



Campbell Soup Company
1 Campbell Place
Camden, NJ 08103

April 17, 2006

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

RE: Docket 2006D-0066

To Whom It May Concern:

Campbell Soup Company submits these comments in response to FDA's Draft Guidance for Industry and FDA Staff: Whole Grain Label Statements, dated February 16, 2006.

Campbell Soup Company supports FDA's action to provide guidance to industry to assist in labeling products relative to their whole grain content. Campbell concurs that truthful and not misleading statements about whole grains should be allowed such as "100% whole grain" or recital of the actual amount of whole grain content present. Campbell also supports FDA in opposing statements that characterize a particular level of whole grains, i.e., "good" or "excellent" source.

Campbell Soup Company reiterates our previous position (copy attached) for defining 'good' and 'excellent' claims for whole grains. See our letter to FDA dated July 28, 2005 opposing General Mills' citizen's petition that urged FDA to permit source claims for whole grains. We believe that nutrient content claims for whole grain are simply not the best vehicle for educating consumers about whole grains. Whole grains are not a nutrient, and as such do not have a quantitative Daily Value. We believe that issuance of a guidance document supporting declarations of quantity for whole grains based upon serving definitions elaborated in USDA's MyPyramid, would better educate and guide the public to increase their consumption of whole grains. Statements on product labels communicating the presence of whole grains need to be consistent with USDA's MyPyramid recommendations. If not, consumers will receive inconsistent messages, which will undermine FDA and USDA's educational efforts behind the 2005 Dietary Guidelines and the MyPyramid programs.

Source Claims for Whole Grains

Campbell does not support development of quantitative "source" claim definitions for whole grains. Source claims are used to indicate significant levels of nutrients based on a single quantitative Daily Value derived from scientifically based nutrient requirements. Establishing a single quantitative Daily Value based on one grain type i.e. wheat is not appropriate for whole grains because of the varieties of grains in this category. Whole

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grains are a category of diverse ingredients with various biological actions. Campbell is also concerned that establishing a Daily Value for whole grains this way would set a precedent of developing Daily Values and source claims for other ingredients, such as, vegetables, fruits, oils. Such action could undermine the value of current nutrient content claims for consumers.

We fully support well-considered efforts to encourage the public consumption of whole grains, and applaud FDA's and USDA's efforts to do so. The recent 2005 Dietary Guidelines for Americans and the 2005 USDA's MyPyramid both emphasize the importance of whole grains consumption. The FDA could help educate the public about the importance of whole grains by issuing a guidance document that builds on the MyPyramid's concept of ounce equivalents of whole grain.

Companies should be encouraged to express the whole grain content of their products in such units to assist consumers in achieving the whole grain ounce equivalent targets set in the Dietary Guidelines and MyPyramid. Specifically, if, as elaborated in the MyPyramid document, the food is classified as a grain food (*e.g.*, bread, crackers, English muffins), and 100 percent of the grain in the food is whole grain, then each one ounce portion of the food can claim that it delivers a one ounce equivalent serving of whole grains. Similarly, if a food is classified as a grain food and contains less than 100 percent of the grain as whole grain, the number of whole grain servings can be determined by multiplying the fraction of whole grain over total grain by serving size, divided by one ounce. Thus, for example, for a hypothetical 50g labeled serving of a bagel formulated with 70 percent of whole grain flour and 30 percent refined flour, the equivalent serving of whole grain would be determined by the following calculation: $(50/28.4) \times 70/100 = 1.23$ ounce equivalent serving of whole grain. As a third example, if a food is a combination of non-grain food and grain food containing a whole grain ingredient, *e.g.*, soup containing whole grain rice, the ounce equivalent of whole grain would be determined by the previous calculation multiplied by the fraction of the combination food that is a whole grain food.

We do not believe that consumers would clearly benefit from "source" definitions based on a quantitative Daily Value for whole grains derived from nutrient content. Consumers would likely be confused by such definitions, as they would be based on units different from those used in MyPyramid.

Should the FDA wish to move forward with regulations to define "Excellent Source" and "Good Source" of whole grains, then it should apply its customary 20 percent and 10 percent factors to the Food Guide's daily recommended minimum. For example for a 2,000 Kcal diet, the daily whole grain intake recommendation is three 1-ounce equivalent servings of whole grains per day. This would translate to a requirement that a food designated as an "Excellent Source" of whole grain provide at least 0.6-ounce equivalent serving of whole grain, and a food designated as a "Good Source" of whole grain provide a minimum of 0.3-ounce equivalent serving of whole grain.



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“Made With” Whole Grain or use of “Whole Grain” in a product name

Use of the term “Made With” “Whole Grain” as part of the product name on a label should be permitted so long as it does not cause a product to be misbranded. Such a claim should be truthful, not misleading and include additional information as necessary to help consumers understand the context of the claim. (See 21 USC §201 (n)). As with any claim of “Made With” for a non-nutrient, the FDA has ample authority and expertise to determine whether such a claim is misleading as used. To confine “Made With” claims or use of “Whole Grain” in a product name to an arbitrarily high content level would deprive consumers of useful information and potentially discourage the consumption of incrementally beneficial foods containing whole grains.

CONCLUSION:

For the reasons stated above, we support FDA’s position that “source” claims based on a single quantitative value are not appropriate for whole grains. Such definitions based on quantitative amounts are inconsistent with the recently issued 2005 Dietary Guidelines, and the 2005 USDA’s MyPyramid recommendations, and not founded on sound nutritional science. Consumers would be better served by the issuance of a guidance document that would be consistent with, and support, the educational efforts behind the Dietary Guidelines and the MyPyramid programs.

Sincerely,

Chor San Khoo, Ph.D.
VP Global Nutrition & Health