, let's not throw it away, we spent a 17 18 19 20 lot of time working it. 21 The balance of positive and negative 22 nutrients really looks at the complete nutritive 0199 value, have a simple algorithm that's fairly 1 transparent and it's been validated against subjective measures and hopefully we'll help people enjoy healthier diets by getting more nutrition from their calories. 4 5 6 Thank you. 7 (Appl ause) 8 MICHAEL LÁNDA: Our next speaker is 9 Mary K. Young with the National Cattlemen's Beef 10 Association. 11 MARY YOUNG: There we go. Thank you. On behalf of America's beef producers, I appreciate the opportunity to be here today to share some of 12 13 14 our consumer research. 15 While there is not mandatory nutrition labeling in the meat case, we have been long-time supporters of just that. We believe consumers have 16 17 18 the right to know what's in their foods and we have 19 supported USDA's proposed rule on nutrition labeling 20 in the meat case for a very long time.

To that end we've been doing a number of 21 22 different types of research projects on nutrition 0200 labeling and I'm going to share a little bit of that 1 2 today with you. Sticky thing. There we go. 4 the three questions that I'll address today, 5 consumer attitudes towards symbols, the connection 6 7 between symbols as well as the principal display panel and how do consumers use these symbols.

The last couple of days we've all been 8 here because we're trying to help Americans build healthier diets. The FDA obesity working group 9 10 11 called for an action plan to help consumers lead healthier lives through better nutrition and the 12 13 dietary guidelines for Americans in My Pyramid call 14 us to get more nutrition from our calories because of the concern of being overfed yet undernourished.

In fact, the dietary guidelines, in
part, say many Americans consume more calories than 15 16 17 they need without meeting recommended intakes for 18 19 nutrients. This circumstance means that most people 20 need to choose meals and snacks that are high in 21 nutrients but low to moderate in energy content, Page 73

FDA Hearing Day 2.txt that is, meeting nutrient recommendations must go hand in hand with keeping calories under control.

We firmly believe in the need for a

we firmly believe in the need for a unified system and that the nutrition facts panel and the principal display panel can really be powerful tools to help consumers implement the dietary guidelines in My Pyramid.

So, given that, we asked the question does the nutrition facts panel go far enough to actually help Americans get more nutrition from their calories. We've conducted a number of different research projects, the one I'm going to primarily spend some time talking about today is the 800 online adult food shoppers, it's a random sample.

We also talked to registered dietitians in both qualitative and quantitative and I've got a little bit of that data to share with you today.

We tested products across the grocery store. We provided different nutrition facts panels and principal display panels and we tested all different products in random order, et cetera, throughout the project.

And the first question we asked, if we're supposed to be getting more nutrition for our calories, does the nutrition facts panel help consumers do that, given that it only has four micro nutrients, Vitamin A, C, calcium and iron.

So we provided a couple of different samples. On the, I guess your left, you see the current nutrition facts panel and then on the other side you see an expanded panel that is food group specific, provides the nutrients, as an earlier speaker said, we have food groups for a reason and so it expands the nutrition information to provide nutrients, micro nutrients that are found from that food group and this is the spinach examples, the vegetable example.

What did consumers tell us, that overwhelmingly almost 80 percent of consumers prefer the nutrition facts panel that shows the food group specific nutrients on the label and dietitians agree, they like that idea of having all of that information when they're talking to their consumers and having their clients make healthier choices.

Well what about the principal display panel, is it an opportunity to communicate more nutrition information and obviously we've spent two days talking about that. So we first showed the same labels including the milk one, it's not up here, it's just so the slide wouldn't get too busy without any, any kind of symbol on the front of pack at all.

We then said well what about if we put a calorie call-out on the package and this is what that looks like, you can see just a little round circle that says, you know, up there with the spinach, 20 calories per serving.

We then also said well what about a package front that includes calories and nutrient Page 74

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call-outs and then that's what these packages would look like, that spinach again, 20 calories per serving is an excellent source of Vitamin A and Vitamin C.

And consumers, again, almost 70 percent of consumers prefer the front of the package that shows both calories and nutrients and told us that

it would be most effective in helping them choose nutritious foods. And, in fact, only 5 percent of consumers preferred the calories only label on the front. Probably not surprising to those of us in the room that does a lot of consumer research.

But dietitians agree as well, not only do they prefer that front of pack that has both the calories and nutrition information, they believe it will help their clients actually follow the dietary guidelines and choose nutritious foods and get more nutrition from their calories.

Well then what about the combination of the principal display panel and the nutrition facts panel, you know, and how could those work together and is there a combination that would work best for consumers. So, consumers looked at all of those products with a total of six different options of combinations with each of those products and then what did they tell us.

Their preference, and it was an online survey, so they were able to turn the product over online and see the nutrition facts panel, their

preference consistently across the board for all products that, the principal display panel on front that had calories plus nutrients and then the expanded food group specific nutrition facts panel on the bottom and in fact, 57 percent of consumers preferred that.

The second most popular one that was the most, second most liked by 12 percent of consumers was the calorie plus nutrients and the current nutrition facts panel.

nutrition facts panel.

Well, 30 years of talking primarily about fat, we know we've had an unintended consequence of people choosing a lot of low fat foods without regard to calories, so we also asked the question is there a potential unintended consequence of focusing primarily on calories, because we do believe that we should be helping people build better diets by the total nutritive package of their foods.

So, we showed them two labels and what you see here is a low calorie, high nutrient value food, if you can't see the numbers, it's 90 calories

and has a number of vitamins and minerals, good and excellent source of a number of vitamins and minerals, the other product is a low calorie, low nutrient value food at 5 calories are virtually no micro nutrients at all. And we asked consumers which would you choose, which product is the healthier product.

And consumers equally selected diet soda and skim milk which does cause one to be concerned

FDA Hearing Day 2.txt 10 about if we focus only on calories on that principal 11 display panel, for some people will there be an unintended consequence of choosing low calorie foods 12 13 that are not nutrient rich. In summary, we do believe a unified system is important and that the nutrition facts 14 15 panel as well as the principal display panel can be 16 really primarily effective tools in helping 17 18 consumers implement the dietary guidelines in 19 My Pyramid. 20 The nutrition facts panel could go much further by providing the food group specific micro nutrients in helping Americans get more nutrition 21 22 0207 from their calories. The principal display panel that includes calories plus nutrients was the most effective one that we showed consumers in helping them choose nutritious food choices and the 5 combination of that same panel, principal display 6 panel with calories and nutrients plus the expanded 7 food group specific nutrition facts panel was the 8 one that consumers and dietitians preferred as a way 9 to help them purchase nutritious foods. 10 And the last point is we do need to, as we're having these types of deliberations, be 11 concerned about any unintended consequences that 12 could come out of what we do. 13 14 Thank you. 15 (Appl ause) MI CHAEL LANDA: Our final speaker on 16 this panel is Helen Falco with the Coca-Cola 17 18 Company. 19 HELEN FALCO: Good afternoon. I think there's something special about being last on an 20 agenda and on a dreary, rainy afternoon, so it's 21 22 kind of nice to see how full the room still is. 0208 1 My name is Helen Falco, I serve as director of nutrition and health policy for the Coca-Cola Company. We really appreciate the 4 opportunity to be here to share our views on the use 5 of symbols to communicate nutrition information. 6 Before making my remarks, I would like 7 to state that Coca-Cola acknowledges the importance 8 of identifying and implementing solutions that will 9 enhance the health, the well-being and the 10 nutritional status of the public. That's what we're 11 really here for. At Coca-Cola we believe in offering 12 13 people choices and we provide a wide variety of 14 beverages as well as portion sizes to meet consumers need for fun, for refreshment, nutrition and 15 16 hydrati on. From our range of products, package 17 sizes and the information that is provided on these 18 19 packages, including for dual labeling that provide both serving size and for the total package, consumers can make sensible choices that are 20 21 22 compatible with a healthy, active lifestyle.

However, having nutrition information is not enough. The challenge for all of us is to identify what really will work to promote healthy Page 76

FDA Hearing Day 2.txt lifestyles and what will result in positive, sustainable changes in the health of consumers, in particular with respect to obesity. We would like to thank FDA for providing this opportunity to share our viewpoints and for addressing this increasing interest in the use of nutrition symbols. Coca-Cola wishes to provide -to provide brief comments that will cover three main points related to research and education, themes that have been repeated over and over during these two days. Number one, comprehensive U.S. population-based research is needed before embarking on any Governmental approach to nutrition symbols. Number two, concerted, sustained and creative education programs must underpin current and future nutrition labeling initiatives. And three, successful educational initiatives must inform, must motivate and must 0210 empower consumers to achieve better diets and better heal th. $\label{lem:coca-Cola} \hbox{Coca-Cola has participated in industry} \\ \hbox{and Government discussions on the use of nutrition}$ symbols in many parts of the world, including here in the United States. And we have applied objective, fact-based symbols in some countries, in particular where nutrition information is not mandatory. While we continue to learn from the experiences in other countries, we believe that consideration about use of nutrition symbols needs to be addressed in the national context, taking into account existing regulatory conditions as well as consumer health issues and consumer interest. In particular, consideration should be given to the availability of alternate solutions that could be effectively and efficiently utilized to help slow the rate of obesity and eventually reduce its prevalence in our society. FDA has asked challenging questions with respect to existing research on nutrition symbols. 0211 While a number of qualitative and quantitative investigations have been carried out and have been reported on during this hearing, answers to how these programs are understood and utilized within the context of the total diet remain unclear. There simply is no definitive indication at this point that creating yet another on pack representation of nutrition information would be motivating or would make a difference, especially with respect to the prevalence of obesity. Furthermore, there is no definitive indication at this point that broader use of nutrition symbols would help stem the confusion about diet and health. In our opinion, therefore, there is a need for comprehensive U.S. population-based research that would demonstrate whether or not symbols would serve as an effective tool in helping American consumers achieve a healthier overall diet and in doing so, would help reduce the incidents of

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obesity. And if that answer is affirmative, 22 additional research would be needed to identify 0212 which types of symbols and supporting educational initiatives would best achieve the purpose. What is even more crucial, we need 4 5 research to help determine the basic underpinning of what motivates a consumer to read, to understand and to act on nutrition information. We need to 6 7 determine why currently-available information does 8 not yet seem to resonate with so many people. 9 Our ascertaining this basic, but not at all simple question, is absolutely essential. Until such research is available, we believe that it would be premature to embark on any Governmental approach 10 11 12 to use of nutrition symbols in the U.S. population.

Nevertheless, we can't wait for all the 13 14 answers before taking action. At the very least we must use the tools at hand and begin to develop 15 16 necessary educational foundation that will lead to 17 18 changes in diet and changes in health. Where then do we go in the U.S. context? We feel that the U.S. is in a unique position having implemented nutrition labeling some 15 years ago. Consumers see the nutrition facts panel nearly every 19 20 21 22 0213 time they pick up a packaged food or beverage 2 product. They see it, but do they understand the information, can they use it to select an overall healthy diet. Despite the familiarity that consumers have with this grandfather of nutrition symbols, there is good evidence that the answer to these questions is all too often no. 4 5 6 7 8 Certainly improvements to the format and content of the nutrition facts panel can and should 9 10 be considered, but is this enough? We don't think so. Just like any other complex instrument, MP3 players, the hybrid cars, consumers must be taught 11 12 to use the nutrition facts panel before it can impact their lives. 13 14 15 It cannot achieve the desired outcome, 16 better diet and health on its own. It is 17 Coca-Cola's position that through concerted, 18 sustained and creative education programs that are 19 supported by all stakeholders, by Government, consumer groups, health professionals, the food and beverage industry, schools, parents, the media, in other words, by all of us, that we can slowly but 20 21 22 0214 surely help reduce the prevalence of obesity in the 2 3 U.S. population. Well now there are many who say, hmm, 4 5 education, we've tried it, doesn't work. Let's go on to something else. We can agree that scattered, 6 short-term initiatives lack the necessary scientific evaluation to substantiate the work are unlikely to 8 9 have the needed impact. Further, education cannot be just one 10 We have to approach it from many angles and from many disciplines. To that end, just imagine what if we were to harness the collective genius of 11 12 13 all stakeholders to develop and execute programs 14 that inform, that motivate and that empower Page 78

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FDA Hearing Day 2.txt 15 consumers to take charge of their own diets, their 16 own level of physical activity and their own health. Change would not be instantaneous, but 17 we believe it would be observed over time and that 18 19 small steps would eventually lead to big, big 20 successes. 21 One way Coca-Cola is planning to increase understanding of the nutrition facts panel 22 0215 and the ingredient panel, because as we can't 2 3 forget, it does also provide a lot of really good information, is through a program we will be initiating called be label conscious. It is designed to increase the consciousness of consumers as it relates to the food label, to increase their awareness, their knowledge and their understanding 5 6 7 8 of this very important tool. We will keep you 9 updated as progress moves forward. 10 So, as you reflect on the vast amount of information that has been presented over these two 11 days, we encourage you to consider the importance 12 and the power of education. Whether it is education to improve the understanding and use of the current nutrition facts panel or an improved panel or potentially whether it is education to understand 13 14 15 16 and use nutrition symbols. 17 18 Without concerted education programs 19 that motivate and empower the consumer, we will continue to engage in graphic exercises and unfortunately we will leave this problem for the 20 21 22 next generation to resolve. 0216 Thank you for your consideration. will be providing additional detailed comments and we look forward to working with everyone in a 3 4 5 6 7 collaborative manner to find solutions that really will final turn the tide on obesity. Thank you. (Appl ause) 8 MICHAEL LÁNDA: We have a question from 9 Kathy Ellwood. 10 KATHLEEN ELLWOOD: Oh, takes a while. 11 Okay, this is for Dr. Fulgoni and this is really kind of piggybacking on a question that Dr. Schneeman had asked of a speaker this morning 12 13 that in your system, are you taking into account fortification and does it also apply to beverages or 14 15 is it strictly for conventional foods?
VICTOR FULGONI: Yeah, I'l 16 VICTOR FULGONI: Yeah, I'll take the last, the last question first. It applies to both 17 18 food and beverages and frankly all foods that are 19 20 consumed in America. 21 On fortification, it does include 22 fortification, we're not trying to exclude 0217 fortification, nor do we penalize for fortification. However, we do cap at 100 percent of the DV so if something was fortified at 125 percent, it would not 1 2 3 4 get any additional value. 5 MI CHAEL LANDA: We have a question from David Zorn. DAVID ZORN: Ms. Young, my question is for you. On the nutrition call-outs, and I couldn't Page 79

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      really see the slide, what nutrients did you
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      highlight on the front?
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                    MARY YOUNG:
                                   It's a good question, sorry
      they were so small. We, we highlighted nutrients
12
      from that food that were either an excellent or a good source. So the spinach had Vitamin A and
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14
      Vitamin C, I think the milk had calcium and
15
      Vitamin D and then beef had either protein and iron
16
17
      or iron and zinc, something like that.
                    DAVID ZORN:
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                                   So it varied from just
19
      which every
                                  It varied, it was food
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                    MARY YOUNG:
21
      group specific.
                    DAVID ZORN:
22
                                   Okay, so it was almost sort
0218
 1
      of a substitute for a nutrient content claim, sort
 2
      of?
 3
                    MARY YOUNG:
                                   Yeah.
                                            Uh-huh.
                    DAVID ZORN:
                                   Okay, thank you.
 5
                    MICHAEL LANDA: We have a question from
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7
      Felicia Billingslea.
                    FELICIA BILLINGSLEA: Actually,
      Ms. Young, my question is also for you and builds on David's question.
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                    You, you said that one of the findings
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      from your research was that consumers preferred to
11
      have food specific nutrients included in the
12
13
      nutrition facts panel.
14
                    I guess the first part of my question is
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      how would the consumer have been informed that these
     are food group specific; and the second part is if they saw two milk products, let's say, where one had just the mandatory nutrients in the nutrition facts panel, the other included the expanded group, would
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      the consumer take away that those products are
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      different or would they understand that even the
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22
      product that didn't contain those expanded nutrients
0219
     contained those because they were the same food?

MARY YOUNG: Also good questions.

The, before we did the quantitative, we
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      did some qualitative work and what we found in
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      qualitative is that if it's not there, they don't
      think it has it.
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7
                    Now when they were shown the milk
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      products, for instance, they saw it on a container
 9
      of milk, they saw the nutrition facts panel and they
                           So they saw one as it stands today
10
      saw both panels.
      and then they saw the expanded one.

Now we didn't tell them it was food
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12
      group specific, but they saw what the micro
nutrients were and then they selected which panel
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15
      was the one that helped them choose the foods, you
16
      know, nutrition foods. Which one did they prefer
17
      and which would then help them shop for more
18
      nutritious foods.
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                    MICHAEL LANDA: We have a question from
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      Camille Brewer
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                    CAMILLE BREWER:
                                        Thank you. I'd like to
22
      build on Felicia's question. It's not clear to me
0220
      how you're defining food groups, are you talking
      about peaches to peaches, are you talking about milk
                                              Page 80
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FDA Hearing Day 2.txt
      products as a larger category? What does food group
 4
      mean to you?
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                      MARY YOUNG: We used it based on USDA's
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7
      food grouping when they developed the pyramid that
      there are specific nutrients that each food group provides, so fruits provide, you know, these
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 9
      nutri ents, vegetables provide these ones, et cetera,
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                     So those were the ones that we utilized
      et cetera.
      in putting on the label.
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                     MI CHAEL LANDA:
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                                          We have a question from
      Barbara Schneeman.
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                      BARBARA SCHNEEMAN:
14
                                               Thank you.
                      I have a question for Dr. Hager and I'd
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      like to know with the various symbols and systems that are out there in the marketplace, do you know
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      if dietitians, your professional group, are they using them to any extent? If they do use them, how
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19
20
      do they use them?
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                      And also I did note that ADA has at
      times decided to endorse a program, I think you were
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 1
      referred to in the three a day, what criteria the
      organization uses to lend its name to these kinds of
 3
      programs.
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                      MARY HAGER: Right, exactly, but not a
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      specific food product do we endorse, so we don't
 6
      have a symbol for an endorsed or certified food
 7
      product, I'd like to clarify that. And in terms of
      our members using the symbols, that's something that we're going to be looking at in how they use them.

MICHAEL LANDA: I just have a clarifying
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11
      questi on.
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                      When you do endorse, what is it that you
13
      endorse?
14
                      MARY HAGER:
                                      We, what do we endorse, it
      would be a program, we would go into a memorandum of
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16
      agreement for a specific program or we've done that
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      with insurance companies with the wellness program
      for children or that type of thing.

But when it comes to a food product, we
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      would, do not have an icon to say, you know, this food product, per se, on the shelf, would have an ADA symbol on it. Is that clear or did I miss
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22
0222
      something?
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      Like, you know, like we have on our toothpaste or our, like the check system. Progr
                                                             Programs,
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5
      but not products.
      BARBARA SCHNEEMAN: Right, and so if you think about a program that you, I don't know whether endorse is the correct word, but if you think about a program that you have lent your name to, what
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 9
      criteria have you used to make a decision about
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      whether or not you would enter into that?
                     MARY HAGER: Exactly, and I cannot
11
      answer that myself. I would have to contact our
12
      Chi cago group for that.

BARBARA SCHNEEMAN:
13
                                               Thank you.
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                      MICHAEL LANDA: Any other questions from
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16
      the panel?
                      Barbara Schneeman.
                      BARBARA SCHNEEMAN:
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                                                Get a second chance.
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                      I wanted to ask Ms. Young some more
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      questions about the study that they did, so I'm --
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FDA Hearing Day 2.txt
      it almost -- one interpretation of the nutrition
21
      facts labels that you put up for the diet soda and
      the milk is that while consumers did have additional
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0223
      information, it didn't improve the judgment they made about the product and I'm just wondering if you
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 3
      would comment on that.
                      I think you were trying to address, you
      know, do consumers just look at a longer list of
 5
      nutrients and assume a product is more nutritious, but when they compare two products and made a judgment, did that additional information help them.
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 9
                       MARY YOUNG:
                                       They saw that unintended
      consequences section was separate from, and I don't remember what order, I'd have to go back and look at the questionnaire and look at that, but it was
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      separate from the longer panel questions, et cetera.
                       But obviously, one, one of those labels
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15
      had more information and, you know, a good part of
      the population, equal numbers picked the one with
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      more nutrition information. So I would, given that it was higher in calories, it was a 90 calorie food with, you know, lots of vitamins and minerals, but they looked at that information and they used that
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21
      information to choose that as the healthier product.
                       Equal numbers looked at that 5 calories
22
0224
      with no nutrients basing it on that information and
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3
      chose that as the healthier product. Given that
      there's no other information except there -- on that
      label except calories, you can assume they're making that judgment based on that.
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                       BARBARA SCHNEEMAN: I guess additional
      follow-up on that.
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                       Did you then have any additional
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      information about the participants in the study that
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      might have given you some insight as to what they
      were looking for and how that might influence the choice that they made?

MARY YOUNG: Of who they were
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      MARÝ YOUNG: Of who they were demographically, is that, is that what you mean?
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                       BARBARA SCHNEEMAN: No, could there be a
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      difference that some of your group was more interested in calories, other members of the group
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17
      more interested in nutrition, do you have any of
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      that kind of information?
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                      MARY YOUNG: Yeah, there is some in
      there and we can get in and get that out for you. There is some in there that there was a segment that
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0225
      identifies themselves as, you know, more health conscious and I don't know if we've teased that out.
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                       I can look at it to see if the more
      health conscious ones tended towards one or the
 5
      other choices, but there, there was some
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7
      self-selection of were they more or less, more
      health conscious, less or moderate so we can look at that and provide that in the written comments.
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                      MICHAEL LANDA: We have a question from
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      David Zorn.
                       DAVID ZORN: My question's for Ms. Falco
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12
      and I'm sorry if you mentioned this during your
      presentation, I may have missed it, does Čoča-Cola
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FDA Hearing Day 2.txt 14 use any symbols on the front of their packages other 15 than just sort of the normal advertising type of 16 things, any nutrition-related symbols? I realize you have a broad range of products so it may be difficult to cover.

HELEN FALCO: Well, yeah, we have, since we're an international company, in the European 17 18 19 20 Union Coca-Cola is among the companies that are 21 22 leading the way in applying GDAs front of pack, as 0226 1 front as you can be of a round can. 2 In Austrailia, we're also involved in initiatives and in other countries where it's been 4 the appropriate solution. 5 In the United States we have not applied 6 nutrition symbols as such as we have been discussing 7 during these two days. We still feel that there's a 8 need for a great deal of research before we know the 9 way to go, but in other countries it has been fact-based. On many of our U.S.-based products, 10 though, we are applying nutrition claims and health 11 claims where it's appropriate.

DAVID ZORN: Thank you.

MICHAEL LANDA: Any other questions 12 13 14 15 from -- oh, I'm sorry, we have a question from Rob 16 Post. 17 ROBERT POST: Thanks. This is for Helen. You mentioned, kind of made us curious perhaps with the label conscious program, so I 18 19 thought of it as a question, and you said it links or it provides information about nutrition facts and 20 21 22 ingredient statements. 0227 1 Is it intended to be related to being health conscious and what connection is there in the 3 4 nutrition facts and the ingredients statement, because that's one area I don't think we've really 5 heard a lot about. HELEN FALCO: Well the program is in its developmental stages so, you know, specific details I can't give, but it very much does link better health through nutrition and through information and 6 7 8 9 it's done in a fun way, but it's intended to build 10 on existing FDA programs, tools, resources. 11 eventually be looking for partnerships. 12 13 So, you know, as I said in my presentation, we need to -- we use many, many 14 different avenues to get information out to consumers and so that's the idea behind this one. 15 16 17 So stay tuned. MICHAEL LANDA: We have a question from 18 19 Barbara Schneeman. BARBARA SCHNEEMAN: Thank you. I have question for Dr. Fulgoni and, Victor, I know that 20 21 toward the end we sort of, you had to rush through a 22 0228 lot of things and I think I missed what is it that 1 would get communicated to a consumer, how are they 3 made aware, how do they come to understand the system that you're using? VICTOR FULGŎNI: 5 Yeah, that's still 6 under development. That's the consumer research component. We basically, this has been the Page 83

FDA Hearing Day 2.txt component to decide on how to build the index that 9 you could actually evaluate foods and then have the 10 index validated against some measure of diet quality 11 and health outcomes. 12 Now that we have that the next phase is to actually say how do we take that information, is 13 it a 10 point scale, is it a 5 point scale, is it no scale at all, is it, you know, and work that and 14 15 that's the next phase of the nutrition, Nutrient 16 Rich Foods Coalition is going to be doing.

BARBARA SCHNEEMAN: All right. I guess as you move forward with that, are you anticipating 17 18 19 it as something that goes on the food package itself or in an educational context or is it in a retail 20 21 22 environment? 0229 1 What is your thinking in terms of where 2 the consumer would become aware of it? 4 5 pack scenario where you would actually be able to say you have an index that measures nutrient density or total nutrient value of a food and that relates to total diet quality, that if people would select these foods that rank higher in this index, they 6 7 8 9 should get a better diet and hopefully better health 10 11 outcomes. 12 BARBARA SCHNEEMAN: In that context, given what you've told us about the system you're developing, I would anticipate that some of the foods are not traditionally packaged foods, so I'm 13 14 15 wondering if you've given some thought to how it gets communicated with those foods. 16 17 VICTOR FULGONI: 18 Yeah, I mean it would 19 be relatively, you could apply it almost anywhere. 20 I mean if you wanted to do it in menus, you could, if it was in a retail -- in a restaurant or 21 something of that sort. But all of that needs to be 22 0230 worked out to see what, how the consumer wants to receive that and to figure that out because that's really the next big piece of work that the coalition needs to address 5 6 7 MICHAEL LANDA: Any other questions from the panel? Thank you very much. 8 (Appl ause) 9 As I mentioned earlier, we didn't have enough time for questioning yesterday of the first panel which was the panel on the international 10 11 experience Government activities. 12 If members of that panel would come 13 forward now, that's Claire Boville in the UK, the 14 15 Food Standards Agency. Jan-Willem van den Brink from the Netherlands Ministry of Health, Welfare and 16 Sport, Tipvon Parinyasiri, Thailand Food and Drug Administration, and Mary L'Abbe from Health Canada. 17 18 19 20 21 22 0231

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       Claire Boville
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       Jan-William van den Brink
       Tipvon Parinyasiri
Mary L'Abbe
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0232
                         MR. LANDA: Let me just thank you all
       for agreeing to return for another round of
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                         We very much appreciate it.
Why don't we start with Felicia
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       questions.
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       Billingslea.
                         FELICIA BILLINGSLEA: Yes, my question,
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       the first question I have is directed to the
       countries that have voluntary nutrition labeling and I was wondering if sign posting or the use of sign posting triggers nutrition fact labeling in your, on your products, because if I understood, there are certain features on the food label that would
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 9
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12
       trigger nutrition labeling and is sign posting one
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       of those?
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15
                         If it is not, then how would the
16
       consumer get further information about the product?
17
       If you could address that.
                         MR. van den BRINK: Thank you, well
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19
       first of all, thank you for inviting us back, it's a
20
       real honor.
21
                         We thought we could get away with
22
       15 minutes.
                          No.
0233
                         I think I could speak for Claire as well
       because in the European community, it's, it's
European regulated, it's European law that whenever
you make a claim on a product and a choice, a
Healthy Choice logo or the Choices logo, if such a
claim or any other claim, you must then declare the
nutrients that are in the product and there are, we
 4
 5
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 7
 8
       have the big four and the big eight, that's the two
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       types of nutrition labeling that are, is, is
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       mandatory whenever you make a claim.
                         So, short answer is yes.
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                                                                I'm not sure
       if you want to add something to that.

CLAIRE BOVILLE: Yes, I agree with all the points that Jan-Willem has made, that that is
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       what's laid down in the European law.
                         In terms how the front of pack sign
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       posting works in the UK, we consider the traffic
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       lights approach to be nutritional labeling
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FDA Hearing Day 2.txt information so --MICHAEL LANDA: Claire could you speak 20 up a little bit. 21 22 CLAIRE BOVILLE: Oh, I'm not usually 0234 accused of being too quiet. 2 3 In the UK the traffic light labeling system, we consider that to be nutritional labeling, so it always, if you apply that on the front, it 5 would always be accompanied by more detailed 6 7 nutritional labeling information on the back of the pack. So the information should not in any way 8 contradict or provide conflicting information. 9 that answers your question.
MI CHAEL LANDA: 10 We have a question from 11 Camille Brewer 12 CAMILLE BREWER: Thank you. 13 Ms. Boville, I'd like to probe a little bit on 14 educati on. Can you talk about specific education on sign posting in the UK? Which sector is in the lead? Is it a lead Government responsibility, is it 15 16 17 done jointly with industry, how's it coordinated and what are the costs? Thank you.

CLAIRE BOVILLE: That's a very 18 19 20 interesting question. I did have in my presentation 21 but unfortunately didn't have time to show you some 22 0235 of the education activities that we have carried out 1 2 as part of the awareness raising with the sign post labeling that we have in the UK. We see that when the agency Board made its recommendations on what should be in the sign 5 post labeling scheme, part of its commitment was that it would support it with communication and 6 7 8 education activities to raise awareness of it. 9 And that was considered to be an 10 important element because of the form with which the 11 recommendations took in that they were principles, 12 they were not a logo. So, therefore, you have the opportunity for companies to use their creative powers to come 13 14 15 up with a design for a logo which incorporates the four core principles, but which best matches the 16 17 corporate values or design for that company. I'm making myself clear, yeah.
So, in that situation what you end up with is, is a series of logos which can look 18 19 20 different but actually the underpinning basis for them is all the same. So it's important, therefore, 21 22 0236 1 that the consumer was aware that they were all part of the Government scheme and that they all had the 2 3 4 same criteria. So, we started that, a number of things 5 One was an awareness raising activity happened. 6 7 sort of in the media called range of media activity, an advertising campaign which included a poster campaign, and I've got a copy here of it. This just a small, small-scale image. That appeared 8 9

much, much bigger in size on billboards, on buses

and was given away as posters, as well, for people

10 11

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to have.

FDA Hearing Day 2.txt MI CHAEL LANDA: Could you describe that 14 please just for the transcript. 15 CLAIRE BOVILLE: Oh, yes, of course. has the -- it's a very simple design, it has the word food written down the side and in this sort of 16 17 roundness of the F is the color red and in the 0 --18 19 in the O is the red, in the second red there's the 20 amber and in the round of the D is the green and it's the design that looks like a traffic light and 21 22 then the words say to it, there is a new labeling 0237 system on food. It tells you the levels of sugars, 1 2 fat, saturated fat and salt. Red means high, amber means medium, green means Iow. The Food Standards Agency helping you make healthier choices and then there's the Website address which is 5 6 7 Eatwell.gov.UK/trafficlights. So it's referring the consumer to a place where they can find more 8 information and it's, it's sort of saying look out 9 for this. And then that was supported by a TV advertising campaign and again, in the presentation I did have a clip of it so hopefully you'll have an opportunity after today to play it, but it features 10 11 12 13 this kind of graphic and that was supported then, 14 that ran in early this year for a number of weeks, 15 about 12 weeks and then that was supported by 16 17 further communication and education activities, 18 mainly aimed at the health professionals and dietitians and that group and some leaflets. And there's always an article in FSA News, every single month, telling people about, you know, who the new doctors are, what it looks like and there's a whole 19 20 21 22 0238 section on our Eat Well Website where you can have a 2 3 4 look at who is adopting, what their logo looks like and there's a statement about their reasons for adopting, why they made that choice themselves. 5 And then in addition to that, we have what we call an adopt a supporter group which is where all those companies who have chosen to use the sign posting approach and all of the organizations 6 7 8 9 which are behind it so the consumer organizations, 10 the medical and professional organizations which are behind it come together to discuss communication and 11 12 education activities to ensure that they're giving 13 out the same message and using their different 14 powers and their different channels for getting that message across 15 I have a pack here which summarizes this 16 17 and I'd be happy to give you a copy before I leave 18 today. 19 MICHAEL LANDA: A question from David 20 Zorn. 21 DAVID ZORN: I actually have a few 22 questions, but I'll just do one at a time and you 0239 can stop calling on me.
I'll start with my question for 2 3 Mr. van den Brink, you mentioned that the plan or the thinking currently is to update the criteria for the symbol. I think you mentioned either two or five years, it was every two years, and the reason Page 87

FDA Hearing Day 2. txt was that you would, you would encourage people to 8 keep improving their products over time. Want to prejudice you, but it seemed like a, I don't want to prejudice you, but it seemed like a very expensive proposition to keep changing the symbols because it's one thing to earn it this year, but if, if I don't earn it the next year, I can't just say oh, well I won't re-formulate my product, I also have to remove it from my label 9 10 11 12 13 14 15 have to remove it from my label. 16 Again, I was just trying to get a sense of how did you get feedback from the, your producers of what they thought of that prospect?

MR. van den BRINK: Well, thank you.

Good question. Well first of all it, it's not that 17 18 19 20 we as a ministry of health came up with that, it's 21 22 the proposition made by Choices, the organization, 0240 itself, and based on their, on the work that the 2 scientific commission has done to establish the 3 criteria that they have right now. The commission said, take salt, for instance, they said, well, for some product groups we have sat a threshold for salt a little lower than 5 6 you would -- sorry, you would want to, but in two years time we need to look at it again and see if, 7 8 9 if we could raise the thresholds so that, so that 10 product -- that companies are stimulated to make product re-formulation, do product re-formulation and -- well, to be honest, it's the industry, itself, that came up with this, that proposal, the industry, the departments in the local the Chaical and appear 11 12 13 14 Healthy Choice logo and especially the scientific commission, but it was backed by the foundation 15 16 which, which -- of, well the companies that are a 17 member of the foundation are present, so it's their, 18 19 it's their call 20 MI CHAEL LANDA: Dr. Schneeman has a 21 questi on. 22 BARBARA SCHNEEMAN: I just wanted to 0241 follow up and clarify, so is that moving target for 2 sodium, is it sodium specific or is it for all of 3 the nutrients across the profile or just the sodium piece of it? 5 MR. van den BRINK: No, I meant to 6 7 mention sodium as an example because it's really stated as one of the thing that they now say that they want to look at it in two years, but all the nutrients will be reviewed, the whole system will be 8 9 reviewed in two years, so see if, two reasons, see if the scientific insight has changed over the years 10 11 12 and also to see how many products satisfy or eligible for a claim, for a logo. 13 14 If more than 20 percent of the products in the main products groups, for something, one 15 product, the main product group, say bread, more than 20 percent of breads products that are on the market are eligible for a claim, then we need to change that and set the levels higher so that it, 16 17 18 19 again, stimulates producers to re-formulate.
MICHAEL LANDA: All right. David Zorn, 20 21 22 did you have an additional question? 0242

FDA Hearing Day 2.txt DAVID ZORN: Yes, let me ask, and I'm not sure if all three of the non-North American speakers mentioned, but at least two mentioned that industry was not excited about the colors, the red, yellow, green, they more preferred a one color solution. I'm wondering if you have a sense, and I realize you can't necessarily speak for them, but do you have a sense of maybe it's because of the additional expense of printing in more colors than just doing a one color logo? TIPVON PARINYĂSIRI: In Thailand we discuss about the voluntary logo and the company proposed the GDA, they started, they have the color, but their color have no meaning. It just make it attractive to the consumer. However, the NGO group, they prefer to have the traffic light color but that, that logo no level of nutrition, so we think about to combine, they should have some color and 20 have some meaning, however they, you know.

But the second step, they can peak information on that one, so we have to, FDA have to 0243 take another approach that both, both side doesn't want to combine, so maybe we'll come up with our suggestion that combine traffic light and GDA and since we have a voluntary nutritional labeling, it's, for the food format and also short, brief format, the Thai consumer doesn't read that much and even though it's already launched for nine year, but for the, they become popular among the big company because they think it's the, it's good to have the nutritional labeling even though the consumer doesn't read, but it looks healthy, that's what, that's what Thai, I mean perception of the industry. However, we, we think with the 14 nutritional labeling, the food format, we need a lot of tremendous education program which is difficult for Thai people and we think about the logo, we have something to attract the consumer to look at the nutrition and have some arrow to bring it to the That's what we thinking about and it will 20 attract consumer more to help, to have healthier food. That's what among Thai, among our officer. MR. van den BRINK: I'm quessing here, 0244 but I think that a lot of companies do not voluntarily want to have something on saying that it's not a good product, so, but in UK they have other examples for that, so.

CLAIRE BOVILLE: Certainly the, one Certainly the, one of the arguments that was given very early on when we were in the process of consulting and discussing what may or may not be in the recommendations for a sign posting scheme, the issue of cost was raised 10 by, by some -- by some businesses, but what actually happened in reality once this, once the recommendations were made was that we saw an increasing number of companies adopting it. Now you might think, yeah, they're all 15 big companies. Far from that being the case. fact, actually, we have a mix, we have big 16 multi-nationals, we have medium companies and we Page 89

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FDA Hearing Day 2.txt have a high level of small companies. And so you 19 might think well, you know, how can a small company bear that cost, but it's because they, if you ask them and you look at their, look at their statements 20 21 and part of their reasons for doing it is in some 22 0245 cases it's because they felt it was the right thing to do and it felt, and it fitted well with their, 2 their brand image and their corporate values. In other cases it was because they saw a 5 big commercial advantage for that and it was a good way of distinguishing their product from another product on the market. They say we're producing a healthy food. This gives us an opportunity to shout about it and it gives us the leverage of being part 6 7 8 9 10 of a nice big Government system and saying get, 11 giving it some sort of credibility. So those were some of the reasons. It's 12 different for every company, but that's some of the 13 14 reasons. 15 MICHAEL LANDA: Next question from Rob 16 Post. 17 ROBERT POST: Thanks. This question actually is for any of the 18 19 panelists and it relates to some comments from some 20 of you about third-party programs and I'll probably reflect my USDA connection here because I keep 21 22 talking about organic or programs like that where 0246 accreditation by a Government agency is involved.

And I'm not sure in your experience
you've got somewhat advanced thoughts on the use of 1 3 4 5 sign posting and programs underway and research underway, have you considered approaches using 6 7 third, third parties but using a sort of Government endorsed set of criteria then that would lead to 8 some kind of accreditation by the Government entity 9 without actually having had to regulate the activity as a daily activity?

CLAIRE BOVILLE: Yes, we gave that issue some consideration and dismissed it. We decided 10 11 12 13 that, that if it was our criteria and our recommendations, that we would much rather -- we've 14 also produced, I should highlight, very technical guidelines for those, any -- they are on the Website 15 16 for anyone to look at which explain how to apply the 17 18 sign posting approach in the way that the agency envisaged it and that there -- and we can direct anybody who's considering using it or has inquiries 19 20 about it to go and look at those guidelines. 21 22 And we have a commitment to update them 0247 and review them in the light of experience and 2 3 practice and any other developments. And we feel that a large part of our responsibility is to be there for the businesses that want to do that and to help, to support them through that process and answer their questions and maybe part of that I'd like to think has been something to, towards some of the success that I feel could be had in that they could pick up the 4 5 6 7 8 9 10 phone and they can talk through it. 11 Some, in some cases some businesses have Page 90

FDA Hearing Day 2.txt 12 sent to us their product portfolio with their 13 nutrition information which they have color-coded and said can you just check this to make sure we're getting it right. So, we've got that nice kind of dialogue and we're seeing this kind of what I like to think, perceive as kind of friendly and helpful 14 15 16 17 and working with and maybe that's helped spread the 18 19 word they're not on their own. So we see this as a partnership that 20 21 we're all trying to do something which is for the 22 good of the, the good of the consumer, but I have to 0248 say it's largely due to two of my team that spend 1 quite a lot of their time dealing with that.
You know, they have other parts of their 2 job, but they are the face of the people that 4 5 6 7 provide that technical support. I hope that answers your question. ROBERT POST: Yes. 8 And I'd just like to add MARY L'ABBE: that our experience, because we have a fairly large third-party program that's run through the Heart and Stroke Foundation of Canada and that is, I mean, 9 10 11 strictly a program distinct from Government, but in 12 the establishment when they were developing their 13 program, there was a lot of advice and interaction 14 back and forth with staff in our bureau to both help 15 16 interpret what the regulations were, where the numbers were, but ultimately it was their program 17 and so that they are, you know, it's, it's a program detached from Government, but it was in everyone's interest while they were developing them where they post questions to help clarify and to aid them to 18 19 20 21 22 ensure that the program obviously was as consistent 0249 as possible with many of the, our Government 2 3 policies or the food guide, so it was very much an assistive role. 4 5 ROBERT POST: Thank you. MICHAEL LANDA: We have a question from 6 7 Loui sa Ni ckerson. LOUISA NICKERSON: If I understood the 8 presentations yesterday correctly, all of your 9 systems for front of pack nutrition sign posting are 10 voluntary and I was just wondering, have you given 11 any thought to making some sort of nutrition labeling on front of pack, whether it be symbols or 12 something else, have you given any thought to making that mandatory and if not, is that due to lack of legal authority or is it for other reasons?

MARY L'ABBE: I'll make one comment and 13 14 15 16 I guess it's probably a comment with regards to one 17 of the reasons why we are actually looking at the 18 19 front of package labeling and symbols in a Canadian 20 context is we have actually been directed by the standing committee of health that called upon the 21 22 Government to actually look at, one of the words, if 0250 I pull my presentation, one of the words were to call on Government to implement a mandatory 2 3 standardized, so they used the word mandatory, so our responsibility in response to that is to incorporate and to evaluate such a system in the

FDA Hearing Day 2.txt context of the Canadian, well in the context of the 7 Canadian situation. 8 CLAIRE BOVILLE: In the EU, nutrition 9 labeling matters are controlled and front of pack 10 sign post labeling is a fairly new initiative. The 11 nutrition -12 MI CHAEL LANDA: Could you speak up a 13 bit. 14 CLAIRE BOVILLE: The nutrition labeling directive is 19, it's over 10 years, yeah, more than 10 years old so this idea of logos and things wasn't 15 16 about at that time in terms of nutrition labeling information; however, the European commission is currently reviewing the need for and the nature of nutritional labeling legislation. And it is very aware of what is going on in terms of front of pack labeling, both on the sort of health logo format and 17 18 19 20 21 22 0251 1 of the nutritional labeling format and it's giving 2 consideration to that matter as part of its 3 del i berati ons. 4 5 We're waiting to hear what it is going to propose. 6 MR. van den BRINK: May I add to that, it would be maybe lack of legal authority due to 7 8 lack of consensus within the European community at 9 this point. 10 MICHAEL LANDA: We have a question from Felicia Billingslea. 11 FELICIA BILLINGSLEA: Yeah, my question is directed to Mr. Van den Brink. I think in your presentation you mentioned that you all do permit competing logos to the Choices sign post and I was 12 13 14 15 wondering if those competing logos are based on the 16 same principles or nutrients, is that a requirement for a competing logo or does the manufacturer have 17 18 19 flexibility in deciding what nutrients they would 20 want to highlight? 21 MR. van den BRINK: Thank you, good 22 questi on. 0252 The competing logo, well there is only 1 one other competing logo and that's by the largest 2 3 4 supermarket chain, Albert Heijn. They use the clover, which is quite similar to the system, the 5 Swedish keyhole in Sweden, which unfortunately we 6 7 didn't have a chance to see yesterday. And so there are only two logos, but we, we do not have the legal possibilities to prohibit 8 9 that such a logo to appear unless of course it would be misleading, but that's not the case. 10 Šo, the system is pretty much the same, 11 it's about the same -- it's the same nutrients and 12 13 there are -- that are behind this logo system and I think there are few changes in the products groups 14 and maybe some thresholds are maybe different, but 15 in essence it's a, it's the same type of system.

I hope this answers your question.

MI CHAEL LANDA: We have a question from 16 17 18 19 Kathy Ellwood 20 KATHLEEN ELLWOOD: There we go. Thanks. I want to go back to this question on 21 22 the need to update the criteria that's been set Page 92

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because I'm not quite sure I understand from the Netherlands, it sounded like you wanted to raise the bar and when you want to raise the bar, someone's decided let's do this, industry hits a certain mark, well let's raise it, and industry hits it again.

Is there anything dealing with health outcomes because, see, in this country we're beginning our regulatory process to update what we have in the nutrition facts panel, but what has triggered that in the more than 10 years we've -- is there's been a lot of scientific evolution and a lot of changes based on in what we call our dietary reference intakes, in addition to what's been done in the most recent dietary guidelines.

So, that's what's spurring us, but this

has been over many years, not just two or even five years, so I, I'd kind of like a little more input there and maybe others on the panel, too, for when you see -- what's going to trigger your need to update, is it going to be based on a health outcome when major reports come out, so, or that, and I also have another question, but I'll end with that first

one.

I know you have to do more than one, otherwise --

MR. van den BRINK: Thank you. indeed, the idea is that whenever industry hits that target, then it should be up, the thresholds should be up, but that would be done by a scientific commission.

And as the Choices International Foundation that has been set up internationally, now has its Dutch part, the Dutch nutritionists in the scientific commission will absolutely look at what the Netherlands Nutrition Center and the Health Council for the Netherlands are devising on the dietary intake and what are the -- forgive me, I'm not a nutritionist, so some terms are, especially in English, are not always easy, but what they advise on what your intake should be and so when the criteria are evaluated and it shouldn't -- it probably wouldn't be something completely different because he have one -- nutrition profiling is being done for years and it's, you know, the figure stays

a bit, but they will look at what is relevant for the -- for the Netherlands in this case.

CLAIRE BOVILLE: In the UK we committed, again, at the time when the Board made its recommendations on what should be the principles of sign posting and it committed to the education program and it also committed to undertake the independent evaluation work, same time it committed to review the criteria in the light of time and experi ence.

And we made a commitment that we would tend to take that first review in 2008 and that date was chosen because it fitted in with the date that had already been given for a review of the salt re-formulation program.

We have a target that we're trying to Page 93

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FDA Hearing Day 2.txt 17 meet and we have a program of initiatives to get 18 foods re-formulated to take the salt out and we said, right, we need to check a set point for are we on track to make that target. So we're linking those two things in so that that will be a good 19 20 21 22 opportunity not just to look at the salts criteria, 0256 but to look at, look at the whole thing again and if there are any tweaks or adjustments that need to be 3 4 made in the light of the experience of those that have used it, that would be the time at which we 5 would do it for the first time. Obviously all of the criteria is based on scientific evidence. If there were any developments in terms of scientific knowledge or 6 7 8 9 opinion from the Nutritional Advisory Committee for 10 the Government in that time or later on, we would 11 need to figure that, factor that into and update on the basis of that. 12 TIPVON PARINYASIRI: In Thailand, since 13 we have a regulation on nutritional labeling for 14 15 nine years and we just finished the national survey last, last two year, so now we up, we have to updating our nutritional labeling regulation and we 16 17 also have the scientific committee to review all the 18 criteria; however, since they have a third-party 19 Heart Foundation in Thailand, they propose the 20 21 criteria for the multiple nutrient. We have to 22 review and make a consistency between the logo, 0257 traffic light or -- and also have to, since we focus, very focus on snack at the beginning of the first phase but we have to think about the next step will be the meal, so we have to be ready, I mean 5 6 7 look at the scope and the exact criteria which we can apply to all food in the future; therefore, we have to take different approach on the, to propose 8 to the food -- to the scientific committee to make 9 sure that our criteria and message will be, for Thai 10 consumer can understand correctly MR. van den BRINK: Íf I may clai that word I was looking for of course was of If I may clarify, 11 12 13 food-based dietary guidelines, and our health 14 council has just recently come up with new 15 food-based dietary guidelines and as an -- in fact, 16 as I was mentioning in the presentation as well, the scientific commission reviewed the level of salt or 17 18 sodium and adjusted that and that meant that in last Summer one product got a -- got a logo, it had to remove the logo because criteria were stronger, so.

MI CHAEL LANDA: We have a question from 19 20 21 Steve Bradbard. 22 0258 STEVE BRADBARD: Yes, I would -- earlier you mentioned that alternate types of front panel symbols are permitted if they're not misleading and 4 5 6

I want to just ask the entire group have you had an occasion yet where you've had to identify a symbol as being misleading and if so, what criteria have you had to use in terms of doing so? Have you been able to just simply assert this is misleading or have you been required to empirically demonstrate that the symbol is misleading and any other comments Page 94

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      whether you think it would be likely to occur that
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      you'd ever be put in that position.
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                    CLAIRE BOVILLE:
                                         That would be a role
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      for enforcement bodies and enforcement.
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                    MI CHAEL LANDA: Could you speak up a
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                     CLAIRE BOVILLE: That's the role for
      enforcement bodies. If something was considered
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      misleading, that would be their role to investigate
      it and take whatever action that they considered to be appropriate and enforcement in the UK is carried
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      out at a local level. It's not a role that the Food
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      Standards Agency has.
Obviously if the, if we saw something or
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      became aware of something that we felt that somebody
      questioned, we would -- we could, we could
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      investigate it and take the matter up on a, on a
      less formal basis if you, not an enforcement basis
      with the parties concerned.
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                    STEVE BRADBARD:
                                         So as I understand it,
      then, this would be a local matter and they would not necessarily turn to you and say we need some consumer studies evidence from you to back up our contention that this is misleading? They could
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      simply just say this is misleading?
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                     CLÁIRE BOVILLE:
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                                         Yeah.
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                    MI CHAEL LANDA:
                                       Anyone else care to
      respond to Steve Bradbard's question?
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                     MARY L'ABBE: I will do, attempt to a
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      bi t.
             That is a challenging issue for us, examples
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      do arise on occasion. The responsibility for
      enforcement in Canada relies with the Canadian Food
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      Inspection Agency.
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                     Obviously the two agencies do talk to
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      each other to, to ensure clarity of understanding of
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      the labeling.
                       Many cases areas of where labels are
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      considered misleading, they're often dealt with
      quite early in the process rather than in a, you know, what would be a regulatory enforcement action, but those types of issues are difficult and
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      challenging, sometimes.
                     TIPVON PARINYASIRI: In Thailand, since
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      we have the post marketing control by FDA, we
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      have -- if the label is misleading, we take legal
      action toward the industry.
STEVE BRADBARD:
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                                          So as an example in
      Thailand, what might be an example of a label that
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     is misleading? Can you recall an instance where you had to take action? Not false, but misleading.

TIPVON PARINYASIRI: Yeah, we, the first
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      we take legal action and we discuss with the company
      to remove, voluntary remove, because our regulation -- we have no enforcement to recall;
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      however, we ask, we put announcement in the company,
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      we request them to voluntarily recall all the
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      product.
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                     MICHAEL LANDA: We have a question from
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      Barbara Schneeman.
                     BARBARA SCHNEEMAN:
                                             Hopefully this will
      be a short question. It was my understanding from
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FDA Hearing Day 2.txt the presentations yesterday that Canada and Thailand both have a nutrition facts labeling system where you not only prescribe what the nutrients that go into the nutrition facts, but you prescribe the format as well, the font size, how it's presented in the table, the table format.

And I had the impression from the various presentations, not just the presentations on this panel, that while there is some consistency in terms of the nutrients that are declared, there is variation amongst manufacturers in the European countries in terms of how they would present that information in the table and I think we also saw some examples where manufacturers were adding some additional information to the table and may be using coloring and so it seemed like while you were prescribing the content, the format was not necessarily prescribed.

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> And I just also wanted to clarify, it was my understanding, you said that the manufacturer is able to set the portion size or the serving size that's used for labeling purposes and I don't, I think Thailand and Canada, you use prescribed serving sizes and for the record it would be good if you comment, I'm seeing heads nod and shake, but if you could just comment.

> MARY L'ABBE: I'll comment first then, we actually do have in regulations defined both format, content, a nutritional facts panel must have the 13 core nutrients and then we have alternate formats for if you want to include a fuller list, the order, the font size, the appearance of the nutrition facts panel is all prescribed in regulations.

> And you don't touch the actual nutrition facts panel and we do list reference values in the regulations that promulgated the nutrition labeling regulations that also listed reference values in those regulations for a number of foods and those are used for labeling purposes, those reference

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20 21 serving sizes.

TIPVON PARINYASIRI: Similar like to Thailand, we have a similar system.

MR. van den BRINK: I think you described the situation in Europe correctly and just to also to say that the, that it is currently under review by the European commission because we are expecting a new proposal on nutrition labeling this Fall, actually.

MICHAEL LANDA: Question from Kathy

KATHLEEN ELLWOOD: I wanted to go back and re-visit calories, and the reason I'm asking is that it seems like some of these sign posts, it's really accenting some of the nutrients you want to limit and we've talked about some of the -- what we had when we were signalling low fat, but it was not a low calorie product. And there's some other instances where we have that you have to say not a low calorie product on your label and also in our obesity task force report what came out and that's

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22 why we called it calories count and we even did an 0264

advanced notice of proposed rule-making as trying to get some information as to how could we accent calories on the food label as it currently appears and we had several comments on that.

So, I, I was just curious as to how you're showing calories or is it too early, maybe? I'm thinking mostly in the European countries, that you're trying to see how it's working with some of these other nutrients that you're trying to accent in your sign posting, because I'm -- it just seemed like calories aren't that clear. Maybe they are and I'm just not seeing it based on your presentations, and correct me, please.

CLAIRE BOVILLE: Calories is the first thing that appears on the back of pack nutritional label, on the back of the pack, so where it's

provided, it's always there.

You may remember yesterday I described why calories wasn't one of the nutrients that the agency was recommending as being their -- as a sort of, as a minimum, we don't mind if it's there as an extra, but we didn't say that it had to be there as

one of the minimum requirements.

The reason was that from the consumer research, that was the one nutrient that the consumer, A, understood and knew where to find and the consumer took the view that they didn't need to have information on the front of the pack which they already could easily find and were using and comfortable with on the back of the pack. It was the other elements that they felt were kind of, they were there, but they needed to be highlighted for them on the front. They found that beneficial.

MICHAEL LANDA: Barbara Schneeman has a

questi on.

BARBARA SCHNEEMAN: I wanted to follow up on that and just to make sure I understand, so for the front of the pack traffic light, is that based on the same serving size as the back of the pack is based on?

CLAIRE BOVILLE: Right, the traffic light sign post provides the color-coding information per 100 grams and the back of the pack information is required in EU law to be given per

100 grams, that's why we kind of took that approach, but you can also by EU law, you're allowed if you wish to provide information per serving size as an additional piece of information on the back of the pack.

The difference is that the per serving information is determined by the manufacturer, so that's a big difference in Europe to the U.S.

So to go to the front of the pack, we have the color-coding per 100 grams, but in addition we ask people to provide the numerical amount in the serving size so that the information that's on the back of the pack is also there on the front.

MICHAEL LANDA: Two more questions, first one, sorry, from Camille -- oh, I'm sorry.

FDA Hearing Day 2.txt MR. van den BRINK: Just wanted to answer the question on the energy, if I may, it 17 probably wasn't clear from the presentation because I didn't go into too much detail in the criteria, 18 19 but for several products groups in the Healthy Choice Logo, Healthy Choices system, there is a 20 21 criteria for energy, also, so, for soups, for 22 0267 sauces, for drinks and for ready meals, the 1 2 3 criterion for energy has also been set by the commissioner. 4 5 MICHAEL LANDA: Question from Camille Brewer. 6 7 CAMILLE BREWER: Just a follow-on question about calories, are you finding that your 8 research shows that consumers look at the front and the back; to any extent does the front label 9 10 information truncate the need to go to the back? 11 Does that, does the information search stop at the front label? 12 CLAIRE BOVILLE: It depends. It depends on the consumer, it depends on the food, it depends 13 14 15 on the package. To go back to the times before there was 16 any sign posting on the front and that piece of 17 research which was done, which we did where we 18 19 looked at how each different sign posting performed, 20 what we did was we had boards made up which were visuals of real products that existed in the 21 marketplace, the front of the pack and the back of 22 0268 the pack and the side of the pack. 2 So it had, there were a range of products, they were cakes, there was breakfast cereals, they were ready meals, there were snacks 4 5 6 7 and in some of those cases, so it appeared literally as it was in the shop. So in some cases it had, I can remember one of the breakfast cereals had, had information which was in a nice heart-shaped image and it might have all sorts of other things like good for your heart with extra vitamins and minerals, good source 8 ĕ 10 11 12 of this, that and the other, as well. 13 So what happened was that we got an 14 insight as to what the -- what the consumer did with 15 that information. Some looked at that information and they looked at the picture and some turned over the board and looked at the back of the package, the nutritional information and looked at the front 16 17 18 again, some looked at the sign post and some didn't, but it's a whole mix of those things which inform 19 20 what it is that the consumer uses to make a 21 22 deci si on. 0269 1 But what was clear was, and this was really I found very interesting, that when you had a product where the consumer had a perceived image of the healthiness or not of that food stuff and then they had the sign post information on it and if it 2 5 6 7 contradicted or conflicted with what they had been led to believe about the product, there was outrage. 8 There was outrage.

> Because they felt they had been misled Page 98

FDA Hearing Day 2.txt 10 and they felt that how could this be allowed and they said we need this kind of information. 11 what we should have been having all along, we wanted the clear facts and we can make the judgment. If I had been buying this product to give to my kids because I thought this was the 12 13 14 15 healthy option, I thought I was making a good choice for them, I'm furious. You know, I'm not 16 17 exaggerating, because I was sitting there next to 18 19 these people and these -- the emotion that came from 20 them and how they felt betrayed, really, it was, yeah, yeah, they were really shocked and they said we -- this is what we need. We need, we've been 21 22 0270 needing this for years, you know. You must make 2 this happen. Now what's interesting is, you know, when you try to explain to them well actually we 5 have to, we have to work with Europe, too, on this 6 7 and they're saying well just do it, just do it, this is what we need. 8 So, we're doing the best we can within 9 the legal constraints in terms of meeting the consumers' needs, something which empowers them and 10 helps them to make healthier choices in an honest 11 and transparent way and the reaction is that the 12 13 consumer likes it and is using it. 14 MI CHAEL LANDA: Steve Bradbard has a 15 questi on. STEVE BRADBARD: Yes, Claire, this 16 actually touches on your last response but it goes back further to our discussion this morning, I asked 17 18 you a question, I thought your answer was provocative, so I figured I'd ask it again because I 19 20 21 thought the attendees here might like hearing your 22 answer as well. 0271 1 I asked you this morning why you thought that perhaps consumers in the UK might not like the schemes that have been proposed by companies like Hannaford or the ONQI scheme or even this afternoon 4 5 the scheme you heard about on nutrient density as 6 opposed to a scheme that has multiple traffic lights for different nutrients and you did offer a response as to why you think it would be preferable for 7 8 9 people in the UK to have the multiple traffic 10 lights. 11 And I think it was interesting what you 12 had to say, especially in light of the fact that you just indicated that consumers in the UK really are 13 wrinkled when they learn that perhaps there was 14 something about a product that they didn't pick up 15 that made it less healthful than it really was. 16 17 CLAIRE BOVILLE: Well it goes back to, my answer to your question goes back to the four 18 principles with which we recommended a sign posting 19 20 approach should be based and that's based on the 21 consumer research. One of the symbols that was tested $% \left(1\right) =\left(1\right) \left(1$ 22 0272 1 was --MI CHAEL LANDA: Could you speak up a little, please.

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FDA Hearing Day 2.txt
                      CLAIRE BOVILLE:
                                            One of the symbols that
 5
      was tested was a simple logo which gave an overall
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7
      assessment about the healthiness or otherwise of a
      food stuff and the consumers didn't react as
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      positively as you might have expected to that
      because they felt it was directive and they felt that it wouldn't enable -- it wouldn't be applied to
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      all foods, so it would only, because it would only be applied to certain foods, it would also only be relevant to a subsection of the population. Those
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      people who were always interested in looking for a
      healthier food stuff, so always interested in the better in class version rather than providing
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      information which enabled them to make an informed
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      choice themselves.
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                      So, it, and it performed poorly in the
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      consumer research.
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                      Where there were schemes that provided
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      individual information about particular nutrients,
0273
      the consumer liked that and they found that they could use it, but they wanted to have an
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      interpretive element on top to give them a fast at-a-glance guide, but they wanted both elements.
                      So a scheme which gives some level of,
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      of discrimination without giving information which is there for the consumer to use and interpret and
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      see for themselves was not liked and did not perform
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      well. It was one of the elements they wanted, they
      want the information with an interpretive element so
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      that they are empowered to make the decision.
      They have the information themselves, they can decide how they, how they use it. After
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13
      all, each customer consumer is different and has
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      different information needs and requirements and by
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      providing that information, you're enabling them to do it rather than somebody making a decision as to
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      this is all you need to know.
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      MR. van den BRINK: If I may respond
that, yesterday I left out some information about
                                                If I may respond to
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      what consumers in the Netherlands seem to want and
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      no surprise, 51 percent wants a Healthy Choice Logo,
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      though I've seen many figures these two days about
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      what consumers want to see and we expect them to
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                      I didn't put it in the slides because I
      thought, well, it's not perceived expectation or what we accept and what is, what I want to know could vary by the questions you ask them, of course, and we just want to see how it, what really works,
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      so we want to have actual data, actual real life
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      data on consumption of these products and the
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      affects of it on the diet in the Netherlands.
                      Thank you.
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                      MICHAEL LANDA: Well, let me thank you
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      very much for agreeing to undergo a second round of
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      questioning. We expect you back tomorrow morning
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      for round three.
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                      (Laughter)
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                      Thanks again, very, very much.
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                      (Appl ause)
                      MICHAEL LÁNDA: We actually have Marty
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                                                 Page 100
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FDA Hearing Day 2.txt Ordman from Dole who was scheduled for the seventh 22 panel which was the registered comments, commentors 0275 1 has arrived and will speak to us next. MARTY ORDMAN: Thank you very much. I'm sorry I was a little late, I got a little scheduling 4 5 conflict there, but I have about 12 slides to take you through, very brief, I should only be five or 6 7 ten minutes or so. Does this work the -- slides on the 8 nutrition symbols, these are by the Dole Food 9 Company and as I said, I'm Marty Ordman, vice 10 president of marketing and communication. I set up the presentations based on the issues and questions 11 that was put in the brief, so issue number one was information on foods that use symbols and the 12 13 14 nutrient requirements for those symbols. 15 At Dole the use of nutrition symbols is mainly restricted to the use of our SuperFood 16 As you can see up on the slide, there are symboľs. 17 nine of these and they all consist of a shield 18 displaying the health category each refers to and the URL directing the consumer to the Website containing all the relevant information. 19 20 21 22 Question one was in what product 0276 categories are nutrition symbols used? At Dole 2 3 we've used it, the SuperFoods symbols on various products including but not restricted to bananas, pineapples, frozen berries, packaged dates, raisins, prunes and broccoli and cauliflower. 5 Originally the Dole SuperFoods was designed to be applicable to only whole foods, 6 7 8 however, in order to be consistent, SuperFood qualifications were extended to include products that were blends of whole food ingredients as long 9 10 as the criteria were met, for example, packaged 11 12 salads and frozen fruit blends. 13 Question two was what symbols are nutrient specific and which are summary symbols based on multiple nutrients? All Dole SuperFood, symbols can be considered as summary symbols. For 14 15 16 For 17 example, the SuperFood for the heart category consideration fiber, potassium, folate, Vitamin B 6, Magnesium, Vitamin C and anti-oxidant vital 18 19 20 chemicals such as carotenoids and a nithiazine. The individual criteria for each 21 22 SuperFood category is different and we explain those 0277 on our Website www.dole.SuperFood.com, but all of 2 3 them with two exceptions require certain levels of multiple nutrients. The two sessions are SuperFood for your eyes, which is a level of Vitamin A and 4 5 6 7 then SuperFood for the joints has the appropriate level of bromelin that's in pineapple. Question three, what are the nutritional criteria, including calories included in a symbol system and how were those chosen for inclusion? criteria for all the SuperFood symbols are health 8 9 10 function specific. Generally food qualification 11 depends on whether a serving of that food provides a 12 minimum level of RDA for multiple vitamins and 13 14 minerals linked to that specific health function or Page 101

FDA Hearing Day 2.txt has a minimum anti-oxidant content as measured loric, loric contains the specific vital chemical melin, for example, bromelin.

None of the criteria for Dole SuperFood symbols involves calories, fats or salt, with few exception. Fresh fruits and vegetables are naturally low in all of these, so we saw no need for their inclusion in our criteria. I have an example 0278 here, SuperFood for the heart. To be a SuperFood

for the heart, a serving of the food must contain a minimum of the three of the following heart healthy nutrients and a 10 percent or higher of the adult labeling RDA or contain two nutrients at this level and also contain anti-oxidant vital chemicals. The heart healthy nutrients are fiber, Potassium, folate, Vitamin B 6, Magnesium, Vitamin C and anti-oxidant vital chemicals.

 $\label{thm:continuity} \mbox{Why these particular nutrients are the science behind the SuperFood symbols, these}$ individual nutrients are considered heart healthy due to the publication of high-quality scientific research indicating associations between nutrient intake and aspects of heart health and I have an example here of three types of research that we would put on our Website.

Question four, what nutrient thresholds and/or algorithms are used to determine if a food product may display nutrient specific or summary symbol.

As I mentioned earlier, the criteria of

all SuperFoods symbols are health function specific, however, the criteria are clear and exact and the food qualifies or it does not. And here's an example of bananas and SuperFoods for the heart, for bananas to qualify to have a SuperFood for the heart symbol, one serving, one large banana contains 12 percent fiber, 13 percent Potassium, 20 percent of Vitamin C and 25 percent of Vitamin B 6.

Question five, are nutrient symbols

presented together with the front label nutritioning claim such as low fat or a good source of calcium and if so, to what extent and for what types of cl ai ms?

On SuperFoods, symbols are used. are no accompanying claims. Obviously not all products qualify as SuperFoods, but the Dole Nutrition Institute encourages each product in our portfolio to have at least one nutrition message front and center, whether that be a SuperFood symbol or simply a nutrient content or other qualified heal th claim.

For instance, our loose products,

commodity products, like bananas, pineapples, broccoli, et cetera, there's no packaging area to put the further claims on it, so therefore, not easy to display the nutritional information. The SuperFood symbols, the sticker on a banana or a hang tag on a pineapple are very useful in this case. For our packaged products like our

frozen berries or our packaged salads, the SuperFood

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FDA Hearing Day 2.txt symbols are usually placed on the front of the packaging in direct view for the consumer, they are 10 not usually accompanied by relevant nutrition content claims, however we do encourage inclusion of 11 12 the relevant nutrients on the nutrition facts panel. Question six, are there programs to 13 14 educate consumers to understand the nutrition 15 symbols or is all information contained in the 16 symbols? When education programs are available, how are they presented? Primarily for our SuperFoods program, it's the information is on our Website, 17 18 19 20 Dol eSuperFoods.com. 21 And then each SuperFood category of our 22 nine categories, then there's a full explanation of 0281 the criteria, examples, the studies, et cetera, as 1 well as the Website, we do have some collateral 3 We make available to retailers materials. We've published a SuperFoods SuperFoods posters. 5 recipe cookbook. We have a health body wheel that 6 7 we make available and we also produced a SuperFoods recipe cooking DVD. 8 Issue two, information on consumer 9 research, what supported the development of such 10 programs and how the programs are understood by the consumer. We've done limited research, but we did 11 12 talk to some consumers via focus groups and the main 13 findings that there is an awareness to the term 14 SuperFood was a little bit low, but the interest was high when explained to them and that new products 15 16 that met these criteria were compelling for possible 17 purchase. And then lastly, information of the economic impact of the utilization of such programs, 18 19 20 you know, we, basically the printing of the stickers and applying them to the bananas is minimal in cost, 21 22 versus changing printing plates for packaged items 0282 can get a little bit more expensive but is fairly 1 minimal, so the economic impact is expected to be 3 relatively low. 4 Thank you very much, I appreciate the 5 6 7 time. (Appl ause) MICHAEL LANDA: Any of the FDA panel 8 members have any questions for Marty? Davi d Zorn. 9 10 DAVID ZORN: Just one quick question about your last point, in another context we've 11 heard a number of times applying stickers is, is an expensive activity. I wonder is there maybe something different maybe because people are already 12 13 14 15 having to put stickers on the bananas, it's just one 16 more sticker or is it different if you're a packaged, for your putting a sticker on your 17 packaged product or? 18 MARTY ORDMAN: You hit it exactly, we are putting the stickers, the Dole logo stickers 19 20 21 with the PLU number on there already, so to put 22 another sticker is relatively inexpensive versus a 0283 packaged product, usually that has to be done here in the United States and it gets very timely and

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     cost, you know, costs a lot.
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                   DAVID ZORN:
                                 Thanks for that
     cl ari fi cati on.
                   MI CHAEL LANDA:
                                     Any other questions?
                   Thank you.
MARTY ORDMAN:
                                    Thank you very much.
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                   (Appl ause)
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                   MICHAEL LÁNDA: Let me just say a couple
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     of things as we wrap up.
                   The first is a reminder that this
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     hearing really initiated our public inquiry.
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                                                          There
     is a docket, it remains open until November 12. We
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     strongly encourage you to submit any comments, data,
     information you have.
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                    assure you we will look at it, review
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     it, all of it. In terms of next steps, as I
     mentioned when we started yesterday, the information
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     we've received in these two days and expect to
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     receive in submissions to the docket is information
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     that will inform our decision on the citizen
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     petition that Mike Jacobson discussed a little bit
this morning. It will also, I think, help inform
the research we choose to do or perhaps in some
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     cases choose to enlist others to do, there's
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     certainly plenty of opportunity for research in this
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     area.
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                   Lastly, let me just once again thank all
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     the presenters, the FDA panelists and finally
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     Juanita Yates who was here who I don't see at the
     moment and her staff who really, who took care of all of the logistical arrangements for us who made
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11
     the hearing run as smooth as it did. And finally,
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     let me thank all of you for attending and for
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     participating and we look forward to seeing you
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     again and I hope to seeing your comments on the
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     docket in this matter.
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                   Again, they're due November 12th.
                                                          Thank
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     you.
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                   (Appl ause)
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                   (Hearing concluded 3:41 p.m.)
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                   CERTIFICATE OF TRANSCRIBER
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                  I, Monica Voorhees, do hereby certify that
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