CSPI Center for Science in the Public Interest

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

Re: FDA's Guidance on Whole Grain Label Statements [Docket No. 2006D-0066]

I. Introduction

The Dietary Guidelines for Americans and USDA's new food pyramid encourage the public to "make half your grains whole." This recommendation is appropriate given the growing body of evidence that people who eat more whole grains have a lower risk of heart disease, diabetes, and obesity. However, many whole grain claims are misleading because they appear on foods that are not whole grain, and some are largely refined grain (see Attachment, pages 1-7).

In its February 2006 guidance on Whole Grain Label Statements, FDA said that "manufacturers can make factual statements about whole grains on the label of their products such as "100% whole grain " (as percentage labeling under 21 CFR 102.5(b)) or "10 grams of whole grains " (21 CFR 101.13(i) (3)) provided that the statements are not false or misleading under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the Act) and do not imply a particular level of the ingredient, i.e., "high " or "excellent" source.

2006D-0066

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IH-D-6

FDA's voluntary guidance will discourage companies from making some misleading claims, such as "good source of whole grain" or "excellent source of whole grain." However, the guidance does not go far enough to ensure that consumers are not misled because the policy is voluntary and because it does not address other commonly made whole grain claims, such as "made with whole grain." Furthermore, FDA's guidance does not require labels to disclose whole grain content using clear, informative units such as percentages.

To encourage the consumption of whole grains and prevent deceptive label claims, CSPI urges the FDA to:

- Require all foods that make whole grain (or similar) claims to disclose on the principal display panel the percentage of grain that is whole grain.
- If FDA does not require a percentage whole grain disclosure, it should prohibit the use of claims such as "made with whole grain" or "a good source of whole grain" to avoid misleading people who are trying to consume more whole grains.

II. FDA's recommended disclosures are misleading because they fail to disclose the refined grain content of the food.

Disclosures such as "10 grams of whole grain," "one ounce of whole grain," or "one serving of whole grain" may be misleading on non-whole grain foods because they imply that the food is all or primarily whole grain. In fact, a food that contains 10 grams of whole grain per serving might also contain 20 or 30 grams of refined grain per serving. Without a disclosure that reveals the refined grain content of the food, many

consumers would assume that food contains no refined grains. Consumers could check the ingredient list, but even that does not declare the foods' relative proportion of refined and whole grains. Without that information, consumers might unknowingly increase their intake of refined grains substantially in an effort to get more whole grains.

III. FDA's proposed disclosures do not help people follow the Dietary Guidelines' advice.

FDA's proposed disclosures, such as "10 grams of whole grain," do not help people follow the Dietary Guidelines' advice to "make half your grains whole." That advice encourages people to consume a minimum *proportion* of their grains as whole grains. Without knowing how many grams of refined grain are in a food that claims to contain X grams of whole grain, consumers cannot determine whether half their grains are whole.[1]

The Dietary Guidelines also recommends that people consume at least 3 servings of whole grains a day. However, that advice was designed to give consumers a rule of thumb regarding the number of servings of whole grains they should consume. It is less applicable than the advice to "make half your grains whole," because some people consume more—and others fewer—than 6 servings of grains each day.

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[1] FDA's proposed disclosures also fail to help people follow the Dietary Guidelines' advice to consume at least 3 servings of whole grains a day, because the disclosures use units like grams or ounces rather than servings. There is no easy way to convert grams or ounces into servings, because the amount of grain in a serving varies from food to food. The FDA could not solve this problem by requiring labels to disclose the number of servings of whole grains that a food provides. It would confuse many people to see that one serving of cereal, rice, bread, etc. supplied ½ or 2 servings of whole grains.

Urging people to consume at least 3 servings of whole grains could mislead people to assume that more is always better. In fact, encouraging people to consume more calories than they should from grains, whole or refined, could promote weight gain.

IV. Disclosures such as "10 grams of whole grain" make it difficult to compare foods.

FDA's proposed disclosures, such as "10 grams of whole grain" or "one ounce of whole grain" make it difficult to compare foods because the total grain content of foods varies so widely. For example, 10 grams of whole grain could be 60 percent of the grain in a slice of bread, but only about 33 percent of the grain in a breakfast cereal with a 30-gram serving size. Even when consumers try to compare cereals to cereals, they will have trouble sizing up a claim such as "10 grams of whole grain," because 10 grams could comprise 33 percent of the grain in a breakfast cereal with a 30-gram serving size but just 18 percent of the grain in a breakfast cereal with a 55-gram serving size. (Both serving sizes are quite common.)

Consumers can check the label to find the weight of a serving, but for most foods, including bread, frozen pizza, and cookies, the weight of a serving is not the same as the total grain content. For foods that contain both whole and refined grains, consumers cannot figure out how the whole grain content compares to the refined grain content of the food.

As noted above, without that information, people may unknowingly consume excess refined grain in a misguided effort to consume more whole grains. FDA could

eliminate this problem by requiring labels with whole grain claims to disclose the percent of grain that is whole grain.

V. Some people may confuse grams of whole grain with grams of fiber.

Consumers may confuse grams of whole grains with grams of fiber, because they know that whole grains are usually a good source of fiber and fiber is one of the key benefits of eating whole grains. Furthermore, this confusion would lead people to overestimate the whole grain content of food. A food that contains 5 grams of fiber, for example, supplies 20 percent of the Daily Value for fiber. In contrast, a food that contains 5 grams of whole grains supplies only a small fraction of a day's worth of whole grains. A percent-whole-grain disclosure would resolve this problem.

VI. Recommendations

A. FDA should require labels with whole grain claims to disclose the percentage of grain that is whole.

FDA should require labels with whole grain claims to disclose what percent of the food's grain is whole grain.[2] A percent-whole-grain claim makes it clear that, unless the food is 100 percent whole grain, it also contains refined grain. People understand that a food could be, say, 50 percent whole grain and 50 percent refined grain. In fact, companies often advertise the percentage of whole grain in their products when the

[2] This disclosure should appear adjacent to the whole grain claim and in type that is similar in size and prominence to the whole grain claim.

foods are 100% whole grain.[3] There is no reason to think that they would have trouble understanding smaller percentages.

If the food contains a whole grain component, the principal display panel (PDP) should disclose what percent of the component is whole grain. For example, a noodle soup might bear a disclosure such as "100% whole grain noodles," a frozen entrée might declare "60% whole grain pasta," and a pizza label might state "20% whole grain crust."[4]

Percent-whole-grain disclosures would make it easier for consumers to see whether a food helps them follow the advice to "make half your grains whole." Consumers could use that advice to eat an equal number of refined and 100% whole grain foods each day, or they could eat only foods that are at least 50% whole grain. We suspect that more people would use either of those rules of thumb than would tally up the number of grams, ounces, or servings of whole grains they consume each day and strive to reach some unspecified total.

Furthermore, FDA has already approved a health claim for foods that are at least 51 percent whole grain. FDA's approval indicates that it is reasonable to use percentages to evaluate the whole grain content of foods.

B. If FDA does not require a percentage-whole-grain disclosure, it should prohibit such misleading claims as "good source of whole grain" and "made with whole grain."

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[3] Canadian consumers appear to have no trouble understanding the common "60 percent whole grain" claims on breads and other foods.

[4] To prevent companies from making claims about foods that contain very little whole grain, FDA should require a minimum level, such as 4 or 5 grams of whole grain per serving, before any claims can be made.

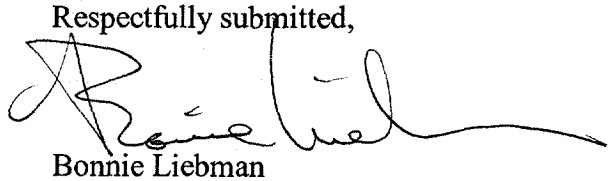
Foods that are labeled "made with whole grain" or "good (or excellent) source of whole grain," but also contain refined grain, are misleading because consumers may assume that the foods are made with only whole grains. In fact, many such foods are made with more refined than whole grains (see Attachment 1, pages 6 and 7). Many people would never think to check the ingredient list to see if a food with a whole grain claim also contains refined grains. However, even consumers who check the ingredient list would be unable to determine what fraction of the grains are whole. Without that information, they would not know if the food could help them follow advice to "make half your grains whole."

Furthermore, requiring labels with whole grain claims to disclose the grams or ounces of whole grain per serving would not eliminate the deception because consumers would not know how many grams or ounces of refined grains the food contained. In order to follow advice to "make half your grains whole," consumers need to know what percent of the grain in a food is whole and what percent is refined.

C. FDA should require labels with whole-grain-like claims to disclose the percentage of grain that is whole.

Many people think "multigrain" or "12 grain" or "harvest grain" or "wheat bread" means whole grain. Those claims should also trigger a percentage-whole-grain disclosure. Some food manufacturers might argue that such a disclosure is unnecessary because consumers know that the food contains little or no whole grain. In that case, they should not worry that such a disclosure would make the food less appealing to customers.

Respectfully submitted,



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