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

**Re: Docket No. 2004P-0223
Petition by General Mills, Inc. for descriptive claims for whole grains,
submitted May 10, 2004 and revised December 20, 2004
Comments by Unilever United States, Inc.**

To Whom It May Concern:

This letter provides comments by Unilever United States, Inc. ("Unilever") on the above-referenced petition by General Mills, Inc. for descriptive claims for whole grains. Unilever is one of the world's leading food companies, dedicated to helping people enjoy food, health and life. Our brands include such recognized names as Ben & Jerry's, Bertolli, Breyers, Good Humor, Hellmann's, I Can't Believe It's Not Butter, Knorr, Lawry's, Lipton, Promise, Ragú, Shedd's Spread Country Crock, Skippy, Slim•Fast and Wish-Bone.

Summary

Unilever supports the General Mills petition with two modifications.

1. General Mills recommends that an "excellent source" of whole grains be defined as a food that contains 16 grams (g) or more of whole grain per serving. We agree, but also believe that "whole grain foods" that provide a one-ounce serving (consistent with 2005 Dietary Guidelines) should be eligible for the "excellent source" claim. Therefore, we would propose that "excellent source" also be defined as a food that contains 51% or more whole grain ingredients and has a serving size of at least one ounce.
2. The General Mills petition correctly notes that the health benefits of whole grain can be attributed to the entire substance, not merely its fiber content. Nevertheless, an underlying goal of the 2005 Dietary Guidelines is to encourage

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consumption of fiber. Therefore, to help consumers understand the relationship between whole grain claims and fiber content, we recommend that, if a food bearing a whole grain claim is not also at least a good source of fiber, the claim should be accompanied by a referral statement such as "See nutrition information for fiber content."

With these modifications, we urge FDA to act promptly to implement this claim.

Background

On May 10, 2004, General Mills submitted a petition to FDA that makes the following points:

- It requests that FDA establish the descriptive claims "excellent source," "good source," and "made with" for whole grain content. On December 20, 2004, General Mills amended its petition to define whole grains as containing all of the essential parts and naturally-occurring nutrients of the entire grain seed. If the grain has been processed (e.g., cracked, crushed, rolled extruded, lightly pearled and/or cooked), the food product should deliver approximately the same rich balance of nutrients that are found in the original grain seed.
- It requests that FDA establish these claims under the Agency's authority to prevent false and misleading food labeling statements. Because "whole grain" is a food substance, not a nutrient, General Mills concludes that these claims should not be regulated as nutrient content claims or health claims (under §403(r) of the Federal Food, Drug, and Cosmetic Act ("Act")). Rather, they should be regulated under FDA's general authority to prevent false and misleading claims (under §§201(n), 403(a)(1) and 701(a) of the Act).
- It requests that FDA issue a guidance document to implement the requested claims in a timely manner, while assuring compliance through the exercise of enforcement discretion when evaluating the use of these claims. Subsequently, FDA should formalize its policy through rulemaking.

Comments

Unilever supports the General Mills petition and urges FDA to act promptly to implement it.

We have two recommendations that would help make the policy outlined by the petition more consistent with dietary recommendations. These recommendations are as follows:

1. The claim “excellent source of whole grain” should be available for a whole grain food that has a serving size of at least one ounce.

The General Mills petition provides that the claim “excellent source” and synonyms may be used on the label and in labeling of foods provided that the food contains 16 g or more of whole grain per labeled serving. Although this is a reasonable level, some foods that provide a full serving of whole grains might not be able to meet this level.

For example, a one-ounce granola bar that contains about 14.5 g of whole grain per serving would contain more than 51% of whole grains. As a result, it would meet the definition for “whole grain food” that has been accepted by FDA.¹ It would also provide a full, one-ounce serving of a whole grain food, consistent with the 2005 Dietary Guidelines’ recommendation that Americans “consume three or more ounce-equivalents of whole-grain products per day.”² As requested by the petition, a food that provides one full serving of whole grain and satisfies one-third of the minimum daily recommended intake is an “excellent source” of whole grain.³ Thus, even though this granola bar contains slightly less than 16 g whole grains per serving, it should be eligible to bear an “excellent source” claim.

We therefore recommend that the criteria for the “excellent source” claim be modified to read:

The terms “high,” “rich in,” or “excellent source” may be used on the label and in the labeling of a food provided that (a) the food contains 16 grams (g) or more of whole grain per serving size declared on the package, or (b) the food contains 51% or more whole grain ingredient(s) by weight per reference amount customarily consumed (RACC) and has a serving size of at least one ounce.

2. If a product that is an “excellent” or “good” source of whole grain, or “made with” whole grain, is not also at least a “good source” of dietary fiber, its label should bear a referral statement about fiber content.

The General Mills petition correctly notes that the health benefits of whole grain can be attributed to the entire substance, not merely its fiber content. The petition recommends that FDA recognize that claims about whole grains are claims about the substance as a whole, and are not merely implied nutrient content claims about fiber content. Unilever supports this recommendation. The proposed claims about whole grains help promote

¹ “Whole grain foods” are defined as foods that contain 51% or more whole grain ingredient(s) by weight per reference amount customarily consumed in authoritative statement notifications for health claims submitted to FDA on March 10, 1999 (notification by General Mills) and August 8, 2003 (notification by Kraft Foods). FDA did not object to these notifications. In addition, this definition has been acknowledged in the 2005 Dietary Guidelines (ch. 5).

² 2005 Dietary Guidelines, ch. 5.

³ Petition, p. 27.

the 2005 Dietary Guidelines objective to increase Americans' intake of whole grain, and there is no legal, scientific or public health basis for restricting claims about whole grains based on a theoretical assumption that they carry implied messages about fiber.

Nevertheless, an underlying goal of the 2005 Dietary Guidelines is to encourage consumption of whole grains and other food groups that will provide increased intake of fiber.⁴ Fiber has recognized health benefits, as FDA has acknowledged in its health claim regulations.⁵ Therefore, fiber content is an important nutrient for consumers to be aware of when choosing foods. For this reason, we recommend that, if a food bearing a whole grain claim is not also at least a good source of fiber, the claim should be accompanied by a referral statement such as "See nutrition information for fiber content."

Conclusion

The claims requested by the General Mills petition, together with the modifications suggested above, will help encourage increased consumption of whole grains, as recommended by the 2005 Dietary Guidelines. Accordingly, we urge that FDA act promptly to provide guidance to industry on the consistent use of these claims.

Respectfully submitted,



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⁴ 2005 Dietary Guidelines, ch. 5.

⁵ 21 CFR §§101.76, 101.77, 101.81.