GENERAL MILLS

June 20, 2005

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

Re: Docket No. 2004N-0456; Advanced Notice of Proposed Rulemaking; Food Labeling: Serving Sizes of Products That Can Reasonably Be Consumed At One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes. **70 Fed. Reg. 10710 (April 4, 2005)**

Dear Sir or Madam:

General Mills (GMI) submits these comments in response to the Food and Drug Administration's (FDA's) advanced notice of proposed rulemaking on serving sizes of products that can reasonably be consumed at one eating occasion; updating of reference amounts customarily consumed and approaches for recommending smaller portion sizes.

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. GMI firmly supports changes in food-labeling practices that will provide consumers with nutrition information more relevant to today's needs.

GMI supports changes to the Nutrition Facts Panel (NFP) to help increase awareness around serving size information if research can show the revisions would be meaningful and easy for consumers to understand and use to make food choices. Given FDA's multiple initiatives concerning the food label (i.e., calories, serving sizes, Daily Values)

all changes should be coordinated to occur during the same timeframe to reduce the number of packaging changes and to help minimize the economic burden to food companies.

Updating RACCs

Use of Food Consumption Data

GMI believes it is important for FDA to analyze and share with stakeholders the most current dietary intake data (e.g., NHANES 1999 - 2002) to assess how portion sizes may have shifted over the last three decades. Given the prevalence of obesity in the United States, careful consideration should be given to changing RACCs in order to avoid unintended consequences. It is important to understand changes in portion sizes before launching a major initiative that could have far-reaching changes for food labels.

GMI supports updating RACCs if identified, relevant data suggests a need to do so. In addition, it may be appropriate to create new RACCs for items within certain food categories. Although FDA sought to ensure that foods within product categories had similar dietary usage and product traits, establishing RACCs for 131 product categories has resulted in groupings of products that may no longer have similar dietary usage. For example, biscuits, bagels, tortillas and hush puppies are grouped together under the "Bakery Products" category and all have a 55g RACC. While this may have been appropriate based on then-available data, current data may reveal that these products are used in different ways. For example, data may reveal that bagels are now generally much larger, and that the amount customarily consumed is much greater than 55g. Greater differentiation within categories to reflect these differences may result in RACCs that more closely reflect actual consumption, but these changes should only be made if supported by a thorough review of the current data.

Criteria for Changing RACCs

Establishing criteria for changing RACCs that would involve a percentage change in intake of the current RACC should not be done without careful consideration of differences in actual gram weights of these foods. Applying percentages broadly across product categories would penalize those products with smaller serving sizes. For example, a 20% increase in the intake of a cereal with a 15g RACC would equal a 4g increase in intake versus a 20% increase in intake of a 55g RACC cereal would amount to an 11g increase. Using percentages in this manner could lead to changes that may not be warranted so it is imperative that the actual change in weight (e.g., grams) be considered or volume (e.g., milliliters) for liquids.

Consumer Understanding of Serving Size Changes

There are limited studies that have examined consumer use and interpretation of serving size information on the nutrition facts panel. GMI believes research should assess if changes in serving size would suggest to consumers that more or less of a particular food should be eaten. For example, research should explore whether changing the definition or the term "serving size" would be meaningful to consumers. FDA could consider testing terms such as "suggested", "reasonable" or "sensible" serving size to evaluate consumer usefulness.

Alignment of RACCs and MyPyramid

Currently, the RACCs used for nutrition labeling and the portion sizes used for MyPyramid do not align for most food categories or if they do align, there is little awareness or understanding among health professionals or consumers. Many comments concerning the 2005 Dietary Guidelines to DHHS and USDA encouraged alignment of the serving sizes for food packages and the Pyramid. While we support this idea conceptually, how to achieve alignment is not straightforward.

This approach requires a careful analysis of food products and needs to be thoroughly researched with consumers to determine if it is a viable option. RACCs that parallel recommendations in the Dietary Guidelines and MyPyramid may not be easily applicable to all food categories. For example, equating reference amounts and labeled serving sizes to MyPyramid serving suggestions may be relatively simple for products that consist of primarily one ingredient (e.g., milk or vegetables). Products containing ingredients from several food groups (e.g., soup or a casserole), however, would be more difficult to equate into MyPyramid servings and would require a standardized method in order to do so. Providing this information on every food label would be a huge undertaking for the food industry, so once again, consumer testing would be essential before implementation. As consumers become more familiar with MyPyramid, this approach may be of greater interest and value to them. Reference amounts that correspond to MyPyramid quantities could be an easier and more accurate way for consumers to track their intake from various food groups. Such an effort would require considerable coordination between FDA and USDA to implement on packages and to educate consumers as well as a deliberate, well-researched rationale.

Single-Serve Packages and Products That Can Reasonably Be Consumed At One Eating Occasion: Labeling As The Entire Package vs. Dual Column Labeling

GMI supports ***voluntary***, not mandatory, dual-column labeling of products considered to be "single-serve" and those that could "reasonably be consumed in one sitting". We do not believe that manufacturers should be mandated to provide nutrition information based solely on an entire package. Labeling nutrition information based only on an entire package may suggest to consumers that the entire contents could (or should) be eaten during one eating occasion.

Voluntary dual-column labeling would provide the consumer a way to compare nutrition information for the entire product versus FDA's standard serving size. This may help the consumer determine whether the entire product should be consumed at one time, but it also may overwhelm the consumer with too much information. GMI suggests that ***quantitative*** research be conducted to assess consumer understanding of dual-column labeling.

Calories and the Number of Servings Declared on the Principal Display Panel (PDP)

GMI supports the ***voluntary*** listing of calories on the PDP. In recent years, GMI has added information on the calories/serving to the PDP of a variety of food products including cereals, many soups, certain snack products and vegetables. The decision to include calorie information depends on the product's positioning, its intended use and whether the information is compelling and/or useful to consumers. It is likely that the marketplace will continue to encourage competition in this area, especially as consumer awareness and interest in calories grows.

GMI opposes the ***mandatory*** declaration of calories on the principal display panel (PDP) for several reasons. The declaration of calorie information on the PDP overly emphasizes calorie information, and may result in consumers focusing on calories to the exclusion of other important nutrition attributes of a food product. This in turn, may have unintended consequences on the selection of foods, and possibly the intake of other dietary components (e.g., saturated fat, sodium, vitamins, minerals). As noted above, focusing on calories at the expense of other nutrients is not consistent with recent dietary recommendations.

Consumers are accustomed to using the NFP for nutrition information. Highlighting select nutrition information on the principal display panel may discourage consumers from referring to the NFP and may result in a missed opportunity for consumers to better understand a food's total nutritional contribution.

An alternative approach to labeling products with calories on the PDP is to explore ***voluntary*** listing of the number of servings on the PDP. Research is needed to

address consumer understanding and awareness of servings per package on the PDP and in the nutrition facts panel, especially for products with serving sizes that could be consumed in one sitting. Findings from such research is critical before moving forward with implementing the number of servings on the PDP.

Comparative Calorie Claims for Smaller Portions of Identical Foods

GMI does not support making comparative calorie claims based only on serving size differences because it could lead to consumer confusion in each of the following examples:

1) Calorie differences for similar foods with different portion sizes (e.g., **one** 15g cookie vs **two** 15g cookies).
2) Calorie differences based on different serving sizes of the **same** product (e.g., 8 fl oz bottle of juice vs a 12 fl oz bottle).

This approach may not enable consumers to understand the relationship between portion sizes and calories.

Overweight and obesity are significant concerns in the US population. In today's environment, it is extremely important to provide useful information about a food's nutritional value, relative to serving size, in a truthful and straightforward manner.

GMI commends FDA on their efforts to develop an approach for improving the food label. We appreciate the opportunity to comment on this important food labeling issue, and look forward to working with the Agency in the months ahead.

Respectfully submitted,

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