GENERAL MILLS

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

Re: Docket No. 1994P-0390 and 1995P-0241
Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims; Reopening of the Comment Period
69 Fed. Reg. 24541 (May 4, 2004) and 69 Fed. Reg. 67513 (November 18, 2004)

Dear Sir or Madam:

General Mills (GMI) submits these comments in response to the Food and Drug Administration's (FDA's) reopening of the comment period on the proposed rule, referenced above, which in part would provide additional flexibility in the use of health and nutrient content claims on food products. GMI first submitted comments to this docket in July of 1996, and we continue to support revisions to the FDA regulations that improve the communication of and encourage the use of health and nutrient content claims on food products.

GMI is a Delaware Corporation with its general offices at No. 1 General Mills Boulevard, Minneapolis, MN 55426. GMI is a major packaged-food manufacturer engaged for over 75 years in the development and production of food products including flour, ready-eat-cereals, refrigerated dough products, cake and other dessert mixes, soups, vegetables, snacks and numerous other products.

We have been committed to nutrition labeling for over 30 years beginning with voluntary labeling in 1974. We currently have nutrition labeling on more than 1500 retail products. Over the years, we have added additional information and claims to our products in response to increased consumer interest in the relationship between diet and health. General Mills firmly supports changes in food-labeling practices that will provide consumers with nutrition information more relevant to today's needs.

GMI recognizes that health and nutrient content claims are an important tool for communicating health messages to consumers, and welcomes the opportunity to

comment on FDA's proposed rule offering flexibility in the use of health and nutrient content claims on food products.

We support changes to the health claim regulations that allow more flexibility while still ensuring truthful and non-misleading health and nutrition information on food product labels. Allowing appropriate, consumer-friendly health information on food labels not only gives consumers a greater opportunity to make more informed food choices consistent with the Dietary Guidelines, but it also provides food manufacturers added incentives to develop and/or promote products with health-related attributes.

Health Claims

A. Minimum nutrient contribution for health claims

GMI believes that health claims should reinforce principles of the Dietary Guidelines and help consumers achieve nutrient-rich, well-balanced, healthful diets. It is to the benefit of consumers to require a minimum nutrient requirement (10% RDI or DRV). We recommend, however, that the present standard be extended beyond the currently eligible nutrients (vitamin A, vitamin C, iron, calcium, protein and fiber) in recognition of the important health contribution of other nutrients.

GMI proposes that a food bearing a health claim be at least a good source (10% DV) of at least one positive nutrient with an established RDI or DRV. Science and public health needs have evolved since the formation of the original requirements. For example, the critical contribution to health of nutrients such as folic acid and potassium is better understood. Expanding the list of eligible nutrients to any positive nutrient with a RDI would consumers to benefit from the continued advancement of nutrition science while maintaining the relevance of the minimum nutrient requirement for health claims.

B. Disqualifying nutrient levels for health claims

GMI opposes FDA's 1995 proposal which would maintain disqualifying levels for total fat, saturated fat, cholesterol and sodium for all health claims, except for foods for which FDA has approved a specific exemption.

GMI instead recommends that the FDA regulations permit foods with qualifying levels of nutrients related to the health claim and disqualifying levels of nutrients unrelated to the claim to bear a health claim with disclosure of the disqualifying nutrient. This should be permitted without going through the process of individual exemption petitions, which discourages the use of relevant health claims on foods that can contribute to a healthy diet and disease risk reduction. Disqualifying levels, however, should still apply when the nutrient is associated with the disease that is

the subject of the claim. This is similar to the approach that we recommended in our 1996 comments.

The following examples help illustrate our recommended approach.

- A food that meets all requirements of the calcium/osteoporosis claim, except for containing >480 mg sodium, would be allowed to make the claim as long as the product clearly states "see nutrition information for sodium content" immediately adjacent to the claim. [Sodium intake is not a known risk factor for osteoporosis.]
- A food that meets all requirements of the soluble fiber/heart disease claim, but contains >480 mg sodium, would not be allowed to carry the health claim. [Sodium intake is a known risk factor for heart disease.]

C. Use of the word "may" in health claims

GMI believes that the term "may" is unnecessary for health claims based on significant scientific agreement (SSA; including those based on authoritative statements) and encourages FDA to eliminate "may" as a qualifier from such claims.

We agree with FDA that the word "may" could be interpreted by consumers as a reflection of the scientific support for the claim rather than the multi-factorial nature of a disease, as originally intended by the regulations. Although it is true that many factors contribute to the diseases for which there are FDA-approved health claims, this is communicated through "reduces risk." We believe that consumers understand that diseases are not caused by one factor, alone.

As presently worded, SSA health claims include two qualifiers: 1) "may" and 2) "reduces risk," and both are not necessary. Stating that a substance, within the context of a healthy diet, "reduces risk" [of a disease] adequately communicates the scientific evidence about the relationship between a substance and the disease for SSA health claims.

We expect that "may reduce risk" and "reduces risk" convey similar messages to consumers. Food manufacturers should be able to use the simplest, most consumer-friendly language that clearly and accurately communicates the scientifically established relationship between a food component and disease. Such messages are more likely to be attractive and understood by consumers than long, cumbersome claims.

The use of the word "may" should be reserved for certain qualified health claims to help communicate that there is less scientific certainty about a relationship between a dietary substance and disease, as described in our comments to FDA's advance notice of proposed rulemaking (ANPRM) in February 2004 [Docket No. 2003N-0496].

D. Use of abbreviated health claims

GMI supports FDA's proposed changes to make optional some elements currently required in health claims such as the communication of the multi-factorial nature of diseases. This would result in the shortening of many claims and may encourage the use of certain health claims on food products.

We recommend that FDA review the scientific evidence for health claims and shorten claim language where appropriate. For example, based on the current scientific support, it is possible that the calcium/osteoporosis claim could be substantially shortened to "Healthful diets with adequate calcium may reduce risk of osteoporosis."

In some instances, however, the complete health claim may still remain too long given available space on certain food packages (e.g., yogurt, granola bars) and/or be too complex for easy consumer understanding. To encourage the use of health claims and the dissemination of important health information to consumers, manufacturers should be allowed to use abbreviated claims with headlines or symbols with a referral statement to the complete health claim elsewhere on the food label.

We continue to believe, as we expressed in our 1996 comments, that it is essential that health claims be presented in consumer-friendly language. Lengthy discussions about the relationship between certain substances and diseases may act as obstacles to gaining consumer attention. Short, simplified messages, that are truthful and not misleading, should be allowed to be used on food products to communicate the relationship between a substance and a disease. This will enable more products to carry appropriate health claims and advance consumer knowledge of health benefits of a wider array of foods.

E. Additional considerations relevant to existing health claims

GMI recommends that FDA review requirements for all approved health claims. Since the 1993 regulations were published, there have been numerous scientific advances including a better understanding of the relationship between diet (foods and nutrients) and the development of certain diseases, especially heart disease. For example, FDA may want to consider whether the total fat (low-fat) requirement is necessary for health claims about the relationship between fruits, vegetables and grain products with soluble fiber and heart disease. As an initial screen, GMI encourages FDA to review the Dietary Reference Intakes reports which were recently completed by the Institute of Medicine of the National Academies of Science for a current evaluation of the relationships among various nutrients and certain diseases.

Nutrient Content Claims

A. Use of unlisted synonyms in nutrient content claims

GMI supports extending approved nutrient content descriptors (e.g., good/ excellent source, low) to include other terms with similar meaning to consumers. We do not support, however, FDA's proposed approach which would require un-approved terms to be anchored to FDA-approved descriptors. Our reason is twofold:

- Consumers may not be familiar with the criteria for FDA-approved terms and anchoring it to that term may not aid in consumer understanding.
- Secondly, two terms characterizing nutrient content appearing adjacent to one another may lead to consumer confusion.

One potential approach that should be considered is to require un-approved terms to be anchored to the quantitative amount of the nutrient (immediately adjacent to the most prominent placement of the claim). With this approach, a food could carry the claim, "super source of calcium" followed immediately by the statement "30% Daily Value."

By allowing unapproved terms to be anchored to the quantitative amount of the nutrient, consumers would have immediate access to nutrient content information that is helpful in achieving healthful dietary practices.

B. Additional considerations relevant to existing nutrient content claims

Revise definition for "low calorie"
GMI encourages FDA to consider re-defining "low calorie" as specified in 21 CFR 101.60. The current definition (≤40 calories), which is based on the ubiquity of calories in the food supply (2% DV of 2000 calories), is unduly restrictive. It excludes many nutrient dense, low calorie foods whose consumption is encouraged by the new Dietary Guidelines.

We recommend that "low calorie" instead be defined as ≤100 calories (≤5% of the DV for calories). This is a practical approach that would help consumers better manage their calorie intake while meeting the Dietary Guidelines. This recommendation is also supported by our analysis of food consumption data from NHANES 1999-2000 indicating that adults on average consume 15.5 foods and beverages daily. If an individual consumes only "low calorie" foods based on our proposed definition (15.5 foods x 100 calories), energy intake for adults would still be below recommended daily energy needs for adults as listed in the Dietary Guidelines (1600-3200 calories).

Overweight and obesity threaten the health and well-being of millions of Americans and it is now even more important to provide useful information about the calorie content of foods to consumers. The report from FDA's Obesity Working Group (March 2004) and the Dietary Guidelines (January 2005) both emphasize the importance of watching calories for weight management. The Dietary Guidelines further recommend that consumers consider the nutrient density of foods along with calories when making decisions about foods.

Few products in the marketplace that meet FDA's current definition for "low calorie" also provide important nutrients to the diet. By broadening the definition for "low calorie" to ≤100 calories, more wholesome and nutrient dense foods, such as certain fruits, vegetables, soups, and low-fat yogurt, would be allowed to bear this claim, thereby facilitating the provision of important information about the caloric content of foods to consumers.

Respectfully submitted,

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