

NWX-FDA OC

Moderator: Renee Tchoulakian
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Coordinator: Welcome and thank you for standing by. Today's conference is being recorded. If you have any objections, you may disconnect at this time. All participants are in a listen only mode until the question and answer session at the end of today's presentation. To ask a question during that time, please press Star one and clearly state your name and organization before asking your question. I would now like to turn the call over to your host Kari Barrett. Thank you.

Kari Barrett: Great and thank you operator and good afternoon and thank you to everyone for participating in today's call. Again my name is Kari Barrett. I'm an advisor for strategic communications and public engagement in FDA's Office of Foods and Veterinary Medicine. And I will be moderating today's call. Again we want to thank you for attending today. We are going to discuss the supplemental draft guidance for menu labeling.

Today, I'm joined by Dr. Susan Mayne, Director of FDA's Center for Food Safety and Applied Nutrition or CFSAN; Claudine Kavanaugh, Senior Advisor for the Nutrition Policy in the Office of Foods and Veterinary Medicine; Felicia Billingslea, Director of Food Labeling and Standards Staff in our Office of Nutrition and Food Labeling CFSAN; and Lynn Szybist, our

Supervisory Consumer Safety Officer who is also with the Office of Nutrition and Food Labeling in CFSAN.

Before we begin, I do want to reference that given today's technical difficulties with our Web site, we've been unable to post materials associated with the draft guidance for menu labeling. But we have tried as much as we can to send out information via email.

One of the documents that we did send out was a PowerPoint presentation. And Dr. Kavanaugh will walk through that PowerPoint following Dr. Mayne's remarks. If you didn't receive it, please note that again we will post it as soon as we're able and our Web site is back in operation. And with that, Dr. Mayne I'll turn it over to you to provide some opening remarks.

Susan Mayne: Thanks Kari. Thank you for joining us today at this webinar on the Draft Supplemental Menu Labeling Guidance we released today. It is a major step in our effort to meet our public health obligations but to also ensure that we have done all we can to increase flexibility and reduce regulatory burdens. As we have been saying for some time, consumers need information about the food they eat so they can make informed decisions.

Having calorie information on menus and other nutrient information available on request is an important way of getting consumers what they need to make informed decisions. This is especially true when we consider that Americans eat and drink about 1/3 of their calories away from home and that recent data from the Centers for Disease Control and Prevention show that obesity in the U.S. remains a significant public health problem.

Providing calorie information consistently from state to state or city to city has two benefits. It reduces confusion for consumers and reduces the regulatory

burden on companies that market products in multiple locations. The draft guidance we are releasing today is designed to ensure that restaurants and other establishments that are subject to these provisions have clarity and certainty as to how they can efficiently meet the new menu labeling requirements.

In response to comments we've received on our interim final rules issued in May of 2017 which extended the compliance deadline and highlighted areas of concern voiced by industry. Since that time we have been diligently working to address the comments we have received.

We determined that the most expeditious way forward to address industry concerns was through a supplemental guidance. The new draft guidance demonstrates practical ways to comply with the requirements, many of which were inspired by menu labeling that we can see already in place. It also provides more flexible solutions to address industry concerns. As an example, we explain that marketing materials such as coupons would not be considered as menus and thus would not require the calories be declared.

Today, Dr. Claudine Kavanaugh will walk through the new draft guidance and she and Felicia Billingslea and Lynn Szybist will answer any questions. We know you haven't had time to review the document. So we are providing 60 days for you to comment after which we finalize the guidance to ensure that you have adequate time to implement the requirements by May 7 of 2018. Now I'm turning the presentation over to Dr. Kavanaugh.

Claudine Kavanaugh: Thank you Dr. Mayne. I'm happy to be here today to talk about supplemental draft guidance on menu labeling for the industry. So I'm starting on Slide two. The initial draft guidance addresses concerns that were

raised about challenges establishment safe and understanding how to meet their obligations of the new menu labeling regulations.

We have been diligently working to address the comments we received and to establish a sustainable framework for enabling this establishment to effectively meet the new menu labeling provisions. The guidance has some expanded and new policy interpretations identifying flexible and practical ways to comply with the requirements.

We also saw some innovative ways the industry has already implemented the requirements and it has highlighted some of these practices in our guidance. We have a 60 day comment period as Dr. Mayne said and we want your feedback. Comments would greatly be appreciated to help us further improve the guidance. We plan to finalize the guidance quickly in time for the May 7, 2018 compliance date. We are not planning to extend the comment period.

On Slide three, I outlined the topics that are covered in the guidance. We cover many different topics and we put it in a question and answer format. We have also included a lot of graphics to communicate our thinking. Some topics covered in the guidance are the calorie disclosure for self-service food, the criteria for distinguishing between menus and marketing materials, methods for providing calorie disclosure information, compliance and enforcement, determining the nutrient content for standard menu items, as well as some questions on covered establishments, standard menu items and alcohol.

Turning to Slide three, I'm going to review two topics to - or four topics today. The criteria for distinguishing menus and marketing materials, the calorie disclosure for self-service foods, methods for providing calorie disclosure, and also compliance and enforcement. We encourage you to go to the guidance

and look at all the other ones that we are not covering, but we're going to provide a broad overview of these topics today.

So moving to Slide five, the criteria for distinguishing menus from marketing materials. Marketing materials will generally not require - be considered a menu or menu board and would not require calorie labeling. Some examples would be pizza coupon, posters in store windows, signs on gas pumps, billboards and banners, and newspaper inserts. The primary purpose of the materials listed above is really to entice customers into establishments. They would not meet the criteria of a primary writing by which a consumer would make an order selection.

We actually provide some examples if you move onto Slide six. On Slide six, we show a picture of two for \$2.99 with hotdogs and sausages. This would be an example of a poster or a banner in a window you might see at a convenience store or on a gas pump. And this would not require a calorie declaration. It's more to entice the customer to come into the establishment.

On slide seven, we show an example of a marketing board which would not require calorie labeling. It's - it would not be the primary writing through which a customer would make an order selection. It's more used to market or entice the food to the consumers.

Moving onto Slide eight, we want to review some of the calorie disclosure for self-service food including buffet food. We heard a lot of concerns from industry groups that self-service foods require individual signs for every food. The regulation actually provides a lot of flexibility. Calories for self-service foods can be declared in a variety of ways.

The consumer just needs to view the names, the calorie declaration and the serving of the particular menu item while selecting that item. Individual signs again are not required. Menus and menu boards are also not required at each self-service location. However, the calorie declarations for self-service foods do need to be declared.

Now I'm going to go through a few graphics that illustrate how different ways that the calories can be displayed on self-service foods. On Slide nine, we show an example of declaring calories for multiple items for a self-service salad bar using a single sign attached to the sleeve guard. As you can see from the picture, there is a variety of food on the salad bar, but the consumer can actually see the sign, the one large sign, that has all the information listed on the salad bar while serving their stuff. I encourage you to look for guidance which actually has. We provide an enlarged version of design as well for your information.

Moving onto Slide ten, this is an example of declaring calories for self-service foods using individual signs which are actually prominent place card holders on the sleeve guard and then there's paper underneath that can be interchangeable. One of the issues that we've heard from a lot of establishments that have salad bars and (unintelligible) foods is that they need the flexibility to be able to change out different things on the salad bar based on their availability. Having these permanent place hold - place card holders and being able to just flip out the paper with the calorie information and the serving information is very easy.

On Slide 11, we have an example of declaring calories for multiple items on a self-service buffet using a single sign hanging below the sleeve guard. As you can see there's about five items that are viewable from the buffet and all of those items are listed on the sign below the sleeve guard.

Moving onto Slide 12, you can see another example of the same self-service buffet but on this we're using individual signs and they're actually gel clings on the sleeve guard. These gel clings allow the establishments to make quick changes in case food needs to be swapped out. You can just peel the gel cling off and put the new gel cling on.

On Slide 13, we show an example for declaring calories for multiple self-service items on a single sign. And in this example, it's a bakery display case. Each type of donut does not have to be individually labeled. So one sign is consistent so as long as the consumer can see the sign while making their selection.

On the next Slide, Slide 14, we show some examples of grab and go food that meet the calorie declaration requirements by using a front pack calorie declaration or really just a sticker that can be viewed by the consumer before making their purchase. Stickers would also work on a variety of other individually wrapped grab and go foods like sandwiches, fruit cups, and yogurt parfaits. In this slide presentation, we just provided a few examples for you. Our guidance has many more examples for you to view. Please go to the guidance and look at some of our other examples.

Now moving onto Slide 15, we want to discuss the methods for providing calorie disclosures. Calorie declarations need to be adjacent to either the name or the price of the associated standard menu item. In considering what would be clear and adjacent, FDA really expects the name or the price and the calorie declaration to be displayed in such a way that the consumer can determine which calories are posted for each standard menu item. We also note that the menu labeling regulations does not mandate that establishments

have menu boards. However if you do have menu boards, they need to be labeled.

Moving onto Slide 16, we have heard a lot of concerns around the calorie disclosure for build your own pieces and the challenges of providing calorie information for so many different options. Many pizza restaurants have different types of crusts, sauces, as well as many topping options for various sizes of pizza.

We really took this account with developing some models for how calories can be communicated to consumers and not overburden the pizza establishment. Calories may be declared in a range if there are three or more toppings, crust or sauce options for each size pizza. Toppings and crust and sauce options can - that have the same number of calories can also be grouped together.

On Slide 17, we actually provide an example of declaring the calories per slice or build your own pizzas using a column format. In this example, they're providing calorie declaration again per slice and we require the number of slices per each pizza size as you can see is at the top of the menu board in yellow above the small, medium, large and extra-large.

We're also providing ranges for the various different types of crust, sauces and toppings. We included a succinct statement and the availability of the written nutrition information statement. There are other ways to meet the requirements such as labeling pies. We are just providing some examples. Establishments can certainly use other ways to provide the information as long as they meet the requirements.

On the next Slide, Slide 18, we are showing how you can declare calories again using the build your own pizza format using the string only format. Many establishments use this type of display in their menus. And then on slide 19, we wanted to provide many different examples. Our previous two examples used more of a horizontal type menu board. So we provided an example using a vertical board.

Moving onto Slide 20, compliance and enforcement, FDA plans to work cooperatively with covered establishments to come into compliance with the menu labeling requirements. We have had a lot of public workshops, actually three last year, and we have had many meetings with the industry to help them come into compliance. We plan to continue this education and outreach and especially have that be our focus in the first year.

If menus and menu boards are not in compliance, FDA will work flexibly and cooperatively with individual establishments that are making a good faith effort to comply with the requirements. We will work with an establishment to make an appropriate to - establishment on an appropriate timeframe to which to make any corrections.

Moving on to Slide 21, FDA does not intend to penalize or recommend the use of criminal penalties for minor violations. In our guidance, we actually give some examples of what we think would be minor violations. This would be inadvertently missing a calorie declaration for a standard menu item on a buffet when all the other items are labeled. We certainly know that a consumer could knock away a sign or something like that. That would be considered a minor violation.

Other minor violations would be minor discrepancies in the type size or color and contrast of the calorie declaration as well as minimal variations or

inadvertent errors that would minimally impact the calorie declaration. Some examples would be adding a couple extra slices of pepperoni on a pizza or perhaps adding an extra dollop of ketchup on a hamburger when it's not added. All of those would be considered minor violations and we would not recommend the use of criminal penalties for these types of violations.

Finally on the last Slide, Slide 22, again we are requesting feedback on our draft guidance. You have 60 days. Please provide feedback by January 8, 2018 and we have the docket number as well as the Web site www.regulations.gov is where you need to go to provide the feedback. And now I'm going to hand it back over to Kari.

Kari Barrett: Great. Thank you so much. Let's go - first let's again thank both of our speakers and then we'll go to the operator to open the phone lines and provide instructions for our callers who may have questions. If you do have a question if you'll please state your name and the name of your organization prior to asking a question. Operator?

Coordinator: Thank you. At this time, we'll begin today's question and answer session of the conference. Please press Star one and clearly state your name and organization before asking your question. Again to ask a question, please press Star one and clearly state your name and organization before asking your question. One moment please to see if we gather questions. Our first question comes from (Joseph Markus). Your line is now open. Our next question will come from Matthew Foley. Your line is now open.

Matthew Foley: Hi. This is Matt Foley with the National Grocers Association. First of all, thanks so much for hosting this call. We really appreciate it and all the work that you guys have put into putting out this guidance. A question about the guidance and the interaction with the underlying rules. With regard to private

rights of action, what effect does the guidance and some of the changes and the clarification that you all have put out in the guidance, what effect does that have in the underlying rule in how potential legal action might take place?

Claudine Kavanaugh: Thank you Matt for your question. The draft supplemental guidance actually doesn't address private rights of action. And we would defer you to Congress for those questions.

Kari Barrett: Operator do we have additional questions?

Coordinator: And at this time, I show no additional questions at this time.

Claudine Kavanaugh: Why don't we (unintelligible) - if you have a question, we'll hold on for a few seconds here. Please don't hesitate to ask.

Coordinator: It looks like we've had a question come in and the question is from (Patricia Wincoop). Your line is now open.

(Patricia Wincoop): Thank you. I just want some clarification between menu and marketing materials. We have a pizza coupon that gives like the name of the product and the price line but we put a phone number or a Web site to order form. Does that become a primary writing or does it remain a marketing material?

Claudine Kavanaugh: So I was going to say we have in our guidance that pizza coupons generally are not required to have the calorie declaration. However for specific questions like that, we think you need to submit comments. This is because of feedback that we would need. So I direct you really to look at the guidance that gives more detail on the specific questions around the marketing materials. We just provided a broad overview today. And then if you still

have questions, that's the type of feedback that we need if we need to make the guidance a little bit more clear.

(Patricia Wincoop): Thank you.

Coordinator: Our next question comes from (Richard Bobby). Your line is now open. (Richard) please check your mute button. Your line is open.

(Richard Bobby): Sorry about that. Hi. I had a question about getting some clarification on nutritional calculators for our Web site. Could those be used in lieu of having calorie information on the Web site menus?

Claudine Kavanaugh: I was going to say we definitely want feedback. So but normally if you have menus or menu boards whether they're online or in the store they need to have calorie declarations. But we welcome feedback.

(Richard Bobby): Okay. Thank you.

Coordinator: And at this time, I'm showing no additional questions.

Kari Barrett: Okay. Well having no additional questions, we will go ahead and conclude today's stakeholder call. Thank you again for your participation and as mentioned we welcome your comments and look forward your review of the guidance. Thank you again.

Coordinator: This concludes today's conference. All participants may disconnect at this time. Thank you for your participation.

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