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FDA PUBLIC HEARING SEPTEMBER 10, 2007



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PROCEEDINGS

MICHAEL LANDA: I first want to announce that we have the services of a sign language interpreter for the hearing impaired here. anyone requires those services, would you please

identify yourself by raising your hand?

Well I guess we don't need those services, at least there's no indication we do. will have the interpreter here until 2:00 this afternoon in case the need arises later.

Let me just get, take care of one little bit of housekeeping which has to do with parking, apparently there have been a number of questions. There's no charge for parking. As you exit, simply inform the attendant that you were attending the FDA public hearing and you won't be charged for parking.

With that, good morning, welcome, my name's Michael Landa, I'm Deputy Director for Regulatory Affairs of the Center for Food Safety and Applied Nutrition and it's my pleasure to see you

Applied Nútrition and it's my pleasure to see you all here this morning and to officially open this public hearing.

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The Center's responsible for, among other things, ensuring the safety, ensuring the safe, sanitary, wholesome and honestly labeled status of food products in this country to protect and promote the public health. It's important to remember that applied nutrition is part of our name. It doesn't -- it has I suppose the lion's share of it. And nutrition obviously is a key component of what we do.

The purpose of today's hearing is to obtain comments about front label symbols currently in use here and abroad. In recent years various domestic food manufacturers, retailers, trade organizations, health organizations as well as international groups have begun to include symbols that indicate nutritional quality on the label or in the labeling of food.

Each symbol has different nutritional criteria in terms of the included nutrients and the nutrient levels required for product eligibility. Each symbol program also differs in the consumer research and market experience to date.

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We've observed this trend, of course, But we and we're interested in how it develops. really don't have adequate information about the various programs to understand how their criteria works, how they're understood and used by consumers which is, after all, the point of these programs, and how they may have affected food choices available in the marketplace.

As we stated in the Federal Register Notice announcing this hearing, we'll focus on three Page 2

FDA Hearing Day 1.txt main issues today and tomorrow. The first is nutritional criteria, these are important because they directly affect the number, type and nutritional profiles of products that are eligible for a symbol, which in turn can affect the characteristics and mixes of products available to consumers.

We're interested in several nutritional

criteria questions such as product categories, nutrient specific versus summary symbols, included nutrients and their thresholds and the criterion and symbol presentation with front of package claims.

Second general area is consumer research. The presence of nutrition symbols could help consumer food choices, but such symbols also have the potential to confuse, therefore, the usefulness and impacts of the symbol program are closely related to how consumers understand and use the symbol in making food choices.

We're interested in consumer research questions such as consumer attitudes towards symbols, when symbols are used and for what purposes, consumer interpretations of nutritional and non-nutritional profiles of symbol carrying products and do symbols affect the quality of the total diet, which is I suppose the 64,000 dollar question. Or maybe given inflation, it's the 640,000 or 6.4 million dollar question.

640,000 or 6.4 million dollar question.

Economic research is the third and final main area of interest for us. The availability of nutrition symbol for use on the food label could have an impact on cost both for industry and for consumers and presumably on product re-formulation or an influence on product re-formulation. We're

 interested in possible economic impacts such as the extent of product re-formulation to qualify for a nutrition symbol, costs for product re-formulation, development of re-formulation and any price differentials between products with and without a symbol.

To gather information about these issues, we've organized this two-day hearing. I should emphasize there's no hidden agenda here, there's no foregone conclusion, we don't have any advanced working documents to share with you. This is really an information-gathering enterprise for us. We have received a petition, it's called a citizen petition requesting that we consider the use of symbols in labeling.

I have no doubt that the information we receive today, the information we'll receive in comments submitted to the docket will help inform our decision-making with respect to that petition and with respect to any actions or research activities that we may undertake in the future.

But again, I emphasize there is no, no

hidden agenda and no foregone conclusion that we have reached.

I should add finally that we'll hear more about the petition later in the hearing.

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The hearing will be divided as follows, there will be seven sessions to hear presentations on international and domestic research and experiences starting with two sessions of international speakers this morning. The remaining sessions focus on U.S. experience.

Each session will last an hour and a half with a half-hour break between each in the morning and afternoon sessions. There's a one-hour lunch break on each day. Each session will include time for questioning of the presenters by an FDA panel and in addition we've asked several colleagues from other Federal agencies to join us on that panel. I should emphasize, the only people allowed to ask questions in this hearing are the people on the panel.

This is obviously a very informal hearing. There isn't direct examination or

cross-examination or redirect or re-cross. There isn't testimony under oath, but the one rule that we do have is the only people who get to ask questions are the people on the panel.

With that, let me introduce our panel of

With that, let me introduce our panel of questioners. Just briefly. There will be more information about them as we proceed today and tomorrow.

The questioners are Barbara Schneeman, Camille Brewer, Felicia Billingslea, Kathleen Ellwood, Vincent de Jesus, all from our Office of Nutrition, Labeling and Dietary Supplements.

Additional questioners are Steve Bradbard, David Zorn, Jordan Lin and Alan Levy from the Office of Regulations, Policy and Social Science. We also have as a questioner Louisa Nickerson from the Food and Drug Division of our Office of General Counsel and Robert Post who is with the USDA.

In terms of public participation, we will have time tomorrow afternoon for people who have registered for this meeting to speak to us all. There's also a public comment period associated with

the docket.

The hearing, by the way, will conclude by tomorrow at 5 o'clock. The audio portion is going to be simultaneously available on the Web so although there's a relatively small number of us here, under 100, we anticipate that there are many more listening because of the interest we've heard in this hearing. A transcript by the way should be available in about 30 days.

Now to some housekeeping and then we'll get on to the meat of the proceedings. The staff will be available throughout the day at the registration desk if you need help. There are restrooms outside the doors in the hallway immediately parallel to this conference room, that's that away.

There will be refreshments available right outside the meeting room both through the morning and afternoon breaks and there's a large cafeteria and a restaurant on the premises for lunch. We'll be hosting a reception at the end of

FDA Hearing Day 1.txt today's proceedings in the Chesapeake room. 0012 the first salon when you come into the building. 1 Our staff can direct you. In just a moment or two I'll invite Dr. Schneeman to the podium, she'll provide an overview presentation on the existing regulatory 4 5 6 framework for nutrition information on labels. She'll also review the questions from the Federal 8 Register Notice for this meeting to set the stage 9 for the upcoming panels. 10 Following her presentation, we'll move immediately to our first panel which will explore the experience of other Governments on developing front label symbol programs. Ms. Leslye Fraser, Director of the Office of Regulations, Policy and 11 12 13 14 15 Social Science will moderate that session. 16 Due to time constraints, as I mentioned earlier, we're not going to be reading biographies, 17 but information on session participants is available 18 19 on the program book. Just two quick notes, there are two 20 21 last-minute changes, Ana Paula Rezende Peretti, the discussant for our first session, was unable to make 22 0013 it here, that's not reflected in your program. 1 2 3 same is true for Brad Sperber who is the discussant for the last session today. He, too, will not be 4 with us today. 5 With that, let me turn it over to 6 7 Dr. Schneeman. DR. SCHNEEMAN: Great, thank you, Mike, 8 and let me add my welcome to everyone. We have 9 people who come quite a distance to participate in 10 this hearing and we really do appreciate your 11 willingness to be involved. We're looking forward to a vigorous discussion over the next couple of days and while 12 13 the panel gets to do the questioning in the formal presentations, we hope that you will use the opportunities during breaks or lunch or the 14 15 16 reception to foster a good exchange amongst the 17 18 various participants. So, again, welcome and thank you for 19 20 being here and helping us learn more about this 21 important area. 22 So as indicated, I'm going to speak to 0014 the current regulatory environment within the United States for particularly nutrition labeling and at the end of my presentation I'll go over the specific 2 3 questions that were asked in the Federal Register 4 5 6 7 Noti ce. So in terms of the general labeling provisions, FDA's authority to regulate food 8 labeling is provided in three laws as they have been amended through Congressional and Presidential action. The Federal Food Drug and Cosmetic Act, which was initially enacted in 1938, the Fair 9 10 11 Packaging and Labeling Act and the Public Health 12 Service Act. So that is where we derive our legal 13 14 authority. 15 Usually once a law is enacted, FDA will

FDA Hearing Day 1.txt often take the step of developing regulations, either regulations or guidance to industry to ensure that there's a good common understanding of how to implement the legal framework.

With respect to mandatory labeling requirements for foods including dietary supplements, I've listed on this slide the mandatory

elements that all labels must contain, the identity of food, the ingredient statement, amount of food in package, name and place of business, nutrition information. There are certain conditions where a food might be exempt from nutrition labeling, but generally in the United States nutrition information is a mandatory element.

Information disclosing material facts about the food, that's information the consumer must know in order to use the food appropriately and since 2006 allergin labeling is also a mandatory element on the nutrition -- on the food label.

So we're going to focus on the nutrition information and the legal framework around the nutrition information.

Nutrition labeling was first made mandatory under the Nutrition Labeling and Education Act which was passed in 1990. It made nutrition information mandatory on most packaged foods. It specified the format and content for nutrition labeling and specifying that format was important so consumers would have a consistent way to look for

that information on a food package and it also allowed for nutrient content claims and health claims on foods.

The goals of NLEA, the Nutrition Labeling Act, are summarized in this slide. First to make nutrition information available so that we could assist consumers in selecting foods that lead to a healthier diet, to eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent. Pre-NLEA, I think the phrase used in the United States was the Tower of Babel for nutrient and other types of claims on food packages, to help consumers maintain healthy dietary practice and protect consumers from unfounded claims and finally, to encourage product innovation through development and marketing of nutritionally improved foods.

And certainly we've seen this last goal play out when FDA most recently issued regulations for mandatory trans fat or trans fatty acid labeling. We have, in fact, seen quite a bit of re-formulation of products.

And just to remind many of you of the public health context, at the time that NLEA was enacted, I think it's best summarized by this quote from the Surgeon General's report which was published in the late 1980s that the report's main conclusion is that overconsumption of certain dietary components is now a major concern for Americans.

While many food factors are involved, Page 6

FDA Hearing Day 1.txt among them is the disproportionate consumption of 10 11 foods high in fats often at the expense of foods 12 high in complex carbohydrates and fiber that may be 13 more conductive to health. The type of labeling that was used prior to NLEA probably put more emphasis on micro nutrients and this statement clearly began to 14 15 16 re-shift the focus toward the macro nutrients that 17 were in foods. 18 19 The Surgeon General's report was 20 certainly a key document that was used to summarize 21 the scientific justification. Two other major 22 reports that were important for the implementation 0018 of NLEA were the dietary guidelines for Americans that have been published in 1990 and the diet and 2 3 health report that was published at about the same time that the Surgeon General's report. 5 So, then, to summarize, if we take the goals of NLEA, those goals really played out in two 6 major ways. One was the nutrition facts which became a part of most packaged food labels and again following that defined format, but then also through the authorization of health claims and nutrient 7 8 9 10 content claims that could be used in food labeling. 11 This is just a reminder for you of the 12 nutrients that were to be listed in the nutrition 13 14 facts on most food packages, the reasons why you don't see these nutrients on all foods, but these 15 are the ones that were accounted for with the 16 17 nutrition facts. Now, we need to shift then and talk a 18 19 bit about the types of claims related to health and 20 nutrition that were, could be used in food labeling. There are two categories, dietary guidance, which 21 22 are messages that refer to a general category of 0019 foods and heal th. The classic example are fruits 1 and vegetables are a part of a healthful diet would be an example of a dietary guidance message. These statements cannot convey an implied health claim. And then there are also nutrition support statements 4 5 6 which are probably used most commonly with dietary 7 supplements and were defined with DSHEA, with the 8 Dietary Supplement Health and Education Act. 9 These refer to structure function claims 10 which are about maintaining health, well-being claims and some of them will refer to classic 11 12 nutrient deficiencies but also indicate the prevalence and again, this is more commonly used 13 with dietary supplements.

These two categories of claims do not 14 15 require a pre-market review by the Food and Drug 16 17 Administration. Manufacturers are responsible to make sure that they are truthful and not misleading, 18 but it doesn't involve a pre-market review. 19 20 Now nutrient content claims and health claims, which I'm going to go into in a little bit more detail do, in fact, require some pre-market 21 22

activity by the Food and Drug Administration. A nutrient content claim is a claim on the label or in labeling of foods that expressly or implicitly Page 7

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FDA Hearing Day 1.txt characterizes the level of a nutrient in the food. In health claims, including a category that we use in the United States of qualified health claims, characterizes the relationship between a food or food component and a disease or health-related condition.

So we'll talk first about the nutrient content claims. This gives first of all the relevant regulations within the Code of Federal Regulations, that's the CFR for those of you who are not from the United States, and that outlines the general principles for nutrient content claims. There's also a sub part D of Part 101 in the CFR which gives specific requirements for nutrient content claims.

In terms of the general requirements for nutrient content claims, most of our nutrient content claims are based on an established daily value. There are specification for the style and

size of font that can be used for nutrient content claims and there are also conditions for when a disclosure statement is needed and that disclosure is based on the levels of fat, saturated fat, cholesterol or sodium in the food product.

Now the most commonly used type of nutrient content claims are expressed nutrient content claims, and I've categorized them here in three general categories. One is that they describe the level of a nutrient or a dietary substance, so terms such as free, high, low in a nutrient, contains a nutrient, referring to something as being a good or excellent source would be examples of these types of nutrient content claims.

A second category are comparative claims which compare the level of a nutrient or a dietary substance to another food. It has more of a specific nutrient or it's reduced in a particular nutrient or it's, the term light is often used in a comparative way.

There's a third category which are percentage claims for dietary supplements which

we're not really going to be addressing here because we're focusing more on food.

Now there can also be implied nutrient content claims, and so one way that a nutrient content claim might be implied, if it suggests that a nutrient is present or absent in a certain amount, contains no oil, could imply that a product is fat free. Use of the word only might imply that it's, has a limited amount of a particular nutrient, so it's an implied nutrient content claim.

Likewise, there could also be equivalence claims. The example I've given here is as much Vitamin C as an 8-ounce glass of orange juice, so again, it's making an equivalence type of statement.

And then the third category are claims that a food may be useful in maintaining healthful dietary practices. And here the most common example is use of the term healthy or variations of the term healthy.

FDA Hearing Day 1.txt And the regulations define criteria for the use of the word healthy and for right now we'll 22 0023 just focus on the criteria within an individual food, that that food should be low in total fat, meet the criteria for low in total fat, meet the criteria for low in saturated fat, have 480 milligrams or less of sodium, 60 milligrams or 5 6 less of cholesterol and then have at least a 7 certain, at least 10 percent of certain beneficial 8 nutrients within the food and these criteria are laid out for seafood, game, main dish and meal products. And I don't want to get into all the 9 10 definition of main dish, meal product, I just have an example of what those are. 11 12 13 I should point out for those of you not familiar with the U.S. system, you see the phrase 14 RACC, R-A-C-C, this is actually the Reference Amount 15 16 Customarily Consumed, which is how NLEA defined serving size, as the reference amount customarily 17 18 consumed, that that was the expectation for 19 I abel i ng. Again, not to go into this next slide in detail, but just to point out that within the CFR, 20 21 the definition for individual food, main dish 22 0024 products and meal products are listed and I should 2 3 have also mentioned, some might ask why do you only do this for seafood and game meat, it's because those are the products that FDA regulates. Other types of meat are regulated by USDA but we do, in 4 5 fact, work closely with USDA to make sure that there 6 7 is appropriate consistency in our regulations. 8 Okay, so for nutrient content claims, the nutritional criteria for making a nutrient 9 10 content claim is based on the referenced daily intake, or the RDI, or the daily reference values, the DRV, which are established within the Code of 11 12 Federal Regulations. 13 14 So one can find those reference values published by FDA and we are certainly, we're in a 15 process where we hope to be updating those based on 16 17 the new dietary reference intakes. So most -- whoops, I meant the laser. 18 19 Most regulations apply only to those nutrients or 20 dietary substances that have this established daily value and again, an example would be excellent 21 22 source of Vitamin C means that the product contains 0025 at least 20 percent of the RDI for Vitamin C per 2 3 reference amount customarily consumed or per serving si ze. 4 5 So, again, it's a way of defining those terms so the consumer knows that there is, in fact, 67 some consistency in the meaning of those terms as used in food labeling. So let's shift and talk a little bit about health claims. Again the purpose of health 8 9 10 claims is to allow foods to bear certain science-backed claims about reducing disease risk in 11 their labeling without being regulated as drugs and 12 13 the important point is that these are risk reduction

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claims.

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So it's not about preventing, mitigating or treating disease, they are simply about reducing risk of the disease or a health-related condition. The key elements of the health claim.

The health claim should refer to a specific substance, which is a specific food or food component, whether in a conventional food or dietary

supplement form and that substance is defined as

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> related to the nutritive value of the food product. The second element of a health claim is the specific disease or health-related condition and it's the health claim is then about the relationship between that substance and reducing risks for the disease or health-related condition.

There are several ways that health claims are used in food labeling. What was established through the Nutrition Labeling and Education Act are claims that are authorized by the Food and Drug Administration. These claims are based on significant scientific agreement, that's what was defined under NLEA and the Agency goes through a rule-making process to authorize those types of claims.

Beginning in 2003, the Agency started using qualified health claims, these are different in that the, these are claims that characterize the quality and strength of the scientific evidence if the claims are not based on significant scientific agreement. And the Agency basically is exercising its enforcement discretion under interim guidelines

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for qualified health claims. That's how manufacturers use those claims.

There's a third way that health claims can be developed for food labeling and these are claims based on authoritative statements. These are often referred to as FDAMA claims, FDAMA refers to the FDA Modernization Act which allowed for the use of authoritative statements of a scientific body of the Government or of the National Academy of Sciences to be used as the basis of a health claim. These go through a notification process.

The Agency is notified, they have an opportunity to review and communicate back and forth with the notifier, but eventually if the Agency does object, it would have to take some rule-making acti vi ty.

Now as there are implied nutrient content claims, there are also implied health claims and implied health claims could capture statements, symbols, vignettes or other forms of communication that suggest a relationship between the presence or level of a substance in the food and a disease or a

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health-related condition.

So examples are, indeed, third-party references, terms or symbols such as a heart all could be implied health claims if they are used in, in food labeling.

Now I mentioned under nutrient content claims that there are disclosure requirements. health claims there are disqualifying requirements,

FDA Hearing Day 1.txt certain foods are not eligible to bear a claim 10 unless we have specific scientific information. 11 So the requirements for disclosure statements on nutrient content claims is if the 12 product exceeds certain level of fat, saturated fat, cholesterol or sodium, then it would require a 13 14 15 statement to say see nutrition information for, fill in whatever that nutrient is. 16 17 For health claims, a product must meet 18 certain criteria, including that the food contains 19 without fortification 10 percent or more of the 20 daily value for one or more of Vitamin A, Vitamin C, 21 iron, calcium or fiber and then the food contains less than the specified amount for fat, saturated 22 0029 fat, cholesterol or sodium. Again, those are disqualifying criteria. The food would not be eligible to bear the claim. And this just summarizes the minimum 5 levels for that disclosure or the disqualifying 6 7 requirements on claims, and again if we focus on the individual food, it looks at fat, less than 13 grams, saturated fat is 4 grams, cholesterol is 60 milligrams or less, sodium, 480 milligrams or 8 9 less, again, just to require the disclosure or the 10 11 di squal i fi er. 12 So, with label information, then we 13 have certain elements that are considered mandatory 14 elements within food labeling. These are required by the relevant statutes and governed by the 15 16 regulations in the Code of Federal Regulations. focus primarily on the nutrition elements, both the mandatory piece in terms of nutrition facts, but 17 18 also then voluntary information in terms of claims 19 that are being made by the manufacturer. 20 And voluntary information is information 21 22 that is used at the manufacturer's discretion, 0030 claims, marketing statements, promotion, et cetera. It is important to keep in mind that all food 1 3 labeling must meet the criteria of being truthful 4 and not misleading to consumers. And manufacturers have that burden, that 5 6 7 responsibility to make sure that the labeling is truthful and not misleading. 8 Just one additional slide on the 9 provisions regarding false or misleading labeling, since that applies to voluntary statements. food is misbranded in its labeling if its 10 11 mislabeling is false and misleading in any particular and in determining whether labeling is 12 13 misleading, FDA and Courts take into account any 14 representations that are made or suggested by 15 16 statement, word, design, device or any combination thereof and whether or not the labeling reveals material facts in light of representation in the 17 18 labeling and the consequences of use of the product. 19 So, to move on, then, to our public hearing, what I want to do now is just review for 20 21 you the questions that we posed in the Federal 22 0031 Register Notice that then highlight the areas that the Agency is hoping to gather information through

FDA Hearing Day 1.txt this public hearing process and the comment period that will still be open after the public hearing. So, as Mr. Landa indicated, the first issue deals with nutritional criteria. The fact that there are many of these programs in place, both domestically and internationally. The system uses different nutritional criterion and requirements and so we would like information on the food products that bear symbols and the nutritional requirements of those symbols. The questions that we've asked under this category, in what product categories are

nutrition symbols used, which symbols are nutrient specific and which are summary symbols based on multiple nutrients.

We've asked what are the nutritional criteria, including calories included in a symbol system and how were those particular nutritional criteria chosen for inclusion. What nutrient thresholds and/or algorithms are used to determine

if a food product may display a specific -- a nutrient specific or a summary symbol.

Are nutrition symbols presented together

with front label nutrition claims such as low fat or a good source of calcium and if so, to what extent and for what types of claims.

Are there programs to educate consumers to understand the nutrition symbols or is all of the information contained within the symbols.

When education programs are available,

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18 19 how are they presented?

The second issue deals with consumer We recognize that the presence could research. affect food purchasing decisions of consumers. could help consumers make food choice, but it's also possible they could introduce some confusion with consumer decisions, so we would like information on consumer research that supported the development of the programs as well as research that illustrates how the programs are understood and utilized by consumers.

Again, the questions that we ask under

this category, what are consumer attitudes toward nutrition symbols. What are consumer attitudes toward products or brands that carry a nutrition symbol compared to other products or brand in the same product category and in other categories that do not carry such a symbol.

What are consumer interpretations of

symbol carrying products or brands in terms of their overall healthfulness, specific health benefits, featured nutrition attributes, non-featured nutrition attributes, quality, safety and other non-nutrition attributes.

And what is consumer perception of the presence of multiple and different nutrition symbols on front labels of different brands in a given

product category. What is consumer interpretation of the coexistence on the food label of symbols and/or

other nutrition messages when present and

FDA Hearing Day 1.txt quantitative nutrition information, for example, the 21 nutrition facts label used in the United States. 22 What is consumer interpretation of the 0034 coexistence of front label nutrition symbols and 2 nutrition symbols present on the tags of supermarket 3 shelves when available. When do consumers use nutrition symbols and what do they use them for? Do nutrition symbols 5 6 7 on food labels direct consumers toward purchase of foods that bear them and if so, to what extent. 8 Do symbols affect the nutritional quality of the total diet of consumers who use the symbols and if so, to what extent.

The third issue addresses economic 9 10 11 12 research. How the availability of a nutrition 13 symbol could have an impact on the cost for both 14 industry and consumers and other possible economic 15 impacts. 16 So our questions posed under this topic 17 area, to what extent, if any, have products been 18 developed or re-formulated to qualify them for a 19 What are the costs given nutrition symbol. associated with product development, re-formulation 20 21 or both. What are the costs associated with putting symbols on packages. What, if any, are the price 22 0035 differences between symbol carrying products and 2 other products within the same category and has inclusion of nutrition symbols on the label, labels 4 of food products affected the sales of those 5 products. 6 So those are the questions that we are You'll hear the panel come back to those 7 posi ng. 8 questions in various ways and with that, I'm going 9 to turn the program over to Leslye Fraser, our first Thank you. LESLYE FRASER: 10 moderator. LESLYE FRASER: Thank you, Barbara, and good morning. I have the privilege of serving as the moderator of the first panel and the name of it is the international experience Government 11 12 13 14 activities. As we noted in our Federal Register 15 16 Notice, a few countries around the world have 17 already instituted voluntary labeling systems for Government designed front label nutrition symbols. 18 These symbol systems vary in their format.

Some systems have detailed graphic 19 20 21 illustrations that indicate the content of a number 22 of selected nutrients, while others simply present a 0036 single icon indicating that a food is helpful --healthful with further information available 3 4 elsewhere, such as in booklets and Websites. We are very grateful that we have presenters who are willing to come and share their experiences abroad and I'd like to invite the 5 6 7 panelists to come forward. Our speakers today, and my apologies in advance if I am not pronouncing names correctly, 8 9 Claire Boville from the United Kingdom Food 10 Standards Agency, she will be our first speaker and she actually can take her place at the podium. We 11 12 13 also have Jan-Willem van den Brink from the

FDA Hearing Day 1.txt Netherlands Ministry of Health, Welfare and Sport, 15 if he would join me at the table. Tipvon Parinyasiri from the Thailand Food and Drug Administration and Mary L'Abbe from Health Canada will be our fourth speaker. 16 17 18 And, again, Sweden sends their apologies, they had a personal emergency and could 19 20 21 not join us, but they do hope to send comments to 22 the docket. 0037 Each speaker will have 15 minutes to 2 We will have a five-minute warning and a speak. one-minute warning, both from a person in the audience, and I will get to be the bad guy, but I know they'll keep within the time frame. 5 6 7 So with that, welcome. Again, we appreciate your being here and we'll start with 8 Ms. Boville. Thank you. 9 CLAIRE BOVILLE: Okay, good morning, ladies and gentlemen, and I just wanted to say very 10 personally how delighted I am to have been invited to today's hearing to represent the UK and to 11 12 explain and share some of the experiences of our 13 14 system in the UK. 15 Just by way of introduction, the Food Standards Agency is an independent Government 16 17 department which has responsibility in the UK for 18 all matters to do with food safety and nutrition and 19 we have three main objectives, which are to put the consumers first and to make sure that everything we 20 21 do is based on good scientific evidence and that we do so in an open and transparent way. 22 0038 1 Okay. Let's see if I can get this to Okay, excellent. 2 3 4 5 work. I have tried to answer the 20 questions that were set out in the FDA Federal Registration Notice and it has been a tough task, so'l'm going to, all of the slides that I've got today answer those questions but I'm going to have to, because of time, whiz through some of them and cut some out.

What I'm going to try and do today is 6 7 8 9 10 explain to you what nutrition labeling looks like in the UK and why we have introduced on a voluntary 11 basis sign post labeling and what's actually 12 13 happened in the marketplace. Well, in the UK, nutritional labeling is provided on food packaging in the majority of cases, but nutritional labeling is laid down by European 14 15 law and it is a voluntary requirement unless there is a claim made about the nutrition of the food. 17 18 If it is provided, and the UK is one of 19 20 the countries where the industry has voluntarily 21 chosen to provide nutritional labeling information 22 because they think it's in the interest of the 0039 consumer, they have provided it on the back of pack for about 80 percent of the products; however, despite that being the case for over 10 years, there are rising levels of obesity in the UK and there are 5 also health-related illnesses associated with that. 6 And those are largely resulting from the consumers eating far too much saturated fat, salt Page 14

and sugars.

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So, while we have the nutritional labeling information on the back of pack on a voluntary basis and the consumers know that it's there, they are -- find it too complicated and detailed to use in practice, which means that in reality they often choose to ignore it. That's r That's not to say they don't want it; they do want it, but they can't use it. So that's just a quick illustration of the type of information that you might find in the UK.

So, recognizing that the current labeling arrangements weren't working, the Government decided that it needed to tackle the issue and that one of the activities and initiatives

that it could undertake to address that was to address labeling issues. It's only one of a whole strategy of arrangements that we have in the UK to address obesity.

And the Agency was given the task of undertaking the work to develop the sign post labeling scheme and it carried out comprehensive evaluation of consumer -- what consumers needs and wants over a two-year period. And what I'm going to briefly go through now is the history of that sign posting research which looks at what consumers want and what works in practice.

Well the first stage of research was carried out in November '05 when we looked at five different concepts for sign post labeling schemes and they could be broadly divided into two groups.

The top part of the slide covers those

which could be considered to give you Healthy Choice logos, that is to say, they give you an overall assessment about the heal thiness or otherwise of the food based on criteria devised somewhere else which You just have to the consumer isn't told about.

trust the scheme that it's healthy or not.

And the bottom part of the slide were schemes which tried to give the consumer a bit more information so that they could decide themselves whether something was healthy or not. And it was all based on the key nutrients which consumers in the UK are eating too much of, which I mentioned earlier, fat, salt, saturated fat and sugars.

It doesn't want to move on. Ah, okay. From that research what we found was that the option, one of the options that was on that included information on guideline daily amounts and that, it actually didn't perform very well with consumers. Consumers didn't like it and the reason for that was largely because it was quite crowded and had a lot of information.

But the industry is quite a fan of GDAs and has for a number of years been providing that information on the back of pack and on a voluntary basis and felt that it had a role in a front of pack sign posting scheme and asked that we test some more formats with that type of information presented on

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them.

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So in March we carried out work based with consumers, again, testing seven different looks of presentation of information based on guideline daily amounts. Three of them are shown bere on this

daily amounts. Three of them are shown here on this slide and they give the actual GDA reference value and the amount of the nutrient in a serving. Some of them include color-coding, red, amber, green, to give the consumer at-a-glance information on whether it's high, medium or low in a particular nutrient and the others are completely neutral and the

consumer just has to interpret the information themselves. And the bottom slide is the original one that was tested and which consumers didn't like

one that was tested and which consumers didn't like.

Four other GDA formats were tested and these ones all tried to do some level of interpretation of the GDA information. They gave the information in terms of the percentage. Two were bar charts and at the time those bar charts actually were being used by Kelloggs, well in the one without the color-coding was being used by Kelloggs at that time. So we tested that and we

tested it with an interpretive element of the red, amber, green color-coding and then we used an approach which was very much like the traffic light which had performed well in the very first phase of the research but with numbers in terms of the percentages, as well. So you had two levels of information in those two schemes.

And what did we learn? Well, we found that the consumers found the color-coding with the red, amber, green to indicate whether a nutrient was high, medium or low to be the most helpful and straightforward of them. A lot of the consumers were, looked at these, these approaches, found that the per serving and the GDA information and percentages confusing.

Now that might be a factor of UK population in terms of their literacy levels and ability to use numbers, but nevertheless that was the case, they found that information too complicated.

And they found that the bar chart approach was difficult to interpret.

So, of those seven formats which included GDA information, the one that the consumer liked the best and found the most easy to use was the one with the color applied to it.

So from here, the next stage was to test what worked with the consumer. So far we've learned about what consumers like, but what we're interested in is what works. So we tested the, of those sign posts that we developed, those which showed the most promise. So the first, all three of them have color because we know that's what the consumer can use and likes at a glance when they're in a, in a, wanting to make a quick and easy comparison between foods.

to make a quick and easy comparison between foods.

And the bottom one, the monochrome GDA was included at the request of industry because they felt that that should be tested again to see how a non-color-coded version worked as opposed to a colored version. And we also included work with no

FDA Hearing Day 1.txt sign posts so that we had a baseline to see which --20 how, if any of these, sign posts were actually helping consumers to make healthier choices. 21 22 So, what did that result, that results 0045 show? Well, it showed that basically sign posting is, is better than not having any sign posting because in the tests where consumers could choose a healthier food product with all of the sign posts 5 except for one, that was the, the simple traffic light, that's the one at the top. So that one which 6 7 is essentially a healthy eating logo performed worse than not having anything.

All the others performed better, but what we can see is this slide, you must read it carefully because this is the amount of incorrect 8 9 10 11 12

answers, so the one that performed the best was the multiple traffic light.

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In the second test where we compared two similar products, so you say against this pizza or this pizza, which one is higher or lower in a particular nutrient and all the foods that we tested were chosen to make sure that they had unusual nutritional compositions so that the consumer could not correctly guess the right answer. They had to use the information to get the right answer and we see a similar trend here.

Again, the simple, simple traffic light, the one that gives a no -- the health mark performed worse than not having anything and the others performed better. This time the color GDA approach came out the best, but there was, they were broadly similar. The monochrome GDA and the multiple This time the color GDA approach traffic light also performed well. So we want to understand why.

Now when we chose the products that we were testing, we chose foods that had in some cases similar color-coding, so if you're saying between this bag of crisps and this bag of crisps which one's the healthier in terms of which one has higher levels of fat, if they both have red, the consumer found it difficult to make a choice using the multiple traffic light at that time because there was no numerical information on it so red and red, they looked the same. So unless you turned over to the back of the pack where you had the exact nutritional information, you couldn't make that choi ce.

So, the colored GDA option is the most

complex of those sign posts. It has a number of components to it and we wanted to understand from -with the consumer which of those components was actually driving their, their understanding of the I think that slide speaks for itself. sign post. The overwhelming element that they were using to interpret the information and correctly determine which one was a healthier choice was

Then they were, they were using preserving information in some cases which showed that they misunderstood how the label worked and in some cases using GDA, but that was by far the least effective

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In this research we also wanted to find out where we should be, if, indeed, this sign posting scheme was going to be useful, where it should be applied. Should it be applied across all foods or should it be applied to certain categories of foods.

Consumers in the UK didn't feel that it needed to be applied to all foods, they felt that it only needed to be applied to those foods which they

were having difficulty understanding the nutritional composition of and essentially those are the processed composite foods, the ready meals, the pizzas, the meal components, the burgers, the sandwiches, the types of things that they were eating in large amounts regularly or that they were concerned that children were eating.

So, what we learned from this research was that consumers did want front of pack sign post labeling and that if it was applied, it could work for them in terms of helping them make healthier choices, particularly if it provided separate information on fat, saturated fat, salt and sugar and had a color-coding system to indicate whether the levels of those nutrients were high, medium or low, and that if GDA information was provided on with percentages, it was confusing to them.
So based on that, the Agency made its

recommendations for a voluntary sign post labeling scheme which was based on those four principles. didn't come up with an exact logo, it said you can design the logo as you like, provided it has these

elements, separate information on sat, saturated fat, salt and sugar, a color-coding, which is red, amber or green to indicate whether the nutrients are high, medium or low and the criteria will be based derived by the Food Standards Agency and that it will also give information on the actual levels of the nutrients in a food.

Now that was a big change and that was a change that was introduced as a result of the consumer research which showed that the additional information on nutrients helped to interpret the color-coding where you had similar products with similar color codes and that that information should be applied to processed foods which consumers had difficulty understanding.

In addition, the Agency said that those using this type of approach could voluntarily add in information on calories. Now the reason that the Agency didn't recommend it or make it a requirement for its, its approach was that the consumer research showed that consumers already understood calories and knew where to find that information on the back

of the pack and didn't feel that they needed it to be highlighted specifically on the front.

And the Agency also said that guideline daily amount information was okay to apply on the front of the pack, provided it was included with the red, amber, green color-coding.

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FDA Hearing Day 1.txt The reason for that being is that we 8 know that it's the red, amber, green that works for 9 consumers. 10 LESLYE FRASER: Ms. Boville, my apologies, if you can have a summary statement.
CLAIRE BOVILLE: Yes, of course.
LESLYE FRASER: Thank you very much.
CLAIRE BOVILLE: That's just to show you 11 12 13 14 the criteria and it's on the slide, it's on the 15 16 Website and to show you what it might look like in various illustrations and to show you that we have a 17 18 whole range of consumers -- of businesses that are using it, eight retailers to date, four service providers, 14 manufacturers, I don't know if the battery is dying in this, 14 manufacturers and a 19 20 21 whole range of others that are coming on board. 22 0051 It's supported by a whole range of organizations, 2 professional bodies, medical bodies, enforcement 3 bodi es and consumer groups. 4 And that whole range of consumers like it and can use it and the important thing is that we know that it is actually changing what's happening in the marketplace. A whole range of manufacturers 5 6 7 and retailers, whether using this scheme or not, are 8 re-formulating their products according to the 10 criteria and that this is -- means that we are 11 having a healthier range of foods available to the 12 consumer and that the consumer is choosing them. So, we are seeing an increase in the amount of sales of foods which have a higher level of greens and ambers and a reduction in the sales of 13 14 15 those that have a high level of reds. 16 17 Now the very interesting piece of research, and I will close just after I've talked 18 19 about this one, is that we did some research with 20 consumers once it was on pack to find out how they 21 were using it in practice and the consumers told us 22 that the sign post with traffic light colors helps 0052 them to give an assessment about the overall 2 healthiness of a food and, as well as providing 3 information about the individual balance of individual nutrients, whereas compared to a 5 monochrome GDA approach, which is also used in the UK voluntarily by some businesses, where consumers found, felt that that acted like wallpaper, they didn't really use that information to assess the healthiness of a food unless they were looking at a particular nutrient. So if they were concerned 6 8 9 10 about salt, they looked at that nutrient and so they 11 tended to look at it for culprit foods. 12 And very finally just to say that we're 13 doing more independent evaluation of the sign 14 posting schemes operating in the UK to assess what's 15 actually working for the consumer in terms of making 16 a healthier choice and that research is going to be commissioned later this year. And we hope to have the results and that will give us a definitive 17 18 19 answer to the question what is actually helping to 20 make consumers to make heal thier choices next year, 21 22 this time next year, hopefully.

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2 3 4 5 LESLYE FRASER: Thank you very much. (Appl ause) And I know we have given a tremendous challenge to our panelists to reduce years of research and excellent work in a finite time period, 6 7 8 so we thank you for that excellent overview and I do 9 believe the slides will be going into the docket so 10 that the full package and the full presentation will And again, we thank you.

And with that, I will ask the gentleman be available. 11 12 from the Netherlands to come forward, Mr. Jan-Willem 13 ık. Thank you. MR. van den BRINK: 14 van den Brink. 15 Good morning. 16 name is Jan-Willem van den Brink. 17 I'm involved with food labeling at the 18 Dutch Ministry of Health. Let me begin by thanking 19 Dr. Schneeman for giving us the opportunity to 20 present our approach to logos, share our experience 21 and learn from yours. I'vé prepared a small presentation on 22 0054 the Dutch policy and you've just heard from Claire Boville from the UK on their perspective on sign posting and, well now I'll give you the Dutch 3 approach. And although we strive, we all strive to 5 help make consumers -- help consumers to make a 6 7 healthy choice in food, the different approaches indicate that the use of logos and symbols to 8 communicate the nutritional quality of products is a hot topic within the European community, as well.

Now a little of the content, I did file 9 10 my presentation as follows and I will not try to 11 attempt or attempt to answer all the questions in 12 the presentation and I hope it will be clear why. 13 First, I would like to give you a little bit of context of the food industry and the healthy lifestyle policy in the Netherlands. Then I will give you an overview of the events that led to the introduction of the Healthy Choice Logo in the 14 15 16 17 18 Netherlands. Then I will very briefly look into the 19 20 criteria for receiving a Healthy Choice logo, or a 21 stamp, and after that I will explain the conditions 22 of the Government endorsements and indicate some 0055 1 concerns as well as ambitions. Now, some context about the food industry in the Netherlands. The agri food i The agri food industry is of great importance in the Dutch economy, for the Dutch economy. It is the biggest industrial sector 5 6 7 in the Netherlands and accounts for 10 percent of our GDP, over 600,000 people are employed in this 8 sector, and bear in mind we are a small country. 9 20 percent of our total exports is generated by the 10 food industry and the Netherlands is the biggest EU, 11 intra EU trader. 12 Some major companies from the Netherlands include Unilever, which is both UK and 13 Dutch, Banniker and Royal Friesland Foods. 14 15 Well, I'll skip the information about of course what you all know about what a healthy diet 16 17 is, work for, but our healthy diet policy is based Page 20

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I'm really sorry I've run out of time, I

could talk for hours.

FDA Hearing Day 1.txt on norms and guidelines of the Health Council in the Netherl ands. The diversity of foods with adequate amounts of vegetables and fruit and low consumptions of fat together form the basis for healthy nutrition. To promote a healthy lifestyle, the Ministry informs the public through communication and adaptation policies -- projects, many projects are focused on the education of children.

Furthermore, the Ministry encouraged the food industry to modify their products by, for instance, decreasing the amount of saturated fats or trans fats and one of our campaigns, the hidden fat campaign, has been very successful in lower the amount of trans fatty acids throughout the food chain.

Well, given the presence of the large food industry in the Netherlands, characteristic of our policy is the promotion of innovation in food and nutrition and last year top institute for food and nutrition was established in the Netherlands, it's a unique public -- private partnership which we will hope generates scientific breakthrough in food and nutrition and this then will lead hopefully to development of innovative products and technologies that will respond to the consumer demands for safe, tasty and above all, healthy foods.

In addition to our industrial and

research partners, the Dutch Government has contributed 61 million Euros up to 2010.

Now, some -- the, some history about the Healthy Choice logo and partnership with industry, as I explained, is an important element in our policy. And in order to tackle obesity and overweight in the Netherlands, the food industry, retailers, caterers and the Government signed a covenant on overweight and obesity.

The parties agreed that it is important to maintain or restore the balance between eating and physical activity. This could be achieved by encouraging people to choose a healthy diet and a healthy lifestyle, for example, by offering them healthy food options and making those options more attractive.

Well three large food and beverage manufacturers, Unilever, Royal Freisland Foods and Campena, the last two are dairy companies, they took the initiative to develop a logo that would enable consumers to make a healthy choice in foods and in May 2006, this Healthy Choice logo was presented to

the Dutch Ministry of Health. I will show you the logo later on.

This initiative by those industry partners was immediately supported by some major retailers, caterers, as well as the Dutch consumer organization and the Netherlands nutrition center. A little over a year ago products with the Healthy Choice logo appeared in shops and recently the scientific commission, which is part of the Healthy Choice organization, evaluated the criteria they've started with and came up with stricter criteria.

FDA Hearing Day 1.txt Now, here is the logo, it's a front of 13 pack stamp. It's a single tick and research 14 indicates that a simple front of pack label labeling format seems more appropriate in the shop, 15 shopping environment where quick decisions are made. And this is the international version of the logo, so it's based on international dietary guidelines.

Now let us briefly look at the 16 17 18 19 20 qualifying criteria and the products groups. order to be eligible for, to carry a stamp, a product must satisfy the criteria of the product 21 22 0059 group to which it belongs. There are two sorts of 1 groups, six main product groups and four supplemental product groups. An example of a main 3 product groups is bread, grains, potatoes and pasta, so the sources of carbohydrates. Or a group with 5 6 7 meat, fish, poultry and eggs. A non-basic group, or supplemental group, for example, are soups or snacks. For the 8 9 main product groups, the four criteria for saturated fat, trans fat, sodium and added sugar are determined and the criteria are derived from WHO standards. Additional criteria have been drawn up 10 11 12 13 for a situation in which the intake of essential or useful nutrients is of importance, so like bread 14 should contribute to the intake of fiber. 15 16 For supplemental product groups, some criteria have been replaced. For soup, for example, the sodium threshold is lower, of course because 17 18 otherwise no soup would be eligible for a stamp and 19 20 consumers would not be able to choose a healthier 21 opti on. 22 Well, in essence its an across the board 0060 system, because when a product doesn't fit in one of 2 the product groups, there's also always, there are 3 always the levels for trans fat, sodium, added sugar 4 5 and saturated fat. This criteria are the criteria. I'm not showing you them, they are in the brochure, as well, they are not static. Every now and then, and it 6 7 seems that every two years now the criteria are 8 9 evaluated and re-aligned with the latest scientific 10 insight and to see how many product fit the 11 criteria, because if more than 20 percent is eligible for a stamp, the criteria need to become 12 stricter. This dynamic process we think will stimulate innovation. For more details on the 13 14 criteria itself, I would like to direct the 15 commission to the information that was provided by 16 17 Choices International. Well this is a slide I keep on changing 18 19 over and over because there are about, about now, 20 about 600 pre-packed products in the supermarket 21 with a stamp. A number of supermarket chains has 22 also adapted the system for their private logos and 0061 together they have a market share for over 50 percent in the Netherlands. And fair is fair, the biggest supermarket chain, that's Albert Hein, 2 which is part of Ahold, is not yet part of the Choices Foundation in the Netherlands and they have

FDA Hearing Day 1.txt got their own almost similar or in essence similar system. Okay, the Government conditions, I've explained that this is a private initiative and the Dutch Government endorsed the industry initiative on introduction last year, but not without conditions and we monitored those conditions. We are very clear that we have made very clear that this system should be open, an open initiative for others to join, so other manufacturers, retailers, caterers, they would, could join this, this initiative and that is the case. On introduction the criteria needed to be -- needed to be developed further by the scientific commission and the commission did so and came up with stricter criteria in May this year and 0062 this meant that some product groups couldn't carry a stamp anymore. We will have the Health Council in Netherlands, that's an independent council, advise us under the Government on the system and the criteria used and the Health Council is in the process of doing so right now. Of course we are all aware that healthy diet is just one of the components for healthy living and along with a healthy diet, appropriate regular physical activity is a major component in preventing chronic disease and the Ministry of Health -- the Minister of Health has made it clear that in communication and education about this logo, the physical activity is also promoted.

And not -- last, but not least, and l think Ms. Boville pointed it out as well, the affects of the logo on consumer behavior must be monitored. We need to know what really works for consumers and for that the interpretation of sales data and dietary intake data is crucial. So this is still a private initiative, but endorsed by the 0063 Ministry of Health by the Government and there's no Government regulation in place, nor are there any funds directed to this foundation. Other logos may occur and as I pointed out earlier, there is similar initiative from one of the large retailers in the Netherlands. LESLYE FRASER: You have about two mi nutes. MR. van den BRINK: Okay, thank you. Recently at the European nutrition conference in Paris, Choices International was This is an international version of the Dutch logo and of course we are proud to, to be the country where Choice's logo originated from and we

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are also glad to see that the International Scientific Commission was, will build on the work of the Dutch Scientific Commission has done and we still believe that this system helps consumers in making a healthier choice in food. And we believe that it will stimulate the food industry towards product innovation.

But as I said before, we, we'll need to Page 23

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keep on monitoring the developments of the system

and other initiatives from industry.

Maybe there are too many logos on the market, are the criteria have the logos aligned or not, will the healthier choice, of course, lead to more balanced consumption. Does it lead to the proper type of innovation.

And please allow me to summarize with

the following figure.

This is nothing scientific, I just drew some points I wanted to make. A horizontal axis is the nutritional quality of products, so it fits with both, within the healthy diet or it doesn't fit in the healthy diet and the vertical axis is the consumption balance by consumers, either they buy or consume a product that fits their balanced diet or unbal anced diet.

Now, at any given time this is a snapshot of products that are bought in shops and consumers buy -- by consumers at any given time the products are consumed and I've marked out some random intersections of that. Through our policies

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19 20 21 we try to, and communication, education products, we try of course to, well to lower the healthy balance campaign, for instance, have consumers make a healthier choice and a balanced choices in their food and through the innovation funds on the right there, we try to direct the industry to product innovation and the nutritional quality of the product. So those are the powers of -- the forces on the sheet

The Healthy Choice Logo, well, you could draw a line like that and the Healthy Choice, the Healthy Choice logo is a nutrition profile so every product is that situated on this side is eligible to carry a stamp and to be honest, this is a bit our concern, that industry is more stimulated to make products that fit in this range instead of this range, so they're stimulated to make products with a better nutritional quality but will encourage people

to choose a healthy -- unhealthy diet.

Now, I've just one minute to conclude and that should be sufficient to say that this is, of course, a private initiative and I'm glad to be

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here to present you why the Dutch Government choose to support this, endorse this system, but on conditions, because we feel that the Healthy Choice logo is, will help consumers make a Healthy Choice and stimulate industry to, for product re-formulation.

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But as Ms. Boville also pointed out, the need for research must be -- there's a need for more research on front of pack labeling as well and that's why I'm very interested to hear, to hear from you, as well, what -- on what kind of research there

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Thank you very much. (Appl ause)

LESLYE FRASER: Our third speaker is

from Thailand's Government Food and Drug Page 24

FDA Hearing Day 1.txt 17 Administration and we welcome Ms. Parinyasiri. 18 Thank you. 19 TIPVON PARINYASIRI: First of all, I would like to thank you, Dr. Schneeman, to give me and my colleague an opportunity to share the 20 21 experience which we have learned, we have listened 22 0067 and Learned from Thai FDA. We hope that this activity you continue, we can exchange the 3 4 networking and learning. Even though this time I cannot answer all your question, but I will go back 5 and collect information about the economic impact 6 7 and some more research which we going through next year, so I, I owe you the homework.

First of all I'd like to share the, the 8 9 outline that since Thai FDA have learned through the 10 difficult situation among the limitation of the 11 staff and budget, the outline that I will presented is how do Thai FDA work and the second is the affect 12 13 on the consumer protection in Thailand and the third 14 experience of the Thai FDA on nutritional labeling. 15 Thai FDA use the food law as a tool and we, for consumer protection on safety, nutrition, identity and efficacy and -- sorry, it's -- no, and the Thai FDA have the registration notification and 16 17 18 19 responsibility and we have a pre-marketing control 20 on the product and post marketing control and also 21 we have (inaudible) and support cooperative and 22 technical knowledge on the consumer behavior. 0068 That's our target on the safety, nutrition identity, 2 effi cacy. Since every country have the same affect on the consumer activity on the food incident and 4 5 6 7 the globalization and modernization and from the past to present, we move forward from communicative disease to the non-communicative disease and now we 8 have a big challenge on behavior-related disease and 9 That has an impact on our consumer affect. protection activity. 10 Since the nine years, FDA have introduced the nutritional labeling with the 11 12 13 voluntary approach, the format similar to the one that you have in the United States for the food 14 format and we also have the symbol format for 15 However, it mandatory for the 16 nutritional labeling. foreign food required nutritional labeling on food 17 18 with the nutrition claim and food with nutrition for sale promotion and third is the food's stating 19 specific group of consumer for sale promotion. 20 The objective of the labeling is to 21 inform the better choice for consumer and we have 22 0069 activity of educated consumer through mobile unit. 2 3 We have about, Thailand have 75 provinces, we have 23 mobile unit on each province and now we promote activity through the local officer to have their own mobile unit. Hopefully we will have 50 -- we have a campaign to have them, they have their local authority, they have their own budget, so we promote 4 5 6

the model of mobile unit and we hope that will be effective tool to educate consumer in the -- you

know, in the community and the school.

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So we do a rapid survey, research endurement and empowerment on the consumer and also manufacturer, especially for the small, medium scale.

Thailand have the same problem about the obesity. We, the -- dietitian reported in Thailand 40 obesity problem increase among the children below 6 years old and they have case incident of the child obesity and heart and kidney failure on, to the six years old.

So we, the approach of Thailand through the nutritional labeling, through the children food,

so we have, we take the measure on Thailand since the current situation, Thailand agreed to view is the mandatory approach to require nutritional labeling symbol format, and affected, it will effective within the third -- 90 days for the new manufacturer to make a new labeling and we give the grace periods for one year to, for the manufacturer that already have the product in the market.

Since the -- our concern related to children, so we think the first step we will move toward to the snack. The first phase we introduced a five priority of the snack food and the mandatory nutritional labeling we concentrate on the calorie, fat, sodium, sugar and cholesterol. And we have the warning on the package, take less and exercise for health, that's what mandatory, and we have a warranty nutritional sign post which is proposed by NGO academy field and also the manufacturer field.

That's the sign post proposed by NGO, they have a, multiple traffic light, energy, fat, sugar and sodium. The company doesn't like that approach very much. We have all of the bad among

the -- all academy and manufacturer. Next week we have another meeting among the Thai FDA and academy and also manufacturer to decide it or to take a forward approach and also they have the private company proposed the guideline for GDA and one in Thailand is the Tesco Lotis, they have that on the package now.

That's the nutritional sign post on criteria which we, since we, the -- for the Thai RDI, we have a 2,000 calorie per day consumption, so we think if you take that approach for the snack, the serving size about 30 gram on the snack food, so we take that 30 gram from -- to, we take 30 gram and then if we, the amount of the traffic light will be green, it will be less than 5 and we give, we give the yellow between 5 to 10 because we think the children should not eat the snack more than 10 percent of the calorie per day. Therefore, we, we think we have the shorter -- I mean shorter range than UK because you have a, you give a broader range on yellow criteria. I'm not sure you still have that criteria, but for energy we be less than

100 and fat we be, to get green we be at 3.25 and sugar we be 2.5 and sodium we be 120 we be green.

So if the red, we be, that label more than 10, more than 200, more than 65, more than Page 26

FDA Hearing Day 1.txt 5 and more than 240. That's the criteria that we propose and we still have to debate to the, with the

company.

However, the, in the -- multiple traffic light they have an issue, discussion on the pro and con. You know, we have, we do some research on consumer testing. I think is spontaneous decision for the consumer and consumer respond positively, however for the con, the argument among the industry that the red means stop, danger, warning and the traffic light should not empower or educate consumer by basic nutrition and for the company proposal for the GDA, they say the pro concept would be color is not misleaded to a clear symbol, however since the problem we deal with children, children cannot calculate GDA, too difficult, even, even us, among us adult, I mean consumer, they think it's too complicated.

So, they complain no different between the normal, just bring the nutritional table, I mean item to become a, that sign post and so we have to, we have lot of challenge to discuss and we have to do some more research on how the Thai, especially children, we understand.

And since we have a lot of approach to the education program, we, we put the campaign, lately the company -- the Ministry of Public Health put the campaign on the, national campaign on the nutritional issue on the sugar, salt and fat campaign so we used that educational program to, we call, entertainment, because we put the song, we put the games and we put the leaflet and we do a lot of contests on the topic of the, how to educate the Thai young consumer.

And we also have other nutritional symbol through the Thai Heart Association in Thailand, they have a logo that multiple nutrient on that symbol, that's just one example that they give and they propose to Thai FDA now. They do it voluntary, but we have to, we have to reconsider if

 it, the criteria that they have, for example, for the cereal they have different criteria on each item. They have fat, if the, to get that logo they should have fat less than 3 gram per 100 gram and sugar less than 7 gram from 100 gram, sodium will be less than 250 milligram through 100 gram. Fiber, more than 2 gram per 100 gram and then if the criteria if meet, they would get that logo and this is logo from Nutrition Health Department in Thailand.

10 Thailand

Since Thailand we have deficiency on the iron, vitamin, iodine deficiency, if the, any manufacturer fortify these nutrient in that product more than 20 times RDA, they would get that logo.

That's a campaign through the nutrient deficiency in Thailand which help the, for the children in the rural area. So that the logo, we, is going and another one that proposed by nutrition department in health -- nutrition division in Health Department, they will, they going to release another logo that a fork and spoon on the plate will be

FDA Hearing Day 1. txt another logo that we will discuss in Thailand, so we 0075 still have a lot of -- I think we have the common 1 issue how to get the good educated material or the labeling for the consumer in Thailand.

So we thank you very much and I appreciate all the discussion and I hope we have a 4 5 6 7 good discussion during this time and we can learn And I bring back the, all the from this meeting. information what I have learned to precede the activity in Thailand and we expect we can bring it, 8 9 10 the knowledge back and share among the Government i nternati onāl l y. 11 12 Thank you. 13 (Appl ause) LESLYE FRASER: 14 Thank you for that presentation and our last speaker for this panel is 15 from Health Canada, Dr. Mary L'Abbe. Thank you. DR. MARY L'ABBE: Thank you very much. 16 17 I'd like to thank the members of the FDA for 18 19 inviting me here today to give you an overview of 20 the situation regarding nutrition labels on the front of packaging in Čanada.

I just thought I would just sort of put 21 22 0076 this in context, this is a recent cartoon, but I have been working a lot with trans fat lately so 3 it's a place to talk about labeling as well as trans 4 fat. And I thought this was an interesting cartoon, 5 but it really points to the importance and the role 6 that labels and claims on foods play to the 7 consumer. 8 In Canada, similar to what you, the 9 situation that you have in the U.S., we have a 10 nutrition information that's built on the foundation, which is nutrition labeling, we have a 11 12 nutrition facts table that provides the basic 13 information to consumers. We also define by regulation 14 nutrient content claims, those claims 14 for, for example, the amount of nutrients, whether it be source claims like good, excellent sources, a well as comparative claims, reduced, lower, as well 15 16 17 18 as finally the health claims which in Canada are 19 both the biological role claims as well as disease 20 risk reduction claims and those are defined by 21 regulation. 22 So we have this hierarchy of nutrition 0077 information, all with the goal to help consumers in making healthier food choices which will enhance 3 their health and reduce the risk of chronic disease. And we, this is our nutrition labeling, 5 6 7 our nutrition facts panel. The regulations came into place in December 2002 making the nutrition facts panel mandatory in Canada and it contains the 8 calories and 13 core nutrients which must always 9 appear and then additional nutrients must appear if 10 they're the subject of a claim.

And we've had -- whoops. We've had something like, for example, trans fats, one of the differences for quite a while in Canada and we have a referenced amount of daily value that's the sum of both sat fats and trans.

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In February of this year we released our new, Canada's food guide and this food guide was released after a five-year consultation period and a couple of interesting points. It's not a six-page food guide as opposed to our previous one-page, two sides. And on the food guide, in the accompanying information is points to the nutrition facts panel

and it gives an example on the messaging in the food guide and points to it for consumers as a tool for comparing the nutrient value of foods. And it also has a number of key messages and the key messages focus on choosing products that contain less fat,

saturated fat, trans fat, sugar and sodium.

Now, what's one of the most recent
developments in Canada, our, we have a standing
committee of health and this is comprised of the elected members of Parliament comprising all three main political parties and in May -- in March of 2007, this standing committee of health released a report entitled healthy weights for healthy kids. And in that report one of the recommendations was they recommended that the Government implement a mandatory, standardized, simple front of packaging labeling requirement for prepackaged food for easy identification of nutritional value.

So, we are in the process of responding to this mandate from our standing committee of heal th.

Now, what's the current situation in

Canada? We have a number of labeling and logo symbols in Canada. We have a, a very wide-spread, and I know you're going to hear from Mr. Terry Dean from the Heart and Stroke Foundation of Canada, but we have a Health Check program through the Heart and Stroke Foundation of Canada. It is a third-party It was developed and led by the Heart and Stroke Foundation of Canada.

It was launched in actually 1999 before mandatory nutritional labeling came into force and its criteria are food category specific and are based on Canada's food guide. So they are now in the process of updating it to reflect the most recent Canada's food qui de.

We also have a number of manufacturer led programs in the country and in these programs the conditions for displaying the symbols are actually set by the manufacturer, not by Government. The conditions for the symbols vary from one program to another, within programs of the same company and also in many cases from one food category to another.

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There are healthier choice type symbols based on one or more criteria, some based on a single nutrient criteria and others a panel of nutrients, as well as we see claim specific symbols that refer to nutritional characteristic of the food. And just to give you an idea, this is some of the types of, this is just a smattering of some of the symbols that can be seen in Canada, but this panel here on the, your left are those that would be FDA Hearing Day 1.txt
Healthy Choice type symbols, the Health Check logo,
this by a food manufacturer, this by one of the
largest food retailer chains and another food
manufacturer.

We also have a number of symbols that are seen in products that are really basically based on nutrient content claims, groupings of symbols that represent either the higher or lower reduced, for example, lower in fat or the quantities of a variety of different nutrients.

And finally we have the third category which purport in pictograph version a number of what could be biological role claims or functions of

nutrients and in many cases some of those were considered to be implied health claims.

So, what's the current situation that we see in Canada? We see a number of symbols that are used to represent a range of nutritional characteristics of foods and there are actually proliferating throughout the marketplace, both in -- on products and in advertising and these nutritional symbols communicate information about the nutritional quality and benefits of foods in an eye-catching format and they range, as I mentioned, from icons representing healthy choices, claims specific symbols about nutritional characteristics or biological roles or health claims. And also we see, we see foods that may have multiple symbols on them.

So, what is some of the concerns that were raised both in Government by health NGOs and by our Parliament. One of the noticeable things is there is a lack of consistency amongst programs, there's no standardized criteria as the basis of many of the programs.

There is also a concern that it is the oversimplification of complex messages, particularly when the symbol refers to a health benefit and as I mentioned, the criteria used for any particular claim are often not readily identified by the consumer, so that they can't tell whether, what's the basis of a symbol of one product versus the basis of a symbol of another product. And there is concern that it may be less consideration given to the complete information that is found in the nutrition facts table, i.e., the overall nutritional characteristics of the food.

So, as a result, with the proliferation of these types of symbols, there's actually concern that consumers are not able to compare one product with another because of the varying criteria around these symbols. The consumers may misinterpret similar symbols as having the same meaning when, in fact, they're based on different criteria. Consumers may view products with these symbols as being healthier than those products without symbols and there's also criticism from health professionals

and consumers when symbols appear on foods that may have some negative health attributes.

So, what's some of the consumer research

FDA Hearing Day 1.txt that we have in Canada? From the Canadian Council of Food and Nutrition tracking nutrition trends that was released last Summer, this is the sixth issue of tracking nutrition trends that's been produced every couple of years, first off an important that the nutrition facts table is seen as the number one source of trusted information by 77 percent of Canadians.

Also, almost half of Canadians who look at labels say they look at health claims for a healthier, better choice slogan or symbol on the food, so about half of Canadians look for that, some type of symbol and just to give you the actual data is the, the information that they look for was ingredients by 87 percent, similarly to the nutrition facts table followed by nutrient claims, 64 claims, by health claims, 47 percent and Healthy Choice logos, 47 percent, so it is the furthest down the list.

In a recently released A.C. Nielsen health and wellness study, one-quarter of Canadian households have purchased one brand over another because it had a healthy logo or symbol on the package. However, half of the households also reported that these logos or symbols are not important in making their food choices, but I thought it interesting statistics in this report was that for those that found the logos or symbol very or extremely important, it was highest in the low income group, which was up to 20 percent and other income groups decreased down to I think 11 or 12 percent and highest in the older age groups, those over 55.

 Oh, I'm not sure what was there.
So, what is the regulatory framework in Canada governing logos and symbol. There are no specific regulations in Canada governing the use of symbols that imply a nutrition or health benefit on food; however, like all other claims, symbols or food labeling, the, they are subject to Section 5.1 of the Food and Drug's Act which says they must not

 be false, misleading or deceptive.

There is also a policy on the use of third-party endorsements, logos and seals and this policy actually dates back to 1991 and it's published in the CFIA guide to food labeling and advertising but it was never really developed to deal with the situation of logos and symbols. It was really developed to give companies information in their educational programs around healthy eating messages, so it really wasn't developed for the type of situation we're seeing in the marketplace and most recently we have come out with guidelines on how to use the principles for using Canada's food guides in advertising and labeling.

guides in advertising and labeling.

So, where are we at right now? We're looking at the situation with regards to the front the of package labeling, including symbols, and we're in the preliminary phase of looking at that. We plan to consult on the use of front of package labeling this Fall. We have a discussion paper

FDA Hearing Day 1.txt entitled towards a modernized framework for managing 22 health claims on foods and we expect to release it 0086 this Fall and it has a chapter on the whole issue and questions surrounding the use of front of package and symbols on, in labeling. And it will be used to form our future policy development in this 5 area. 6 7 We're also planning consumer research on the use of front of package labeling and we'll be 8 guided by the information that we receive from stakeholders this Fall as well as some targeted consultations on the issue of front of package labeling, which will all in turn lead to our policy 9 10 11 development in this area. 12 13 So with that I'd like to thank you very 14 much and if you want more information, you can find it on the Health Canada Website, I've given you the 15 address here and if you search under foods and 16 nutrition, you can find more information on the food 17 guide, nutrition labeling, the regulations and 18 19 issues around nutrient content claims, health claims 20 as well as our regulations. Thank you very much. (Appl ause) 21 LESLYE FRÁSER: 22 I'd like to thank you 0087 all of our panelists again for those excellent 2 3 presentations and one of my observations as the Government regulators and regulator to regulator, we do share a concern and observations of trying to 5 help consumers make healthy dietary choices, the obesity theme, poor choices on the conflict side also resonated. 6 7 8 As Mr. Landa comes forward, he's going to moderate the question and answer period, but I 9 guess a question I have for each of the panelists 10 11 and I think various ones touched on it, but related to question seven, do you see the use of symbols in 12 your countries being used by consumers who do look at the package to supplement what's on the nutrition facts panel or the ingredient or to replace what's 13 14 15 on, replace their consideration of what's on the 16 17 nutritions facts panel, so that's sort of my initial and you each touched on it in a different way, but 18 19 perhaps not quite expressly in that manner. Whoever would like, and if you could 20 21 turn on the microphones on the panelists table, 22 pl ease. 8800 CLAIRE BOVILLE: Yeah, and it's a good 2 3 In the UK, certainly the sign post questi on. labeling recommendations are in addition to the back 4 5 of pack nutritional information. There's no intention that it would be instead of because the 6 nutritional back of pack information provides more detailed information and it covers other nutrients which are not covered on the sign post labeling.

The reason that we have recommended that 8 ō

because it is making the consumer very much aware of the nutrients which we know they're eating too much of. So it's giving, making that top of mind for them, so it's doing an education thing as well as an Page 32

we have this sort of shorthand on the front is

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information exercise in the same time.

And what we know from the consumer research is that the consumer uses it in that way. They, when, we have to be realistic here about what happens in the shopping environment. When you're zooming around a supermarket with a four-year-old screaming its head off, you want to get in and get out fast and you want to be able to make healthy

choices quickly at a glance and you need some system which is simple and works for you that you can understand intuitively and without a whole lot of education.

And what we know from the consumer research that I touched on in one of the slides is that the traffic light approach, the benefit of it as the consumer sees it is that it enables them to do that. They can see at a glance the -- how, whether something is high, medium or low in an individual nutrient that they need to be concerned about, but they can also look at the overall balance of the food because they've got the color-coding for each of those nutrients. So they make that judgment themselves and weigh up, they do the trade-off when they're putting this item and that item in the basket to see well, look, how many reds have I got here, can't -- do I need to put some more greens in there, what kind of occasion is it that I'm shopping for.

All of those kind of decisions, whereas the scheme that doesn't have the traffic light

color-coding, what the consumer told us was that they didn't really get that sense of the overall balance. They only used it when they were looking at a particular nutrient, so if somebody was concerned about high blood pressure, they would zoom in for the salt thing and they really scrutinized that piece of information, but that's only one of the nutrients. They don't get that overall sense of, of the composition of the food and that's, that's the major difference with how the consumer uses those two pieces of information.

The only time they may use this scheme without the color-coding is if they're particularly concerned about food, so if they're going to -- a culprit food, as they described them, so something that they're a bit suspicious about and they think it might not be too good for them, then they might scrutinize it. But they have to do quite a lot of work themselves to interpret the information and what we know is that for a lot of the UK consumers, they were concerned that they weren't confident that they were interpreting those numbers correctly, that

they didn't have that concern with the color-coded scheme.

LESLYE FRASER: Thank you. Go ahead.
MR. van den BRINK: Sorry, yes. Well,
in Netherlands we, like the UK, have the same
regulation because it's European community
regulation, but we also see it as a supplement, as
an extra way of informing consumers about the
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FDA Hearing Day 1. txt nutritional quality of the products. 10 And like Ms. Boville's pointed out, the at a glance is very important with one single thing that is probably the best glance I could think of 11 12 and, but from, so we've -- it is supplemental, but I'm, I think many consumers will base their, their 13 14 15 purchase on it because the -- but research has shown in the Netherlands is that although consumers want 16 the nutritional panel on the back of the pack, 17 18 hardly used, at least not to buy by all groups of 19 consumers. So, it's -- and we are researching that 20 21 at this moment also, whether or not people try to 22 use the back of pack information or the front of 0092 pack when they buy a product. DR. MARY L'ABBE: 1 I guess I probably 3 4 don't have too much to add to what's been said. We're probably very much in the earlier, more 5 preliminary stages, so we haven't got good evaluative data on the use of symbols and logos, so 6 7 we're really just presented some of it today, but we're probably very much in the preliminary stage to make any definitive answers on that one. 8 9 10 TIPVON PARINYASIRI: Okay, since in 11 Thailand we have a unique system, we have a 12 question -- since we introduced the nutritional 13 labeling for nine years, we don't have any success 14 on the, how to educate consumer because they think 15 too complicate. 16 We have to deal with the advertisement and they have some research statement that the advertisement make consumer's choice before they 17 18 even go to supermarket, so they already decided 19 before they go to the shop; therefore, they don't 20 have time to, I mean they just want a minute to, to 21 22 decided what information or even labeling, even 0093 general regulation on labeling. 1 We, the consumer in Thailand, read very few on the labeling and they still, some research, they say that Thai consumer doesn't understand fully 3 5 format of nutritional labeling. So Thai FDA move forward to have a simplified, simple format for the 6 7 food which is related to children. So we think the 8 sign post will be the good choice for children to 9 decide it; however, we think the education, 10 educational program, we call edutainment, is very 11 important to make the children understand. So we have to do campaign and do the 12 13 research if the children can decide it themselves through the simple nutritional labeling or sign 14 15 I have, we have to do a lot of work on that; however, the first step will be the five type of the 16 snack, I'm not sure I mention on the slide, but the 17 next step would be 19 snack and the next one would 18 19 be the meal, which is in the packaged food and also 20 we have the program to campaign between the Health 21 Department, nutrition division also. 22 So, we think we need something simple 0094 and educated for the young consumer in Thailand. Thank you.

FDA Hearing Day 1.txt LESLYE FRASER: Thank you very much. 4 MI CHAEL LANDA: Thank you. For the 5 panel, why don't we start with Dr. Schneeman. 6 DR. SCHNEEMAN: Actually I have several different questions for different panelists, but 8 I'll just do one, okay. I'll start with Barbara --9 (Your mic's not on). 10 DR. SCHNEEMAN: 11 Well it says it's on. 12 Is that better, can you -- can you still not hear? 13 14 MI CHAEL LANDA: Can you get closer to 15 it, maybe. DR. SCHNEEMAN: I get to do my performance mode, is that -- there we go. 16 17 18 One of the things that I'm, several of 19 you have referred to additional consumer research 20 and I'm particularly interested in whether or not 21 the consumer research will get at the question of what the total diet looks like. Obviously there's 22 0095 one aspect of making a choice relative to the food, but the ultimate goal, of course, is that the overall dietary pattern that consumers select is, in 3 fact, a healthful diet pattern and I'm wondering as 5 you construct your research, are you primarily 6 looking at how they understand the food and whether 7 or not they judge the food correctly, but are you also then, do you have a means to look at the total 8 9 diet and the total diet impact of such a program? 10 MR. van den BRINK: Thank you. We are trying to see if we could have the information in our dietary intake databases and 11 12 be combined with, with the information on which 13 product is eligible for a stamp and carries a logo 14 and so it's, it should be possible, but I must 15 admit, it's not our primary concern at this moment. 16 It's more that the, the option to -- people buy the same product probably or at least they buy a product which they have in their diet, in their basket, I mean, every week and this logo will help to identify 17 18 19 20 in the shop the products that fit the criteria and 21 22 are they heal thy. 0096 So I must admit that although the, it's 2 3 attempting to find that out eventually, but at this moment it's not our primary focus, to be honest.
MICHAEL LANDA: Anyone else on the p Anyone else on the panel 5 care to respond? 6 CLAIRE BOVILLE: Well we're doing it in, 7 sort of in an iterative way. The research that we've done to date has looked at individual food 8 9 stuffs and it's looked at comparative food stuffs so 10 if you're choosing within a category, if you've made up your mind you're going to have pizza, if you're 11 going to have a pizza, you can chose between them, so we've done it on an individual level and 12 13 14 comparative. 15 We've also got information on what's 16 happening in terms of sales trends, so we know what consumers are purchasing by the people that have 17 18 adopted the various schemes and what we were seeing 19 is that they are moving to healthier options in Page 35

FDA Hearing Day 1.txt particular product categories. 21 In terms of the overall diet, we 22 obviously have our national dietary survey, but 0097 that's carried out -- it's not carried out every year at the moment and we are moving to a rolling 2 program starting next year, hopefully, so we will have that type of information, but it will take a 3 4 5 little while to collect and obviously we will 6 7 compare it to that. But the big independent study which 8 we're hoping to commission later this year will look very closely at what consumers do in practice and understand, try to get behind the rationale for the decisions that they make and how they use food in the homes. So we'll look at not only what they 9 10 11 12 purchase in the shop, but what happens when the food goes, is at home and how long is it stored in the 13 14 15 cupboard, in the freezer, how they make their meals together, how they use all that information. 16 But I can't really give you any more 17 18 details on that at this time because we haven't 19 commissioned the research. 20 DR. MARY L'ABBE: I'll just say one comment, in our planning, one of the data that we 21 have so far is really on, just on consumer attitudes 22 0098 and that's why one of the main objectives of our 2 3 consumer research that we're planning is to actually see how those consumer attitudes and opinions will translate into actions, which is sales and changing in eating habits and I think that's the next step that's an important one to capture in this 5 6 7 evaluative process. 8 TIPVON PARINYASIRI: Right now I cannot 9 answer that question, but they have some research 10 going on with the University and Tesco Lotis in 11 Thailand, so I will see if they have some research 12 on the, that one on the total diet impact; however, we, we, as a Government, we will think about multiple traffic light since the company, they move 13 14 forward to that GDA, but they afraid of the multiple 15 16 traffic light. So most, a lot of academy would like to 17 18 introduce that system which food company already 19 accept and going to announce this guideline soon and we will, we think in the future I, we can answer 20 21 that question since we need the research in Thailand 22 more. 0099 Thank you. MI CHAEL LANDA: 1 2 Robert Post, do you have 3 4 a question for the panel?

ROBERT POST: I do, oh, good, this is 5 worki ng. That's always nice to know. 6 7 I've got a question for Ms. Boville and it relates to the definition of processed foods and 8 how the definition came about and how broad things 9 and how detailed it is and the consideration given 10 to that. 11 CLAIRE BOVILLE: We don't really define 12 processed foods as such. We have a list of categories of foods which broadly encompass that and 13

FDA Hearing Day 1.txt those categories of foods were determined on the 15 basis of the consumer research. We broke down foods into about 16 17 25 different food categories and we asked them which of these particular categories they felt front of pack sign post labeling would be helpful on. 18 19 And the summation of all of that 20 research, which was done with over 2,600 consumers 21 22 and across the UK, different age groups, different 0100 1 socioeconomic backgrounds, et cetera, came to the conclusions that it should be pizzas, sandwiches, 2 ready meals, breakfast cereals and meal centers, so that's kind of the burgers, the re-formed type of foods. So it was chicken fillets, that type of thing, and it was largely because they were the foods that they felt -- that they had the most 5 6 7 difficulty understanding the nutritional composition of. They didn't think it was necessary on the 8 9 10 chocolates, the snacks, the fizzy drinks, those kind of convenient foods because largely they know what was in them and they didn't feel that any kind of 11 12 sign post labeling was going to add anything to them in terms of understanding what was or was not in 13 14 them from a nutritional health point of view. 15 Does that answer your question? ROBERT POST: It does. 16 17 CLAIRE BOVILLE: Yeah. ROBERT POST: Actually, I have a 18 19 follow-up also for you. 20 Did you consider or have you considered other aspects of dietary guidance, for instance, the 21 22 0101 1 healthy lifestyle contributions of physical activity and how that contributes also to providing 3 4 5 meaningful information to consumers? CLAIRE BOVILLE: Well, the whole Government program to deal with obesity and healthy eating has many, many strands and I've just touched on one of those strands which is the labeling aspects. And those strands of the policy are 6 7 8 divided between different Government departments. 9 10 Physical education is not an activity -- is not an activity which is -- has the food standards Agency 11 12 has the mandate for. 13 So while obviously it's important, it's, 14 we're more concerned with the composition of what 15 goes into the food and the information to the So other parts of the 16 consumer about the food. Government are dealing with that aspect.

However, I think that, that there has been quite a lot of people who maybe overplayed the 17 18 19 20 role of education and physical activity in terms of 21 what it can do to, to turn the corner on this, this 22 big issue that we have in the UK. Not saying 0102 they're not important, but they're just one, one piece of the jigsaw and what we know from the 3 labeling initiative is that it's having a big impact in large ways. It's not just about telling -- it's driving the food, the production of the food that's 5 6 available to the consumer and it's empowering the consumer and educating in the way that the consumer Page 37

FDA Hearing Day 1.txt can make choices that they always wanted to make but 9 they just weren't able. 10 So, it's having those, it's achieving those two goals and so it's, you know, they're working together. I think it will have a bigger 11 12 13 impact in the long-term, but we're only at the start 14 of the process MI CHAEL LANDA: 15 Thank you. Steve 16 Bradbard, you have a question. STEVE BRADBARD: 17 Good morning, very interesting presentations, thank you. 18 19 We know from our FDA research what 20 people do and do not use the nutrition facts label 21 for. We know that people from our national survey 22 data will use the nutrition facts label to compare 0103 the profiles of products from similar categories. We know also that people will use the nutrition 3 facts to track nutrients of particular interest to them. We know that they don't use it much to plan 4 5 their daily diets and we know that they don't use it 6 7 much to decide how much of a certain food they should eat. 8 And looking at your front panel symbols, 9 I did hear Claire mention that people seem to be reporting that they may want to look at their basket 10 11 and see how many greens, how many yellows and how 12 many reds and that does go toward planning the, how all foods fit together and that's encouraging to 13 hear. 14 15 As far as how much you should eat, and I'm wondering in terms of that question, is it overly ambitious to think that these front panel 16 17 symbols can cue people on how much they should eat 18 beyond just saying this is for a single serving or 19 20 is there a way to, you think, to use these front 21 panel symbols to actually remind people what we're 22 talking about with these declarations of signs is a 0104 single serving of that product.

If you eat, if you eat 8 servings of the most healthful frozen pizza, it probably would be 2 3 better if you chose the less healthful one and only 5 ate one or two servings. 6 CLAIRE BOVILLE: Yeah, yeah, for sure. 7 I think in the UK what we know is that the consumer understands that you have to, all of this information is useful, but if you don't put it into the context of the quantity and how often you eat it, then, then you're kind of -- that's the other 8 9 10 11 12 side of the equation, as it were, and the consumer understands that in the UK. 13 Of course understanding is not always 14 15 the same as doing, but we're working on that. part of -- it's not, it's not in my area of responsibility, but the Agency does have a strategy 16 17 which it's just consulting on at the moment on how to try to -- we've done a lot of work on salt reduction and it's been hugely successful. In a 18 19 20 sense that's been easy because you can take it out, 21 you know, step by step, and replace it with herbs 22 0105 and things and it doesn't have a big cost on cost

FDA Hearing Day 1.txt for the industry, so that's been easy. But we're trying to do the same with saturated fats and with calories, trying to get them so that they are healthier foods re-formulation

calories, trying to get them so that they are healthier foods, re-formulation.

And one of our proposals is also to try to encourage the industry to think carefully about the portion sizes with which it produces the food and to make them a bit more realistic. I mean if you're going to offer a muffin, do you really need to have a jumbo-size muffin because if you eat a muffin, you know when you buy, when you buy these kind of foods, you eat what's provided, whether you really need it or not because it's kind of, same with a bottle of Coke, do you really need 330 mils of Coke. Did you really need that, did you really want that amount of Coke when you bought that Coke, just to give examples off the top of my head. And so we're encouraging the manufacturers to think about what is a realistic and sensible portion size.

Now, we have another thing that's happening in the UK in some cases, where we have

some manufacturers using a GDA type of sign post, the one without the traffic light color-coding. Some, they -- that system works on the basis of the portion size and it's the portion size as determined by the manufacturer.

And there are some examples of products out there where I would suggest that the portion size information that's been provided is not terribly helpful. There is an example of a chocolate bar where the information is given on the basis of one square. Now I don't know about you, but if I'm eating a chocolate bar, I don't eat one square and I have some real concerns about that because to think about the children, if you've got, if you've got a parent who kind of understands that chocolate isn't something that they should be eating that often, it's a treat food and they're trying to educate their child in that way, too, and then you've got a scheme which has -- apparently is giving something on the basis of one square and the child goes up and says look, mom, mom, it's only got, it's only got 1.5 percent or whatever, it's

only 1.5 of the fat here and the mom doesn't really, you know she's busy, she's got lots of stuff going on here and she goes oh, that's not as bad as I thought.

If she hasn't really read, read it properly, the information is all there, but she has to understand that she has to multiply that by the number of squares that the kid's going to eat or she's going to eat to get the correct information.

So, you have to be a bit careful about this stuff, I think. I don't know if I've answered your question. I've rambled a bit there, I'm sorry.

STEVE BRADBARD: No, I appreciate it.
Again, anyone else on the panel, too, as far as

Again, anyone else on the panel, too, as far as whether it is reasonable to think that you can communicate with these front panel symbols

information about serving size will really get people's attention and hopefully change their

19 behavior, as well.

DR. MARY L'ABBE: I'll just make one comment and it really depends on what vehicle you choose for that education message. In Canada we

focused a lot of the education on serving size on the food guide and not only does it list the foods, when you open it up, there actually are portion sizes reflective to what a serving should be, so right now that's the vehicle we've chosen to give the messaging about serving size, is the Canada's food guide.

MR. van den BRINK: Very briefly. It's often that problem you pointed out is also the problem I try to emphasize on the sheet that it is the healthy eruption, but you shouldn't, of course, eat six pizzas, although it could be the healthier pizza in range. And I think the most important that are other projects and communicating them on a healthy and balanced diet should, should be focused on that and the Health Choice logo is not related to the portioning and as a -- I have to check the criteria on that, as well, but it's not, it's not saying that this portion is the healthy option, something like that.

TIPVON PARINYASIRI: Since FDA, Thai FDA responsible only labeling but the other campaign on

the school, for example, soft drink campaign so they think, you know, combination of the program put in Thailand, for example, now education ministry joined with the public health, now they remove the soft drink out of some school, you know, they have orange drink.

And also they add on the TV to motivate the consumer to eat a lot of food so that -- for example, the children, so we have a limitation of the ad, maybe eight minute during the weekend, not more than eight minute and also we have, I heard that the UK also have the campaign limitation and also we have the group CDC also joined the program on the reduced fat and salt amount community.

And in Thailand we have the, another campaign on the children on the Thai, Thai children eat less wheat, so with the combination we hope it affect on the total diet and also other physical activity.

So I think the approach should be combination and then we, we'll see what, what the -- I mean pre, before and after what it really affect

on the health of the children in Thailand.

We have to do the survey since my presentation that the 40 children in the school have an overweight, so we, we'll see after we put all the program in the, intact, I hope it will affect the total diet of the, you know, and health of the children in the school.

MICHAEL LANDA: Thank you, I think that concludes our first session. We're running a little late.

I would ask that people resume, I'd like to resume at 11:30, which is the regular schedule, Page 40

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FDA Hearing Day 1.txt
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       and how about a round of applause for our first
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       panel.
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                        (Appl ause)
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                        Thank you.
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                        (Recessed 11: 12 a.m.)
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                           SECOND SESSION SPEAKERS:
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       Leslye Fraser, Moderator
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       Josephine Wills
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       Mi ke Rayner
       Breda Mitchell
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                        (Reconvened 11: 31 a.m.)
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                        LESLYE FRASER: Good morning, again.
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       I could ask our panelists to join us at the front,
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       we will get re-started.
       We will continue our informational exchange on the international experience and at this
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       point we will turn to research and other perspectives. And this panel is comprised of
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       international non-Government, non-profit
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       associations and one retailer.
       So starting with my far right, we have Ms. Josephine Wills from the European Food
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       Information Council, followed by Mike Rayner from
the British Heart Foundation, Breda Mitchell from
Tesco. We will then have Terry Dean from the Heart
and Stroke Foundation of Canada and we will then
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       follow up before we return to our panel for questions, our discussant will be Trevor Webb from
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       the Food Standards in Australia.
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                        So with that, I welcome Josephine Wills.
       I was also asked to ask the panelists if they could
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       speak directly into the microphones as well as on
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       the table because the back of the room is having a little bit of difficulty hearing as people move in and out and the same for the people as they're
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       asking their questions on the front table.
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                        Thank you very much.
JOSEPHINE WILLS: Th
                                                  Thank you.
                                                                   Good
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FDA Hearing Day 1.txt morning and thank you to the FDA for the invitation to present our work in this area. There are two pieces of work that I'm going to cover. First we looked at energy-based front of pack communication both energy in and energy out and with obesity being such a growing public health issue, we felt that communication and energy balance might be a good way forward.

The second study is a review conducted for us by Professor Klaus Grunert of the our house school of business in Denmark. This is a review of research on consumer response to nutrition information on food packaging in EU member States from 2003 to 2006.

from 2003 to 2006.

Now I'm not going to be able to cover this work in much depth in 15 minutes, so it will

just be an overview, however the papers are now published online, prior to publication in the Journal of Public Health Nutrition and that's the energy one and in the Journal of Public Health and that's the review. And if anybody wants copies of these papers, subject to copyright restrictions, I'd be happy to, to either give you a link to them or let you have them.

Now this work forms part of our commitments to the European Commission's platform for action on diet, physical activity and health. That's a multi-stakeholder platform that was set up two and a half years ago to collectively address the issues, the growing issues we've got in Europe on diet, obesity and health and lack of physical activity.

Now the mission of the European Food Information Council is to communicate science-based food information to healthy nutrition professionals, educators and journalists in a way that promotes consumer understanding.

Now we're supported by companies of the

European food and drinks industries going from farm to fork, companies that are interested in animal health and welfare on --

(Microphone problems).

JOSEPHINE WILLS: Oh, I've been shot,
all the way through to ingredient suppliers, food
processors, retail and the food service. And we're
also receive funding from the European Commission.
To find out more about what we do and the materials
that we produce, that's our Website, EUFIC.org, it's
a multi-lingual Website.

Now previous studies have shown that calories are often on the top of the list of the most frequently looked for nutritional information on label. Consumers understand the concept of calories and energy, but they find it hard to apply or to even estimate their daily needs. So this qualitative research was carried out in focus groups based in France, Germany, Netherlands and the United Kingdom. It looked at a range of life stages and a range of socio demographic criteria. Half of the respondents were self-reported regular users of

FDA Hearing Day 1.txt

nutrition labels and half were occasional users.

These were the eight different front of

pack options that were, were shown to the respondents, not exactly in this manner because they were actually on products that the consumers were familiar with in those different countries.

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The first two is -- the energy content of the per 100 grams, then per serving, then per serving with an encouraging phrase, balance your Four, five and six there also include a guideline daily amount for energy, male and female, expressed as a percentage or an absolute number or a bar chart and in number seven is an energy out, how much activity would a consumer have to do to compensate for the energy in that product, not strictly correct as we know from a nutrition and metabolism physiology perspective, but it gives you, gives them the idea that they'd have to do something to use up the energy in that food and then the last one was everything combined.

So, summary reactions to these They found that communicating energy proposal s.

front of pack was highly innovative, they found that quite a promising approach. A preferred energy to be expressed in calories, some liked kilo calories. Nobody really liked kilojewels, but overall using the same energy measure is key. In some, on some European packs of foods you can get all three measures there, calories, kilo calories and kilojewels on the same pack.

But just having energy front of pack, calories front of pack did not fulfill everybody's requirements. Some consumers, particularly those over the age of 55, wanted specific nutrients or ingredients such as salt and fat and that was in

particular from the UK.

The clear front of pack winners are the simpler front of pack flags, so calories per portion or calories per 100 grams, with or without reference to a guideline daily amount for calories.

But one thing that was key is that there

needs to be more clarity around defining a portion or a serving size, which we've already discussed earlier on this morning. They want something that

is a well-defined consumption unit that's easy to relate to.

Complex front of pack flags with graphs and percentages are least liked by the elderly. The younger consumers found it more easy to relate to graphs and percentages.

Now reference to exercise or energy out was extremely polarizing. The respondents understood that it's a clear message and it's a simple message, but it was not for food packaging. It propagates guilt, it takes away the pleasure of buying and consuming food and the pleasure of what food is all about and for some it's hard to believe that you'd have to do, expend so much energy for that piece of food that you're consuming. feeling of frustration and it is quite confrontational.

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The results were quite consistent across all countries. France and UK wanted front of pack calorie flags, simple ones with the guideline daily amount. Germans and Netherlands preferred that guideline daily amount reference to be on the back

of pack and the German respondents, the focus groups in Germany were the least positive about the energy

out exercise aspect.

So in summary of what respondents liked, they liked front of pack flagging. They liked calories as a message front of pack. They liked simplicity, they want it on all packs, they want a consistent execution. The back of pack needs to be more clearly laid out.

Reference values for energy could be front of pack or back of pack, but they do want reference values and a Website to provide further information, but for the elderly, because they might not be familiar with the Web, also wanted a phone

number.

 What they didn't like is complex graphs, calculations with percentages and energy out message on the front of pack, poor legibility and redundant terminology such as kilojewels on the back of pack, the additional advice phrase on the front of pack, non-official Websites, a Website in a language other than their own and this unclear definition of

understanding a portion size or a serving size.
So that was the first study or the first piece of work that I'm going to take you through. The second is this review that we did with Professor Grunert of research on consumer response to nutrition information on food packaging from 2003 to 2006 in EU member States.

So a comprehensive research was carried out in scientific databases for refereed peer reviewed publications, but to locate all of that research that's unpublished or research that's in the so-called gray literature, EUFIC contacted companies, retailers, modern restaurants, either directly to those companies or through their trade association or via the EU platform for action on diet, physical activity and health, the multi-stakeholder platform I referred to.

In total, there are 58 distinct separate studies, of which 13 are peer reviewed academic papers and 45 are from a range of reports and presentations.

And these came from a variety of

stakeholders, from food companies, retailers, official bodies, consumer groups and so on.

None of those reports or presentations at this point were peer reviewed. Some of them are

starting to become peer reviewed now.

Breaking the 58 studies down by country and basic methodology, quantitative and qualitative methodology, you can see that the most studies were from the UK. These mainly focused on a variety of front of pack formats that included traffic light color-coding of nutrient levels and also guideline

FDA Hearing Day 1.txt 12 daily amounts of energy and specific nutrients. 13 Data extracted from the studies and 14 categorized and analyzed using this theoretical framework and the framework involves consumer 15 decision-making, attitude information and change. Now research is looking for the information and that increases the chances of exposure to that information. Perception is reading the information, 16 17 18 19 20 taking it in and perception leads to a degree of understanding and liking and that understanding can 21 22 be subjective or perceived or it can be objective. 0122 So subjective is what the consumer thinks they've understood from the label and objective is when 2 they're tested what do they really understand, is it what the purveyor of the information is trying to 4 5 get the consumer to understand. 6 Now liking of the label may not be 7 linked -- needn't be linked to understanding, but it 8 does seem to have an impact on use and consumers are all individuals, so their level of interest in nutrition, their knowledge of nutrition, their demographics all obviously have an impact on these results and as does the label format, itself.

Now I've gathed in this consumer. 9 10 11 12 13 formats that were reviewed in this consumer 14 Now some of these may not be currently on 15 16 the marketplace because they could have bombed out in the consumer research, but just to give you an 17 18 idea of the types of things over the last three years in Europe that have been tested through 19 20 consumer research. 21 So, these are, we've gathered as front of pack health indicators, which may be nutrient 22 0123 profile based or logos, you see stars and smilies and ticks and protection factors. We've heard about 3 the my choice logo, the Swedish keyhole statement 4 5 there that's on some confectionary about being treat 6 7 I've talked about energy.

I've talked about energy. Another grouping is different education -- executions of guideline daily amounts, the absolute numbers, pie charts, bar charts, over on the far right there, that's what the European food and drinks industries are using at the moment, which is the absolute number with the percentage of an adult's guideline daily amount.

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And then different uses of color-coding of nutrient levels or the use of the term low, medium and high. And Claire's already taken you through all of the work that the food standards Agency has done and people are using. And then combinations of traffic lights and guideline daily amounts, which again Claire also alluded to where you've got the guideline daily amount and it's overlaid with the traffic light nutrient level.

So in results, again, just headline results, first of all on interest and knowledge, nutrition and health is not the first interest with food for consumers and I'm afraid we have to, yeah, we have to admit that. Taste is, is paramount.

FDA Hearing Day 1.txt Cost is also quite close, but freshness, best before 7 date in some studies have a higher priority. 8 interest is from women for aesthetic reasons or for weight management, parents, particularly of pre-teen-aged children, the elderly, particularly if there's a medical problem and there does seem to be 9 10 11 a divide north Europe, south Europe with northern Europeans having more interest, less interest coming 12 13 from France, Spain and Greece. 14 15 Interest is mostly with regard to processed products, as Claire mentioned. 16 not particularly interested in knowing about fruit and veg or meat when it comes to nutrition labeling. 17 18 There's confusion over terminology, we've already mentioned the issue over how to express energy and 19 20 21 when there is new and conflicting information in the 22 nutrition field and as nutrition research 0125 1 progresses, there's always different conflicting 2 information coming out. 3 Consumers have good understanding of calories, of fat, of carbohydrates, of sugar and salt, but less understood is saturated fat, fatty 4 5 6 acids, cholesterol and sodium and consumers are 7 aware that they should decrease their fat and sugar 8 consumption and increase their fruit and vegetable 9 consumption. 10 LESLYE FRASER? You have about two mi nutes. 11 JOSEPHINE WILLS: Two minutes. Fine. 12 Main results on liking while in a real shopping situation, consumers have limited time. So simplify nutrition labels and front of pack information is liked by consumers, but the degree of liking is determined by three directions. 13 14 15 16 17 liking is determined by three dimensions. First, simplification, they like it to 18 be simple, but they also want complete information. What does this information stand for, what does this 19 20 symbol mean, how was it derived. And thirdly, they don't want to feel as though they're being pushed or 21 22 0126 patronized or coerced into, into making a decision, 1 into making their choices about what they're going 2 3 4 to eat or what they're buying for their family. The simple traffic lights where you've got one color on a product and health logos are less liked, that's probably because it answers the simplification side of things, but it isn't 5 6 7 answering the two other aspects, which is they want complete information and they don't want to feel as though they're being coerced into making a decision. 8 9 10 Comparisons of guideline daily amounts 11 and multiple traffic lights, now a lot of research has been carried out in this area in the UK, there 12 13 14 is no clear result one way or the other whether multiple traffic lights are liked more or less than 15 guideline daily amounts or the other way around.

Looking at the format of guideline daily amounts, there's less liking for bar charts and pie 16 17 18 charts and when you compare per 100 grams with per 19 serving of what do they like, it depends on how the 20 consumer is going to use the information. 21 22 If you're comparing two products, they

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FDA Hearing Day 1.txt want it per 100 grams. If they're just going to consume a product, they want to know how much is in it per serving. But as I said before, there needs to be clarity on exactly what is a serving.
Main results and understanding. Subjective understanding, they say that all simple sign post schemes are easy to understand, so when you ask them do you understand it, they, you know, they'll say, they'll say yes.
Objective understanding, when they are tested to see if they really do understand it, most consumers can repeat back the information that's given on the label, but the percentage of correct answers does depend on the way you're asking the question and the way the information is there on the pack. If they have to do any sort of processing, they'll get a decrease in percentage of correct answers. No particular format works better with lower socioeconomic groups. Different results come using different formats and there doesn't seem to be one better than the other. And there is no data from real life setting. This is my final slide, looking at main results and use. From the papers they were grouped into self-reported use, hypothetical use, buying intentions and actual use. Self-reported use is high. It's probably highly over-reported. From the, say if you ask do you use nutrition labels and then the answer comes back yes, yes, I do. It's highest in the UK, about 57 percent. 20 to 30 percent in other European member States. If you look at hypothetical use for sign posting information, so you're asking the consumer if you had this in the marketplace, how would you use it, using it as a means to screen products rapidly, but again coming back is that red lights would not be a deterrent over taste or if they wanted to purchase the product as a treat. Buying intentions for less healthy products decreased when sign posting information is available and that again doesn't seem to be dependent on the format of the sign post, and most importantly there's very little insight into actual Sales figures from UK retailers using either use. the multiple traffic lights approach or the guideline daily amounts approach are starting to show behavior shifts to better viewed products and I think we'll probably hear more about that from the Tescos from Breda later on. Thank you very much. (Appl ause) LESLYE FRASER: I'd like to thank

Ms. Wills for a very concise presentation of quite a number of studies. We appreciate her participation.

And we next will hear from Mike Rayner from the British Heart Foundation. Thank you. MIKE RAYNER: Thank you very much for

inviting me here today.

I should say I'm here in my capacity as Page 47

FDA Hearing Day 1. txt 17 the director of the British Heart Foundation and 18 health promotion research group in the University of 19 I'm not representing the British Heart 20 Foundation, their views are šlightly different from 21 mine, but generally the same. 22 In my presentation I simply want to 0130 1 present what I think is a logical framework for thinking about nutrition labeling, including front of pack nutrition sign posting or symbols. 4 This framework assumes that such 5 labeling is and should be designed to communicate 6 7 comprehensible information about the nutrition content of foods. And this logical framework sees nutrition labeling as a way of helping consumers 8 9 make sense of dietary guidelines or population 10 dietary goals. To use nutritional labeling to make 11 sense of population dietary goals, labeling has to direct consumer's attention to what is important 12 13 14 about the nutrient content of food and secondly to 15 convey to the consumer that information in a way that makes sense to them. So my presentation addresses issue one, questions three to four of issues and questions for discussion in the Federal 16 17 18 19 Register Notice. 20 So in this presentation I will argue --21 how do I do this. That population dietary goals leads to guideline daily amounts or daily values in 22 0131 the U.S. and having done that to a percentage of GDAs per serving or per reference amount of food, these lead to traffic light labeling of nutrients 2 3 and those lead to traffic light labeling of foods. 4 5 6 7 In the remainder of my talk will amplify this logical framework or progression. So here's the basic front of pack format 8 for nutrition labeling prescribed by EU law. is the labeling for a pizza. Almost everyone agrees and all the research points to this that this form of nutrition labeling is almost impossible for 9 10 11 12 consumers to understand. Here is a quote from a 13 piece of research which we did in the mid-1990s when 14 this former labeling that I just showed you was 15 virtually the only form. For this research, we taught consumers 16 17 some basics of thinking aloud and then persuaded them to think aloud to a tape recorder when they were going on their regular shop.

Why can't the consumer understand this 18 19 20 form of labeling? I think this is for two main reasons. Firstly, there's just too much information 21 22 0132 and no indication of which piece of the label is 2 3 most important. Secondly, the information it contains seems to bear no relationship to their personal health and most nutritionists have sought to 4 5 6 7 characterize what would be a healthy diet for the population by producing tables of dietary goals, such as this one. This is the one for Europe. 8 As you can see, this is of little help 10 in helping the consumer interpret the nutrition

FDA Hearing Day 1. txt labeling table should they even attempt to do so 12 because the ideal levels for nutrient intake in the 13 table of population goals are expressed in a way 14 that bears no obvious relationship to the way nutrient levels are presented in the nutrition labeling table. 15 16 17 To get around this problem nutritionists have turned population dietary goals 18 19 into amounts per day. These are called quideline daily amounts in the UK and in Europe, but daily values in the U.S. and Carol Williams and I were the 20 21 22 first people to develop guideline daily amounts in 0133 2

the UK in this leaflet published by the UK Government's Ministry of Agriculture, Fisheries and Foods in 1996 and these were the guideline daily amounts that we came up with.

In the UK the food industry initially opposed the use of GDAs but have more recently come around to putting them, have started to putting them on food packets here. This is an old packet from Oxon Spencer's dating back about five or ten years

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The next logical step was to display the percentage of GDAs in the serving of food within the nutrition labeling panel, as here. Now you can see that what was a list of rather incomprehensible numbers becomes somewhat more comprehensible. pizza is now found to contain 22 percent of the GDA for sodium rather than .5 grams. Some UK companies have started to put GDAs, percent GDAs in the nutrition labeling panel and of course this is essentially the format prescribed by the U.S. Nutrition Labeling and Education Act. And about two years ago now, some UK

companies started to put the percent GDAs for the selection in percent of nutrients on the front of pack, so-called nutrition sign posting and the companies agreed amongst themselves what the GDAs should be and these were essentially the ones that we used -- we developed for to use your label.

They are, they agreed to what the nutrient levels should be, what nutrient levels should be displayed and as you can see, they agreed the basic shape of the sign post and the basic shape was developed, first developed by the biggest retailer in the UK, Tesco's and I'm sure we're going to hear more about that later.

But this format to my mind has, presents two problems, firstly, because it is voluntary, it is not star, in particular there is no standard list of serving sizes, so food manufacturers chose their reference amounts unlike, of course, in the U.S., here's particularly a rather awful example.

And this brings me to the second major problem with this format, it gives the consumer no idea whether the percent GDAs are high, low, or good

And a simple way around this is to convert the levels into bands. In using your label we came up with some simple rules of thumb for using GDAs to create definitions of what count as a lot or a

FDA Hearing Day 1.txt little of a nutrient in food. And we said that 3 percent of the GDA was a little and 20 percent was a lot. And the words that are most logical to use seemed to be high and low. These are the sort of words that manufacturers use for nutrition claims.

And in the mid-1990s, like that, it was the, the co-op retailer in the UK started to use this form of nutrition labeling on back of pack. Although this format is clearer than numeric formats, the simple way of making it even clearer is to color code the levels of the nutrients, red for high, orange for medium and green for low and this speeds up recognition of which of the levels of key nutrients are high or low and this also gives the impression the overall healthiness of the food. A food with lots of red is basically unhealthy and a food with lots of greens is basically healthy.

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> In UK some food manufacturers and retailers have started to use this so-called traffic light labeling or nutrients back of pack for packs more significantly. They've also started to use traffic light labeling front of pack. In fact, Tesco was the first retailer to experiment with this form of sign post, sign posting shown here, but they gave it up in favor of the percent of GDA format which I showed you earlier. And Sainsbury's of the -- second biggest retailer in the UK has also used this form of traffic light labeling of nutri ents.

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> And this all prompted the UK Government or UK, as I say, to do some research into front of pack nutrient sign posting which Claire has told us all about so I just summarize that.

And you'll know that as she said, their recommended format means that traffic light labeling of nutrients, fats, saturated fat, sugar and salt using three colors to indicate high, low and medium and using, they recommend that people use them at -their criteria and also to represent the amount per

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serving on the pack.

But of course not all manufacturers and retailers have seen the sense behind the FSA's recommendation which note, of course, are recommendations only, they can't be part of the UK law because food labeling law is controlled by the European commission.

And this resulted in a competition between two forms of nutrient sign posting represented by the two major retailers in the UK. But what is quite interesting that both these retailers are beginning to produce data from sales data to show that these, both these forms of

labeling have had affects on sales.

And as many have pointed out, this, this form of labeling is proliferating in the UK and partly in Europe, as well, so on the left you have different iterations of the percent GDA based format, on the right we have different iterations of the traffic light labeling format. Indeed we have compromised formats where you give percent GDAs and

the traffic lights.

 But of course the two formats are not -of course they're not a million miles apart based,
they are really on the percentage of, the traffic
lights being based really on the percentage of GDAs
in a serving.

I still think there are problems with the traffic light labeling of nutrients. It works really well for foods at the extremes. Here on the top left is the traffic light labeling for apple crumble, on the bottom is that for an apple and you can easily see at a glance the apple is healthier than the apple crumble. It's not so easy when the distinction between the products is subtler.

On the top right you have the traffic light labeling for a pizza and on the bottom the traffic light labeling for a breakfast cereal and I'm suggesting you might go for one or other if you're looking for a healthier snack, but can you tell whether three oranges, a green and a red are healthier or less healthy than three greens and two reds. I don't think so.

The solution to this is to come up with

traffic light labeling of foods as here, in other words, to produce a summary score of the levels of key nutrients in the food.

How would this work? Well firstly being an algorithm for determining healthy, intermediate and unhealthy foods and the process for doing this is coming to be called at least in Europe nutrient profiling, defined as the signs of categorizing foods according to their nutritional composition.

And of course this has been going on for years, lots of people have produced healthy eating symbols, i.e., the healthier food, coming up with definitions of healthier foods. We have the Swedish keyhole here on the left, the Australian Heart Foundation's tick scheme next, the sensible solution mark for Kraft and the healthy eating logo for, from Pepsi Co.

I'm suggesting, however, that that's not enough and what we also need is a mark for less healthy foods, as here.

Nutrient profiling is a way of coming up with definitions of healthier and unhealthy foods

 and in the UK the most significant work on nutrient profiling has been done under the auspices of the Forwards Standards Agency, again, in connection with developing a nutrient profiling model for defining an unhealthy food, for new rules on the television advertising of foods to children and these rules have now come into force as of July and these foods defined as unhealthy by the FSAs model cannot be shown during programs targeted at children.

9 shown during programs targeted at children.
10 The FSA funded -- that's the final
11 report on the new regulations. The FSA funded my
12 research group to help with the development of the

model and this is it. It's a simple,

across-the-board model based on seven components, energy, saturated fat, total sugar, sodium, protein

FDA Hearing Day 1.txt and fiber, fruit and vegetable and nuts. 17 points for the top four nutrients and you lose points for the bottom four nutrients. 18 You come up with an overall score and if you get more than four, you're deemed to be a less healthy food and in the 19 20 future you won't be able to show that, that 21 22 product -- advertisements for that product in 0141 advertise -- in programs specifically designed for 2 3 chi I dren. And it characterizes foods in this sort 4 of way, so examples of healthier foods would be 5 peaches, lettuce, whole meal bread and walnuts. Intermediate foods, mackerel, oven chips, fried rice, whole meal and diet cola and examples of unhealthy foods, Mars bars, crisps, jam doughnuts, 6 7 8 9 currants and cola, not entirely uncontroversial. 10 (Laughter). But it works reasonably well and there 11 12 are always going to be exceptions and this model is 13 a simple model based on seven nutrients and no model 14 is going to be perfect. 15 This model, I should say, was not designed for food labeling but it could be. 16 17 in its consumer research, well just to point out that we've been doing some work on validating this 18 19 model against whole diets. We showed in this study 20 published in public health nutrition, it's forthcoming in public health nutrition that people 21 22 are eating less healthily in this country, are 0142 eating about twice as much, many of the less healthy foods as defined by a model as the most healthy 2 3 group. 4 5 6 7 I could talk for ages on nutrient profiling, this is really my favorite subject, but talk to me about it afterwards. As I said, the model wasn't designed for food labeling, but it could be. And as you remember, the food sciences Agency tested two different or a varying -- lots of different formats 8 ĕ 10 and it came up with this one as its recommended 11 12 format and they rejected this format on the basis of 13 really I think on consumer preference studies. 14 As Josephine has pointed out, a lot of the research points out to the fact, points to the 15 fact that people don't like very simple apparently dictatorial schemes, but I don't think this is 16 17 sufficient to overturn the idea that this scheme, 18 the top, top scheme might, might also be helpful to 19 consumers as sort of evidence by the proliferation 20 of healthy eating logos as we heard earlier today. 21 22 So I had suggested that also that 0143 1 they're not mutually exclusive and they give you different sorts of information, the format on the top, the traffic light labeling of foods gives you a summary information, the traffic light labeling of the nutrients gives you more detailed information.

LESLYE FRASER: Two minutes. 2 5 6 MIKE RAYNER: And this is basically how 8 it would appear on a packet of fish fingers, fish fingers is in, according to our model, an okay sort

FDA Hearing Day 1.txt 10 of food, an intermediate sort of food and it would have the traffic light labeling of nutrients on it, 11 12 as well. 13 So, what I'm arguing for, that there's a 14 natural progression, as I said earlier. Once you have population dietary goals and once you have nutrition labeling on foods, you need to relate the 15 16 two to help the population meet the goals. 17 Firstly, the goals need translating into 18 guideline daily amounts, daily values in the U.S. Then it's logical to put the percentage of the GDA 19 20 in the food on the label as you've done in the U.S., but the percentage isn't enough. It needs to be 21 22 0144 translated into plain English to indicate whether 1 2 3 the percentage is high or low and these levels can then be color-coded, i.e., traffic light labeling of 4 nutri ents. 5 Once that's been done, the consumer can 6 get a general impression of the healthiness of the 7 food but to get a more precise idea, the levels need 8 to be integrated into an overall score which allows 9 foods to be categorized on the basis of healthiness and this categorization can be displayed on the 10 11 label and it's called traffic light labeling of 12 foods. 13 Thank you very much. 14 (Appl ause). LESLYE FRASER: Thank you very much.
Our next presenter will be from the 15 16 17 retail perspective and Breda Mitchell will tell us rience. Welcome, Breda. BREDA MITCHELL: Good morning, everyone, 18 Tesco's experience. 19 20 and thank you for the invitation to come along and speak today. 21 22 I'm not quite sure that I've actually 0145 got much left to say because I think most of my 1 presentations appeared on the screen already in one form or another. But what I thought I'd do is just tell 4 5 you a little bit about who we are as a retailer, 6 introduce you to some of the health initiatives that 7 we've actually had over the last 20, 25 years. Say a little bit about the customer base 8 that we have in the UK, that's where I'm primarily 9 basing my presentation on today. Introduce --10 11 sorry. Introduce you to our GDA sign post, excuse me, also provide some data on the outcomes and then talk a little bit more about the work that 13 14 15 we've put in place to actually support the launch and help customers understand a little bit more 16 17 about the initiative. So hopefully I've tried to address all 18 19 the questions that were outlined in the briefing paper, but we'll see. 20 Okay. So who are Tesco? Well we are 21 the number one retailer in the UK. We have about 22 0146 14 million customers coming through our doors in the 1 UK alone every week. We also have operations in Asia and Central Europe and I was glad to hear my

FDA Hearing Day 1.txt colleague from Thailand mentioning our operation there where we're actually working very closely with

the Government.

And we're not new to the health debate and I just wanted to put something up on the screen to give you a little overview of some of the work that we've been involved in since the early '80s. So back in 1984 we developed something called our healthy living range, it actually was called healthy eating range at that point in time because the focus was very much on food and the food ranges that we had.

One thing I should just say to put things in context, as a retailer in the UK, about 50 percent of the product range that we offer in our stores is actually private label. So this gives us an opportunity to actually develop schemes ourselves and bring things to market very quickly and that, that applies and extends to some of the healthy,

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healthy food initiatives that we've run.

So the Tesco Healthy -- excuse me, living range was brought around by us talking to customers, they telling us they want something that would help them make healthier choices in food, and remember, this is back in 1984. And what we did then was we created something called a pillar brand within our overall private label range and we actually indicated to customers on front of pack that there was, what was healthier about this product versus the overall standard product that we had on our shelves and I will have an example later on just to show you.

We moved on, we actually brought in quite a high range of organic. We created something called our healthy living club and as you can see, it's not an insignificant number of members and this is about communication with our customers on how they can change their lifestyles. Food obviously being essential to that, but also about exercise and just basically healthier lifestyle choices. Our Tesco free from range, this was very

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popular, we created it back in 2002 and that actually offered customers with food intolerances or allergies a range to select from. So we have glutin free or wheat free ranges and they've proved quite

popular with our customer base.

In 2002 we did actually undertake review of the back of pack information and in 2003 we introduced our very first front of pack labeling, and I'm not talking about the actual GDA labeling which came a little bit later, we then went on in 2004 to introduce GI or glycemic index information on the front of pack.

Again, this is something that our customers were interested in finding out about, so we had actually indicated where they were low GI values in a particular food or associated with a particular food.

In 2005 we moved on and we did some work with, on your kids range, we had a kids range for a number of years, but again, we increased that and we

FDA Hearing Day 1.txt reviewed the actual nutrient content of the range in 22 2005 and re-launched it and put some emphasis on 0149 things like lunch boxes and helping families select something healthier for, to send with their children 3 to school. 4 In 2005 we started to launch our GDA 5 scheme. The figure there actually is slight 6 7 underestimate, so we've now got it on just under 7,000 lines on our store, so it's across all of our private label range and I should mention that in 8 addition it's also, I believe, featured on something 9 10 around 3,000 branded lines, so that's just about 10,000 products in our stores that carry the labeling at this point in time. 11 12 13 Whole foods is another pillar brand that 14 we have which has helped customers understand the 15 benefits of nuts and pulses, et cetera. 16 So I thought you might like to see a little bit about who exactly are our customers. 17 18 We've done some analysis looking at, because understanding customers is key to our business, as you can imagine, and we have a wide range of ways of capturing feedback from them, but we understand that 19 20 21 actually roughly 27 percent would fall into the less 22 0150 healthy category, 41 percent, which would be more 2 3 health challenged, 12 percent dieters and then the remaining would be the health leaders or people who 4 are actually more informed about their food choices. I know this is very busy slide so apologies for that, but it tries to capture some of the feedback that we get from these groups and about their constant struggle to help understand what it 5 6 7 8 is they're eating and how they go about achieving a 9 10 heal thier diet. 11 And I think it's, you know, if you look at the, the comments and the summaries on the 12 bottom, I think it sums it up for itself, but I think, you know, if you look at the health challenge, it's hard, I try and steer the kids in the right direction, but they always want to buy 13 14 15 16 17 sweetiēs. Well, I think we all appreciate and at. Or I constantly feel under pressure 18 19 recognize that. 20 to watch what I eat. So in all of that we've been trying to 21 22 help people make these choices and make it easier 0151 for them to understand what it is that's in the food 2 3 that they're buying. So they wanted the labeling to be at a 4 5 glance and to answer the questions is this good for me and is it safe to key things that they're very concerned about and they didn't like some of our 6 initiatives. I talked earlier on about how we actually reviewed our back of pack information back in 2003 and it's still quite busy. 8 9 I mean we've captured everything from cooking instructions, the ingredients, the standard 10 11 nutrition panel and the GDA information and some 12 13 other information that customers were interested in 14 and then we also, we did try to summarize some of

FDA Hearing Day 1. txt 15 this by putting a panel on the front of the pack, 16 which is some basic information about what the per serving and fat calories and salt content was, and that was just an extract from the back of pack and 17 18 19 flashing it on the front helped shopping a little 20 bit easier. I think I've heard some, a piece of 21 22 market research that customers on average spend 0152 something around 14 seconds making a product choice 2 in a supermarket, so they don't have much time to actually stand around. I think Josephine's telling me it's even 5 shorter. 6 So, this is what we came up with. 7 we did actually put, it's exactly as has been described earlier on, so we started off, we chose to 8 9 provide the information on front of pack around 10 sugar, fats, saturates and salt. We gave the basic, the standard nutritional information and then we put 11 that in context for customers by placing it as a percentage of their GDA intake and that's now 12 13 14 appearing, as I said, on 7,000 of our own lines in 15 our stores. 16 So just to help you put it in context a little bit, I've put it on, showed you one of our 17 product labels. I've chosen baked beans as being a 18 19 standard British fair, some people can understand, 20 but I talked earlier about our healthy living range, just so you can understand. 21 22 So this was one of the healthy living 0153 products that we launched some time ago and what was healthier about this compared to our standard beans was that it was half the salt level compared to our standard offer and that was flagged on the front of 5 6 7 pack already for customers to understand that if they were interested in salt, so that's been on the pack for a number of years.

We also have some indications about whether it's suitable for vegetarians, the GI measure that I talked about earlier and also just an 8 9 10 11 indication it was a benefit from this product, it was a source of fiber. 12 13 And then we said each can contains, this 14 is a relatively small can and those were the stats 15 for that particular product. So, I've talked about how we talk to our customers, but they have a very effective way of talking back to us. And this is what they told us 16 17 18 about some of the products we had on sale after we 19 20 put the nutritional sign posts on the front of pack. 21 So we looked first of all at sandwiches, 22 that was one of the first ranges that we tackled, 0154 and as you can see, there was a significant impact 1 on our sales on the less healthy products, so these sandwiches just, to put this in context, were side by side on the shelves, so everybody could actually 4

themselves.

They had the information now and it's obvious that maybe people weren't turning over to Page 56

make the choice and make the decision for

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FDA Hearing Day 1.txt read the nutrition pack, panel before, but this actually highlighted the importance of reading that information to them and you could see there was a significant impact.

 And what we took was the weekly sales eight weeks before and then eight weeks after the GDA sign posts were added. I do have some other examples. Lower salt ready meals outsold higher salt products by 10 percent when the GDA sign posts were placed on the front of pack.

Now this is in, a line Claire mentioned earlier on some of the work that was going on in the UK around salt and salt reduction and it was a very significant campaign run by the Food Standards

Agency at the time and it actually focused people's minds, so it created a demand for lower salt products and this actually helped people understand a little bit more about, you know, what was going on in our products.

Again, these products would all be pretty much side by side on the shelves, so they could actually see for themselves. Just another example on this time, it's concerned with lower fat ready meals.

This is quite an interesting slide, but -- well interesting for me, it was around the impact on cereals. The red bars indicate negative impact on sales and the green, the opposite. So that we had a 39.1 percent increase in muesli sales, and a 50.7 percent decrease in Tesco Choco Snaps, so again, the customers were able to make up their own minds about what was in the product and what they wanted on their breakfast table.

So, I think we've all talked a little bit this morning about the importance of helping customers understand the information that's put in

front of them, so there's no point in launching the GDA sign posting without actually helping customers understand what it was about. So we did quite -- we had quite a few initiatives running.

So, for instance, to promote the sign posts we delivered it to major program of customer education and information. This was in January of 2006, we started to launch the sign posts in 2005, so we did a big re-launch again in January the following year where we had this type of information going on in the stores.

One million new leaflets were circulated at the time to explain the labeling and then we gave out some little credit card style guides to the labels and they were given out to customers.

We also gave just another fact, we gave our store staff, because it was important that they actually were able to communicate to customers on this as well, so we launched a big program of education with them and they all had a GDA sign post T-shirts to wear around the stores for the first few months after the launch, so again it was prompting

customers to ask what's this about, tell me a little bit more about it, what does it mean for me.

FDA Hearing Day 1.txt And then moving on to health in store, 4 we have, we are continuously promoting the issue of health around the store. You can see here this is some signage that appears. I think one of the things that I would like to say as well is that the actual, the GDA sign post and the feedback that 5 6 7 8 9 we're getting from customers is actually making us 10 re-formulate the products, so we have a significant campaign going on internally about stripping out the 11 fats, saturated fats, salt and sugar and we had already started that work. And this was again in 12 13 line with some of the work that was going on with 14 15 the Food Standards Agency and we were telling customers a little bit about that. 16 So, that was a, a flag in the middle and then just providing some key health messages, as 17 18 19 well. 20 LESLYE FRASER: You've got two minutes. 21 BREDA MITCHELL: Okay. We also tried to, we launched a media campaign just to help our 22 0158 customers again understand what was going on and it was quite a significant number of customers. TV ads, and again, we tried to make them 3 light-hearted because the whole idea was to make customers want to buy into this and understand what it was and that it was for their benefit, so sort of 5 6 7 a sponge being an example, serving suggestion, one 8 every now and again. In addition to all of the other activity, we also have our food club magazine which goes out to 700,000, actually, sorry, customers four times a year and we use every opportunity to promote the information to customers through that and also 10 11 12 13 this contains a lot of information on lifestyle 14 And we also have another healthy living 15 magazine that goes out, so we do a lot of communication with our customers. 16 17 And finally the last slide I had was on, 18 something that was on our Website which actually helps people if they want to go on and research something about our products or understand a little 19 20 21 22 bit about putting together a lunch box selection and 0159 what the actual GDA information, what's the nutrient 2 3 profile of the actual products that they could put in there. I should also say that we've just recently added the information to our Tesco.com 5 on-line grocery shopping service and there's been a 6 7 significant demand for that as well so when 8 customers log on to make a purchase now, they can 9 actually understand the GDA information for any 10 particular product before they buy it. 11 Thank you. 12 (Appl ause) 13 LESLYE FRASER: Thank you very much, 14 Breda. 15 Our last panelist before we hear from 16 our discussant is from the Heart and Stroke Foundation of Canada, Terry Dean, thank you. 17 TERRY DEAN: 18 Good afternoon and on behalf of the Heart and Stroke Foundation of Canada, 19 Page 58

FDA Hearing Day 1.txt I'd like to thank the FDA for the opportunity to 21 speak about our Health Check program. It's one of many healthy eating 22 0160 initiatives that the Foundation has launched, one 2 that is clearly very close to my heart, pardon the 3 pun. I'll very quickly go through what we're going to cover in the next 15 minutes and we'll give 5 6 7 you a little bit of background on the program, we'll talk about the nutrition criteria, we'll speak a 8 little bit about some of the results we're experi enci ng. 9 We'll talk to you about what we think would be critical elements if we're going to develop a single front of pack approach and then very 10 11 12 quickly go through the environment in Canada which 13 Dr. L'Abbe nicely covered off this morning. 14 15 So, let's talk about Health Check, we developed 24 guiding principles before launching the 16 program in 1999 which we continue to use to manage 17 the program on a daily basis and it, it really, the program started in response to consumer questions about how to identify healthy food products. 18 19 20 We're not in the food business, but 21 people do view us as a health authority and ask 22 0161 those subsequent questions. 2 3 So we very quickly looked and said we wanted to do a public awareness campaign that would focus on helping people identify healthy choices. We positioned it as a nutrition information program. It's not an approval or an endorsement program and 5 6 7 it's certainly aligned with all of health Canada's 8 recommendations. We use Canada's food guide as a basis 10 with a general healthy eating approach. We look at it from a total diet approach, not just heart 11 health, and certainly it applies to all chronic disease diet-related components. It's open to all 12 13 products but they must first meet the nutrient 14 criteria and we evaluate the product in its 15 16 totality, not just a specific ingredient or a 17 nutri ent. 18 We operate the program in a cost 19 recovery model so we don't take any money from the foundation's efforts, nor do we receive any money from the Government, however a small manufacturer can join the program for as little as 300 dollars. 20 21 0162 One of those guiding principles is also that those prices would not result in increased food prices in 3 4 Canada. So why were the program, or why would 5 the foundation enter into this type of thing. unfortunately many Canadians eat poorly and we know that a high fat diet is certainly a risk factor, a major risk factor for heart disease and stroke. 6 7 8 9 As we looked around the world, and in an 10 article published in the Canadian Journal of Dietetic Practice in 2002 told us that they, in 11 12 fact, do have an impact. They impact people's

purchase behavior, they do have an impact on their

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FDA Hearing Day 1.txt dietary intake and they can impact the healthfulness 15 of the food supply. We continue to do ongoing market 16 17 research here in Canada. We heard this this 18 morning, it's the same in Canada, many Canadians 19 certainly acknowledge nutrition as important, but 20 today they find the information very confusing and 21 insufficient to help them make the proper choice. 92 percent of Canadians trust the foundation to run 22 0163 1 a program like Health Check and finally the notion of an unbiased third-party certainly resonates from a trust perspective when it comes to impacting and 2 assisting the consumer. 5 The consumer message is very simple, it 6 7 really provides a quick visual reference for them. The logo guarantees that the product meets specific 8 nutrient guidelines that are based on Canada's food 9 We talk about a general healthy diet and it's important to understand this, it's not all 10 11 about heart health, although the foundation has taken on this, but we go to great lengths to explain that we're looking at the product in its totality.

Our nutrition criteria is supported as 12 13 14 many of the efforts of the foundation are by a 15 volunteer technical advisory committee. It's made 16 17 up of dietitians and nutrition experts from across 18 Canada as well as representatives from the United 19 Kingdom. Our current marketing campaign in fact incorporates that and certainly resonates with consumers. When we say check for Health Check, it's like shopping with the foundation's dietitians. 20 21 22 0164 1 Very quickly here's what the, it would look like in store, we've chosen a cereal product, but everyone must display three critical elements. 2 3 4 5 First and foremost, the Health Check logo. Secondly, the nutrition facts table which we've demanded on product since we launched it in 1999, became mandatory in 2005, and the third thing is an explanatory message which helps a consumer understand how this specific product fits into a 6 7 8 9 10 heal thy diet. 11 We believe Health Check actually 12 compliments mandatory nutrition labels. 13 speak to consumers, they tell us that their biggest challenge in the grocery store is time. The other thing we know is that 40 percent of Canadians have a 14 15 literacy challenge, so they really do appreciate that Health Check has done the math for them and we 17 hear this many times when we're speaking to 18 19 consumers. 20 How do companies join the process? 21 very easy. We can turn a company around in as 22 little as two weeks. It all starts with the 0165 product. So you provide a certified lab analysis that details the nutrients that we require that match up with our criteria, we evaluate and certainly assess the nutrients to ensure they do comply. You sign a mandatory legal agreement

> You submit all marketing and the Page 60

through a licensing agreement.

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FDA Hearing Day 1. txt packaging to our group for approval to ensure it 9 aligns with our graphic standards, as well. We do annual monitoring and evaluation, we pull randomly products on an annual basis and I'm proud to say that since we've launched in 1999, we've yet to ask 10 11 12 13 a company to leave the program because they ve been 14 out of compliance. 15 And finally, as I said earlier, the 16 fleas -- the fleas, the fees are flexible and 17 certainly we try to keep them down. As I said, a 18 small company can join for as little as 300 dollars and we have both corporate and company maximums to 19 20 ensure to an incentive for companies to add products 21 to the program. 22 Here are some of the guidelines. As I 0166 said earlier, they've been developed and they're actually maintained by our volunteer committee. 3 must comply with all Federal regulatory guidelines, 4 which are all detailed in the Fŏod and Drug Act as 5 well as we use nutrition recommendations for 6 7 Canadians. We reflect the messages and the key direction of Canada's food guide and will be changing our criteria because our food guide went 8 9 under a change that was launched in March of 2007. 10 Ĭt's a very comprehensive criteria and 11 we ensure that the product is assessed for its total 12 contribution to a healthy diet. We incorporate nutrient content claims as well as health claims and 13 14 DRI recommended amounts as well. 15 We certainly consider market realities as an example, a soup product with 120 milligrams of sodium probably wouldn't do very well in the market 16 17 18 so we try to work with manufacturers to try to put them within the content claim amounts and then 19 20 certainly make sure that we continue to monitor 21 Sodium is our biggest challenge in Canada, 22 there's a lot of energy around that right now and 0167 we're continuing to work with the food industry to try and lower those levels even though they are at very restricted levels right now with our criteria. We have a very regulated food 5 Some might argue overly regulated, but environment. 6 we know that the regulations certainly help us from 7 a monitoring perspective. We have a very safe 8 supply of food in Canada and certainly the 9 regulatory environment helps us with compliance with 10 our program, as well. We look at a number of nutrients and 11 12 here's a long list. Our criteria is transparent. It is on our Website, it is available for anyone to 13 I've summarized it here. 14 take a look at. 15 taken Canada's food guide and broken it into over 16 70 different categories at this stage, largely 17 because we started out with the five -- four food groups and other foods, but certainly as companies brought products to us that didn't quite fit the 18 19 20 definition, we looked to ensure that we could enroll 21 them and provide the proper criteria limits. 22 But we do look at fat, we do look at 0168 sodium, fiber, carbohydrates and protein, calcium, Page 61

FDA Hearing Day 1.txt certain vitamins and sugar, because there's a new directional statement within Canada's food guide on this issuance is something that we've adopted and we'll be putting in in 2007. We, I talked about the total diet approach and its contribution, so we look at the negative nutrient contributors but we also look at the positive nutrients such as fiber and protein to ensure that those are being consumed in adequate amounts and are represented in each of the products in the program. Are we having an impact, we believe we are. An environics pool in 19 -- or, sorry, in 2005 said that 64 percent of consumers use the logo to identify healthy products. A large percentage of dietitians are recommending the program as people go to the grocery store. We know that many new products have been, either been developed as a result of our criteria or we've seen some very significant re-formulations as a result of the criteria that we've got and certainly if an existing product fits the criteria, that's very easy to enroll as well. We've spoken to retailers, we've spoken to manufacturers and we know that many companies are tying sales of their products to participation in the program. In Canada we have one source of market information, it's very expensive and beyond our ability to purchase today but we were able to get some sneak peaks at some of the data that the s have. It's very compelling. We're also proud to say that we have manufacturers have. three of Canada's top five retailers in our program, Lablas is number one, we're still working on them, but we have Sobeys, Overwaitea's and Safeway who all have developed products to meet our criteria. We're talking about front of pack grocery products today. In Canada 40 percent of the food consumed in our country is consumed on meals created outside products bought in the grocery store. It's a 50 billion dollar business in Canada. I suspect the 10 to 1 rule would say it would be 500 billion perhaps in the U.S. 0170 We want to take a look at that and we've now gone into that sector. In 2006 we have two national restaurant chains on board, we're speaking to two other ones and we're working on a, sorry, a project in British Columbia, our western most province working with the Government to try and change the restaurant food supply in that province as a lead-up to the 2010 Olympics. Taking a look at some of our results, we've had some tremendous growth and you'll note the correlation between 2005 and mandatory nutrition labeling in Canada. We've experienced tremendous growth there. We ended our year, which was August 31st, at 1,225 products, 1,400 is very doable and since my boss isn't in the room, I'm able to say we should achieve that by the end of this calendar year, actually, so we're very pleased with the growth. I'm hoping he's not listening on line.

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FDA Hearing Day 1.txt So that's the manufacturers and when we 20 talk to the consumers, we use a public service announcement, PSA to communicate to consumers 21 because we are a health charity so we develop a 22 0171 product that's multi-media, both in, all in TV, radio and print and promote the program that way and we've seen amongst principal grocery shoppers we've grown to a 73 percent awareness number. 5 In order to proceed with a single front 6 7 of pack approach, we think it requires three things and that would be clearly a very strong science-based, in Canada, Canada's food guide provides that for us and certainly you have to comply with the local regulatory environment. 8 9 10 11 We believe transparent governance and a 12 sufficient promotional support are also critical, we 13 have to be able to tell consumers about our efforts and certainly a meaningful visual identity and a 14 third-party endorsement when it comes to trusting people that we're doing the right thing certainly resonates in our market today and Health Check embodies all of these initiatives. 15 16 17 18 19 When it talks to trust, a recent survey we did in March of this year showed us that the 20 industry type program as well as those from health 21 22 authorities, per se, certainly are looked upon very 0172 differently when it comes to trusted sources, when 1 it relates to identifying healthy food products. 2 Dr. L'Abbe went through this this morning so I certainly won't belabor the point, but our Government is acting on the recommendation of 4 5 6 7 the standing committee on health and certainly will be partaking in the consultations that are going on 8 to help Canada develop the best model. 9 That said, we believe Canada has a front of pack logo, it's called Health Check. We've be in the market since 1999. It's embraced by both 10 We've been 11 industry and consumers, we have retailers and we also have the food service industry also coming on 12 13 14 board. 15 It's very comprehensive at this stage. We'll participate in the consultations, it's going 16 17 to take some time, but we will continue to market 18 forward with our program and at this stage, I'm happy to say thank you very much for your time. 19 (Applause) LESLYE FRASER: I will now turn the 20 21 22 floor over to our discussant for observations and 0173 perhaps initial comments and then Mr. Landa will 1 come forward and take questions from the panel. 2 3 4 Thank you. TREVOR WEBB: Good morning and thanks for the opportunity to be here today, I come from Food Standards Austrailia New Zealand, although my tag does say that I'm from Food Standards Australia Canada, so I don't know if there's something still 5 6 7 8 hanging on from the mother country there, but I'm 9 10 not sure. 11 FSANZ is the, is a bi-national regulator 12 in Australia, it looks after -- sorry, Australia and Page 63

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New Zeal and, it looks after the regulation of food labels and additives and composition for food for both countries. We are a regulatory body and not an enforcement body. The States and the country of New Zeal and itself is responsible for enforcement and implementation, itself.

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Front of pack labeling has become an increasingly important topic within Australia and New Zealand and many of the comments that we've heard this morning, particularly the concerns around

competing programs, the proliferation of programs, the combination of traffic lights versus GDA type programs are, are very prominent within the debate within Australia and New Zealand at the moment, so we're really fortunate that you guys were holding this public hearing to save our Government the money of doing so.

We're in the process at the moment of trying to develop a scheme or look at the evidence towards a scheme and that's at a very preliminary stage, a bit like Canada I suppose in terms of where

To sort of summarize the full presentation which is a bit of a task in itself, they come from four different directions and cover four different topics, in a way, but I think the way I sort of look at them I suppose is we started off with two, two talks by Josephine and Mike that looked at some broader issues.

Josephine looking primarily at the literature around consumer behavior and how consumers respond and use nutrition labeling as one

of the part evidence base, and Mike took us through if I like a natural history of the development of traffic light labeling in the UK as the example and highlighted the importance in that, in that context for the development of some sort of system or nutritional profiling, the science, if you like, of categorizing foods based on their nutritional content.

We then had two examples of systems in place, one of them being the check for Health Check, which is very similar to other systems around including in Australia, a voluntary system around the pick the tick around National Heart Foundation and an industry-based system based on GDA, which is also quite prominent in Australia, using thumbnails and GDA promotions.

The sort of evidence that we were showing about the various schemes was information about levels of awareness of schemes, information about hypothetical levels of use and we're starting to get some information about changes in actual sales which I think is the really exciting area in

0176 this, in this part of the debate, this sort of work to see where the front of pack labeling and nutritional labeling in more simplified formats because we know that people have difficulty with the nutrition facts labels, whether those labels actually have an impact on peoples purchasing

FDA Hearing Day 1.txt choices as a, you know, as an indication of their consumption behavior. 8 9 I suppose as a summary or as an opening 10 question the question I'd like to pose to the panel would be given that much of the research shows that people in lower socioeconomic sort of groups have 11 12 difficulty with nutritional information and 13 nutritional labeling in general, to what extent do 14 you think that front of pack labeling in the sorts 15 of schemes that you're talking about will assist 16 particular groups as opposed to broad populations 17 18 which is the sort of data we have rather than data on individual groups? 19 MIKE RAYNER: 20 I do think on the evidence based around consumer understanding of different forms of front of packs nutritional labeling is very 21 22 0177 poor, but that, but our question was specifically 2 about difference in, say, understanding among 3 soci oeconomi c groups. 4 I think there is some research, notably 5 recently for example from FSANZ Agency, research shows that, showing that people in low socioeconomic groups have particular problems with things like percentages and things like more interpretive forms 6 7 8 like sign posting, color-coding are helpful to 10 people in lower socioeconomic groups but I don't 11 think we know really enough to be honest and particularly in actual use. 12 13 I think we are at an interesting stage that we now are beginning to get these forms of labeling proliferating and it has its problems, but it also has the opportunity of actually carrying out some real life analysis of what the impact of these 14 15 16 17 forms of sign posting on, on consumption patterns.

JOSEPHINE WILLS: There's research out 18 19 There's research out 20 there that will, that shows that low socioeconomic groups have troubles with some forms of labeling and 21 22 then there's repeated research that shows that they 0178 don't have problems with certain forms of labeling, so it really, I think at this stage it's very 2 3 difficult to come to a hard and fast conclusion about Iow socioeconomic groups. 5 I think one of the big questions is in 6 7 actually, in practice, will low socioeconomic groups actually use them anyway, it's the difference 8 between what they say they might do and what they ŏ actually do in practice.

So how important is this area to lower 10 socioeconomic groups.

BREDA MITCHELL: If I could just add, I 11 12 agree that I think there's little research at the 13 14 moment but I think what we were trying to do was 15 actually create a consistent approach across our store so that they would get used to actually see
the type of labeling and sign posting.

But just to emphasize again, labeling is
just one small part of the overall key to this and a 16 17 18 19 lot of it is based around ongoing consumer or 20 21 customer information and education and I think, you 22 know, as long as retailers and the Government

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FDA Hearing Day 1.txt continue to do as much as they can in those areas, 2 3 we'll wait and see. TERRY DEAN: Our challenge for our 4 5 program up until the last year was that with 500 products in the grocery store, we pretty much knew what the answer would be to our question but as we approach 1,400 to 2,000 products, we now have a critical scale that will help us understand that for 6 7 8 9 a couple of reasons. We want to understand how we 10 target our messages to certain groups and certainly 11 from a health perspective as a national health charity, we need an answer to that question and we have money budgeted in our 2008 budget to take a 12 13 14 look at it specifically MICHAEL LANDA: 15 Thank you, I think we'll 16 turn now to the FDA panel. 17 Loui sa Ni ckerson. 18 LOUISA NICKERSON: Yes, we've heard that 19 when there are some products with, say, a green light and others with red that consumers tend to 20 21 shift away from the red light products to the green 22 light products, but I'm wondering when you've got a 0180 voluntary symbol system and some products just have no symbol on them at all with regard to nutrition 2 3 quality, how does that affect sales of products? TERRY DEAN: I can really only speak to the products that are in the program. The evidence 5 6 7 would support them doing very well versus their competitive set, but we don't really get a chance to speak with the companies who have chosen not to enter our program so it's something I'm not able to comment on on that stage. 8 9 10 MI CHAEL LAŇDA: 11 Mike Rayner. MIKE RAYNER: Yeah, I think there is a 12 13 real problem with voluntary food certification schemes such as the tick schemes and the Swedish 14 keyhole schemes and some of the industry schemes because of this issue, but what is, what does a product which doesn't bear the tick or the keyhole actually mean to a consumer and even the best of these schemes, and I would think the Canadian scheme 15 16 17 18 19 20 is a good scheme in this regard, only extreme --21 achieve very small penetration in the market, so we 22 were talking earlier about, I think it's only about 0181 20 percent of products actually could carry their 1 tick; is that right? 234567 TERRÝ DEAN: A little higher, about 60 --MIKE RAYNER: And what percentage of the products? TERRY DEAN: We would be about 8 10 percent right now. 9 MÎKE RAYNER: 10 percent of the eligible products actually carry the tick.

So it is still very low in terms of the penetration and similarly for the Australian tick scheme, they are really only talking about

16 percent of the eligible products carrying the 10 11 12 13 14 scheme actually have the tick on the foods. 15 16 So, I mean this is an argument clearly 17 for mandatory certification schemes if nothing else, Page 66

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18 I think.
19 MICHAEL LANDA: Barbara Schneeman has a
20 question.
21 DR. SCHNEEMAN: Great, great, thank you.
22 I will try to get closer to the mic.
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Actually I was very interested in Louisa's question as well and I note the person from Tesco did not comment and I thought since you mentioned specifically trying to create an environment where there was more information, it might be interesting to hear you comment on that, that same aspect.

I don't know the degree to which the labeling is throughout the store on all products, but I also wanted some comment or some information as one has looked at the research, it seems like there may be some unevenness in what has been referred to as the back of the pack or perhaps the side of the pack, that where there's not a standard format, that's one thing to ask a question of how does a consumer use the front of pack in the context of back of the pack information, but where there is a standard format, is there research to tell us how consumers use that front of the pack?

I'm just, perhaps the broader question is how does the research deal with those two different pieces and control for that in the

studi es.

 Thank you.

MIKE RÁYNER: Again, I think you asked this earlier, I mean I don't, I mean Josephine will know better because I think the EUFIC review is a very good review of the available literature on the understanding of the front of pack labeling, but I think there's very little information to, very little research evidence that look at the interaction between use of front of pack and back of pack and I would suggest that's a rather obvious research hole, but I don't know whether Josephine would agree on that.

JOSEPHINE WILLS: Yeah, I mean this whole area of actual uses of before is an area that needs to be filled. We need more research on how are they actually using all of the information that's available to them and it's not just back of pack, it's even the ingredients list, you know, so, you know, consumers make inferences about the healthiness of a product and that could be based on a number of different factors.

And I don't think we know exactly what the balances of all the different factors of information that's on the panel, you know the ingredients, it's the back of pack information, it's the front of pack, it's the symbols and where you've got a number of these things playing, what is it that's driving that choice.

So, for example, with the Tescos, were they looking at the, the sales of the better for you product, what was it that drove that choice, was it the calories, that it was lower in calories, was

FDA Hearing Day 1.txt 12 that it was lower in salt. I don't think we know. BREDA MITCHELL: 13 I think what we were trying to do is actually provide a snapshot from the back of pack on to the front of pack so that customers would help -- you know, hopefully it will promote their use of the back of pack even more 14 15 16 17 because all we've done is literally take that snapshot and put it right in their face, so, again, 18 19 I don't actually know what that level of interaction 20 21 is, unfortunately. 22 You asked about the level of 0185 participation across the store and just to say that I said that just under 7,000 products in our store in our private label range, food range have now been labeled, well that probably accounts for all of our private label food range so that's right across the 3 5 6 7 There are very few categories or products that we haven't labeled, so, for instance, tea and 8 coffee or perhaps flour, which is used in a wide range of settings, and it would be very difficult to actually define a GDA measure.

But then I think we've seen that the 9 10 11 branded manufacturers are also using a similar 12 scheme and their presence in our store brings the 13 numbers up to just under 10,000, that's the latest 14 15 figures I had. 16 DR. SCHNEEMAN: Just as a follow-up, do you do any shelf labeling for products that are not part of your store brand, but do you do any shelf labeling at all with the same sort of format?

BREDA MITCHELL: When you say not part of our store brand, so this is for branded lines? 17 18 19 20 21 22 DR. SCHNEEMAN: Just for things that 0186 you're not putting the GDA on, do you use shelf 2 labeling for those other products in the store? 3 BREDA MITCHELL: Well as I say, it's a very, very limited range that isn't actually 4 5 included now, I said teas and coffees and I think flours and some of the other smaller grocery lines, but apart from that, no, we don't tend to flag 6 7 anything there, but the information is right across 8 9 our store, so for all of the other lines. But, no, 10 we don't actually put anything on for those that we 11 have exceptions to the rule. MI CHAEL LANDA: I just have one, one 12 13 follow-up, I think you said 10,000 products you 14 estimated. 15 BREDA MITCHELL: Yes. MI CHAEL LANDA: And that's of, how many 16 products do you carry, what percentage is that of 17 the products you carry, roughly?

BREDA MITCHELL: I don't know, to be 18 19 20 honest, because I know that we have, it's probably 21 60, 70 percent. MI CHAEL LANDA: Okay, thank you. 22 0187 JOSEPHINE WILLS: Bred, just to add to 1 that for clarity, I think, I think the question was 2 for branded goods that are not Tesco's goods, do you convert the information on those products into GDAs? I think the answer is no.

FDA Hearing Day 1.txt BREDA MI TCHELL: The answer is no, we 7 don't, because we obviously don't have access to the 8 detailed nutritional information in order to allow 9 us to do that, so where manufacturers, where branded manufacturers are offering that information on their products, it's obviously visible for our customers 10 11 but we don't, the other manufacturers are not, that 12 13 haven't chosen to take up this scheme, well then 14 there isn't any other information other than the 15 back of pack information available to the customer. MI CHAEL LANDA: We have a question from 16 17 Kathleen Ellwood. KATHLEEN ELLWOOD: Okay, the first 18 speaker from EUFIC stated that consumers had a good understanding of calories, fat, carbs, sugar and salt, but then went on and named so many nutrients 19 20 21 22 that consumers were less familiar with, like 0188 1 saturated fats and cholesterol, but these are encompassed, some of these other nutrients, under 2 3 the nutrients they supposedly had a good 4 5 understanding, so I was curious what kind of understanding did consumers take away then, because this seems to be what's being targeted in the program, these major kinds of nutrients, so what is 6 7 it that they do understand and you also say that 8 9 they don't want any additional advice on the 10 package, so if you could just elaborate, that's what l'm ašking. 11 JOSEPHINE WILLS: Well they understand terms such as energy and fat, but they don't understand saturated fat. I mean some research, where you start to break down different types of 12 13 14 15 fat, they don't really know what's a good fat or 16 what's a bad fat, so, and this is over a number of 17 different types of qualitative research. 18 19 Then your point about additional 20 statements, one was, one area is being what we've done on energy, they don't like the exercise, a 21 22 balance your energy needs type statement and they 0189 don't like reference to energy on the front of pack 1 of how much they would have to, activity they'd have 2 3 4 to conduct. KATHLEEN ELLWOOD: So energy as a 5 physical activity 6 7 JOSEPHINE WILLS: As in physical activity rather than energy as a figure of calories?

MI CHAEL LANDA: We have a question from 8 9 Alan Levy. 10 ALAN LEVY: ALAN LEVY: Hi, this is directed -- (Microphone not on). 11 12 ALAN LEVY: Oh, I'm sorry 13 Hi, this is directed at the Tesco Have you considered looking at the 14 representati ve. impact of your GDA program on the sales of the 15 branded products in the same categories that you've introduced your own private label branding?

BREDA MITCHELL: Well, I think that they would probably be doing that piece of analysis themselves, actually. I'll be surprised if we don't 16 17 18 19 20 hear more from them later on today, but, no, we 21 22 haven't, we've analyzed our own, our own sales data. Page 69

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MIKE RAYNER: I think that's a very interesting question and I have personally thought of trying to do that, to using sales data from Tescos and Sainsbury's and the other people who are introducing this thing.

One of the problems with the existing data presented by the retailers is that it's very difficult to get a hold of the methods, so some of the, I showed a slide where you're looking at equivalent changes in sales of Sainsbury's ready meals and Tesco's ready meals but of course they're over different time spans, you're not really entirely sure what else is going on even in terms of things like price and other forms of labeling. Are these products selected products or are they representative products and so forth.

And I think it would be -- I mean as I said earlier, if Governments and retailers could get together at the moment, it's a fantastic opportunity to collect some of this data and to analyze the sort of question that you've just asked.

MI CHAEL LANDA: We have a question from

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Rob Post.

ROBERT POST: Yeah, this may have just been addressed by Dr. Rayner, but labeling I guess is really something that's taken in its full context in terms of its value to consumers or lack of value, as we heard in some presentations, but to what extent has the research that you're familiar with considered the implications of other information? I know Breda mentioned allergins-related statements that might be front of pack, it's actually transferring information from ingredients Price, taste, we heard about, on to front of pack. but price or convenience of preparation or even, even other safety-related things where, you know, recalls that are, you know, recent might affect purchase decisions and how has that been dismissed or separated from testing the value of the nutrition information?

MIKE RAYNER: Well it hasn't, I don't think, is the question. I mean there are interesting ways you can do this, I mean the sort of studies that I -- we've done and I know a few others

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have done in terms of follow -- protocol analysis where you follow consumers around stores getting them to think aloud about the sort of decisions they're making when they're shopping gives you some of that sort of opportunity. Take the transcripts of their thoughts, you can unpick to some degree, I mean interactions between informations, but clearly that's not entirely satisfactory.

Again, sales data, you could in theory unpick some of these effects, but my impression being, Josephine might be able to answer this, is that the research is very poor in this area, but, and needs to be cleared up.

I mean what we do know from protocol analysis, for example, is that consumers aren't using nutrition information very much or at least Page 70

FDA Hearing Day 1.txt in, in the UK, as far as I'm aware, they're using 17 18 price and taste and other things as, in, in the 19 decision much more than nutrition information, but 20 information that's partly because the format is so incomprehensible in my view. JOSEPHINE WILLS: 21 22 I agree with Mike 0193 1 that, no, we need to start to unravel all of these things and the research isn't there, it's not sophisticated enough, it has to be more 4 sophisticated where it is trying to unpick and 5 unravel all of these aspects to see what are the 6 7 main factors that is influencing consumer decision-making around food choice.

ROBERT POST: Thank you.

MI CHAEL LANDA: We have a question from 8 9 10 Jordan Lin. 11 JORDAN LIN: Yeah, I have a question regarding the GDA labeling. I understand that the 12 13 GDA has been on food labels on the back in several 14 countries for quite a while and now some new symbols just, you know, summarize the information and put it 15 16 on the front. 17 Is there any consumer research that 18 shows that by doing this, does consumers' 19 understanding of the GDA and its contents been improved by the front symbols or there hasn't been 20 any change or other findings? 21 BREDA MITCHELL: So I think, yeah, we've 22 0194 put GDA information on the back of our packaging for several years and when we actually took that snapshot and put it on the front of pack, I think we were surprised ourselves about the actual impact on 4 5 6 7 the sales and Robert was asking about the data and the analysis. I mean what we tried to do was take a 8 period of time as close as possible to when we 9 actually started to do the roll-out and we allowed for eight weeks pre and post, so that was as much as we, we could do to narrow it down at that point in 10 11 time. We will be continuing to look at this. 12 But I think just about the general use 13 of GDA and the general understanding, I think what we're hoping is, the answer is I don't, I don't 14 15 know, I mean there is research and there is another 16 17 organization within the UK called the IGD which has done quite a significant piece of research on the understanding around GDAs and that's been quite 18 19 interesting in that it did actually support the premise that people understood what, you know, what 20 21 22 it was about. 0195 But what we're hoping is that the level 2 3 of information and consumer training that we're putting in place and the leafletting and all the rest is going to raise the profile of GDAs and therefore enhance customer's understanding of what the overall messaging is about. 4 5 6 7 MIKE ŘAYŇER: Although you're right to 8 say in the UK, for example, GDAs have been put back of pack, I mean the initial stage was just to give 10 you GDAs, not the percentage of GDAs in a serving of

FDA Hearing Day 1.txt the food. It's only relatively recently have 12 manufacturers and retailers in the UK and in Europe put percentage of GDAs in, within the nutrition 13 14 information panel or the nutrition facts panel, 15 unlike of course your situation where you've had it 16 for years. 17 And the revolution in the UK is to put percent of GDA information on front of pack and 18 that's the quantitative difference, people generally have put the GDAs straight front of pack, they're 19 20 putting percent GDA per serving of the food and that I think is what's making the difference. And I 21 22 0196 think, you know, as a format, although I'm in favor of traffic light labeling of nutrients, it's better 2 than nothing and it's like, and it is -- I think if you, if you look at the, some of the sales data that people like Tescos and others are producing having 6 7 some influence over consumer purchasing behavior, but, you know, to my mind it doesn't go far enough. 8 9 MICHAEL LANDA: Question from Felicia Billingslea. FELICIA BILLINGSLEA: Yeah, my question 10 actually follows up on Robert Post's question a bit 11 12 regarding other information that may appear on front of pack with the GDA or sign posting.

From what I've observed, the GDA sign 13 14 15 posting typically focuses on those nutrients that are adviséd to limit or reduce. 16 17 What about claims about products that 18 contain vitamins or minerals in increased amounts or health claims, has there been any consideration or research that looks at the impact of both types of 19 20 statements on front of pack and how that might 21 affect consumer choice? 22 0197 1 MI CHAEL LANDA: Mike Rayner. Sorry, yes, the basic 2 MIKE RAYNER: format which has generally been agreed is for calories, saturated fat, fat, sugars and sodium, but some manufacturers and retailers have put percent 4 5 6 GDAs for other nutrients along the front of -- also part of the sign post, so there has been a few 7 instances, actually not a few, quite a few instances 8 9 of putting calcium and fiber, iron and so forth, 10 along the, along the sign post. Is that the sort of 11 thing you mean? 12 And actually in Australia, for example, 13 the sign posting which the Australian food industry are proposing has within the sign post not just 14 those -- not just energy, saturated fat, fat, sugars 15 and sodium but also protein and carbohydrate because 16 17 those are the components of the nutritional 18 information panel, the nutritional facts panel. they're putting them as part of the sign post, so I think, I think that introduces an extra level of 19 20 complexity. So sometimes the percentage of the GDA in the food will be good with the vitamins, minerals $\,$ 21 0198 and fiber and possibly protein, but sometime it will be bad when it's for the other saturated fat, the

fat and the sugar and so forth.
So I think there's a question there
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FDA Hearing Day 1.txt
      about the understanding of some of these sign posts
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      where you have percentages of GDAs which sometimes
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      are good and sometimes are bad.
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                      MI CHAEL LANDA:
                                            Question from Alan Levy.
                      ALAN LEVY: No, I'm sorry.
MICHAEL LANDA: I guess we don't.
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       the last question of this morning will go to Leslye
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      Fraser.
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                      LESLYE FRASER:
                                           Thank you.
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      reflecting on the first panel this morning, in
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      particular some of the comments from the
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      representative from Thailand with respect to obesity
      in children, are you aware of any research that looks at, in terms of the use of the various symbols, how that may affect children as children are in particular the tween group ages, 9 to 12 or
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      13, or are we just looking at research that's using
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       the purchaser as a surrogate for, you know, mom
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      brings home or dad brings home the food assuming
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      that it's going to be better for the child, but is
      there anything that you're aware of that's targeted to what is maybe not only what that tweens or children prefer and/or understand about the
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      heal thiness of a product?
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                      MIKE RAYNER:
                                        No.
                       BREDA MITCHELL: I could add that just
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      from the point of view who's making the purchase,
      what we're trying to do is actually enhance their knowledge of what the GDA for a child is and there
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      has been some new developments in that area so there
      is now that similar information available for children in the UK, at least, and l\mbox{'m} not sure
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      whether Josephine wants to talk a little bit more
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      about that from a European perspective.
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                      JOSEPHINE WILLS:
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                                             No, I mean I'm not
      aware of a huge amount of research that has used
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      focus groups of children or young adolescents and it
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      would be quite interesting just to see how that group might respond to, to something like a red traffic lights to see, is it going to make them say
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      right, I'm going to eat more of these rather than
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      less, so I think that -- you know, when the next
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      phases of research get carried out just to see how
       they respond to those authoritative messages.
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                      MIKE RAYNER: I think the answer
      probably is no, but I think under, what is interesting I think is that traffic light labeling of foods which is what I'm advocating, where that has been most tried out has been in school canteens,
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      but there again, the Australian experience is worth
      looking at here but some other, and British canteens and so forth where they do use traffic light
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      labeling of foods to help the kids choose between,
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      between foods in the canteens and I think, you know,
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      well what's good for the kids is good for the
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      adults, but.
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                      MICHAEL LANDA: Thank you. I think this
      concludes our morning session. Let's have a hand
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      for the panel.
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                       (Appl ause)
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                      Until 2:00, we're scheduled for lunch.
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FDA Hearing Day 1.txt
      There's a, there are two restaurants, one as you
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       enter this building and one down the corridor on
       your right. If we could resume at 2, that would be
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       great.
                       Thank you.
                       (Morning session concluded 1:08 p.m.)
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                    AFTERNOON FIRST SESSION SPEAKERS:
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       Barbara Schneeman, Moderator
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       Richard Black
      Nancy Green
Kathy Weimer
Celeste Clark
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       Douglas Balentine
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       Linda Myers, Discussant
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       BARBARA SCHNEEMAN: Okay, once again we, we'll have a tight schedule with some excellent
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       presentations planned for the afternoon session, so
       I'd like to get started and first of all, my
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       compliments to the panel. You are seated and in
      place and ready to go.

So the panel for this afternoon is now focusing more toward the U.S. experience and our panelists this afternoon will be speaking to manufacturer activities. And it's over the next two panels that we'll examine then the U.S. experience
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       with front of pack labeling and focus first on the
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       U.S. food manufacturers.
                       Our presentations will be given by Kraft
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       Foods, we have Richard Black here. Nancy Green is
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FDA Hearing Day 1.txt here from PepsiCo, Kathy Weimer from General Mills, Celeste Clark from Kellogg Company and Douglas 17 18 Balentine from Unilever. And Linda Myers from the Institute of Medicine, the National Academy of Sciences has graciously agreed to be our discussant at the end of 19 20 21 22 the panel. 0204 And I should point out to the panelists, 1 2 3 we are providing time information so you don't have to wait for me to say something nasty to you. 4 have two people here who will hold up yellow and red 5 to signal you. 6 7 So with that, we'll begin with Richard Black, Kraft Foods 8 RICHARD BLACK: Thanks very much, 9 Good afternoon, everybody. I hope this is 10 going to go fairly quickly and on time. Given it's right after lunch, I know we're all going to have 11 the afternoon dozies for a bit. 12 I'd like to take you through the Kraft Food Sensible Solution program. I'll go through it 13 14 reasonably quickly because of time constraints.

Quickly what I'm going to be covering,
just the background goals and guiding principles of 15 16 17 Sensible Solutions which is our on pack logo if you 18 want to identify better for you products, some of 19 20 the alternate standards that we evaluated, a description of the program, itself, some of our 21 consumer insights and I think this is really where 22 0205 the rubber hits the road. 2 3 Sensible Solution implementation, the market performance of those products. It has been 4 5 exceptional, we've all read recently about Hannaford stars and how that's grown their businesses. 6 7 seeing the same thing with Sensible Solutions and then some recommendations for the FDA to consider, 8 9 based on our learnings, not answers, but just things to consider. 10 So, Sensible Solution nutrition standards were introduced in 2005. They were 11 12 developed internally within Kraft by our nutrition 13 experts, reviewed with our worldwide health and 14 wealth advisory council, as well there are two key goals for our Sensible Solution programs, one is to 15 expand better for you options. This does not say 16 healthy, this says better for you.

We had the example this morning from the 17 18 UK of two different kinds of crisps, which one is the one that I should choose if I m going to eat 19 20 potato chips or crisps, I don't think either one is 21 22 going to be a healthy food, but one of them could be 0206 the better for you choice and that's what this 1 program's designed to do, significantly better for 2 3 4 you choi ces.

look for on pack and what's easy and simple and Page 75

then to drive those things, also to enable then consumers to easily identify the better for you

products within the category. This is critical, we've heard before all about consumers and what they

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New products and product re-formulations

FDA Hearing Day 1.txt 10 straightforward. If they don't know what the symbol 11 means, it's useless. Three guiding principles, then, practical, category specific guidelines and we chose 12 13 to base these on serving size, ensures the outcomes -- ensuring outcomes that support the 14 15 dietary guidelines. A one size fits all approach we 16 17 felt was inconsistent with the diet, the 2005 18 dietary guidelines. 19 The achievable, achievable targets to 20 encourage positive outcomes, we didn't set the 21 hurdle at 15 meters high, we set the hurdle at 22 something that the business and the product 0207 formulation -- or the product developers could jump 2 3 over. So, healthier versions of familiar foods 4 5 6 7 are more realistic versus eliminating entire categories. For example, cheese, you could say, gee, there's a lot of saturated fat in cheese, but we think there's a lot of good in cheese.
Overly prescriptive targets limit choice 8 and may not promote positive changes in eating behavior. We've all seen what happens if you get 9 10 overly prescriptive, people just tune you out, so we 11 have to move people along at a reasonable pace. 12 13 Reasonable small step change then is crucial to 14 implementation. 15 We looked at doing this on a 100 gram basis, we heard about that this morning, as well. It's easy to compare between foods in different 16 17 categories on that basis, but we didn't feel it was relevant to the nutrition facts panel and serving 18 19 sizes and that's the way food is consumed here in 20 21 the U.S. and that's the way it's labeled in the U.S. 22 One set of upper limits for all foods, 0208 1 we looked at that, as well. This does not have unfortunately any recognition for the roles of different foods in the diet nor of unique nutrient contribution of specific food groups, so, for instance, under that kind of a scenario, olive oil 4 5 6 7 is always going to have a red, don't eat this kind of a flag on it. 8 Single algorithm system, we didn't feel 9 that was transparent, it was very complex. And remember, what we're trying to do is give guidance 10 11 to product developers that make the foods people eat. If the system is overly complex, they don't know where to push on a food formula to get the 12 13 outcome that they want in terms of an overall 14 heal thy bal anced profile. 15 You've got to be able to know where the 16 17 inputs are that you have control over as a food developer so that you know what you're going to get 18 on the other side. And an overly complex formula is not going to allow us to do that, giving potentially unbalanced results and also eliminating categories 19 20 21 22 of food, unrealistic and not sustainable in our 0209 1

view.

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Sensible Solution program is, in fact, then grounded in public health recommendations, the Page 76

FDA Hearing Day 1.txt 2005 dietary guidelines, the FDA labeling regulations and we also looked at Canadian 5 6 7 regulations and guidance and from the EU, as well. Nutrition criteria per serving, we have limits on nutrients of concern, so all the different standards that we have limits on these specific 8 9 10 nutri ents. 11 Calories, a lot of them don't pay 12 attention to total calories and it's beyond me given the obesity issue. Fat, sat plus trans, we lumped these together. We felt that we did not want to see 13 14 if trans are going down, we didn't want to see the solution being saturated fats going up. They go 15 16 Sugar and sodium.
We also encourage positive foods, or 17 together. 18 nutrients, so we looked at dietary guidelines shortfall nutrients, fiber is part of it, whole 19 20 21 grains, fruits and vegetables. 22 There we go. Criteria varies by 0210 category, as I indicated. There were 12 main food and beverage categories, 42 altogether if you take 1 the subcategories. It does get a little complex at that level. That's not what the consumer sees. The 5 consumer sees a single flag icon on the pack. 6 7 Packing and canning, beverages, bars, biscuits, cereal, cheese, you can read the rest of the different categories that we have here.

All qualifying products are limited in calories. They're limited in fat, as I said before, 8 9 10 saturated fat, plus trans fat, sodium and/or sugar. Many are reduced or low or free when compared to 11 12 13 similar products. 14 Again, to highlight, this is a better for you choice within a category. Many provide one or more of positive benefits such as 10 percent or 15 16 more of the DV of Vitamins A, C and E, could be 17 calcium, Magnesium, potassium, iron, protein or fiber. Could be half a serving of fruit. We put the limit at a half of serving of fruit as defined by, at the time by the USDA, vegetable or whole 18 19 20 21 grain or a functional benefit. 22 0211 Consumers often don't pay attention to the labels, we know that already. Many of you may not know that a consumer typically spends about two seconds evaluating a label. The first -- when 3 4 they're going through the store, two seconds. Not lot of time, so the icon that we're talking about has to be very, very visible, absolutely draw attention to it. 5 6 7 8 Consumers say they tend to use the 10 information on the first purchase and then possibly 11 for comparisons later on. They focus on a few key 12 nutrients, different consumers, we heard this this morning and I'll echo that, focus on different 13 nutrients. I don't pay attention to sodium, at all, just not concerned with it. Fiber I pay attention 14 15 to, Potassium I pay attention to. 16 Varies based on the level of nutritional 17 sophistication and understanding. We categorize 18 19 people as nutritionally savvy, nutritionally naive

and I don't care. The vast majority of people fall

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FDA Hearing Day 1.txt into the I don't care category 22 Awareness of specific front of pack 0212 systems is modest and the understanding is low and the information needs vary among the consumers.

Sensible Solution was most useful for 1 consumers who want to make changes but are not sure 5 This nutritionally savvy know what they're 6 7 looking for, they go to the nutrition facts panel, they'll make use of it but that's not who we're 8 trying to change. 9 The majority of people are receptive, 10 they perceive these things as being credible and trustworthy, the information is more accessible, it 11 does help with purchase decisions in some instances, 12 13 it increases their confidence in food choices. 14 Some, however, are very skeptical or unclear about 15 the nutrition criteria used. What we have done, we've chosen to put 16 all these criteria on the Website, you can look it 17 up on our Website and get all the information you 18 19 The potential solutions include 20 communicating the scientific basis through a 21 22 third-party endorsement, perhaps, calling out 0213 relevant attributes within the flag, for example, 2 2 3 grams of fat. Best practices for a front of pack 4 labeling system based on our consumer insights, the 5 logo or size and placement is critical, it has to be large enough to grab attention, to locate it quickly and easily. It has to be consistent, in a consistent location on the front panel, consistent 6 7 8 9 appearance and format. Don't separate the elements, 10 don't reverse or change the colors, it's got to be 11 consi stent. 12 Drop-down nutritional information is helpful to highlight to four key nutrients by 13 14 15 16 17

category but again, you want to be consistent within the category. Consumers expect that. They do allow that between categories, yeah, they can change because what's relevant for breakfast cereals is potentially not relevant for deli meats. You're not going to worry about dietary fiber in deli meats. We make Oscar Meyer for those of you that don't know. Always, always list it in the same order, it gets down to the consistency.

The full flag for us includes one to

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> three nutritional ingredient statements, it's relevant to consumers and communicates product qual i fi cati ons. For the execution on product packages, you have full flag on one of the primary display panels, its consistent green color, it's clearly visible and legible with type size requirements and the nutrition call outs, again, are relevant to the categories and/or the product.
>
> To give you an idea of what this is doing in the marketplace, over 500 of our products now carry the flag, more than one, it's more than one-third of our total sales but it represents two to three times the total growth of our revenues.

FDA Hearing Day 1.txt 15 its significantly outpaces the growth of all the 16 other products that we have. So I'm going to go through seven recommendations here and I'm going to tell you right off the top, we don't have the right answer, we just have an answer, an execution of front of pack labeling. It is, I think, critical that we come to 17 18 19 20 21 an agreement on a common way of doing this. 22 0215 Be realistic, use category-based nutrition criteria, and I say that because of the expectation that if you don't use category specific, you're going to get funny results. So avoid unintended results and model out your approaches using real world examples, you really need to model these things out, I would encourage that.

Be flexible and implement these in a step wise manner. You can make nositive changes 2 3 5 6 7 8 9 step wise manner. You can make positive changes 10 over time. You can even map out where you want to get to with the standards and you might have far 11 more success doing this in a step-wise progression which is agreed to up front. 12 13 Improve the nutrition quality with 14 This was raised this morning. 15 positive nutrients. I think this needs to be emphasized, it's not just 16 about removing or limiting nutrients of concern, 17 which you want to reduce, but you want to emphasize 18 19 shortfall nutrients to encourage their inclusion. 20 You want to monitor if you're having an impact and I don't think short of the Hannaford system, that's the first data I've seen from a 21 22 0216 retail outlet, I know we have our own system, data, I'm sure all the other food manufacturing companies do as well, you need to see if what you're doing is being effective. 5 Remain current. I don't think you need 6 to re-define what are the shortfall nutrients, what are the things we want to avoid. There are processes in place for that. The scientists are getting together under the guidance of the USDA of the dietary guidelines for that. Rely on those, 8 9 10 11 don't create another process to do that, that way 12 you'll stick to the evolving science. And then finally, communicate and 13 educate to fully leverage the problem -- or program, 14 15 excuse me. 16 Simple, clear explanation of criteria and rationale and common industry front of pack icon 17 opportunity for consistent messages. If we don't take the time to educate the consumer, we're not 18 19 20 going to win in this at all. And that's it. Thank you. 21 22 (Appl ause). 0217 BARBARA SCHNEEMAN: Great, thank you. 1 And our next presentation is Nancy Green from Pepsi Co. 4 NANCY GREEN: Good afternoon, thank you for including PepsiCo in the forum today. I want to 5 give you a little bit of background on our launch of 6 the Smart Spot program that we have at PepsiCo and some of the consumer research we did with the Page 79

FDA Hearing Day 1.txt launch, a little bit about implementation, what 10 we've learned from the logo in marketplace and then 11 finally conclusions and learnings 12 79 percent -- 78 percent of consumers are confused about health and wellness. I don't 13 think that's a surprise to anyone in the room today, and 76 percent say they're confused about what to 14 15 16 17 How do they cope with that, 47 percent 18 say they rely on the nutrition label, however 19 37 percent say they're confused by the nutrition label or have difficulty understanding it. So, in 2004, PepsiCo Launched our Smart 20 21 22 Spot program and this program had two goals. 0218 was to try to make it easier for consumers to identify our portfolio of products that were better for you or good for you, and secondly, to demonstrate that PepsiCo was part of a solution 5 provider. And you see on the right-hand side and 6 7 you've seen it a couple of times already today, the symbol we use with Smart Spot -- smart choices with 8 a tick made easy. 9 When we were doing the consumer research 10 prior to the launch, there were four key factors that we came up with that we felt like were critical 11 12 as far as communication to make the program 13 successful. Simple, optimistic, real and 14 transparent. 15 Keeping it simple with one simple logo. Every time we tested using stars or rating systems, it never scored as well with consumers as a simple 16 17 Keeping it optimistic, having a positive 18 message rather than a negative message. Making it 19 real, and there's a mandatory statement on our 20 21 packaging to say why the particular product 22 qualifies, and then finally, making it transparent. 0219 Richard referred to an educational 1 program. We've relied a lot on our Website, the Smart Spot Website which is referred to on every package that has the logo. On that Website you can get additional nutritional information as well as 5 6 7 nutrition information about healthy lifestyles, BMI calculator, a number of tools that are there. 8 Our logo system has really three 9 components that are mandatory, the first, as we mentioned, is the smart choices logo, which is on the front right-hand package of all of our products that qualify. Secondly, there's a referral statement on the back of the package that says why the product qualifies. And then third, the 10 11 12 13 the product qualifies. 14 15 reference to our Website. 16 And I want to point out, in those 17 referral statements it starts out like diet Pepsi is a smart choice if you're choosing a soft drink 18 19 because. Baked Lays is a smart choice if you're 20 choosing a potato chip because, so it's not trying 21 to say this is the best snack you could have or this is the best beverage, but if you're in this 22 0220 category, this might be a better choice for you and this is why, it's lower in fat, it's lower in

FDA Hearing Day 1.txt So that transparency was important to cal ori es. 4 have there and then the reference to the Website. 5 And anyone that's worked with these 6 7 programs, I think I would echo what Richard said, we don't have the right answer, we have an answer.

And in looking at the guidelines that we 8 use, there are three ways that products could qualify for our program. The first way was really 9 10 based on FDA definition of healthy. 11 And we 12 supplemented that with some requirements around trans fat and added sugar. 13 A second way is if a product qualified for -- a specific health benefit such as qualifying 14 15 for an FDA approved health claim; and then the third way was products that qualify as reduced and again, 16 17 qualifying for a reduced claim for calories, saturated fat, sodium based on FDA criteria.

I'm not going to go through this chart, but again, the importance of being transparent, 18 19 20 21 here's FDA criteria for healthy, here's what our 22 0221 criteria are for beverages, foods and snacks and then where we used recommendations from National Academy of Sciences about added sugar and also you 3 can see the other two ways with the functional 5 benefit or reduced, so there are three ways. 6 When we talked with consumers about 7 trying to indicate on label which of these three 8 ways it qualified, it just got too complex and they rejected that, but that would be in the flag that we have on the back of the package.

Now I want to move to talking a little bit about how consumers have reacted to this in 9 10 11 12 marketplace and what we've learned. 13 The data that I will be showing is from what we call our attitude 14 and usage study. We track this at least twice a 15 year, the population is geographically diverse enough and large enough that it's generalizable to 16 17 18 the general population and what we learned is that there are about 45 percent of the population that was interested in a logo type symbol.

And about 50 percent of people said that 19 20 21 22 that would help them in making purchase decisions 0222 and that they would be interested in purchasing 2 3 products with the logo. We did see if it would hurt purchase intent because somebody alluded to earlier, is saying that this product is healthier for you going to turn some people off and there was a small 4 5 6 7 percentage that said they were unlikely to buy the product, but around 50 percent showed interest. 8 9 The next thing we did was look at this 10 by brand users, what affect does this have on users of these particular brands. And you can see here in 11 12 an increase in purchase intent and you see this is slightly higher than when we had non-, just a general population and weren't specifically looking at brand users. 13 14 15 But I would point out that you saw the 16 17 biggest increase in interest among those brands that 18 are our healthier products with Quaker and Tropicana 19 having the highest increase in purchase intent with Page 81

20 the logo.

 As far as consumer attitudes on what they think about the label, again, you can see

mid-30s, low 40s of people that say that it does help them identify healthier choices, that they feel like it increases the variety of healthier choices they can look at in the diet. The area where you see the least impact is motivation. This helped inform, but it didn't, it wasn't particularly motivational as far as causing them to really change habits and I think that's a continued challenge for all of us.

As far as source of awareness, the consumers learned about the logo primarily from seeing it on package in store. There was some who saw it at retail, in retail events that increased awareness, but by far the majority learned about it from the package and then the Internet was another place where there was some increase in knowledge about it.

In ask -- one of the questions were asked about how does this impact diet. One of the things that we were able to look at were people who were Smart Spot users who used that in their purchasing, how, how healthy was their shopper,

shopping basket. IRI has a tool that they track looking at number of service of fruits and vegetables, lean meat, low fat dairy and you'll see that 53 percent of Smart Spot shoppers had a healthy market basket where 47 percent of non-Smart Spot shoppers had a healthy basket. So a slight increase there in how healthy those overall market baskets were.

So, from our consumer attitudes in looking at the data that we've collected since the launch in 2004, I think our learning, again, keep it simple so that it's easy for them to understand. It has to be relevant to fit their situation. If you put a logo on a package but I'm not in that category, it's not going to drive me to that category, so it really does need to be relevant to them and it has to be credible.

To really inspire adoption and use, it has to help them overcome hurdles and we saw the logo being particularly used by moms because, again, pressed for time, it didn't drive them to purchase the product, but it was a shortcut for them to look

to say this product might be of interest to me. But it really does need to help them in the long run for it to be adopted.

And as far as the endorsement by a third party, as far as nutrition or health-related organization, our research is mixed on that as far as how much that helps with credibility or not. But we do know consumers react better to information that includes what to do rather than telling them what not to do. To keep it positive and with the message.

Now, looking at results in the marketplace, which was another question we were Page 82

FDA Hearing Day 1. txt asked to address, when we launched the Smart Spot 15 program in 2004, it made up 36 percent of our revenue for North America. By 2005 that was up to 16 40 percent and by 2006 it was up to 43 percent and it continues to increase this year.

When we launched the program on that 17 18 19 20 logo, it said over 100 smart choices from PepsiCo, we're now up to 300. So by having this criteria, 21 it's definitely driven product innovation to 22 0226 1 innovate and develop more products that meet the 2 cri teri a. Internally we have a goal that by 2010 we want to see 50 percent of the North American revenue coming from products that are Smart Spot 4 5 6 7 eligible, so definitely seeing the growth in higher -- in Smart Spot products. 8 As far as costs for implementation, this 9 There's technology costs in order is not trivial. 10 to drive that product innovation, whether it may be different oils that have a healthier profile, less 11 saturated fat, proprietary ingredients, increasing the fruits and vegetables in some of these products, 12 13 14 people investment. 15 The symbol cost, itself, our symbol is one of the simpler ones, it only has two colors in 16 it, but I will tell you the cost per package can vary anywhere from 5,000 to 30,000 to make the 17 18 change in packaging graphics. The larger the package, the simpler it is, the lower the cost. When you get a package that has a lot of colors on 19 20 21 22 it to begin with and you start increasing these, 0227 1 adding these symbols, it is a significant cost to industry. 3 4 5 There's also costs for consumer education and as a number of people have alluded to, if there's not an education component that goes 6 7 along with this, it just isn't going to have the impact that you need. 8 We've had -- the Website has been our 9 primary tool for consumer education and we update 10 that routinely so that we have consumers coming back In addition, we have a Smart Spot dance 11 program that encourages physical activity that's 12 sponsored by Smart Spot. We've had a pretty strong 13 health professional outreach, more to health 14 15 professionals than direct to consumers to have health professionals understand the program, what the criteria is and how products do or do not 17 qualify. And then we've had retail programs where 18 we've grouped Smart Spot eligible products together 19 20 at retail, again to try to drive awareness. 21 Overall, again, to be useful, it, it 22 just, our learnings would say needs to be simple. 0228 One of the questions that we keep asking ourselves is can you explain it to your child. Nutrition 1 standards need to include room for both good for you and better for you products.

For most consumers, you start with 5 small, manageable changes, so they need to have 6

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ways, it's critical to identify reduced products and

FDA Hearing Day 1.txt products that can help them with small changes. 9 The nutrition standards need to be based 10 on credible consensus science and anchored in nutrition authoritative statements. We tried to 11 avoid having a select group of experts come up with criteria, but basing it on FDA, National Academy of 12 13 14 Science consensus statements that evolve over time 15 so that it is updated as the science evolves. There 16 is a need for different criteria for different categories and keeping in mind that those profiles 17 18 change. The other thing that's very difficult is that we have a lot more guidance about diet than we 19 20 21 do about individual foods. Actually with FDA's 22 guidance on the term, healthy is one of the few 0229 statements that you can find that really address a food as opposed to a diet and when you start putting 3 a logo on a food product, it's hard to convey that 4 concept of balance and that indulgent products, 5 you'll have some in your diet, but it's a matter of 6 bal ance. And then finally, questions that weren't asked but that we asked ourselves internally, when, 8 what has the front of pack labeling done for 9 10 PepsiCo; and I would say it has created a set of 11 standards that we've used to innovate against -- for 12 products, as you can see with the increased number of products, it created an umbrella that we've used 13 14 in retail and it also created a tool for 15 communicating with consumers. And I think we probably did better with the first as far as increasing the number of 16 17 products because the standards are there and we 18 19 measure performance. 20 What would we have done differently? I think if we had it to do over again, we would have 21 22 sought to build an industry-wide coalition to create 0230 criteria and logo from the very beginning. PepsiCo is a supporting member of the Keystone initiative on 2 front of pack nutrition communication and we do 3 support the development of a common industry 5 6 7 criteria and icon. Thank you. (Appl ause) 8 BARBARA SCHNEEMAN: Great, thank you. Our next panelist will be Kathy Weimer Mills. Kathy. 9 10 from General Mills. KATHY WEIMER: Thank you very much for 11 12 inviting me to present today. I guess I better figure out how to run 13 There we go. I will be giving our 14 15 perspective around the use of nutrition symbols for 16 front of pack labeling. Oops. 17 Sorry. This side. Oh, okay. I need to 18 get it up more. 19 All right, just some background on s. We are the sixth largest food 20 General Mills. 21 company in the world, 12.4 billion in net sales and we market in more than 100 countries, but clearly 22 0231 we're based here in the U.S. and these, this is just

FDA Hearing Day 1.txt a sampling of many of the products that we have. ranges from shelf stable to frozen to refrigerated and people don't necessarily know our products by General Mills, you know them by the brands, typi cal I y.

Just what I'd like to cover today in the presentation, to address the questions that FDA has raised, I won't be able to address all the questions in the 15 minutes, but I'd like to just address what we've done from front of pack labeling initiatives, both symbols and criteria, and then what we've learned, go over and share some of the research that we've done and then also just some of the things that as we've learned what we would recommend be considered for a system as we moved forward.

We started out in 2004 with a program that we called the Goodness Corner where these icons that we put on the front of our package were used to communicate key nutrition facts. It was a fact-based system that was tied to FDA's labeling and claims regulations.

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So we are really initially -essentially taking the nutrition facts information and putting them on the front of the pack to highlight Key things. We use both calories along with positive and negative nutrients and in some cases food group combinations, and again, this was a very simple communication of the food's nutritional contribution to consumers.

We have used this with and in conjunction with nutrition and health claims and the symbols are pretty simple, straightforward and self-explanatory. We did some research using these symbols and what we found is that consumers do want labeling to have key nutrition facts that they can use to make purchase decisions in a quick fashion. They do like the idea of full disclosure of nutrients, both positive and negative, and they said that they liked to have the right amount of important information. And again, that varies I think among different consumers, but they do like having the percent daily value that we use here in the U.S.

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The idea of being endorsed by a credible third party, not a manufacturer brand was also something that they thought was a good idea and they thought that Government endorsement was important for credibility. And then, tangible, believable and easy to understand and I think we've heard that in many of the presentations today.

And actually, the top-rated format in this consumer test is the one that I'm showing here that includes the icons with the percent DV and that was not the program that we started out with, we only had the icons, not the percent DV associated when we first started this.

Then, also, our counterparts at Cereal Partners Worldwide, which is our cereal group in other parts of the world than the U.S., also did some research looking at the GDA system versus some of the other formats, so this is some research that

FDA Hearing Day 1.txt they did, but I want to raise it because it kind of 20 leads me to where we're headed. 21 The top-rated format and the research 22 done in Europe was this icon plus GDA approach. 0234 consumers found that it was trustworthy, that they felt they could understand the information and had relevant information for them to make their purchase choice and that was included in this research with 5 the traffic lights, the icons and the checkmarks. 6 7 And the feedback they got from consumers was that it just didn't provide them enough information for them 8 to make an educated choice. So, as we've evolved, we are moving toward a system that we are going to be calling nutrition highlights and this should start appearing 9 10 11 12 on packages in October, on our cereal packages in And what it is is very similar to the GDA 13 approach that had -- that we've been talking about 14 today with the thumbnail sketches. 15 The front panel, which is on the left side, we have the icons and then on the side panel 16 17 we will include some explanation for the consumer as 18 19 to how to use this and what the different icons 20 mean. We will also have some information on the back panel, but basically what we're doing based on 21 22 the research is to add the percent DV to the 0235 fact-based system on the cereal package to help 1 consumers quickly see the nutrition facts.

There will be six icons showing the 2 amount, the gram amount and also the daily value for calories, saturated fat, sodium, sugar, although sugar doesn't have a daily value currently, and then 4 5 6 7 two positive nutrients contributed by the product. 8 So again, the idea that we're emphasizing both 9 positives and negatives is an important aspect. 10 Again, I mentioned there will be side 11 and back panel communication to help consumers understand this and beginning in October you'll start seeing this on the shelf. We also have a 12 13 14 research plan to learn more. 15 We are, there's a joint project that General Mills and Kellogg is initiating this Fall 16 and I know Celeste will be covering what they are 17 doing on their packages. It's similar, there are a 18 couple of differences where we're using saturated fat and Kelloggs will be using total fat for the thumbnail and we're using the percent DV and I believe you're using the GDA terminology, but other 19 20 21 22 0236 1 than that, they're very similar and so we felt it was a unique opportunity to learn how the fact-based 2 3 4 system works in the cereal category. It's a large The cereal package is one of the most 5 read items in any home and we're looking to measure 6 7 consumer awareness and healthfulness of this fact-based system.
So, again, as we've worked through this

and we're a part of the Keystone dialogue as well and have had many discussions in that arena so far and I know they're going to continue, but one -some of the principles that we feel are very

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FDA Hearing Day 1. txt critical for any front of pack labeling is that it 13 align with existing regulatory framework, that it should be fact-based, truthful and objective and therefore grounded in science, that it should help 14 15 16 17 consumers make informed food choices and that it should involve the consumer in determining the 18 19 heal thful ness of the food. 20 And we feel that calories are a really 21 critical first step since obesity seems to be the 22 key issue that we're all trying to address. 0237 you think about calories and look at the science and Government recommendations, the dietary guidelines, for example, emphasize that Americans need to eat fewer calories, be more active, make wise good 1 2 5 6 7

choices and that for weight loss, calories count, not, it's not just about the proportion of fat, carbs and protein. And also in the FDA calories count report, it says that it's a scientific fact that weight control requires caloric balance and that consumption and expenditure of calories is the most important for maintenance of a healthy weight,

not the proportion of macro nutrients.

So we feel that calories are really an attainable first step and likely to have fairly

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wide-spread support. And again, nutrition isn't just about calories, so we feel like it's very important that the nutritional quality of the product be considered. And again, the idea of highlighting both positive and negative nutrients,

including those deemed critical. And again, we've talked about in some of the other presentations the dietary guidelines identified certain nutrients of

considerable concern that were lacking in the diet such as calcium, Potassium, fiber, Magnesium and Vitamin E and then also the idea that we should be limiting intakes of sat, trans fat and cholesterol, sodium and added sugar. And then it also, there's an opportunity to highlight some of the key food groups that we're also not getting enough of, such as fruits, vegetables, whole grains and low fat dai ry.

So if you think about a fact-based system, there, it's a quantitative and objective nutrition facts for simple communication and it can be applicable to all foods. Again, Government defined criteria are transparent and there's scientific grounding in those regulatory definitions. It's aligned with the dietary It enables consumers to make their qui del i nes. decision based to best meet their dietary needs. There's no need for consumers to understand individual manufacturers systems. These, this, this system can be applied to all products.

It assures regulatory compliance without

significant economic impact and it motivates ongoing nutrition improvement for products while maintaining taste and consumer appeal

And also, advances in nutrition science can be nimbly incorporated which results in a sustainable system so as the science evolves, we can Page 87

FDA Hearing Day 1.txt continue to evolve the system to make sure that 8 we're addressing those issues. For example, right now we don't have a specific criteria for trans fat, but partly because there's not a DV established, we have not gone down that path, but ultimately if that becomes part of it, I think that would be something 10 11 12 we'd have to be looking at very seriously.

And then there's no unintended 13 14 15 misunderstanding from an oversimplified system for 16 the consumer. There's, we have some concerns around 17 18 potential and intended consequences, if you focus on 19 a better for you system, a system where it's only carried on foods that meet criteria that consumers don't really understand or see. And I think one of the concerns is that there's an underlying 20 21 22 0240 assumption that selecting foods designated as more nutrition would, will stem obesity or that they are 3 better for you and I think that as was pointed out this morning, a person that might select a product with a good for you symbol that might be a low fat pizza or something but decides they're going to eat six slices versus picking the higher fat one slice, 5 7 8 I guess there is something to be thinking about regarding that. 10 And again, the, we feel like there's an 11 opportunity where, as far as better for you symbols may not enable consumers to understand the 12 13 importance of calories and nutrition when they're making their dietary choice. It doesn't rely on their judgment of a food's healthfulness and whether it meets their own dietary needs and what they're 14 15 16 looking for in a food product. And also the concern 17 18 around perpetuating a good versus bad food, there is 19 that potential. 20 And also there, I think there's some 21 opportunity to understand does the system make a 22 difference at point of purchase versus in home and I 0241 don't know that -- I know that we don't know a lot 2 about how our system is used in home, but I think that might be another area where we, where it would be valuable to get some more consumer research. 5 There's also incomplete information may 6 7 impact the consumer's understanding of the product nutrition attributes or the product in the context of the daily diet.
So, again, consumer research is definitely needed to identify the most appropriate 8 10 system and testing the concepts to determine the 11 understanding or the influence on behavior or 12 dietary change is really a critical step. 13 14 So from our standpoint, ideally the front panel labeling system should be fact-based, 15 truthful and objective and fit within the existing 16 17 labeling regulatory framework. Be applicable to all foods, be science based and adaptable as new science emerges and that, you know, again, the opportunity 18 19 to align with the dietary guidelines.

Address both calories and nutrients and 20 21

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with nutrients including both positive and negative

FDA Hearing Day 1.txt nutrients, have a realistic goal as to what a system can accomplish. And again, I think this is really important, that, you know, we, we need to provide 2 3 information to help consumers make appropriate food 5 choices that fits their needs, but I also think we have to keep in mind that if the system, itself, 6 7 probably isn't going to be able to reduce chronic 8 disease including obesity, it has to be a bigger 9 picture and part of a broader approach in trying to 10 address some of the chronic diseases. And again, involve the consumer as a decision-maker of the food's healthfulness and be 11 12 13 relatively easy, simple and understandable for consumers and obviously more research will 14 15 facilitate this objective. 16 Thank you very much. 17 (Appl ause) 18 BARBARA SCHNEEMAN: Thank you very much. 19 Our next presentation is from Celeste 20 Clark, the Kellogg Company. CELEŠŤE CLÁRKÍ Thank you, Barbara, and good afternoon. I am very pleased to be here on 21 22 0243 behalf of Kellogg Company to share with you our experiences on front of pack labeling and because so much has been said this morning about GDAs and because of the experience we have from other 5 6 7 markets, we've chosen to talk to you about our experience with GDAs and our plan to launch GDAs in the U.S. 8 So, I'll just begin. What I'm going to 9 cover really gets into how GDAs are being used and the consumer reported benefits of using GDAs. And 10 say consumer reported because we need to understand 11 that sometimes what consumers say and what they 12 actually do may be two different things. 13 14 with you the learnings that we have from some of the other markets that we've launched GDAs in and then 15 16 looking at the economic impact. So what are GDAs? As you've heard this morning, they are front of pack, easy-to-use symbols that share with consumers at-a-glance information 17 18 19 that they can quickly use to make an informed 20 21 consumer decision. 22 They actually provide nutrients, the GDA 0244 1 system includes those nutrients that consumers should consume more of and those that they should consume less of, and I'm going to come on to show you the label. You can, if you look at the right-hand corner of the slide, you can actually see, to the left those are the nutrients that 5 6 7 consumers should consume less of according to the 8 dietary guidelines, Anne Heins data, and other 9 consensus statement on nutrition and health. 10 And then to the right they are those nutrients that consumers should consume more of. In order for a product to declare those nutrients, they must be present at a 10 percent or above amount and 11 12 13 so those again are those nutrients that have been 14 highlighted as nutrients that consumers should have 15 more of. 16 17 In terms of easy to use, we also wanted Page 89

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a format that some have referred to as an executive summary of the side panel. The information that's used in the U.S. based on GDAs is really taken from the nutrition facts panel and we know that consumers have indicated through various pieces of research

that we've conducted that there are certain nutrients that they're looking to minimize or avoid in their diets and we felt similarly that we should also point out those nutrients that consumers should have more of in their diets.

And then based on our experience, we've launched GDAs in a number of markets. In addition to markets in Europe, we also have launched them in Mexico and Australia and then of course what we try to do is to take the learnings from those markets to expound or improve upon that in the U.S.

For example, when we first launched them in the UK, we had the horizontal format that someone referenced this morning. We changed that horizontal format to be the thumbnail format.

Okay, so what do consumers say? And this is just in summary, now I'm going to come on by market to tell you. But basically based on the research that we've done, in all the markets that we've launched GDAs in, consumers have indicated that they have critical information that is needed in order to make an informed choice. Now whether or

not that choice is translating into behavioral changes is another piece of information that we really, another piece of research that we really need to get at and uncover.

We also know that in the States, because we have the nutrition facts panel and daily value, that our use of GDAs basically in a very simplified manner provides easy access to information from the side of the panel, pulls it to the front of the box. And then of course what we're hoping to do is that once that information is on the front of the box, that consumers would be able to use that to develop their own individual, individualized diets.

So, here we are, and I've mentioned that in Europe Kellogg, along with a number of other companies, are using GDAs and so we've talked about the nutrients, the fat, sugar and sodium and in some countries it's called salt instead of sugar, are shown on pack and along with a number of other companies in Europe are using the similar format as well.

In North America we're going to be

rolling it out, in Canada next month, as well, as in the U.S. next month, as well. Mexico, I mentioned we're already on shelf in Mexico as well as in Australia and with plans for South Korea, as well.

Now, it's really important, we believe, that when you're using a front of pack labeling schematic that you design a very extensive educational campaign. It needs to be a very integrated approach so that there is information on the pack that explains to a consumer how to put the information in perspective relative to the total

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     daily diet.
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                    So we have information that will appear
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      on the side of the pack as well as on the back of
      the pack. We also have established a Website where
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      consumers can go to to get more detailed information on guideline daily amounts as well as an 800 number
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      for those who do not have access to a computer, they
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      would be able to call us on the 800 number and get
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      information, as well. And then in all of the
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      markets that we've launched in thus far, we also
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      have a television advertising campaign and we
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      believe that that is an important education
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      component that will help inform the public on how to
      use GDAs.
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                    And I brought with me a clip and I'd
     just like to share that with you.
                    Can we go back, yeah.
                                                Okay. Thank you.
                     (Short video playing.
 8
                    Every day we use signs to inform us and
      help us make decisions at a glance. So why are the signs so complicated when it comes to choosing the
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                                                  So why are the
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     food we eat. Kelloggs cereals now include guideline daily amounts which shows at a glance what's in a
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      serving of Kelloggs cereal and the percentage it
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      contributes to your daily diet.
                                              Nutrition at a
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      glance, it's a good sign, from Kelloggs.)
15
16
      No sound. This is obviously the execution from Mexico, sorry about the sound.
17
18
                     (Another video playing, no sound)
19
                    And the last one's from Australia.
                    (Short video playing. With the new what's inside guide on many
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      of your favorite foods, you can tell exactly how
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      much of your guideline daily amounts are inside
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3
      here, here and here. So you can decide what to put
      inside here, here and here. The new what's inside
     guide, now on many of your favorite foods in store.)

Okay, so that gives you an idea of the
commercials that will accompany or will be a part of
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      the educational campaign in the markets that we've
 8
      already launched as well as the U.S. version that I
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      showed to you at the beginning.
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                    Now, in terms of consumer learnings,
     what have we learned, and I don't go into detail due to the time constraints, but I will tell you that,
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      again, on a self-reported and an aided basis, what
     consumers have told us is that they're, indeed, much aware of GDAs being on pack and in the markets where we've launched this, I should clarify that we've
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      used the monochrome color for GDAs, that they find
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      them easy to understand and points out the
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      information that they need to help make decisions
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      for an informed choice.
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                    What we have not done is to take that
      another step to say, well, did it really influence
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      you, your purchase decision. I know Tesco has some
      data, but the research that we're planning that I'll
      come on to talk about we're hoping will go that
      extra step to be able to do that.
                    For those consumers who actually had the
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FDA Hearing Day 1.txt concepts in front of them and were able to look at the panels, they said that they thought they would be able to use, and this is using some of their verbiage, from again what they reported with having not being in store but just from having the packages in front of them, that they thought that the information would be useful in helping to control portion sizes, make them more cognizant of the portion sizes that they were eating, compare within categories and also it would be useful to compare across categories when presented on a per serving basi s.

And again, I emphasize on a per serving basis because in the States we're doing it on a per serving basis and the other markets we did per serving, we also had to factor in the per 100 grams according to the regulations, as well.

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And then as I mentioned, Tesco had some data that showed that, indeed, when consumers are presented information in a very simplistic format, that they are able to choose more often those foods that they should include in their diet and to minimize those that they should avoid.

Australia, very similar.

Now in the U.S., and Kathy alluded to us, what we're hoping to do in the U.S. is to do some pre and post data, again some data on consumers so that we can inform the literature. Our hope is not to just use this on a proprietary basis which

typically we do at our prospective companies.

What we're hoping to do is to design a study that will get at not only awareness but also usage and purchase intent. And once we do that on a pre-basis, before we implement GDAs in market and then we'll go back six to nine months later and assess the consumers experience once those products have been in market to really get a feel for what they thought at the pretest was actually what they found after having some use with them.

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In addition to that, we have the ability to use panel data, or market basket data from RI to get a sense did they purchase more of those products that had the call-out of a GDA on the front panel versus what they would have done had it not been there.

So when we gathered this literature, gathered this information, our intent is to make it available on a public, for public use so that we can have better insights as to whether or not GDAs is really the answer or is there some other tool that we should use in order to ultimately inform the consumer about what is the nutrient content of that product and how can that content be used to help them make informed choices.

So, that's our hope going forward and I'm sure you'll hear more about that.
Thanks a lot.

(Appl ause)

BARBARA SCHNEEMAN: And our last presentation from industry is Douglas Balentine from Uni I ever.

DOUGLAS BALENTINE: Good afternoon.
Unilever appreciates this opportunity to present our vision on how the front of food packages can be enhanced to assist U.S. consumers in making healthier dietary choices.

I'd like to discuss the experience we have in the United States and internationally with developing and implementing an on pack front of pack logo system. We'd like to explain why we believe as a company that simple front of pack logo systems represent an -- that represent an analysis of nutrition information can provide a lock step change that benefits the consumer in the marketplace.

In the course of this presentation we'll

In the course of this presentation we'll also address a number of the questions posed by FDA in their notice of hearing.

We believe that a front of pack symbol program should be based on sound science and help meet the goals of dietary guidelines. We believe that a simple system is the best system that synthesizes for the consumer all of the nutritional information they need about a product in a simple

graphic message that is a simple tick or checkmark that is a positive message.

We also believe that this system does not indicate bad foods or unhealthy foods that should be avoided with a red mark or a stop sign.

We believe that all these programs should be endorsed by a credible third party or parties and we believe that it should be supported by a broad-based consumer education campaign.

We believe that Unilever's current U.S. logo program has a lot of the elements that we want in this program. We fully endorse a process by which we can develop a voluntary, newly-designed industry-wide system that is developed to replace the various logo systems currently in the marketplace. We believe this will benefit the consumer by helping to maximize the potential of common education in advertising and promotion around logos with the consumer that may make a difference in public health.

In the United States last year we launched the Eat Smart, Drink Smart logo program.

It's a single tick mark logo program with a positive message called Eat Smart or Drink Smart and it's endorsed by saying that it's based on dietary guidelines.

Like the Kraft system, we have an explanatory text, in that explanatory text that accompanies the logo, we inform consumers positive health messages about following dietary guidelines.

health messages about following dietary guidelines.

It is here that we also communicate with positive components of a food such as that it contains a serving of vegetables or provides meaningful amounts of certain nutrients. It's also here that we direct them to the nutrition facts panel because it's important that we direct them there to deal with more-detailed information that

can be found on the nutrition facts panel.

FDA Hearing Day 1.txt And we also direct them to our Website 17 18 where they can get educational materials about healthy eating patterns and find recipes that accompany the Eat Smart, Drink Smart program.

We launched this program in September of 2006. You'll find the Eat Smart, Drink Smart Logos 19 20 21 22 0256 1 on certain Ragu pasta sauces, Slim Fast meal replacements, Promise spreads, Skippy peanut butter, 3 4 Lipton Tea, Hellmann's and Best Foods mayonnaise and Bertoli Olive Oil. 5 By the end of this year, we'll have 6 7 implemented the logo on over one-third of Unilever's food portfolio in the U.S. based on NPS, excluding 8 ice creams. 9 The basis and the criteria for the program were founded in Unilever's international 10 This is an internal 11 nutrition enhancement program. 12 program where we've evaluated over 16,000 products around the world for their nutritional content. 13 14 We've used this as a basis for innovating and 15 re-formulating our product portfolio and it's led to removal of significant levels of trans fats, saturated fat, sodium and added sugars in our product globally. 16 17 18 19 Products bearing the Eat Smart, Drink 20 Smart logo in the United States must meet strict 21 criteria for saturated fat, trans fat, sodium, These criteria 22 sugar/added sugars and cholesterol. 0257 are aligned with U.S. and international dietary 2 3 gui del i nes. The symbol is designed to inform 4 5 6 7 consumers that the program's criteria are based on U.S. dietary guidelines and it is currently implemented, the details of this program will be submitted in writing as part of this hearing.

The U.S. Eat Smart, Drink Smart program is also part of Unilever's international choices 8 9 program which is now operating in over 22 countries around the world. These are some examples how the same simple logo graphic can be modified to 10 11 12 13 different marketplaces, the commonality is in each 14 logo there is a positive health message such as Eat Smart, Drink Smart, I choose wisely, et cetera, and 15 each logo has, also have the endorsement based on international dietary guidelines or based on a local guidelines that are relevant.

Unilever is also actively participating in the International Choices program which was 16 17 18 19 20 launched in Paris at the Federation of Nutrition 21 Sciences meeting this July. You heard a little bit 22 0258 about that program this morning. The International 2 3 Choices Foundation aims to help consumers select heal thier foods and beverages through the use of an industry-wide system. The governance of the International Choices Foundation resides at national 4 5 6 7 levels within countries where it's operating.

And most importantly, the Foundation is 8 supported by an independent, scientific advisory Board that constantly reviews and updates the 10 eligibility criteria for the program so that it Page 94

FDA Hearing Day 1.txt stays consistent with changes in nutrition science 12 and food technology. In the Netherlands, as you heard this 13 morning, Unilever was part of helping to establishing and participating in the Dutch choices industry-wide Government system, the IKB system which was discussed earlier today. 14 15 16 17 Globally Unilever entails strict 18 criteria to qualify for its products. It must meet criteria for all of the benchmarks, not independent 19 20 The qualifying criteria are based on 21 22 international dietary guidelines in science and 0259 aligned with local regulations. This is consistent 2 with the U.S. approach. 3 The simple symbol designs to inform consumers that the program criteria are based on 5 6 7 either international dietary guidelines, again, this is consistent with our U.S. approach. Unilever supports the development of the IKB industry-wide system that is now working in the Netherlands. The IKB system was derived from the original Unilever Choices program and is based on a 8 ŏ 10 set of criteria which encompasses benchmarks for 11 12 trans fats, saturated fat, sugar/added sugar and sodium, similar to the Unilever system globally. 13 14 However, this system has moved forward 15 and in addition to looking at just nutrients to be limited, it also now looks at positive nutrients 16 for -- that need to be added to the diet and it's 17 18 included in energy element. We understand that you 19 should receive more details on this IKB system in 20 writing from the Dutch authority 21 How did we go about developing these 22 logo programs? We began by the assessment of our 0260 1 foods portfolio, as I said, through the nutrition enhancement process. We then developed our own 2 3 4 5 global system and in the U.S. the Eat Smart, Drink Smart system. Our thinking in terms of the relevant nutritional criteria that the system should be based 6 on that define the logo continues to evolve, particularly as we participate and have learned 7 8 through the discussions we've had in developing the ŏ industry-wide systems at IKB and the International 10 Choices Foundation criteria that is being explained 11 around the world. We are now interested in applying this learning to the U.S. situation and we are doing this around the world as part of the International 12 13 14 15 Choi ces Foundation. Unilever's primary goal as a company is 16 17 to make it easier for all consumers to make 18 healthier choices, including consumers that don't 19 have the time, the inclination or the knowledge to 20 evaluate nutritional information that is provided on many nutrition facts panels around the world.
We believe that the solution is a simple 21 22 0261 front of pack symbol. We believe that this symbol should synthesize and not repeat existing nutritional data. It should be positive and it should convey a positive message, an okay message Page 95

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that this is a good choice -- good food to chose and does not signal that any food should not be included in the diet, for example a red or a stop light signal.

The label appears or it doesn't appear on a product based on meeting the eligibility criteria. The symbol should not appear on all food products but only the ones that are meeting criteria. It is based on avoiding nutrients of concern and avoiding the -- encouraging positive nutrients and positive food groups. It must be endorsed by credible third party or parties. It is supported by a comprehensive multi-platform educational campaign to help consumers understand what the symbol means, how to use it and to make better health choices.

Such a symbol would build consumer confidence in the message and ultimately help

enhance the health of the U.S. population.

Although Unilever has invested heavily in its own symbol programs, we believe there is an opportunity to develop a uniform industry-wide program that represents the collective thinking and experiences of all of us together.

We are currently participating as the other companies in the Keystone conference program to work towards developing a voluntary industry uniform symbol program based on the expectation that this program can reach some serious work by the years end.

As mentioned earlier, a successful industry-wide program is already in place in the Netherlands. Unilever's and others have helped create this program and has broad acceptance by this program in the industry and is it widely used among retailers.

The sales of the logo program based on this year's experience in the U.S. is that we've increased 10 percent in Q 1 and Q 2 in products containing the logo in margarine, soups and

mayonnaise. So, like the other companies, we've seen significant up ticks in products that, that bear the logo versus those that do not bear the logo.

We've also begun discussions in Canada that we also will hope will lead to a uniform front of pack logo system.

We also believe that placing calories on front of pack near the logo may be a benefit and we're willing to consider that option if it will help lead us toward a uniform industry-wide logo system in the United States.

Like many of the other companies you've heard from, we have invested in consumer research. We know that many consumers spend little time reading label information in any kind in the grocery store. Our data says about five seconds looking at packages. Many consumers do not have the knowledge they need to analyze nutrition information and consumer research is showing that it's confusing with existing nutrition information.

FDA Hearing Day 1.txt As mentioned before, the sales data in the United States and in the Netherlands indicates that consumers are responding to simple tick logo systems. We have conducted a number of research 6 7 projects like the other companies. We found in the U.S. based on quantitative research that putting a tick mark on a healthier choice product significantly increases the health perception of those products. In Europe, quantitative research indicates that a simple front of pack logo system is as effective as more elaborate systems and is more useful to less educated consumers. It's also quicker to evaluate.

In the U.S. and European research, we have also found that having some credible endorsement by a Government authority or saying that it's based on U.S. dietary guidelines or international dietary guidelines add credibility to the logo.

It is our view that a qualifying criteria for an industry-wide logo system should be based on broad sciences consensus about nutrients

that should be reduced in the diet and nutrients or food groups that should be encouraged in the diet. It should be designed to both support a symbol program for consumers and encourage manufacturers to formulate healthier foods and to innovate.

I'd like to spend a few minutes just sharing with you how through the Netherlands process we've learned how to develop criteria for a logo system.

Step one was to set generic benchmarks for nutrients of concern, that's trans fat, saturated fat, sodium, sugar/added sugar and cholesterol. These benchmarks should cover all foods and drinks and they should be aligned with dietary guidelines whether they are U.S. or international.

An example of how this is done is, for example, if you look at the -- right there's the nutrients of concern. We have dietary guidelines that have been set either within the U.S. or some numbers that have been set internationally. There's been a slight adjustment because not all of foods

that you eat during a day contain each of those negative nutrients to set a calorie-based set of generic benchmarks.

So, for example, just to name one, saturated fat. For a product to qualify, it should contain no more than 13 percent of energy as saturated fat. And in our system to qualify for a logo system you must meet those benchmarks for each of those logos, not just one of them.

of those logos, not just one of them.

Step two in this system is to set
benchmarks for categories because we do believe that
you need to allow differences for categories. This
is the recognition that different food categories
provide certain nutrients and are important to the
diet in different ways. It also is a recognition

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that here is where you need to add considerations
for energy or calories.

In this system the foods have been
broken into two basic groups called basic foods and
non-basic foods. Based on their role in the diet,
they're evaluated separately for different criteria.
So these are examples of the basic food

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groups, which are fruits and vegetables, breads, grain, pastas, et cetera, and non-basic foods.

And it is in this place where dietary fiber, energy and other positive nutrients are considered as additional benchmarks to qualify for a logo.

The third step in the system, and you heard a little bit about this this morning, is to allow exceptions to some of the category specific or the generic benchmarks. If a food group is an important source of nutrition in the diet, and very few of those products in the marketplace can actually bear a logo and the rule of thumb is for a basic food, the target should be that when appropriate, at least 20 percent of foods in the marketplace should be able to carry a logo and for non-basic food 10 percents of products should be able to carry a logo.

So this is just an example of how this

So this is just an example of how this might look for a few basic foods. For a main dish product, you must meet the criteria for each of the nutrients to be limited. Saturated fat, trans fat,

an adjustment was made here for sodium and also there's the inclusion that it must contain fiber, in addition 150 grams, which is about one-third of the daily requirement of vegetables per portion and they've set an energy limit.

Fruit juices, again, benchmarks for nutrients to limit. They've also said no added sugar, just one minute, and a requirement for dietary fiber.

For non-basic foods you see a similar set of criteria have been established where there's calorie limits, sodium limits and added sugar limits. All other foods must simply meet the generic benchmarks.

The cost of nutrition symbols from Unilever's point of view are part of product development. The cost of educating consumers for us are part of promotional costs. Unilever has not increased the costs as a result of the program. Unilever products that bear the symbols do not differ in costs from similar products in our categories and we anticipate that once a uniform

program is developed and voluntary for industry, costs would be minimal because companies have already compiled the data and are already updating their packaging on a regular basis.

In conclusion, we believe that a simple front of pack system that synthesizes nutrition information for the consumer could represent a meaningful step forward and make a significant contribution to public health. This symbol should

FDA Hearing Day 1.txt 10 be based on sound science and dietary guidelines, 11 convey a positive message, be endorsed by credible third parties and be supported by a broad-based 12 13 education program. 14 Such a program should be voluntary rather than mandated by regulation because a voluntary program would minimize cost to the 15 16 17 Government, promote flexibility in rapidly modifying the criteria as science and food technology emerges 18 19 and facilitate providing uniform symbols to consumer 20 as quickly as possible. Thank you very much.
BARBARA SCHNEEMAN: All right. Thank 21 22 0270 you. And now we've invited Linda Myers from the Institute of Medicine, National Academy of 4 5 Sciences to make some discussant comments. LINDA MYERS: Thank you, I'm really 6 pleased to have been asked to make a few comments. 7 As you noted I'm, as it's noted in the program, I'm 8 from the Institute of Medicine. The Institute of 9 Medicine was actually established in 1970 under the charter of the National Academy of Sciences to 10 provi de independent, objective, evidence-based 11 advice to policy-makers, health professionals, the 12 13 private sector and the public. And we, I think as you know, we achieve our mission through a variety of mechanisms, 14 15 including ad hoc expert committees made up of 16 17 experts who serve without remuneration and who 18 prepare consensus reports. As many of you know, the Institute of Medicine develops the dietary reference intakes and 19 20 we are pleased that they, these numbers have been 21 22 useful in developing assorted schemes. 0271 1 Further, over the past three years, IOM, the Institute of Medicine, has issued several reports that have included considerations related to 4 5 labeling, usually in the context of obesity prevention in children. 6 7 I'm just going to mention a couple briefly because they pertain to the discussion 8 today. The 2005 report preventing childhood obesity, health in the balance, found that childhood obesity is a serious national health problem 9 10 11 requiring urgent action and that it required individual efforts and societal changes and multiple stakeholders needed to be involved. 12 13 14 It then made a variety of recommendations to different sectors and in 15 particular, called on industry to make obesity 16 17 prevention in children and youth a priority by 18 developing and promoting products, opportunities and information that will encourage healthy eating 19 20 behaviors and regular physical activity. And this 21 is clearly happening. 22 With regard to labeling, it recommended 0272 1 that nutrition labeling should be clear and useful so that parents and youth can make informed product comparisons and decisions to achieve and maintain Page 99

FDA Hearing Day 1.txt energy balance. One of the implementation actions was consumer research to maximize use of nutrition label and other food guidance systems and these steps have also been taken clearly to achieve this.

The 2006 report food marketing to children and youth, threat or opportunity, called on food and beverage companies to use their creativity, resources and full range of marketing practices to promote and support more healthful diets and to implement this recommendation, the report called on companies to work with Government, scientific, public health and consumer groups to develop and implement labels and advertising for an empirically validated industry-wide rating system and graphic representation that is appealing to children and youth. It's clear from the discussion today that there's support for this and I know that there are some discussions in progress with the Keystone 0273 di al ogue. That report also called for some development of some mechanism for sharing proprietary data. Then the last report, the 2007 report on progress in preventing childhood obesity, how do we measure up, noted, as we've heard today, progress by the food industry in a number of areas and called for evaluation of industry efforts to promote healthier lifestyles and re-emphasized the need for development of a mechanism for sharing proprietary data as part of fostering information sharing of research and evaluation findings. So, clearly there has been a lot of, a lot of progress and we're pleased that it, it follows along the recommendations that our expert committees have made. I think we all agree and these reports agree that there is more work to be done. And as I look back on the recommendations, and there were more than three in each report, as I look back on the recommendations, 0274 the ones that still jump out that need further work are how can -- relate to how can the tremendous work and lessons learned thus far be harnessed and best accelerated to achieve the industry-wide validated rating system and graphic representation that is appealing and that does benefit public health; and related to that, how can we achieve development of a mechanism for sharing proprietary data to enable broader evaluation of actions. Thanks. BARBARA SCHNEEMAN: So we will now have the opportunity to address questions from the panel to the panel of industry representatives here. Can I ask a question, first?
MICHAEL LANDA: As a panel member, sure.
BARBARA SCHNEEMAN: Actually what I'm hoping, I know all of you spoke to different educational efforts that you have been using and I think the Web was cited by all of you as a tool that you've used in educational efforts.

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FDA Hearing Day 1.txt I would like to just have your own 22 perspective very quickly, what do you regard as 0275 perhaps the most effective way to reach out to consumers to, for you to feel that they do, in fact, understand how to use the programs that you've put 4 together? 5 RICHARD BLACK: I can actually answer 6 7 that perspective -- that question, not necessarily from Kraft's perspective, but certainly from my own 8 and that's outreach to young children in schools, educational programs in schools. I don't think we're going to be able to educate adults to the same 9 10 11 extent we can educate kids. CELESTE CLARK: I'd like to just add 12 13 that the primary purchaser is an adult and so I 14 think that messages where you can help influence the 15 adult of the packaging and of course advertising 16 would be effective means as well. KATHY WEIMER: I would also agree that 17 18 on package, since it is at point of purchase when they are in the store trying to make that decision is probably the most, the biggest priority followed by I think clearly advertising to raise awareness 19 20 21 and then the opportunity to expand the message 22 0276 through the Websites. 2 3 DOUGLAS BALENTINE: As the Unilever Choices in the international system launched in the 4 Netherlands. It was really a multi-faceted system. There was TV advertising, there was print ads, there 5 was radio ads and there was signage in retail marketplaces that consumers really got them from all 6 7 the different touch points that you have. 8 9 think that that's what we're learning is key, is to 10 make it visible in all places, particularly where 11 they shop and where they see signage on a regular 12 basi s. 13 MICHAEL LANDA: Camille Brewer has a questi on. 14 CAMILLE BREWER: 15 I have a question of clarification for Dr. Black. You mentioned that you 16 17 consider saturated fat and trans fat together. In your drop-down logo example, the example showed 18 19 3 grams of saturated fat. 20 What would the consumer assume about trans in that example? 21 22 RICHARD BLACK: I'm sorry, I should be 0277 clear, when I said we consider sat and trans together, that's for our criteria within a particular, for a particular product. So that if you had a certain amount of sat plus trans, you want 4 5 6 7 to get the trans down in the formulation, you could not exceed that number of sat plus trans, if you're just trans -- or sat by itself. From the consumer's point of view, in the drop-down lists we'll still call them out separately because that's what's in the nutrition 8 9 10 facts panel. But for our own, what we're trying to 11 do is ensure that product developers don't get 12 13 around the trans fat issue by simply adding 14 additional saturated fats and so you have to meet Page 101

FDA Hearing Day 1.txt 15 the guide -- they both count equally in our sense 16 that, from our perspective. The other part of that, as Kathy indicated, there's no DB or hard number for trans fats so rather than say it's 10 percent for sat fats, oh, it's 12 -- it's 2 percent for trans or 1 percent for trans, therefore we've got 11 percent 17 18 19 20 21 to play with now. 22 0278 No, we just said 10 percent, this is the 2 3 sat number and trans are included in there. don't get to bump it up any further than that.
MICHAEL LANDA: Barbara Schneeman has a 5 questi on. 6 BARBARA SCHNEEMAN: There was a comment 7 made during the discussion about the, it is interesting that we have two basic systems, one is a 8 9 better for you type system and the other is the GDA and I think, Nancy, you may have made a comment about the better for you symbol keeping people 10 11 within the category and then choosing within the category and I'm just wondering about that in terms of thinking about the overall healthful diet 12 13 14 15 choi ces. 16 Is there any way that the better for you 17 symbol also encourages consumers to think more generally about their total diet and how that food 18 19 then fits into their total diet choices and 20 healthful diet choices? 21 NANCY GREEN: I think that's, I think 22 that's a challenge with either one of these systems, 0279 is to kind of relate back to total diet for 2 consumers. What we found that this was used primarily in store, so I'm standing in front of a 5 retail set of X products and I'm trying to make a 6 health -- the healthier choice within that category, so that's what this was quickly aimed at and then consumers could pick up the package, look at the fact, nutrition fact panel to get more information, see the statement on the back about why this 8 9 10 qualified. But we felt it was important to say this 11 12 is looking within category so that we were not, that we were being transparent and not trying to mislead 13 14 and say this is, you know, the best beverage you 15 could consume. DOUGLAS BALENTINE: 16 One of the experiences on that question from the International 17 Choices Foundation within the Netherlands was that 18 actually when it went across industry, you now had logos in all categories in the grocery store and 19 20 when they modeled the typical Dutch diet on a daily 21 22 basis, if people simply switched from choosing the 0280 same products without logo to the same products with 1 a logo and you looked at the impact that that would have on their diet pattern, you found that their calories and most of their intake of nutrients to 4

limit fell at or below dietary guidelines.
So it would have that impact of actually moving people to be aligned with dietary guidelining if you just model it on the diet basis.

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FDA Hearing Day 1.txt CELESTE CLARK: I was just going to add 10 that in, I think that in a fact-based approach, on a per serving basis, it does to some extent allow 11 consumers to compare across categories and I think it's important because consumers don't just eat within one category. The way they fashion a diet is across multiple categories. So I do think that's an 12 13 14 15 16 important consideration. Not sure how best to get at that, but I 17 think that whatever system we look at should allow those comparisons to take place. 18 19 20 MI CHAEL LANDA: Felicia Billingslea has 21 a question. FELICIA BILLINGSLEA: Yes, my question 22 0281 is primarily directed at I think Kelloggs and General Milis and I know that, you know, we do have information that U.S. consumers have some difficulty in understanding and applying daily values and what that term means. And in looking at the GDA 5 6 7 approach, it seems like that's introducing another term for U.S. consumers. 8 $\,$ Has there been any consideration of how they can align the two, if they understand that a 9 GDA, or what its relationship may be to a daily 10 value, how they take that information and then 11 12 consider what's on a nutrition facts panel? KATHY WEIMER: At this stage, General Mills is using DV here in the U.S., so we will be 13 14 applying, the percentages will reflect daily value and we'll be calling that out on the package.

And what I didn't mention when I talked about our consumer, our U.S. consumer research is we looked at different icon-based programs, those with 15 16 17 18 19 20 and without DV and it was found that the DV did, as 21 long as they understood what that meant with some 22 information, then that was proved to be very useful 0282 to them. 1 CELESTE CLARK: In the other markets outside of the U.S. where we have used guideline daily amounts, our research shows that consumers 5 have an understanding of guideline daily amounts in 6 7 the U.S. We are using GDAs pretty synonymously 8 with daily value. However, when we do the research in a few weeks, one of the things that we want to 9 get at is whether or not there is any confusion created by adding the concept of daily value -- of GDAs versus daily value, so we'll be able to get a 10 11 12 13 read on that. 14 MI CHAEL LANDA: Any other questions from members of the panel? Jordan Lin.

JORDAN LIN: Yes, I have a question 15 16 regarding the claims versus the symbol impact on 17 18 sal es. 19 I mean we have noticed that there is 20 some products in the market now which not only have 21 the symbol but also some content claims, say like low fat or other similar kind of claim. 22 0283 Then has there been any research done in terms of how the -- what are the marginal impacts of

FDA Hearing Day 1. txt adding the symbol to the product if it already has a 4 claim on the product package? 5 NANCY GREEN: l can answer from a 6 PepsiCo perspective, all of the products that had Smart Spot symbol, a number of those products already had nutrient content claim, either for 8 positive nutrients like X -- good source of calcium 9 10 or, you know, low in saturated fat, so those 11 nutrient contents claims were already on package. 12 They stayed on package when we added the logo, the logo was added as yet another tool to try to aid the 13 consumer, but certainly not to replace anything as far as nutrient content claims. 14 15 16 And so it would be hard to differentiate, you know, the effect because they were already there. 17 18 19 KATHY WEIMER: From General Mills' 20 standpoint, again, we also had claims prior to doing the icon programs or the, now the nutrition 21 highlights and I mentioned that we carry both on the 22 0284 package, but, you know, the research that we've focused on so far has really been to understand, you know, the icon system and we haven't teased out that 3 aspect of do the claims, how do they work together, but they certainly were in existence prior to the 5 6 i cons. 7 MICHAEL LANDA: Any other questions from 8 the panel? 9 Rob Post. ROBERT POST: Based on Nancy's last 10 comment, I have a question about the use of nutrient content claims, for example, and logos or symbols and is there a tendency or what is your experience 11 12 13 in testing sort of the shorthand terms used 14 15 sometimes to abbreviate nutrient content claims like using two letters to reflect low fat, is that part of these systems, is that intended to be part of a 16 17 18 system that you're aware of, has that been tested? 19 And it isn't necessarily Nancy, it could 20 be anybody. 21 KATHY WEIMER: Originally the first set 22 of icons that we used, and I'm Kathy, from General 0285 Mills, but the first set of icons that we used were, 2 3 did have like low fat written out inside them and then usually some pictorial symbol to try to help consumers grasp that. So I don't believe that we used just like LF or something like that in any of our, in any of our little icons. 4 5 6 7 NANCY GREEN: Low fat would be part of 8 the criteria that we would have but that would be 9 trans -- the consumer wouldn't see that when they 10 saw the logo. So the product could carry the logo 11 if part of the reason it was qualifying was because 12 it was low fat, that might be on the statement in 13 the back why we say why it is Smart Spot but we would still have probably a nutrient content claim on front of label. 14 15 16 I think consumers are used to those, we certainly would not want to walk away from that 17 18 because I think they're very impactful from our 19 research.

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                        RI CHARD BLACK:
                                              I would just add from
       Kraft's perspective, we have no desire to see a
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       short form in letters like that, LF.
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                        If icons could be developed, and I saw
       the glass of milk, for example, for calcium, I think that might be appropriate, but I've seen some really startling research on how different people interpret
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       the same icon and you may think it's obvious, but
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       half the other people in the room may not and so
       that's problematic, as well.

ROBERT POST: Okay, thank you.
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                        MICHAEL LANDA: We have a question from
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       Barbara Schneeman.
                        BARBARA SCHNEEMAN:
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                                                     A comment was made
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       that, about some reference to how, there might be a
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       difference in how consumers use these symbols at the
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       point of purchase versus how they might use them in
       the home and I'm wondering if you all could comment on that, do you perceive there would be a difference
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       and what do you think might be the difference?

Do you have any consumer data on how they would use that in those two different ways?

NANCY GREEN: We have some ethnographic
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       research that I did not present today just given
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       limitation on time and not wanting to go through,
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       explaining about that, but what we learned from
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       consumers when we went shopping with them as well as
       when we were at home with them when they were in
       when you see it there, it kind of led to my earlier comment. When they're in the store, they tend to be comparing to things in the shelf close to them, so
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       that it is within category.
                        When they get home, then is when they
       may be opening their pantry and looking at what they have in the pantry and they may be then comparing it against something that would not necessarily have
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       been located close to each other in the market.

Consumers told us that they use the logo if, if they were interested in the category, they
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       would turn and look at the nutrition fact panel,
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       they were label readers. If they were not label
       readers, it didn't tend to cause them to read a
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                        So, there wasn't a change in behavior
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       there.
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                        KATHY WEIMER: We, I brought that point
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       up but we have not done that type of research yet
       and I think that would be very interesting to understand the differences. I know EUFIC did some research, some preliminary kind of ethnographic
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       research looking at uses of the label and there was
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       a little bit of a difference between what they did
       in store versus at home. So I think, you know, given that, it's very possible that it could be a similar situation and so that's why I wanted to
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       raise that.
                        MICHAEL LANDA: I just have one
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       questi on.
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                        The research you've just described, did
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14
       it include, follow through to include actual use in
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       the home, consumption?
      NANCY GREEN: It did. We actually spent time, it was 40 different consumers and we spent like an afternoon and evening with them, so it did
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       follow them through.
                        MICHAEL LANDA: All right. Thank you. If that concludes this panel, it's now
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       20 to 4, if I can read that clock correctly.
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       don't we resume at 5 minutes after 4.
                                                              Thank you.
                        (Recessed 3: 39 p.m.)
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                   AFTERNOON SECOND SESSION SPEAKERS:
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       Barbar Schneeman, Moderator
       Caren Epstein
      Paulette Thompson
Elizabeth Pivonka
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       Rose Marie Robertson
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      (Reconvened 4:05 p.m.)
BARBARA SCHNEEMAN: Good afternoon.
We're about ready to start our last session for the day to be followed by a reception, so you have to
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       keep that in mind, panel.
                        We know that today has been a long day
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       and we really appreciate everyone sticking with us
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FDA Hearing Day 1.txt getting through these presentations which have been 9 excellent. 10 So in the panel this afternoon, we will continue the U.S. experience. In this particular 11 12 panel we have both retailers as well as some 13 non-profit organization to talk about their 14 experience with the use of symbols. 15 And I'll just read through the panel names, we have Hannaford Brothers Company, Caren 16 Epstein, Giant Foods, Paulette Thompson, Produce for 17 Better Health Foundation, Elizabeth Pivonka and the 18 19 American Heart Association, Rose Marie Robertson. 20 So we'll start with Caren Epstein, the Hannaford Brothers Company.

CAREN EPSTEIN: Let me begin with a 21 22 0292 1 brief disclaimer, I don't typically testify so I don't have a Power Point presentation and I got up 3 at 3:30 this morning to catch a flight to get here, 4 so if I'm slightly less coherent and less polished 5 than some of the previous speakers, I apologize.
With that as a lead-in, let me begin by 6 saying that I'm here today to talk about Guiding Stars. Guiding Stars is Hannaford's store-wide 8 9 nutrition navigation system. 10 Just a little bit of background about 11 Hannaford, we are a 160 supermarket and pharmacy 12 chain located in the northeast United States with 13 stores in Maine, New Hampshire, Vermont, 14 Massachusetts and New York. In 2008, Hannaford is going to be 15 celebrating its 125th anniversary and one of the reasons that we've been in business for 125 years is 16 17 18 we've stayed very closely connected with our 19 customers. 20 Three years ago we asked 3,300 of those 21 customers -- excuse me while I adjust this, 3,300 of 22 those customers to identify some food-related issues 0293 that were of interest or concern to them. Dependi ng 2 on life stage, their responses varied, but one thing 3 they had in common was that they were confused. 4 They found the plethora of information in the media 5 6 regarding good and bad foods overwhelming and often conflicting. 7 They viewed the proliferation of symbols 8 on packaging as unclear and sometimes self-serving and while they read nutrition labels anywhere from rarely to fairly often, they agreed that they were 9 10 unsure of how to interpret the information on those 11 12 I abel s. 13 Based on those responses, Hannaford developed and tested a series of concepts, which was 14 15 then called Three Stars to Health, which 16 subsequently became Guiding Stars, was the clear 17 wi nner. 18 19 20 nutritious foods in the store quickly and easily. Why is Guiding Stars different or how is Guiding 21 Stars different from any of the other systems you 22 0294 may be familiar with? For one thing, it's a Page 107

FDA Hearing Day 1.txt store-wide system. It's not just private label or branded product, it's the entire store, because that's how customers shop. They're not comparing an apple with an Oreo, they're comparing an apple with watermel on and an Oreo with a graham cracker.

Before we introduced the program in our stores, we tested four versions of the concept. One used just the stars, we called that our control, to denote those products with good, better and best nutritional value.

A second used a combination of the stars with a checkmark in what was designated, forgive me for this, best of the worst. In this version those

A second used a combination of the stars with a checkmark in what was designated, forgive me for this, best of the worst. In this version those products that wouldn't normally earn a star but are still better for you than other products in the particular category would receive a checkmark.

The third version combined the stars with My Pyramid. This version color-coded the stars to correspond to the food group the product represented.

The fourth version designated Eat

Nutritious used just the stars, but instead of defining the system from a good, better and best nutritional standpoint, this version defined them as one star eat regularly, two stars eat these foods every day and three stars eat these foods several times a day.

Both the control concept and the eat nutritious concept were preferred over the My Pyramid and the best of the worst, what a surprise.

Armed with that information, Hannaford began the Guiding Stars efforts by forming a panel of nutrition experts to translate scientific studies and identify a set of criteria that differentiate nutritious foods. Given the limited scientific criteria available to support the eat nutritious

Drawing from leading national and international health organizations, including the FDA, the USDA, the U.S. Department of Health and Human Services, the World Health Organization, the National Academies of Science and others, the panel developed an algorithm to assess all foods sold by

concept, the control concept was selected.

Hannaford.

I want to address up front that we've been challenged about not making our algorithm public. Let me simply say that we've invested heavily in this program both in terms of dollars and intellectual property and the program is patent pending. Having said that, we have offered to meet with any vendor or manufacturer who has a product in our store to go over the ratings and how we determine them for every one of their products.

Guiding Stars is based on information contained on the nutrition facts label. For those

contained on the nutrition facts label. For those items that do not have nutrition facts labels, such as produce, we relied on the USDA national nutrient database. The formula debits a product for the presence of trans fat, saturated fat, cholesterol, added sodium and added sugar and credits a product for vitamins, mineral, dietary fiber and whole

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19 grains. 20 The resulting score represents a weighted total of a product's nutrient content. 21 22 Ratings are based on 100 kilo calorie serving sizes. 0297 At the time the program was launched in September of 2 3 2006, 24 percent of all foods received at least one At the end of August 2007, 28 percent of foods received at least one star. 5 More than 25,500 edible products are 6 7 currently in the database. Some examples of ratings by category include 100 percent of fruits and vegetables, 51 percent of cereals, 41 percent of seafood, 22 percent of dairy, 21 percent of meat, 7 percent of soups and 7 percent of bakery. 8 9 10 We did not initially rate baby foods, 11 bottled water, fats and oils, coffee, tea and spices 12 and alcoholic beverages. Our baby food rating will 13 be out next week and we expect to have fats and oils 14 rated in the fourth quarter of this year. 15 Let me just say that the reason that those were not rated initially is because they 16 17 require adjustments to the algorithm.
It's important to note that with the 18 19 exception of those items that do not have unit price 20 tags, all stars appear on shelf labels, not on 21 22 product packaging. Those items without UPTs, unit 0298 price tags, have stars on either the scale labels 1 2 for items sold in the deli and meat department or department signs for fruit and vegetables and 4 seafood. 5 If the shelf tag has no stars, it means 6 7 that either the product does not meet the nutritional requirements for a star or it is not 8 rated by the program. In the latter case the 9 information is indicated by shelf signs in the 10 category. 11 We communicated the program to consumers on our Website, in brochures, in flyers, bags, stuffers and signs throughout the store. We also 12 13 have a toll free hotline, an ask the nutritionist line and E-mail or phone line point of contact as 14 15 well as on-air advertising. 16 17 Customer response has been overwhelmingly positive. It's important to note that Hannaford did not change our merchandising 18 19 strategy to support Guiding Stars. We did not market, merchandise or advertise products based on their star ratings. Starred products were not moved 20 21 22 0299 1 on the shelves and there were no co-marketing efforts tied to starred products. 2 3 4 Despite no additional merchandising efforts, however, consumer surveys of 744 primary 5 and secondary Hannaford shoppers conducted in August of this year indicated that awareness of Guiding Stars is at 81 percent, the highest for any program we've run, and close to half of those surveyed 6 7 8 9 indicated that they are using the program regularly. 10 That's what customers are saying, but 11 what are they doing. One year into the program, 12 data shows that consumers are choosing more nutrient

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13 dense items in many categories.

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For example, the selection of starred foods defined as edible grocery, that is cereals, canned fruits and vegetables, pasta sauces, soups, crackers, snack foods and beverages where more than 31 percent of all edible items can be found has increased at twice the rate of those without stars. Similar results can be found in categories such as yogurt in dairy, where selection of yogurts with three stars grew three times faster than their no

star counterparts. Selection of starred frozen dinner entrees grew approximately four times faster than those without stars.

Similar results can be found in cereals,

soups and salty snacks.

I'm going to give you some examples to sort of help put this in perspective. I'll use the, I'll use yogurt I guess for an example. Customers selected cups of yogurt with stars 18 percent more frequently than they did at this time last year, while cups of yogurt without stars were selected only 4.73 percent more often than last year. And I can give this information for multiple categories.

One thing that's important to note is that with few exceptions, sales of all products starred and no starred are up and it's not surprising that we would see sales of more non-starred items since they outstrip sales of starred items. Sales of starred items represent 28 percent of all products in the store which means that 72 percent of the products do not have stars. So clearly that's a 2.5 to one ratio, so we expected

to see sales of more non-starred products at this time also.

Fresh fruits and vegetable selections remained constant, however this wasn't a surprise given that virtually all fresh fruits and vegetables

received either two or three stars.

Can we prove that Guiding Stars is the reason for what we're seeing unequivocally? No. Many elements influence shoppers decisions, including price, coupons, special promotion, time of year, advertising, convenience, et cetera.

Because Guiding Stars was rolled out in all Hannaford stores simultaneously, we cannot factor in all of these variables. We can say, however, that the combination of awareness, reported usage and product selection would suggest that the program is impacting customers purchasing decisions to some degree.

Similar results have occurred at our sister chain, Sweet Bay, based in Tampa, Florida. Sweet Bay introduced the Guiding Stars program in March of 2007.

In conclusion, we are participating in the Keystone center discussions working towards a uniform system. I'd like to note that shoppers visit supermarkets on average of 2.1 times per week. That means that supermarkets are uniquely positioned to help educate consumers about nutrition.

FDA Hearing Day 1.txt we're not suggesting that Guiding Stars is the 8 solution to the issue of nutrition symbols or 9 product labeling, we encourage the FDA to consider 10 its merits as part of this proceeding. Thank you. 11 12 (Appl ause) BARBARA SCHNEEMAN: 13 Great, thank you. 14 Our next presentation is Paulette Thompson from Giant Food. 15 PAULETTE THOMPSON: Maybe I better put 16 this down, too, us short people. 17 Okay. Okay, good afternoon and it's a pleasure to be here today and I, too, want to thank Dr. Schneeman and the Center 18 19 for Food Safety and Applied Nutrition for asking me 20 to speak today. 21 I'm going to speak about our information 22 0303 icon program and I think my talk is going to echo much of what we heard today, but that might be a good thing at the end of the day. 3 A little bit of background about Ahold and Ahold USA. I've been billed as Giant Food and I am Giant Food and I'm also Stop and Shop and I'm Ahold, so I wear multiple hats here, but Ahold is an 5 6 7 international retailer and we're based in Europe, in 8 the Netherlands and in Europe. Ahold operates under three major business segments, there's a few others, 10 11 but the major ones are ICA, which is based in Sweden, Albert Heijn, which we heard a little bit about today which is based in the Netherlands and in the Czech Republic operate under the banners of Albert and Hypernova, altogether over 500 stores in 12 13 14 15 eight countries. 16 17 In the United States, Ahold, USA, has two major arenas, two separate businesses. 18 Stop and Shop and Giant Landover and the other one 19 20 is Giant of Carlisle, Pennsylvania, and also they operate under the banners of Tops and Martin's. 21 if you're confused, we're still confused over two 22 0304 Giant Foods, so, but we are sister companies and we 2 work together but we are two separate businesses. Altogether, Ahold USA has approximately 4 5 800 stores in 11 States and the District of Col umbi a. 6 7 Okay, I'm going to talk about, as I said, our information icon program today. Over Over on 8 the right side of the screen you can see some graphics of what the icons look like. They are a front of package labeling program and which we've heard a lot about today and they are on the packages 9 10 11 of all the U.S. banners, so again, that's Stop and 12 Shop, Giant in Landover, Giant in Carlisle, Martin's 13 14 and Tops. So it's really, it's also I guess Ahold 15 USA corporate brands program. We rolled out these 16 17 icons in 2005 and so it's been about two years now. Our purpose in putting out these icons, I guess if you want to put it that way, is to help 18 19 20 customers make an informed positive choice for their health and dietary needs and to highlight the 21 presence or the absence of relevant nutrients and 22 0305

i ngredi ents.

And we also, I think it was Kraft or someone had three guiding principles, we have three guiding principles here also in this program. One is we do feel we have a social responsibility to help customers make informed positive choices for their health.

We are a full service supermarket and, in fact, one of my colleagues in, in the Netherlands often refers to us as selling the good, bad and the ugly and, and since we do sell the good, the bad and the ugly, we do feel that we need to help our customers identify those choices or at least be able to see which choices are the healthy ones.

Our claims must be scientifically sound and regulatory compliant. Our third principle is that our icons be consumer relevant for the product. You will hear that we limit to the number of icons on a package, so some products may qualify for many icons and in that case, we have to make some -- a decision, a judgment call on which ones should we

22 put on the package and it is our goal to pick the 0306

ones that are the most consumer relevant for the product.

Our information icon program was an off-shoot of an existing program that Giant Food in Landover had for many, many years, that program was a shelf label program. It was developed with the Food and Drug Administration and it was called special diet alert. Giant Food was one of the first retailers to identify the absence of negative ingredients, or the presence of positive ingredients and that was, as I said, over 20 years ago now, although we're still hearing the same things today, aren't we.

And we did highlight whether products were low or reduced in sodium, low or reduced in fat and cholesterol, low or reduced in calories or high in poly unsaturated fat was a nutrient of concern at that point in time. And you can see the shelf labeled graphic there where we used arrows right on the unit price tag identifying, I don't know if there was any product that really met all of those criteria, but it showed how it could have up to five

there on the unit price tag.

In the late 1980s we worked with the National Cancer Institute and added good source of fiber to help reduce the risk of cancer.

So, this was Giant Foods shelf label program and as I said, over many, many years.
So, why did we end this program and start with the icon program which was expanded, as I said to all of Ahold's USA companies. A number of reasons, really.

One was that we maintained a nutrient database ourselves in order to maintain this program and it was on brand name products, not just private label products. And it became evident by the early 2000s as supermarkets, when this program started in the 1980s, there was also a booklet that was published along with the shelf labels that listed

FDA Hearing Day 1.txt all of the foods that were in the program and gave 19 the specific numbers for the nutrients. 20 This was, again, too, before the 21 Nutrition Labeling and Education Act so that 22 information wasn't even necessarily on the package 0308 1 So the book was definitely of prime 2 importance so people had the data, as we've been hearing today. That the data is on the package. Well in those days, it wasn't even there. 5 But that book was like 100 -- started 6 7 out as like 100 items. By the time 20 years later came around, it was over, it was about 6,000 items that qualified for the program and the database had over 14,000 items in it. What became apparent was 8 9 that it was very difficult to, for us with our 10 11 resources that we had in our company to maintain 12 that database, so we began to look at alternative ways of providing this information to our customers, and what we could do. 13 14 15 So one of the things that we explored was, or our conclusion was that perhaps we should concentrate on private label because that's what we had the accurate and up-to-date data for. 16 17 18 19 And so when we went to private label, 20 though, also, we went to putting it on the package 21 and it was not a decision to remove it from the 22 shelf label. It is no longer on the shelf label. 0309 That wasn't a conscious decision made that we were 1 going to put it on the packages and now we're going to take it off the labels. That actually was just what happened with an integration of Stop and Shop 3 4 5 and Giant Landover in a change in systems and no 6 7 longer being able to put it on the shelf label at that point in time so that that just sort of 8 occurred simultaneously. So we looked at putting it on package 9 labels and we thought, again, what research do we need to do to sell this program, I guess you could say, to all of the operating companies and not just 10 11 12 13 Giant Landover 14 And we did have some research from our 15 program at Giant Landover, that was done with the 16 Food and Drug Administration and that research 17 published results of a comparison. And at that point in time we had done control stores in 18 Baltimore and rolled the program out in the D.C. stores and we, too, found that sales of shelf labeled products, and this was in eight categories, 19 20 21 increased significantly in the Washington test 22 0310

stores over the Baltimore control stores.

And one point to make here is that we were able to determine that because it was -- we had control stores, some of the promotions were the same in both places, so we were able to get, remove those

factors from, from the data which can complicate

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So we were able to maybe more definitively say that it was due to the shelf labels, themselves, and that the relative increase in market share was 4 to 8 percent for shelf labeled Page 113

FDA Hearing Day 1.txt 12 Also it was a two-year test period which was also significant in that it gave some evidence 13 14 anyway that consumers maintained this over a fairly long time period, that it may indicate a real behavior change and again not just for a certain promotion or a launch of a new product.

But recent consumer research, and we've 15 16 17 18 19 heard a lot today, consumers use the nutrition facts 20 panel, here's some other data, FMI shopping for 21 health, 83 percent, sometimes or always checked the 22 nutrition facts label. Our own Stop and Shop data, 0311 we do do an overall -- overall health and wellness 2 survey of our customers every Fall. primary Stop and Shop and Giant Landover customers as well as some secondary shoppers and 72 percent 5 indicated that they use product labeling in the last 6 7 Some data from Yankelovich, 54 percent indicated that they frequently read nutrition 8 I abel s. 9 So we know that customers use the 10 nutrition facts panel. We also can see from different research, though, that consumers want a simpler message. Package i cons make i t easier. 11 12 This is a study by the beef and pork producers to 13 identify specific attributes; however, that it did 14 not help them plan an overall healthy diet. 15 16 Consumers will seek symbols for 17 simplicity according to the Hartman group and I did, there is some research by Juan Sing and actually, I apologize, but I think part of this sentence has 18 19 been deleted, it was a, he found that combining short health claims on the front of the package with 20 21 more information on the back of the package leads 22 0312 consumers to more fully process and believe the 2 3 claim, which was some interesting research that was on food policy. 4 5 We also know that time constraints and cost are barriers and so a simple icon, again, may 6 help with those time constraints that's on the front 7 of the package. 40 percent of our own customers 8 told us that they felt products called healthy or 9 with health claims usually cost more than regular 10 items and of course putting it on our private label, we hoped to dispel that belief in that they are a 11 good value compared to the name brand product. 12 Our own customers also told us, though, that really it's not that many of them, maybe 19 percent, 1 out of 5, that they want supermarkets to help them identify healthy food choices and that 13 14 15 16 they wished that we would provide more information 17 to help them eat healthier. 18 19 Here are our icons. Our program is word 20 I say it was an off shoot of our shelf reliant. 21 type program which used arrows. This program also 22 generally uses arrows or very simple graphics. It's 0313

word reliant and uses low, very low, reduced, vegan, whole grain, heart healthy and it is generally on the lower left corner of a package and here is a cereal package that has three icons. The claims are all Federally defying claims for nutrients, the Page 114

FDA Hearing Day 1.txt allergin claims are for the absence of the allergin 7 in the ingredients and possibly through 8 cross-contamination. Our suppliers do provide us 9 that information. 10 We -- glutin free is one of the icons 11 and I would say as working in consumer affairs where I'm based, it is, I would say, the most frequently looked at icon. It is certainly the one we get the 12 13 14 most questions about is glutin free. 15 Vegan, also, seems to be a very popular one and we have gotten compliments on including 16 17 vegan. So our strategy was in rolling out the information icon program is our demonstration of our commitment to health and wellness and I would also 18 19 20 21 say as I've heard some other speakers say today, 22 though, that as a retailer, we have many other 0314 1 vehicles to also show our commitment to consumers for health and wellness, how we communicate with our 2 3 customers. 4 5 So this is just one part of what we do. We saw an opportunity, though, to launch these package icons with the trans fat labeling 6 requirements and you will see in my next slide that 7 there is a cost, as we heard before, of packaging changes, but we saw an opportunity that with the 8 9 packaging changes we are going to be doing for trans fat, that it was an opportune time to roll these out 10 11 on our private label and also on new products. And 12 we were launching a new natural organic line so they were the first products really to have the icons.
As I said, we use up to three icons and we do also 13 14 15 16 note allergins. Consumer marketing, as I said, Nature's Promise, we had a brochure that listed the icons, 17 18 they are on our Website. We use our regular 19 20 communication vehicle such as our consumer advisor 21 22 col umn. BARBARA SCHNEEMAN: And we do need you 0315 to finish up. 1 PAULETTE THOMPSON: Finish up, okay. 2 3 4 have two more slides. Current status, over 300 products, all new items, we really haven't had to do many re-formulations due to the icon program, just trans fat and it hasn't affected the price. I think we've already heard some of the costs that can be incurred if one does do re-formulations or packaging. 5 6 7 8 9 And in summary, it's a private label packaging only, highlights the presence or absence 10 11 12 of nutrients and ingredients. It's word reliant, 13 not a symbol program. It's built on the existing shelf labeling program we had and it enhances the nutritions facts panel. 14 15 Thank you. 16 17 (Appl ause) BARBARA SCHNEEMAN: 18 Our next 19 presentation is Elizabeth Pivonka from the Produce 20 for Better Health Foundation. 21 ELIZABETH PIVONKA: Good afternoon and 22 thank you, Barbara, and it's a pleasure to be with Page 115

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you this afternoon and thanks to FDA for inviting me

to speak here today.

I know when they first asked me to present I thought, gee, I don't know if we really belong in this session because I looked at the Federal Register and said we can't answer half of your questions here, but anyway it's a little bit different presentation maybe than some of the others that you've seen.

For those of you who aren't familiar with the Produce for Better Health Foundation, we've been in existence since 1991 and basically we came into existence to partner with the National Cancer Institute on the Five a Day Program as it was going from a State of California program to a national

program.

Five a Day started in California in 1988 and then we took it national in 1991 and PBH was incorporated to interface with the industry because our Government partner didn't want to have to deal with all of the different industry groups, or little fruit and vegetable companies, so that's who PBH is.

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We've been, and we've been working with the National Cancer Institute since 1991 at the national level. About a little over two years ago the lead Federal health authority for the Five a Day Program transferred from the National Cancer Institute to the Center for Disease Control and Prevention which was a big step for the program.

Also right about that time the dietary guidelines were changing and from our research, we could see that consumption wasn't increasing as rapidly as we wanted it to. In fact, at the rate we were going, it's going to be about 100 years before fruit and vegetable consumption is going to increase to the minimum of five servings a day and our dietary gui delines were recommending anywhere between 4 and 13 servings. So we decided we ought to step back and take a look perhaps at our messaging and see if, see if there was something better that we perhaps needed to do.

So we hired a branding firm out of New York to actually help us with a re-branding of Five a Day and we weren't even sure going into it

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8 9 that we were going to re-brand Five a Day, but we

wanted to step back and take a look at it.

After, and I won't go into all of the detail, but after quite a bit of research over a period of a year, a lot of intensive consumer research and consumer research that was done largely with moms and moms because they are still the primary gatekeeper to what the family eats and they are still the primary gatekeeper to the health of the family.

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What we learned from all of our research is that moms didn't want to be made to feel guilty about not doing what they know they should be doing and that is getting their families to eat fruits and They didn't want to be preached to and vegetables. they didn't want to be scared into eating fruits and

17 vegetables.

> One of the other things that we learned is that people who weren't even close to five a day felt alienated by the number, whether they were close or not, it was their perception of whether or not they were close because, and I had often felt

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> for 15 years that perhaps we were doing more to explain what a serving was as opposed to really getting people to increase fruit and vegetable consumpti on.

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18 19 20 So basically what we did is we stepped back from the number and basically just tried to develop a, a message based on positioning, work with moms, a message that tapped into the sense of responsibility to feed her family well.

So we tested this message with moms and then we tested it with a broader population to make sure that it wasn't a turn-off with men's -- with men and with consumers of various age groups.

So just to give you a quick overview of what we had in the past and where we're going. Five a Day was very functionally-based and instructional because it was numeric.

More Matters, we believe, is more emotionally based because we are tapping into that sense of responsibilities of moms and, therefore, we believe it's more inspirational. Five a Day, in theory, was constantly changing because the dietary

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guidelines were updated every five years on fruits and veggies. More Matters we believe is a stake in the ground and one that we intend to keep we hope for the next 15, 20 years and hopefully by then we won't have to use it anymore because consumption will be where it needs to be.

Five a Day in the past was a perceived fresh program and I emphasize the word perceived because it was never intended to be a fresh program. It was always fresh, canned, frozen, dried and 100 percent juice, but for some reason, and we saw this in our research, consumers felt guilty if they weren't feeding their family anythin but fresh fruits and vegetables which was a bit of a concern for us because in this day and age of convenience, canned and frozen, dried, 100 percent juice of other ways of getting fruits and vegetables into consumers. So we're making a re-doubled effort to promote the fact that all forms of fruits and vegetables count.

Five a Day very much focused on all of the benefits and why you should eat fruits and

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vegetables and pretty much consumers know fruits and vegetables are good for them.

Moving forward, we're spending a whole lot more time on the how to, how to incorporate more fruits and vegetables quickly and easily into your daily lives.

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So with that as a bit of background, I wanted to talk to you about what we do as a non-profit organization in trying to get our message out to consumers when you virtually have no budget.

FDA Hearing Day 1. txt Remember, the fruit and vegetable industry doesn't have a lot of profit margin so they really don't have a lot of money to market their product. We are not a check-off program like the beef or the dairy industry, we are a voluntary contribution organization and in part because the fruit and vegetable industry is so fragmented. You know, what happens in apples in Washington State is completely different from onions that are grown in the ground in Colorado, so a very fragmented industry and this is, this is one message that everybody can rally around.

The other interesting thing about the fruits and veggies More Matters research is that just seeing the logo, itself, consumers said, almost two-thirds of consumers said just seeing the logo itself would increase their interest in eating more fruits and vegetables either extremely well or very well.

So, our goal was just to get this logo out in front of consumers as a gentle reminder to do what they already know that they should be doing.

So, so what we, what we do at Produce

for Better Health Foundation is try to encourage message, dissemination of this message. So as with Five a Day, our background structure is similar with Five a Day so we get our message out in the same venues that we did before.

So right now we have about 23,000 supermarkets who have licensed the use of fruits and veggies More Matters, that represents about 70 percent of all of the fresh produce volume. Just to give you an idea of how many supermarkets that is, there's about 30,000 supermarkets in this store, so

all of these folks are licensed to use it, most of them are starting to use the logo in their advertising. About three of them, and I can't tell you which ones yet, but three of them are working on their private label products, both frozen and canned and several of them, probably half of them are doing even more intense activities beyond just their advertising.

We also work to get our message out through the media, so a lot of work both with PBH and the Center for Disease Control reaching consumers through the media.

In our research over the past year as we've been launching fruits and veggies More Matters, which by the way was launched in March of '07, this Spring, the three ways consumers knew about Five a Day in the past, supermarkets, the media and packaging, so media and supermarkets are a real key part of how we get our message out to consumers.

We also have a network of other partners who are helping us increase fruit and vegetable

consumption and these are all, all, some of our partners, CDC and USDA are probably playing the biggest role at this point right now and certainly more that they could all be doing, but we are

6 I'll point out the one at the bottom, 7 National Council of Fruit and Vegetable Nutrition 8 Coordinators, these used to be our State Five a Day coordinators so we had to change their name, they're now our fruit and vegetable nutrition coordinators 9 10 and there is a State coalition in every State that's 11 promoting fruits and vegetables, so we use our 12 13 grass-roots effort basically to reach consumers. 14 So here's an example of what some of 15 them did for the launch, North Dakota, for example, 16 has about nine billboards in North Dakota helping promote the message. A lot of TV work in preparation for the launch and September is National Fruits and Veggies More Matters Month, so a lot of 17 18 19 20 other activities starting up again here this month. 21 We reach out to educators and health professionals with a number of educational 22 0325 1 materials. Again, this is how we get our message out to consumers everywhere we possibly can, we try to include that, that logo. A new Website, FruitsandVeggiesMoreMatters.org was developed as an 4 interactive Website largely targeted to moms, younger moms, in particular, and that's how we're 5 6 7 getting our message to consumer, consumers. 8 So it just so happens that we like to 9 use the packaging as well as a way of getting our message to consumers and we wanted to use the 10 packaging because without a budget it was another 11 way of reaching the consumer to make an impression, but because we were using packages, we were assuming that if anybody saw the logo on a package, they 12 13 14 would think that it would mean automatically that 15 the product was exceptional or good for you. We 16 didn't have any research, we just assumed that that 17 18 was the case. 19 So, assuming that that's the case, that 20 consumers might see it as an endorsement. We 21 developed criteria, what we affectionately call our 22 products promotable criteria and this criteria is 0326 basically the criteria by which a product can carry 1 the logo. I've highlighted those in red that are a 3 little bit different than FDAs healthy definitions by and large, we followed FDAs healthy definitions, 5 but for processed fruits and vegetables, one serving of fruit or vegetable, and those are USDA serving sizes, the product, it has to contain one serving, 6 7 8 for sweeteners it has to be less than or equal to 9 8 calories per serving and concentrated fruit juice counts as a sweetener. We allow a quarter-ounce of 10 11 nuts per serving because of that healthy fat so we 12 don't count that healthy fat against you and then 13 there's a fiber requirement. 14 So I just, I pointed out in red some of 15 those areas that are new that are not FDA healthy 16 definitions. 17 Just so that you know what we consider a serving of fruit or vegetable, all of these are what we consider a serving, fresh, canned, frozen, dried, 100 percent juice. The questions that we're getting 18 19 20 21 today largely from food manufacturers is do flakes Page 119

reaching consumers through all of these venues.

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FDA Hearing Day 1.txt or powders or concentrated purees count and those 0327 are questions that are interesting questions that we 1 haven't been able to answer yet, but those are the kinds of questions that we're getting.

So, as you can imagine, these are the products that we're starting to see the logo on and this is a PILL sticked days in the logo. 4 5 6 7 this is a PLU sticker down in the lower left-hand I've been trying to get the industry to use 8 more PLU stickers with the logo on it and it's just 9 an added cost that they worry about. There's an exception, so, for example, some non-edible items that are useful in helping 10 11 promote fruits and vegetables, we allow these people 12 to carry it on their product.

Some off package reminders, now keep in 13 14 15 mind we're trying-to get our message out to 16 consumers as many places as we can since we don't 17 have an advertising budget, but we also want to be careful that we're not endorsing a product. 18 So, with CDC's permission, and we take this on a case-by-case basis, we are working with 19 20 21 particular companies to help us get the message out to consumers. 'So here's an example of a neck hanger 22 0328 with Hidden Valley Ranch who if any of you saw it 1 2 3 this past Spring, there was a nice magnet on the front with fruits and veggies More Matters and 4 they're helping us, they reached a million 5 consumers, there were a million magnets on these products. It wasn't on the label, itself, it was a neck hanger that went on to the salad dressing, so we were very thankful that they were able to reach a 6 7 8 9 thousand -- a million consumers via that venue. 10 Here's another example of one of Unilever's products, Knorr has a size plus with 11 additional veggies in it. Now it didn't meet our 12 13 product's promotable criteria to carry the logo on the product, itself, but they did provide a full 14 serving of vegetable in the product. It was a 15 little high in sodium and what they're doing is 16 they're helping us use their product in recipes that do meet our criteria, so we're promoting the recipes 17 18 19 that meet our criteria and they're using down at the bottom of this FSI, you can see they're using a proud supporter of the fruits and veggies More 20 21 22 Matters campaign. 0329 A Website, Lean Cuisine, is another 2 example of a product that was a little bit high in 3 sodium, but they have twice the veggies in their products, some great products, they re helping us on their Website. They're also helping us in some tradeshow signs, they're proud supporters of fruits 5 6 7 and veggies More Matters, so trying to get the

message out that way.

McDonald's, while their products didn't quite qualify to carry the logo on their new salads, they actually have been including our messages in case-by-case approved efforts and this happens to be a tour that they did this Summer with in 10 cities promoting some of their new salads. So you can see this was a, it was an exhibit for moms, basically.

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FDA Hearing Day 1.txt And I'm almost done. So, just a quick 17 summary, research, a lot of research supports the fact that fruits and veggies More Matters is a 18 stand-alone motivational message for consumers. There is no research that we have on what consumers 19 20 think of it on packaging in particular. 21 There's no research on the sales impact 22 0330 of it on packaging either. We've been asked that 2 information, we don't have that information. would be interested in a standardized nutrient criteria for symbols on packaging, so if that's where you're headed with this, we would be very 4 5 6 7 interested in entertaining that.

And I'll stop there and thank you. 8 9 (Appl ause) BARBARA SCHNEEMAN: Great, thank you. 10 Great, thank you, and then our last presentation in this panel is Rose Marie Robertson 11 from the American Heart Association. 12 ROSE MARIE ROBERTSON: Thanks, Barbara, and thanks for the opportunity to present the views of the American Heart Association, American Stroke Association. I'm Rose Marie Robertson, chief science officer of the AHA. The AHA is the nation's 13 14 15 16 17 largest voluntary health organization with more than 18 19 22 million volunteers and supporters committed to 20 reducing disability in death from cardiovascular 21 di sease and stroke. And let me first -- I'll talk to you a 22 0331 little while we're getting that together. And I going to begin in any case by conveying the AHA's 2 support for the FDA is efforts to improve how 4 5 nutrition information is communicated to the public. We strongly believe that getting 67 scientifically-based and understandable nutrition information out to the public is critical. We think that, as clearly many of you do here today, that doing that on the package and in stores is important. We think it also needs to be 8 ĕ 10 supported by a well-designed and rigorous consumer 11 12 education program and that that consumer education 13 needs to be consistent to have the most impact. 14 It seems to me that just from being here 15 today that the, this meeting should move us in that di recti on. 16 17 We'll talk, what I'll talk about quickly are the three, your three basic questions, what we've done with the AHA's food certification program 18 19 and our consumer education, what our consumer 20 research shows about the impact of that program and 21 22 then end with our suggestions for a standardized 0332 icon system. 1 2 We, we, I think we all again agree that the nutrition facts panel is one way consumers can get information, but it's clear that consumers both need and recognize that they need more guidance, 5 they need information that they can get quickly, at 6 7 a glance, on the front of the package. And recognizing that, in 1995, the AHA created a food 8 certification program to provide consumers with Page 121

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really a reliable and easy-to-use method to look for

heart healthy food products in stores.

The Heart Check program is not a general health promotion program. It really deals only with heart disease prevention allowing consumers to identify products in stores that meet our criteria and the FDAs criteria for heart healthy foods, so it really serves as a first step but not the whole, not the whole of a sensible eating plan.

The, participating in the food certification program is voluntary. The program is revenue neutral to the association, just supporting its own, its own activities, and the food -- the

food products that meet our certification are eligible for one of two marks, either the standard certification, but also for a whole grain certification.

A wide array of products are eligible for certification, with the exception of candies or confectioneries and cooking oils and by AHA policy, food products from, that are from companies that are either tobacco companies or their subsidiaries. We will certify any other food. There are about 800 products currently certified and carrying the AHA mark, a small sample of which I would have showed you on the screen and may eventually as we bring that up.

To meet the AHA's criteria, and I think we can do this without slides just as well, because the criteria are criteria you'll all recognize. These products have to be low in saturated fat, cholesterol and sodium and they have to meet at least 10 percent of the daily value of the shortfall nutrients, Vitamin A, Vitamin C, iron, calcium, protein or dietary fiber and meats and seafood have

 to also meet the standards for extra lean. The whole grain products have to be at least 51 percent whole grain by weight and meet the minimum dietary fiber content criteria.

Our criteria are not product specific or type specific. All the products have to meet the same requirements and you'll notice that one, or you would notice that for those of you who had watched this program over more than the last decade, there's been a small but significant change recently to include a trans fat criteria of less than 0.5 grams per RACC. As of January of 2008, all the new products have to meet the trans fat criteria and existing products have to be re-formulated by the end of the year.

The whole grain certification has included trans fats from the beginning, and I'd point out as I will again in a minute that the consumer education part of that we think is quite important. We, we agree that the public is, is a little confused about fats, saturated fats and trans fats and we were quite pleased to begin a trans fat

education program. I'd say that McDonald's is supporting that as well because money from the settlement of their trans fat suit is supporting the Page 122

FDA Hearing Day 1. txt trans fat education program we're doing, that program which actually includes cartoon characters, 5 6 7 the bad fats, brothers sat and trans, kind of a cute thing that we're using both in schools and in public education, we thought was important to help us get across the message. 8 9 10 Although we're not a bad food, good food people, we are a bad fats, good fats, better for you 11 fats people. 12 13 So the trans fat program we think, 14 having an education program there is quite 15 important. The criteria we selected for the food 16 17 certification program were selected carefully and they were selected to align with the FDAs A level 18 19 unqualified health claims related to the risk of 20 coronary heart disease and comprised of AHA's 21 nutrition recommendations as well. 22 In addition to having those criteria, 0336 one thing that we have thought was important in this 1 program was to maintain a stringent monitoring and enforcement program. For example, we -- ah, and there are the criteria. And I'll, I don't think 4 I'll go back. I think those are criteria that you 5 6 7 would all be -- well all would recognize. And, and here again, these were put 8 together to align with these unqualified claims in 9 our nutrition recommendations. 10 So, the enforcement program not only includes pre-approval of packaging and promotional materials, but actual annual grocery store audits. We randomly select and test products, verify that the correct products display the mark, we check 11 12 13 14 15 in-store promotional displays and we don't hesitate to say that the mark has to come off products that, 16 17 that slip because of a re-formulation or other issue 18 above the criteria. 19 So, we think that's, that's been an important aspect of this. 20 We require the products to display the 21 mark in its entirety, including the Heart Check 22 0337 symbol here, the AHA name and the statement about meeting AHA food criteria for saturated fat and 1 2 cholesterol for healthy people over the age of 2, and adding in whole grains for the whole grain 3 4 5 certi fi cati on. So, in addition to actually having the 7 mark on products, we also have a consumer education 8 program that includes a wide variety of things. 9 You'll have seen editorial placements in newspapers, TV spots, a lot of in-store campaigns, direct mail. 10 11 We have a Heart Check mark Website that contains easy-to-use information about the program for consumers. It has a grocery list builder so people 12 13 can, can select healthy foods, pop-up nutrition tips that help consumers because we think simply having 14 15 the information in stores is not sufficient. 16 17 We also work with health care professionals, that's a fairly substantial part of 18

our activity in general and we provide them with

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free Pro Packs, which are basically a tool that they Page 123

FDA Hearing Day 1.txt can use when they're counseling their patients about 22 di ets. 0338 These are all, these educational activities associated with the Heart Check program are a small part of what we do in consumer education and nutrition in general, which is much broader, but 5 the Heart Check program gives us the opportunity to 6 engage consumers in some of these other activities. 7 Let me tell you a little bit about what consumer research we've done about the, about the 8 program, the most important question from your perspective I think is does it, does it work, does it have an impact. And what we've found through several sets of market research is that more than 9 10 11 12 13 90 percent of people are aware of the Heart Check 14 mark, 89 percent say that it's helpful for the AHA to certify products and put our mark on food 15 packaging, 91 percent say that it's good or 16 17 excellent. And I think to a great extent this speaks to the credibility of a third party, but also to the credibility of a third party that has, that is a major trusted brand in and of itself. 18 19 20 21 22 Research also found that consumers 0339 pretty much understand what the hard checkmark 2 3 means, they, 82 percent will say it means heart healthy or good. Not all of them understand that that means it meets certain requirements. Again, some say that it's good or healthy for me. A substantial portion, but certainly not all, even though it says it on the 6 7 8 box, understand that it means that it's low in 9 cholesterol or fat. 10 Now, in terms of product selection, what 11 does the consumer actually do with this, 92 percent 12 of people say that it influences the decision to purchase a food. I think what's interesting is that if you compare it with generic hearts or a product that has a manufacturer's symbol, not everybody says they're more likely to select that if it has the AHA 13 14 15 16 17 mark, so there really has been I think a proliferation of marks and the consumers are clearly 18 19 using all of these marks, no question they use this one, this one as well and use it to a great extent.

If we, if we do comparisons of how 20 21 22 useful consumers find it, the, we get a 78 percent 0340 for the AHA mark, but a substantial percentage also find that manufacturer run programs are helpful. 2 I think a place where this mark gives 4 5 more credibility is that they, consumers really do believe that this mark is backed by strong research 6 whereas that's less the case for manufacturer programs. And I think that's the case for, you know, again, a third party, a third party coming in.
Consumers who, who find a product more
healthy and believe that that's backed by science 8 ō 10 11 are more likely to purchase that, as well. What's interesting is is that it depends on where the 12 13 product starts, so if an apple a day keeps the 14 doctor away, an apple with a Heart Check mark still Page 124

FDA Hearing Day 1. txt keeps the doctor away, it's not much different. 15 16 If the product is something like lean 17 pork where the consumer is a little less certain about it, might even think that it was less, that it 18 was a less healthy food, there having a Heart Check mark makes a big difference. 19 20 For example, we don't do research 21 22 looking at, looking at sales and the affect on 0341 sales, but companies tell us that if they display 2 3 the mark and do some promotion, they see an increase in sales. Again, fresh produce not very much, but 5 lean pork saw a 40 percent increase and this ranges in general from 4 to about 20 percent. Pork was an 6 7 unusual, had an unusual affect there. Again, we don't have information because 8 9 we're a third-party program on, on the costs of 10 product development or re-formulation. On the other hand, it's clear that the program has encouraged a 11 number of manufacturers to offer better food 12 choices. Every year we work with manufacturers on between 20 and 40 products that are being re-formulated that require some sort of formula 13 14 15 modification to get certification and many other 16 companies re-formulate before they apply for, for 17 18 certi fi cati on. 19 So, that's not to say this is a perfect program, but it does have an impact on the quality 20 21 of the food. It doesn't provide, as a number of the 22 programs we've seen today do, detailed information 0342 about which components might be healthier or less We're very pleased to be part of healthy in a food. the Keystone dialogue talking about all of those issues as well and would certainly, certainly think 5 that that's helpful information to give the public. Finally, our thoughts on the future of nutrition symbols on food labels, we firmly believe that icons can be of benefit to the customer, to 6 8 9 communicate important nutrition information, 10 encourage customers to make better food choices. 11 We're concerned that there are so many different systems and that they not only very substantially but are not all as transparent as they might be, 12 13 14 although we understand how that has developed in the 15 marketpl ace. 16 We, we'd very much encourage the FDA to 17 establish a standard, standardized comprehensive front of the package food icon system that has 18 19 unified criteria as others have said based on the 20 best available science, featuring consumer education 21 as the ultimate goal. And we think that the system 22 shouldn't be disease specific, despite the fact that 0343 we, that that's what we do with ours, but 1 generalized to the entire population, highlighting foods and nutrients that are good for you and those that should be minimized or avoided. 4 We think all foods and beverages really

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Page 125

should be required to display an icon and there are

a couple of additional elements that we'd like to see, we think would be helpful in a standardized

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icon system.
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                    We think a clear self-explanatory
      nutrition symbol, adequate consumer testing of the
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      system so that we're sure that we understand and consumers understand what it means, a nutrition education campaign. We think that there should be a
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      robust enforcement and monitoring program that
      includes random sampling and we think it should be
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      re-evaluated on a regular basis, at least every five
      years to ensure that it's, that it is consistent
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19
      with the dietary guidelines and DRIs.
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                     We, we think that in the absence of such
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      a program, there will be a continued proliferation
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      of health-related icons and, you know, certainly
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      feel that we and others will want to continue those
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      to provide consumers the information they need,
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      certainly the AHA is committed to doing that, to
      objectively and inform and educate the consumer and
      certify products that comply.
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7
                     Thanks, very much, and I'm happy to take
      questions when you all start talking.
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                    (Appl ause).
MI CHAEL LANDA:
 9
                                        Barbara Schneeman has a
10
      questi on.
                                             Thank you.
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                     BARBARA SCHNEEMAN:
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                     I think it's interesting to reflect on
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      the experience of the retailers and my understanding
      from what we heard from the Hannaford system, one
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      could easily have the star system on the shelf and
then manufacturer logos on the packages and from
what I understood, Giant, you may have your own
logos on the package, but I don't know if you're
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      also still using a shelf system at all.
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                     But I'm just, I would like to hear
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      comment on how consumers are reacting in that
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      environment, do you have any data to indicate what,
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      what, how do consumers react when they see something
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      on the shelf, something on the package, is that message in conflict, is it consistent? Do you have
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 4
      any data on that?
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                     PAULETTE THOMPSON: I think we haven't
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7
      had any consumer comment on that and I think because
      ours is just a nutrient specific program that
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      identifies, enhances the nutrition facts label and
 9
      just identifies nutrients. It doesn't conflict
      with, say, a Sensible Solutions or a Pepsi Smart
Choice, which is an overall symbol program, so we
haven't experienced questions from our consumers on
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      that.
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                     CAREN EPSTEIN:
                                       We, on the other hand,
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              I think what we have found is that consumers
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      are confused.
                        If they see a product that has no
17
      stars and yet they see a symbol on it that would
      seem to indicate that the product is a good for you
18
      product, then they are, in fact, confused.

BARBARA SCHNEEMAN: Are you trying to
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21
      address that in any way with your educational
      programs or do you have ideas in how to address
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0346
      that?
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better and best system as opposed to a good and bad We're saying that items with one star have good nutritional value, two better, three best. So in that way, a consumer may see a product that only has one star but has a particular symbol on it and what we've tried to explain to consumers is that our program looks at several elements whereas the symbol on the package may just look at a particular element.

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Is it challenging for consumers, what they're telling us is that they feel comfortable with the star system and as I mentioned, at the risk of doing irreparable harm to the relationship that we have with manufacturers, is that sometimes they have found those symbols to be self-serving as opposed to informational in nature.

MICHAEL LANDA: Alan Levy.

ALAN LEVY: Some of the programs that we've heard described today, they vary in the extent to which they're mandatory or voluntary. Based on

your experiences, what, what are the advantages of a mandatory program versus a voluntary program or vice versa?

Anyone could take that up.

CAŘEN EPSTEIN: Oh, okay. One of the things we did when we introduced Guiding Stars is we were very clear about saying this is for those customers who are interested in learning more about or making decisions regarding nutrition in food products. We were asked early on by some members of the medical community, not Dr. Robertson here, to put the star symbol on the register receipts so that people would know if what they were buying was nutritious and in talking to consumers, we quickly identified that that would be the death of the Guiding Stars system.

Clearly this needs to be voluntary. you, what we don't want to do is say if you came into our supermarket, for example, and it's your child's birthday and you bought a cake and some ice cream, loser.

So, we have found that consumers just

react much better when they believe that it's a voluntary system, they can use it if they wish and they can ignore it if they wish.

ALAN LEVY: Just as a clarification, the Hannaford system which covers all the products in the supermarket, the way I would use that, I would consider that to be a mandatory system because all products have to carry the system. A voluntary system would be one where it was up to the manufacturer or the retailer to put the symbol on the product.

CAREN EPSTEIN: From that perspective, I guess we don't think about it in terms of mandatory, but we do put every product in the store through the algorithm and it does get rated.

ALAN LEVY: And do you think that's a

good thing, helpful in creating an impact or would a voluntary system work just as well where everything

wasn't rated in the store?

FDA Hearing Day 1.txt CAREN EPSTEIN: I couldn't answer that 21 question because in our store everything is, so I would defer to someone else on that. 22 0349 ROSE MARIE ROBERTSON: You know, we've had, so our system is the opposite, it's a voluntary 2 3 system and there's no question we've had good success working with industry and industry has been 5 eager to re-formulate and create healthier foods and 6 has been innovative in doing that. 7 That said, if I were to look at what's possible for the, for the country and what consumers 8 9 would prefer to have when they walk into a store, I guess I think they would prefer a mandatory system because then they would, in fact, have that information, even if it was simply, you know, an absence of stars and criteria, you know, and then, 10 11 12 13 14 you know, benefits above that. 15 I think they would prefer to have more information and as people become, you know, more 16 competent consumers and are, and are thinking about 17 their individual health issues, so they're not simply thinking about, you know, what's generally healthy for me but they're thinking gee, I've got a terrible family history of osteoporosis, I really want to know if there's calcium in that, I think the 18 19 20 21 22 0350 more information people have, the better they'll do 2 for their health. PAULETTE THOMPSON: I would add that I 4 think a system, whether it's mandatory or voluntary, that having consistent criteria in the system, if it's Federal criteria that everyone has to follow is a benefit to the consumer and I think also and with 5 6 7 our old shelf labeling program which was name brand and private label that customers did use it to 8 9 10 compare products within a category as, you know, 11 they do the nutrition facts label. 12 The book we published was organized by categories and we knew that customers used it to 13 plan their meals. They would open the book and, and decide before they ever went in the store what they 14 15 16 were going to purchase based on being able to 17 compare the products. ELIZABETH PIVONKA: I would echo 18 Paulette on how important it is to be consistent in the criteria and I'll give you a couple of examples.

We've had manufacturers come to us to 19 20 21 22 see if our logo could be used on their product and 0351 they've worked hard to re-formulate it to meet the Heart Association logo but it doesn't qualify to use 3 4 ours and that's very frustrating for some of these compani es. 5 That being said, I know I've also heard 6 7 from some industry groups in the Hannaford program that some of the fruits -- some of what we would count as a qualifying fruit or vegetable don't have 8 9 very high stars in the Hannaford program, so whatever it is, ideally if it could be consistent, it would be better for the consumer that way. 10 11 MI CHAEL LANDA: 12 David Zorn has a 13 questi on.

FDA Hearing Day 1.txt DAVID ZORN: I'd like to -- excuse me, 15 I'd like to follow up a little bit on that issue that Alan raised. 16 17 We've heard and it was mentioned throughout the day and you just mentioned putting, 18 putting a nice symbol on products that people already know are good for them doesn't really change 19 20 21 things very much. People know they ought to eat 22 fruits and vegetables, so telling them that again 0352 1 doesn't really change the, sales didn't change. But there's certainly, if you make it a 2 mandatory across all products, there's a cost of putting that, that symbol on those products and if the retailer is not sort of doing it at Hannaford, 5 6 7 you've, you've borne the cost, Hannaford is paying to put those little labels, you don't tell the 8 manufacturers they have to do it. 9 If there's a different scheme, I'm 10 curious as to how that would play out. You could 11 certainly see situations where consumers don't really feel like there's a whole lot of, or put it this way, I might be able to have a conjecture that consumers wouldn't feel a whole lot of benefit from, 12 13 14 additional benefit from seeing a symbol and yet they 15 might be, manufacturers or whoever is going to do 16 the symbol placement is told that they need to 17 18 expend the resources to do that. 19 I, if I could just, one more thing, because with all of your, especially the vegetable and the Heart Association symbols, those are, 20 21 22 customers come to you sort of, they say can we use 0353 1 your symbol. If -- that's a very voluntary system. 3 4 5 If it's, if it's you will put, you will use the American Heart Association symbol if you can make it and if you can't, then you won't, that's quite a 6 7 different situation. ROSE MARIE ROBERTSON: Yeah, and I think, you know, I guess an issue that actually 8 9 Elizabeth can probably address better than I can is 10 you don't want to disadvantage, you know, the fruit 11 and vegetable producers, for example, you know, who 12 are a small margin. You also don't want to disadvantage 13 14 small companies who are working hard to make healthier products and, you know, and don't have the large margins that larger companies do.

So, I do think that that needs to be 15 16 17 taken into account as we put a system together.
I don't know that I'm, you know, I think 18 19 20 I'm not certain if the premise is exactly right that 21 everybody knows fruits and vegetables are okay, so it doesn't make any difference. It does make some 22 0354 di fference, 1 I think your mark does make a 3 difference. It also makes a difference because people didn't, weren't thinking about canned and frozen and dried fruits and vegetables, so I think there are, there's a lot of teaching that still 5 6 needs to be done and, you know, doing it in an Page 129

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      economically feasible way is important.
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                    MI CHAEL LANDA:
                                        Steve Bradbard has a
10
      questi on.
                    STEVE BRADBARD:
11
                                         Yeah, hi, Caren, I've
      got a question for you, a follow-up to some of the information you presented in your presentation.
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      Are there, how many product categories are there actually in Hannaford's system, how many
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      different categories are there of products?
                    CAŘEN EPSTEIN:
                                       It's not broken down by
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      category, it's broken down by products.
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                                         0kay.
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                    STEVE BRADBARD:
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                    CAREN EPSTEIN:
                                        So we actually looked at
      over 25,000 individual products. I suppose if I wanted to look at it as category, we would look at
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 1
      the perimeter of the store as individual categories.
                                         0kay.
                     STEVE BRADBARD:
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                    CAREN EPSTEIN:
                                        And then we would look
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      at the interior of the store as individual
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                     I will be guessing but my guess would
      categori es.
     probably be 30 or 40.

STEVE BRADBARD: All right, so let's say within one of those 30 to 40 might there be a
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      situation where in that product category you'd have
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      ranging all the way from three stars to no stars at
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      al I ?
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                    CAREN EPSTEIN:
                                        Absolutely. There are
      several of those.
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                    STEVE BRADBARD: Okay, so in your sales
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      data, have you found in those categories, I don't
      know if you have this information with you, that, say, the two and three star products have increased
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      greatly, the zero and one star products just aren't
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      selling anymore?
                    CAREN EPSTEIN: No. What we have found
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      is that the any star products, so it could be a one,
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      two, or a three.
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                     STEVE BRADBARD:
                                         So the ones aren't
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      suffering with the threes increasing
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                    CAREN EPSTEIN: Ones aren't suffering
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      with the threes increasing. It's more the any stars
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      versus the no stars --
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                     STEVE BRADBARD: Right, but then --
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                    CAREN EPSTEIN: -- where we're seeing a
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      significant difference.
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                     STEVE BRADBARD: Okay, so the no star
     products, though, in that category, you'd be seeing a large decrease, but not -- CAREN EPSTEIN: Yes.
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                    STEVE BRADBARD: Any conjecture in terms
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      of why it is that, you know, they have the choice then between a one, two and a three star product and
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      you're saying that the three is clearly superior to
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      the one?
                    CAREN EPSTEIN:
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                                        Because in some
19
      categories there are only ones, in some categories
      there are twos and threes, there are probably a handful of categories that have ones, twos and
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21
22
      threes.
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                    STEVE BRADBARD:
                                         0kay.
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FDA Hearing Day 1.txt
                       MI CHAEL LANDA:
                                           Could I just ask a
 3
      clarifying question there, so your data do not show
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      that, again, with any given category, the three star
      product has, sales have gone up more than the two and the two more than the one?

CAREN EPSTEIN: Varies by category.
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7
      There isn't a one single answer I can give you for that. In some categories, yes, in others, no, and
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10
      we don't have data to account for why that is.
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                       MI CHAEL LANDA: Okay, thank you.
                       Kathleen Ellwood has a question.
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      KATHLEEN ELLWOOD: Do you see symbols replacing nutrient content claims as they appear now, because, and my question is you have limited real estate on packages unless you're a cereal
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      company, they -- and, and if that's the case, then some of these symbols you could have a nutrient
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      content claim such as, I'll just say a good source
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      of calcium but you don't have a symbol for that, is
20
      that confusing consumers?
21
                       I mean what happens then, are you going
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0358
      to limit what can be on that package, say, well we're going to use this one, but we're not going to
 2
      use that one? I think Paulette, I know you don't
      have the icons, but you said you're going to limit
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5
      yours to three.
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7
                       Is that because you feel that's the most
      consumers can handle and which three then would you
      use and I think you know what I'm --
PAULETTE THOMPSON: Right, I think that,
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      yes, you will see, in any package that would use an icon system you would see fewer call-out, other
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12
      call-out claims on the packaging.
                       Yes, we're only using up to three and,
13
       therefore, there is this judgment call that has to
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15
      be made as to which are the three most relevant,
      which of course is true if you were doing it as, you
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      know, just 10 percent of -- or excellent source of calcium on the front of the package.
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      Our concern with our corporate brands office was the look of the icons in the architecture
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21
      of the brand. And, in fact, our Nature's Promise
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      icons, which you probably couldn't see in that
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      little brochure did have a different look than the
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      icons on our regular Giant or Stop and Shop brand
      packages because the Nature's Promise icons, same information, but the look of them is slightly different to fit into the brand architecture.
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      And of course to marketers, which I'm not a marketer, but to marketers, that's very
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9
      important so they want to call out those claims but
      they also want to keep that, that brand of the
10
      package.
                       So I think, you know, those are some of
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      the decisions that a company has to make as to how they're going to call out those attributes.

MICHAEL LANDA: Louisa Nickerson has a
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15
      questi on.
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                       ELIZABETH PIVONKA:
                                                  Well actually let me
17
      follow up on this one.
                       MI CHAEL LANDA:
18
                                             Oh, okay, sure.
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FDA Hearing Day 1.txt 19 ELI ZABETH PI VONKA: Related to fruits and vegetables, first of all, a lot of the fresh stuff doesn't have a package so it's hard for them 20 21 to label other than what the supermarket could do 22 0360 For those that are fresh cut, for for them. example, they may have a lot of nutrient content claims which they can make, it's just far too many, 2 3 it's too wordy, so in those instances our, our icon 5 would probably substitute, so. 6 RÓSE MARIE ROBERTSON: You know, I was, I was really struck today, we've always felt that, you know, the real estate's very valuable and you can't use too much of it, but the GDA kind of system that gives you, I suppose, the most important items in that they actually have sufficient scientific evidence to say that they really do meet a health 8 9 10 11 12 13 claim I would think would be the ones that, that 14 would appear most often. 15 It's not that you're going to get rid of other places to put things, I mean the facts panel could still have other items, but the things that either are very important for a health promotion or disease prevention or differentiate the product from 16 17 18 19 20 others would I think be the ones that would make it 21 on to that front page real estate. LOUISA NICKERSON: I just wanted to 22 0361 follow up on the Giant representative's response to 1 2 Dr. Ellwood's question. Why was it that you decided to limit the number of icons per product to three?

Was that about consumers can only take 4 5 6 7 in three nutritional attributes or was it something el se? 8 PAULETTE THOMPSON: It was something else, it's, again, our brand architecture people.
They really don't, I guess, take, take ownership of what that look and feel of that package is and don't 9 10 11 12 want to clutter it. MICHAEL LANDA: Rob Post has a question. ROBERT POST: Thanks. This is for the 13 14 I have a question about the population you 15 tested and whether, in fact, the population was a general population that you tested in terms of the response or the value of the AHA certification text 16 17 18 and the mark and also in that regard, do the -- of 19 that population, would they have viewed this information or is it your intent for the information to be general nutrition information or something 20 21 22 0362 1 that those with a disease like high blood pressure or a condition like that would be looking for? 2 3 4 ROSE MARIE ROBERTSON: Yeah, so to answer your first question, the, the two studies I cited, and we survey this from time to time, were 5 6 7 the primary shopper in one study and then the primary or secondary shopper, so, you know, these are largely women, they're, you know, largely women 8 in that kind of child-bearing years but can 9 10 certainly be older. So it's not, it's not anybody in the household, it's with a family income of above 11 35,000, so it's, you know, it does get down to 12 Page 132

FDA Hearing Day 1.txt 13 relatively low and this program is designed not to 14 be for patients, but to be for healthy people over 15 the age of 2. So it's not meant for people with hypertension or with high cholesterol. We have 16 17 specific recommendations for them that are more stringent than the ones that we would have here. 18 19 These would be actually absolutely in 20 21 keeping with the USDA dietary recommendations and 22 the dietary guidelines that we have for prevention 0363 of cardiovascular disease and stroke and would fit very well with the Cancer Society and Diabetes 1 2 Association's recommendations as well. ROBERT POST: So even though it's 5 6 7 oriented to heart health, it would still be general nutritional information? ROSE MARIE ROBERTSON: Yes, yes. 8 ROBERT POST: Okay. Thank you. 9 MI CHAEL LANDA: Dr. Schneeman has a 10 questi on. 11 BARBARA SCHNEEMAN: Actually I have a question, one question for Elizabeth and one question for Paulette. 12 13 14 And my question for Elizabeth, actually both of the third-party logo, it's my understanding, I just want to clarify, the American Heart, really 15 16 you only would work with the manufacturer, you don't work with retailers in terms of the use of the logo, 17 18 whereas Elizabeth, if I interpret your comments 19 20 correctly, you actually are working with both retailers as well as manufacturers? 21 22 ROSE MARIE ROBERTSON: So we would work 0364 with the manufacturer in terms of having the logo on the product and we would work with anybody in terms 3 of getting information out so when we do in-store 4 educational programs, we would, you know, be happy 5 to have -- and have the AHA logo available to use in 6 consumer education and encouraging towards healthy foods. 8 ELIZABETH PIVONKA: And as we work with supermarkets, we provide them tool kits with a lot 9 of already prepared ad copy and downloadable photos that they can use. We've even drafted, many of them 10 11 have magazines now that go out to their consumers 12 and we've even drafted what an ad might look like 13 there, so we provide them a lot of tools that they can use at their whim. It used to be back in the '90s we provided materials to retailers that were 14 15 16 17 all pretty standard, but they all wanted to customize it so now we give them all of the tools 18 that they can use to customize it. 19 20 BARBARA SCHNEEMAN: And then, Paulette, my question for you is I noticed that several of your logos used an arrow and of course an arrow 21 22 0365 could mean several different things and I was just 2 curious the degree to which you have consumer tested 3 that to see whether or not consumers understand that arrow to mean what the intent is in terms of the information for that symbol PAULETTE THOMPSON: We have used arrows Page 133

FDA Hearing Day 1.txt on the shelf labeling in Giant shelf labeling 8 programs, so we didn't feel the need to do any 9 consumer research in addition for the icons and the 10 icons are word reliant in that the words are there, it either says low fat or it says very low sodium or it, so, it can be clear to the consumer exactly what 11 12 13 the arrow indicates. And an up arrow, again, too, it says good source or excellent source and 14 15 identifies the exact claim. 16 MI CHAEL LANDA: Are there any other questions from the panel members? Oh, Kathleen 17 18 El I wood. 19 KATHLEEN ELLWOOD: A lot of speakers today have talked about the need to re-evaluate the criteria and look at this and there's, it's been generalities, nobody's been really specific about 20 21 22 0366 what needs to be done to set new criteria. Dr. Robertson, you were a little more specific in saying you should re-evaluate it every five years, which is going along with the dietary guidelines for Americans cycle. I don't, not sure 3 4 5 about the DRIs, that's not quite every five years.

Could you be a little -- expand on this a little bit more how you would envision this, who would be doing this? It's --6 7 8 9 RŎSE MARIE ROBERTSON: 10 You know, I guess the, in thinking about this, we hadn't envisioned a 11 change in how the dietary guidelines or the RDIs were generated, you know, the system for that as I think someone else said today, there's a system for 12 13 14 15 that and that system seems to be a pretty good 16 system. 17 You're asking about how do you then take those criteria and roll them into, roll them into 18 19 the system, into the icon system or symbol system, 20 just as the My Pyramid was developed with the new 21 gui del i nes. 22 I do think that it needs to be done by 0367 people who, who are very good at selling to the consumer. I was really struck by the clips we saw 2 3 earlier today that showed, you know, what you put in your food and what it means on the package. Boy, 5 that was a wonderful explanation in a short period 6 of time. So I think you need to have advertising people be part of how you do that and I think you probably need to revisit that as you move forward 8 ŏ 10 because what appeals to consumers changes over time. I guess I, my, you know, we would think that that might be an FDA task with sufficient 11 12 resources to provide it. 13 No question -- yeah. question that there would be, you know, that there 14 would be, I mean, voluntary health organizations, you know, many of them would be more than happy to 15 16 help with that, with those sorts of activities and of course many of our volunteers, you know, work for and volunteer for Federal agencies, as well. 17 18 19 So, I guess I think a uniform system 20 with uniform criteria seems to us that it might, 21 might come from the FDA. If it seems that that's 22

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FDA Hearing Day 1.txt impossible, it should come from some other sustainable organization or body that can do that over time and that could do that, you know, across, 2 3 4 5 across different health areas. ELIZABETH PIVONKA: Let me add to that, my initial thought was, gee, it would be difficult 6 7 because some systems are based on nutrients and 8 others are based on food, but, for example, the 9 whole grain or the fruit and vegetable, if you used fiber as a marker and there was a fiber as a nutrient requirement, that might get at the fruit and vegetable or the whole grain preference that 10 11 12 we'd like to have on some products, so you probably could work something out. It might not be as difficult as it first sounds. 13 14 15 MICHAEL LANDA: Any other questions? Hearing none, I want to thank the 16 17 presenters today, the members of the panel and also 18 19 the folks who take care of logistics for us, I think 20 the day went off nearly without a single hitch and so I think a round of applause is in order for all 21 22 of those folks. 0369 1 (Appl ause) 2 À couple of notes. We'll start, registration tomorrow is at 8 with a Continental 4 brĕakfast. We'll resume the hearing at 9:00. 5 Reception today starts at 5:30 and actually runs to 6 7 7:30, I think the program says 6:30, but it is in the Chesapeake room down the hall. 8 Thanks again and hope to see you 9 tomorrow. 10 (Hearing adjourned at 5:36 p.m.) 11 12 13 14 15 16 17 18 19 20 21 22 0370 CERTIFICATE OF TRANSCRIBER 1 $\mbox{\sc I}$, Monica Voorhees, do hereby certify that this transcript was prepared from tape to the best 2 3 4 5 6 7 8 of my ability. I am neither counsel nor party to this action nor am I interested in the outcome of this action. 9 10 Moni ca Voorhees 11 12 13 14 15 16

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