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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 2006D-0066; Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements

Nestlé USA, Inc. ("Nestlé") supports the comments submitted by FPA and GMA on this topic, but would like to submit brief comments of its own. The comments from those two associations had to, of course, take into account all member company views, leaving open the need for individual companies to submit their own specific comments, if any.

Nestlé wants to re-emphasize the point that whole grain claims should NOT be viewed as *nutrient* content claims. Rather, they are *ingredient* claims. Still, we strongly agree with the associations' comments that additional claims should be allowed for whole grain content, as consumers are very interested in this information to help improve their diets.

Good Source and Excellent Source claims should be allowed as ingredient claims

We are of the opinion that FDA guidance should establish criteria for Good Source and Excellent Source claims for whole grains. These terms would be useful in permitting consumers an easy means for choosing foods recommended by the Dietary Guidelines. Although Good Source and Excellent Source are regulated terms that currently apply only to nutrient content claims, we see their utility as ingredient claims as well, and strongly recommend that the agency formally change the stance taken in the interim guidance document on this issue.

The next question is, however: Should actual criteria for such claims be provided in agency guidance? Nestlé thinks Yes, this would be the best approach. When it comes to ingredient claims for a food category like this that is specifically recommended in the Dietary Guidelines in terms of ounce equivalents, we think it would be best to have standardized criteria that define these characterizing terms. Without standardization, we believe consumers could become confused by having the terms used differently by different companies. Although whole grains are not nutrients, we view this as conceptually similar to

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Congress' objective in mandating definitions for nutrient content claims (i.e., so that such characterizing terms were standardized for consumers).

We agree with associations' comments that non-misleading uses of these terms could be achieved by disclosing additional information, such as amount per serving and the total daily amount recommended by the Dietary Guidelines. However, in the long run, we feel that the marketplace would eventually have to settle on what was the lowest amount of whole grains that could be substantiated as being "good" or "excellent" anyway, so it would be best to establish those criteria through guidance up front, and avoid the additional claim disclosures and possible consumer confusion.

If criteria should be established, what should they be and why? On this question, we direct you to GMA's comments under C(2) (a) and (b). This section presents rationale for establishing either 5 g and 10g for Good Source and Excellent Source, respectively, or 8 g and 16 g per RAAC. We have reprinted this section at the end of this letter for your quick reference. These paragraphs outline how the agency could approach a reasonable basis for establishing criteria for these claims. Nestlé does not have a recommended choice of these two alternatives, and would leave it to the agency to decide which is preferable.

"Whole grain" does NOT mean 100% whole grain

Nestlé also supports the associations' comments on this point, but wants to emphasize our position. Using "whole grain" to qualify a product identity (such as "whole grain bread") does not mean that the grain component is 100% whole grain because companies using 100% whole grain generally specify "100% whole grain". Thus, it is understood by consumers that an unqualified "whole grain" statement does not mean 100%. We agree that "whole grain" indicates a grain component that is greater than 50% whole grain. Also, we agree that if "whole grain" is used in a product identity whose portion is less than or equal to 50%, the use of "whole grain" should be qualified by including a stated percentage or other disclosure to ensure it is non-misleading (e.g., "40% whole grain bread").

Sincerely,



Kenneth Mercurio
Director, Regulatory and Nutrition
Nestlé USA

Copied by permission from the GMA Comments dated 4/18/06:

FDA Could Define "Good Source" and "Excellent Source" Claims for Use with Whole Grains

By drawing upon the *Dietary Guidelines*, the prerequisites for use of the terms “good source” and “excellent source” can be defined by FDA in a way that ensures that products bearing such label statements contain a meaningful amount of whole grains. While there is no “Daily Value” for whole grains, both MyPyramid and the *Dietary Guidelines* recommend that consumers eat at least 3 one ounce-equivalents of whole grains a day (or at least 48 grams), for a 2000 calorie diet. Thus, the amount of whole grains necessary in a food to qualify for a descriptive claim could be based upon these recommendations. In other words, FDA could use the MyPyramid “3 one ounce-equivalents” recommendation for whole grains as the functional equivalent of the Dietary Reference Intake (DRI) for nutrients. This provides the necessary predicate for deciding how much of added whole grains is a meaningful amount.

The *Dietary Guidelines* recommend the consumption of at least 3 one ounce-equivalents of whole grains per day. USDA has determined that because a slice of white bread contains 16 grams of flour, 1 one ounce-equivalent of whole grains contains 16 grams of grain. Accordingly, 3 one-ounce equivalents of whole grains would provide 48 grams of grain. ^{1/} Using this framework, GMA proposes two different options by which FDA could establish quantitative requirements for “good source” and “excellent source” claims and at the same time provide information to consumers that uses the ounce-equivalents metric established by MyPyramid. Under the first option, 5 grams of whole grains present in food per Reference Amount Customarily Consumed (RACC) and per labeled serving would qualify for a “good source of whole grains” claim, and 10 grams of whole grains present per RACC and per serving would qualify for an “excellent source of whole grains” claim. Under the second option, ½ ounce or 8 grams of whole grains per RACC and per labeled serving would qualify for a “good source” claim and 1 ounce or 16 grams of whole grains would qualify for an “excellent source” claim. The rationale for each option is discussed below:

These two proposals need to be evaluated in conjunction with the attached sample menus prepared by GMA. These menus provide examples of how these options would assist consumers in reaching the recommended goal of at least 48 grams of whole grains per day, as well as the resulting calorie intakes. As noted above, these menus are based on products that are now in the marketplace, will be introduced, or could reasonably be introduced into the marketplace, based on reformulations by GMA member companies and represent foods that are widely consumed within the U.S. population. Thus, they provide a practical “roadmap” to achieving the recommendations of the *Dietary Guidelines* and MyPyramid.

a. Five Grams and Ten Grams

The first option – allowing those foods containing 5 grams of whole grains per RACC and per labeled serving to bear a “good source of whole grains” label statement, and to allow those foods containing 10 grams of whole grains per RACC and per labeled serving to bear an “excellent source of whole grains” label statement – would be based on the amounts that are consistent with the 10% and 20% requirements for nutrient content claims.

That is, 10% of the minimum daily recommended amount of 48 grams is approximately 5 grams, and 20% of the minimum daily recommended amount of whole grains is approximately 10 grams. Just as in other contexts, 10% and 20% of the recommended minimum would be considered meaningful amounts.

At these levels, food manufacturers can add whole grains to a wide variety of foods, without adversely affecting their taste. Additionally, manufacturers would be able to add a meaningful amount of whole grains to foods with smaller RACCs. Consumers would have many more choices of food products that contain whole grains because food manufacturers will be encouraged to add whole grains to their products at these amounts. Although it can be challenging to reach the recommended daily level of 48 grams under this option, that level could be reached by replacing any one or more of the products with a 100% whole grain product. Consumers could consume 40 grams of the daily recommended 48 grams of whole grains from a mixture of products providing 5 grams and 10 grams and an average caloric contribution of 715 calories. Thus, implementation of “good” and “excellent source” claims for foods containing 5 grams or 10 grams of whole grains per RACC and per labeled serving would provide consumers with a plethora of whole grain containing products in order to more easily meet the minimum daily recommended amount of whole grain consumption.

b. Eight Grams and Sixteen Grams

The second option, 8/16 grams of whole grains for good/excellent source claims, is based on using the “ounce-equivalent” metric from the *Dietary Guidelines/MyPyramid* and converting that to grams. As noted above, using bread as a commonly consumed food that is suitable for containing whole grains, the conversion to grams would be 16 grams for 1 “one ounce-equivalent” and 8 grams for ½ “one ounce-equivalent.”

If the agency accepts the proposal that 8 grams of whole grains per RACC and per labeled serving or a ½ ounce equivalent of whole grains qualifies for a “good source” claim, consumers would be receiving 16% of the daily recommended amount for whole grains. Likewise, 1 ounce or 16 grams of whole grains represents 33% of the daily recommended amount of whole grain consumption. Both are significantly more than the 10% and 20% requirements for nutrient content claims and would even more clearly be considered meaningful amounts.

Additionally, products with whole grains at these respective amounts will contribute significant nutritive benefits to consumers, within a reasonable level of caloric consumption. For example, as evidenced in the attached menus, consumers could meet the minimum *Dietary Guidelines* recommendation of 48 grams per day by consuming foods containing 16 grams of whole grains, with an average caloric contribution from the whole grains of 387 calories or by consuming a mixture of products containing at least 8 grams of whole grains and products containing 16 grams of whole grains, with an average caloric contribution from the whole grains of 580 calories. Thus, implementation of “good” and

“excellent source” claims at these levels would promote the consumption of whole grain products in a manner consistent with good dietary practices.