

Unofficial transcript of FDA media teleconference, February 15, 2006

Kim Rawlings, FDA spokeswoman

Thank you all for joining our telebriefing on whole grain today. Today FDA has issued a draft guidance on what the term whole grain may include. Dr. Barbara Schneeman, the director of the office of nutritional products, labeling, and dietary supplements will elaborate on today's announcement with her opening remarks and then will open the line to take questions.

Dr. Barbara Schneeman

I'll keep my opening remarks very brief. I'm sure many of you are familiar with the 2005 Dietary Guidelines for Americans, which included among its recommendations an encouragement for Americans to consume more whole grains, and specifically recommended that at least half of the grain consumption should come from whole grain. So consistent with that and FDA's interest in supporting the 2005 DG recommendations, we have issued today a draft document that provides definition for the term whole grain.

We view this guidance document as assisting manufacturers with understanding what FDA considers appropriate for food labels that are making a whole grain content statement. Also we think it's very important that consumers are able to have consistent and uniform terminology of what constitutes a whole grain. Within the guidance itself it's structured in a question and answer format. We address the basic definition of a whole grain ingredient. We talk about the different types of grains that can be included as whole grains, we also point to some items such as legumes that should not be considered whole grains and we talk about the kind of statements that could be used on packages that contain whole grains. I won't go into the details but will move to answering your questions.

Jennifer Corbett, Dow Jones

- Q. Are these updated guidelines or is this the first set of guidelines that addresses whole grains? I mean, you see whole grains on packaging all the time, so I didn't know what manufacturers have been using up to this point.
- A. This is the first time that FDA has issued a guidance document defining whole grains. We do have standards for, for example, whole wheat bread, there's a standard of identity that manufacturers can use. But this gets to more basic questions about what constitutes a whole grain. So manufacturers would have used perhaps other types of professional organizations' definitions before this time.
- Q. Okay, Do you think these vary from what... Do you think there will be any problems? I guess the only whole grains I think I see are on cereal and bread. But I guess bread has already been operating under some standards.
- A. In developing our guidance document, FDA looked at the kind of definitions that exist in the scientific literature, with industry trade groups, the kinds of definitions... We looked very closely at what is used and what is accepted in terms of defining whole grains. This is draft guidance and we'll be taking comments and suggestions. We anticipate that there will be comments and suggestions that come to us. We think we are reflecting current scientific information on the definition of whole grains.

Sally Squires, Washington Post

- Q. Good morning. Couple of questions. How long will the period be for comments? And what will consumers see during that time in the marketplace? In your

definition are you looking at a certain amount of grain that must be contained in order... I know that the Whole Grains Council has different definitions and I wonder how close what you're suggesting will be to that?

- A. First of all, the comment period is for 60 days so during that period we expect comments and suggestions to come in to the docket that has been opened. And one of the comments that we make in the draft guidance is that manufacturers can make quantitative statements about the amount of whole grain that is in a product, so to say, contains "10 grams of whole grain" or "1/2 an ounce of whole grain" but they should not be making statements that imply a level such as "high" or "excellent source. We've referred to that in the opening part of our guidance."
- Q. OK, so for the WG Stamps that are now being used on a number of products, what happens to those?
- A. You know, for anything like that we would have to do a case by case analysis to look at a product, look at the total amount of information on the label to evaluate if that information is truthful and not misleading to consumers.
- Q. So, because those whole grain stamps have really just started this year, well I guess in 2005, and they are out on a lot of products, so does that mean that that whole... that's going to have to be re-evaluated now by your agency?
- A. You know, again, With respect to any one product, we'd have to do an evaluation to determine if the information is truthful and not misleading. But we have indicated in our Guidance that we want to make sure that any statements used on these products are truthful and not misleading and that they do not imply a particular level of the ingredient such as high or excellent source.
- Q. OK. Are you going to set, so in other words, there would be... I noticed in the press release you said that oatmeal for example whether rolled or quick would be considered a whole grain but something that had 100% bran based on the definition of having all three parts of the grain sounds like it might not be ... Will the FDA say then, well... How are you going to help consumers understand that better?
- A. Certainly the information will be incorporated into any education and outreach materials that the FDA puts forward. So as part of our outreach to consumers and providing information and certainly we hope the media would be helpful in that regard to getting that information to consumers. If you look at our definition, right off the top, one of the first questions deals with what is a whole grain and that inclusion of the bran, germ, and endosperm in the proportions that you would naturally find in the grain, that's what constitutes a whole grain.
- Q. OK and is that going to be available on your website for us?
- A. Yes. [Kim answers] It will be available and if you have problems finding it give me a call. This is Kim Rawlings.

Marian Burros, New York Times

- Q. This guidance, this draft guidance you're sending out. Is this followed by regulations or just guidance? What's the final end result after the 60 day comment period?
- A. After the 60-day comment period is over we can finalize our Guidance. That would be one option for us. Certainly with respect to whole grains, it has been a priority for the agency to develop our whole strategy with regard to whole grains. So, there may be other issues that still need to be resolved. We're going to be looking for what comes in through the comment period to see if there are any other actions that the agency should consider.
- Q. So this is not necessarily going to result in a regulation?

- A. The guidance is intended as guidance. We certainly hope to be able to finalize our guidance in a manner that reflects the comments and suggestions that we've received.
- Q. I'm sorry. I don't mean to press you. But that means that if somebody continues to use Stamps or whatever they want to use on their product that says "Better Source of Whole Grain" or "Good Source of Whole Grain" that they are not going to be out of compliance with anything. They continue to use it unless you happen to pick it up and take a look at it and say, 'You can't do that'? I'm trying to understand just how much force what you're offering right now actually has.
- A. Right. And so, what the guidance does is it tells the industry and it tells consumers what FDA's current thinking is. And we hope in providing that Guidance that it clarifies what the agency might regard as the kind of statements that could be false or misleading to consumers. So we feel that we are clarifying our current thinking and hopefully then the industry uses that information to make sure that their products are consistent with the kind of information we're providing in our guidance.
- Q. But you will have no recourse, the way recourse was available in other instances, if someone does not care to follow your guidance? You cannot prevent them from doing that?
- A. Again, we would look at a product to make sure that the information on that product is truthful and not misleading. So with this guidance the industry has a very good indication of FDA's thinking and they know the kinds of things we're likely to look for in that product labeling information
- Q. And then what's the next step after that if they do not comply with the guidance?
- A. Again, we're going to look to see if material is truthful and not misleading.
- Q. And if it is not truthful and it is misleading? I'm trying to find out what you would do.
- A. Well, if the agency goes through a process and determines that something is fraudulent or potentially misleading to consumers we have several enforcement steps that we can take. Certainly in terms of notifying that manufacturer we have different types of letters that we can use to inform the manufacturer. But there are several steps and obviously we're looking at the particular situation and we'd have to decide what's most appropriate in that context.
- Q. I hate to keep pressing you but I'm trying to see what... The chances of your looking at all these products out here that might be false and misleading is quite small since you have such a small staff and small resources. This is not like somebody putting something on the label that is absolutely forbidden by regulation, I gather?
- A. I'm sorry I lost the thread of your question. Could you repeat it please?
- Q. Yes, this is not the same as someone putting something on a label that is forbidden by regulation which permits the agency to take certain steps. This is a different thing since this is guidance. "You ought to be doing this, but we may not do anything to you if you don't?"
- A. Yeah, again, where we come back with that is, we are letting the industry and consumers know what the agency's current thinking is. And certainly it's our goal and one of the purposes of doing this is to help the industry move in a direction that provides consumers with information that is truthful and not misleading about whole grains. And that's where we hope this guidance will have impact.
- Q. So you're looking for percentages and amounts rather than statements good-better-best? Is that my understanding of what you're saying? It's hard to talk about this without having seen the document; I'm sorry.
- A. Yea, well, what the document addresses is what constitutes a whole grain. What

factors should be considered in determining whether a food is a whole grain in terms of what are the components you need, what are examples of cereal grains. Those are the kinds of questions that we've set up then to provide guidance and our answers to those questions. And the sort of statements that people can make about whole grain content would be quantitative statements on whole grain content – how much does this product contain? Or in some cases where a product is 100% whole grain, we provide that information as well.

Libby Quaid, AP

- Q. Hi. I'd just like to have you talk a little bit more about what the new guidance means for, say, bread on a shelf in a supermarket that currently says "a good source of whole grain." Consumers get very confused by multigrain, hearty grain, 7 grain. How do these guidelines help them know if they're getting the recommended amount?
- A. [note: this section was hard to hear because of background noise; some words are missing]
What this does is help to define the ingredients that would [??] that type of product. The consumer needs to look at the ingredient list to identify which ingredients are whole grain. What we encourage them to do is look for the ingredient that's the first. If a whole grain product is listed first, that tells you that that's the most the [??] ingredient in that particular product. As you note that using the term multigrain or 7 grain doesn't necessarily mean that a product contains whole grain. They need to look for that whole grain terminology in the ingredient list. So what we're doing with this guidance is providing information on what would a whole grain be that could be in that ingredient list.
- Q. And if I could follow up. What does this mean for products that currently say "a good source of whole grains" or that use the Stamps saying excellent source of whole grain? Does that change anything for those products?
- A. Well, the FDA does not feel that that terminology is appropriate to use on these products, in part because it's implying a certain level of whole grain that has not been defined. Those terms have been used for nutrient content claims. When a nutrient content claim is used on a product, such as good source of calcium, a consumer can look at the Nutrition Facts Panel and be able to relate that statement to what shows up on the Nutrition Facts panel. So FDA has indicated in other documents that those terms are more appropriately used for nutrient content claims.
- Q. Does that mean that manufacturers will still be able to use things like those Stamps, or does FDA want them to take the Stamps off?
- A. Again, we would have to look at a particular product to understand the context of that product, whether something is being used appropriately and the information is truthful and not misleading.

Elizabeth Lee, Atlanta Journal Constitution

- Q. Hi I have 2 questions. One specifically. Would you characterize the terms "Excellent Source" or "Good Source of Whole grains" as false and misleading given that there is no definition and some manufacturers have suggested 5g would be a good source and some manufacturers have suggested 8 grams as a good source. Is the term itself false and misleading?
- A. Again, We would have to look at a package and the total labeling information to really evaluate a package and whether the labeling is truthful and not misleading – or false and misleading. What our statement is, that these terms have been used

for nutrient content claims. The agency, in using those terms for nutrient content claims, one of the goals under the Nutrition Labeling and Education Act where nutrient content claims were defined was to make sure that consistent and uniform terminology was developed so consumers could rely on that terminology. That's part of our thinking as to why those terms were defined for nutrient content claims. At this point we can't say that it's appropriate for these types of claims. In addressing this issue we've noticed that there are several steps that the agency would have to go through in order to think about the use of such terminology. For example, do we consider whole grains the way we do a nutrient? Should we consider whole grains a category of food? There are a lot of questions that remain unresolved. For the agency to resolve those kinds of questions we would normally have to go through a process that would require, that would allow for, public comment and public input into the decision-making process.

Q. Is that what you're asking for now with this, or that would be yet another public comment period?

A. That would probably be another comment period. We would need a process where we lay out those kinds of issues and then seek comments from the public on those. We certainly hope that what we will get as comments here in terms of helping us define whole grains and making sure we're doing it in a way that helps consumers choose products that are consistent with the Dietary Guidelines so that consumers are able to make more healthful food choices, and also help the industry develop a common terminology so that that term "whole grains" is used in a more uniform and consistent manner across these products.

Q. Dr. Schneeman, not having seen your guidance, again, it's very hard to ask questions, but is it going to be very close to what USDA issued last fall which is some very specific guidance about what a whole grain is and relating it to My Pyramid servings or is it a more general discussion?

A. I don't think it's exactly the same as what USDA was doing. Part of what we were trying to do... Let me just read to you the first questions. I have to dig through my papers. "What factors should be considered in determining whether a food is a whole grain?" "Cereal grains that consist of the intact, ground, cracked or flaked caryopsis, whose principal anatomical components – the starchy endosperm, germ and bran – are present in the same relative proportions as they exist in the intact caryopsis – should be considered a whole grain food. And then the next question, "What are examples?" and then we talk about the cereal grains that exist. Third question, "Should soybeans and chickpeas be considered whole grains?" And we point out that these are not whole grains, that they are in fact other categories, legumes. There are some questions about corn. There's a question about barley because a lot of barley that's in the marketplace is pearled barley and pearled barley you're removing part of those components, so that is not considered a whole grain. A question about rolled oats, that rolled oats are usually the whole grain that's flattened. "Does the term whole grain mean the same as 100% whole grain?" "If the product is labeled wheat bagel or wheat pizza how much whole wheat should it contain?" And this probably comes the closest. So again, we haven't defined any claims concerning the grain content of whole grain foods. We do have a set of food standards that talk about what is in a standardized product such as whole wheat flour or whole durum flour and then what it means to make a label statement as 100% whole grain, and when can you use the term whole grain vs. the specific grain – the whole wheat or whole corn or whole oats. But these are the kind of question that we are addressing in the guidance.

Q. Kim, I have been looking on your website and have not found the guidance. If it is

possible just to give us the address or point us to a specific area that would be very helpful.

- A. [From Kimberly Rawlings] I will be getting a participants list and I'll email a copy to everyone registered. It should be posted and if not it will be posted very soon. I apologize.
- Q. I have one more question for Dr. Schneeman. In looking at the press release it doesn't seem that your definition is any different from what was already out with the Dietary Guidelines or My Pyramid. Are there any key differences that I'm overlooking?
- A. Again, in the process of developing the definition certainly we looked at the Dietary Guidelines, we looked at the scientific reports on the Dietary Guidelines, other scientific material that was available, so yes we are consistent with what is in the Dietary Guidelines. But we have, our Qs&As probably go into a bit more detail and it gets into more specifics in terms of how it relates to the food standards, the kind of phrases that can be used on products. So I think it's just providing more information and using more examples of how to use that terminology. We are consistent with what's in the Dietary Guidelines.

Christopher Doering [Reuters?]

- Q. I just wanted to clarify that this will be published in the Federal Register for comment, correct?
- A. There is a notice of availability that's in the Federal Register and yes, it is now open for comment and it should be open for 60 days.

Catherine Richart, FDA Week

My questions have already been asked.

Julie Jones, AACC International, Cereal Foods World

- Q. The statement about the number of grams per, would it be per RACC or per one ounce equivalent serving?
- A. Julie, I'm not sure I fully understand your question.
- Q. If they say on the package, you now can make a statement about "This product contains 10 grams of WG" let's say. That is a statement of fact, right?
- A. Right, a statement of fact, yes.
- Q. I have two questions really. One, is that going to be in a context, like "People need 48g in a day?" Or is it just going to be the gram statement and we would need to do nutrition education about the amount that they need in a day?
- A. What currently falls within the regulations in terms of statements on products are quantitative statements that are accurate and yes, would refer to the amount of whole grain that would be in a serving and FDA uses the reference amount customarily consumed, or RACC as the reference serving amt.
- Q. All right, thanks, so in some cases that would be different from the USDA ounce equivalent?
- A. Our servings are in fact those reference amounts customarily consumed. The Food Guide Pyramid where they have a total amount that's recommended or the ounce equivalent, that's based on the pyramid and recommended servings.

Jane Zhang, Wall Street Journal

- Q. Hi Dr. Schneeman, Kim. I have a couple of questions. What is ahead for FDA about this issue? What is your goal of this? You're going to have to define whole grain either as a nutrient or a whole new category? or... what is ahead?

- A. Right. Certainly there is consideration of how should FDA be categorizing something like whole grain: Is it a food category, a food ingredient, a nutrient, or something else? We already had from 2003, we had already requested some comments on dietary guidance statements and we asked some questions about whole grains in that context so we have some comments that we're evaluating, and we need to have a greater opportunity to have input on that. The other area that we've identified that we need to have more input on is: How should we be thinking about whole grains in terms of health benefits? In the original regulations with NLEA (the Nutrition Labeling and Education Act) the agency had indicated that many times whole grain implied a health claim or a nutrient content claim about fiber. What we have from the Dietary Guidelines is scientific information that suggests we should be thinking about whole grain as more than just its fiber content. So there are some scientific issues there that the FDA needs to consider. How should we be thinking about whole grains and their health benefits?
- Q. So this is one step toward that? The guidance document?
- A. Yes, this is one step toward that.
- Q. So what will happen after the 60-day comment period?
- A. Right, so when FDA receives the comments, then we can review those comments, and decide if revisions are needed to our draft guidance document, and then we can move forward with finalizing this piece, the draft guidance.
- Q. So it will still be a Guidance? Or a final policy?
- A. Again, I wouldn't want to prejudge where we come out because we'll obviously want to look at the comments that come in to us. But certainly at this point the agency's intent is to have this as guidance and to reflect our thinking about what constitutes whole grains.
- Q. Well my other question is, What will you do with claims like, you know, "excellent source or good source of" and also maybe if they say like "50% of whole grain" on a package? I know you guys wrote on a petition that General Mills did, but what will happen to them, those kind of claims?
- A. Again, what we would like manufacturers to do is certainly look at our guidance document and use that information in terms of thinking through the kind of statements and information they're providing to consumers on their food package. For the agency itself, we're always in that situation of we would have to evaluate a package and the labeling associated with that package.
- Q. Since you already told General Mills that it's not a truthful statement, you can't use "a Good source or Excellent source of whole grain" are you in the process of telling them not to use that on their packages?
- A. Well, you've probably seen the letter we have sent to General Mills.
- Q. Right.
- A. That is our communication to General Mills about the petition that was submitted. And yes, in that petition we did indicate that we didn't think that those descriptors were appropriate because of their use and association with nutrient content claims.
- Q. So you're telling them not to use that at all?
- A. I think all we... what we have is our letter to General Mills.

Kim Rawlings

Thank you all for joining us. If you have additional questions, you may telephone me at 301-827-6242 or kimberly.rawlings@fda.hhs.gov