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October 13, 2000

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

Amended Comments pertaining to: [Docket No. 94P-0036] Food Labeling:
*Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health
Claims; Proposed Rule*
64 Federal Register 62746, November 17, 1999.

Dear Sir or Madam:

General Mills is a Delaware Corporation with its general offices at No. 1 General Mills Boulevard, Minneapolis, MN 55426. General Mills is a major packaged-food manufacturer engaged for over 60 years in the development and production of food products including flour, ready-eat-cereals, cake and other dessert mixes, snacks and numerous other products.

We have been committed to nutrition labeling for 25 years beginning with voluntary labeling of our consumer products in 1974. We currently have nutrition labeling on more than 600 products. Over the years, we have added additional information and claims to our products in response to consumer interest in newer knowledge about the relationship of 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.

Summary of Comments

General Mills supports disclosure of trans fat in the Nutrition Facts panel as a footnote on a voluntary rather than mandatory basis. We believe that trans fat should be included in the total fat declaration rather than the saturated fat declaration as proposed. General Mills strongly supports the proposal that if the serving contains less than 0.5 gram of saturated fat and less than 0.5 gram of trans fat, the declared content should be expressed as zero. We believe that there is no basis for establishing a Daily Reference Value for trans fat because

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the science is insufficiently developed at this time to support such value. Our comments address either support or alternatives for specific nutrient descriptor claims and corresponding criteria related to trans fat content. General Mills recommends that AOAC Official Method of Analysis 996.06 for Fat be included as one of the approved analytical methods because it can accurately analyze the trans fat content of a complex food matrix compared to methods specified in the proposed regulation. Finally, we urge FDA to establish compliance with the final regulation to be on or after the 2004 uniform effective date or two years following promulgation of the final regulation, whichever occurs later.

I. Disclosure of Trans Fat in Nutrition Facts Panel

General Mills supports the proposed definition of trans fat presented in section 101.9(c) (2)(I), which states that unsaturated fatty acids that contain one or more isolated (i.e. nonconjugated) double bonds in a trans configuration. We support disclosing trans fat in the Nutrition Facts panel as a footnote on a voluntary rather than mandatory basis. The footnote would be required only when trans fat content is 0.5 grams or more per serving or when a trans fat claim is made.

We believe, however, that trans fat should be included with total fat rather than saturated fat as outlined in the proposed regulation. There are several reasons for supporting this approach. The goal of the Nutrition Facts panel is to educate and not mislead consumers about the nutritional composition of a food, allowing them to make an informed product choice. Trans fat is technically not a saturated fat but recent clinical research has shown that the two fats have a comparable effect on serum cholesterol. Traditionally, the nutrition information in the Nutrition Facts panel has been based upon the chemical definition or composition of the food constituent, not upon its impact on health and nutrition. We believe that the label should continue to reflect the composition of the food and not the physiological impact of the constituent, which means that trans fat should not be combined with saturated fat. Trans fat should continue to be included in the total fat declaration on the label. Greater detail about the trans fat content of the product can be provided by using an asterisk and footnote stating "includes __ grams trans fat" when trans is 0.5 grams or higher or an approved trans fat claim is made. Also, there is justification to require saturated fat content to be listed in the Nutrition Facts panel when a trans fat claim is made.

Consideration must be given to the precedence established by combining trans fat with saturated fat. The rationale articulated in the proposed regulation firmly establishes a physiological framework for the labeling definitions of the nutrients listed in the Nutrition Facts panel. While combining trans with saturated fat may help educate consumers about the similar physiological effect as outlined in the proposed regulation, not all saturated fat fractions raise serum cholesterol levels. Recent studies indicate that stearic acid, a saturated fat, may not raise serum cholesterol levels. If the approach is taken to combine trans with saturated fat because of its impact on serum cholesterol, the same rationale would eventually

apply to separating stearic acid from saturated fat content because consumers would expect that all fat declared as saturated fat raises serum cholesterol.

The footnote terminology should state "includes" ___ grams trans fat to help clarify that additional fat should not be added to the number stated in the total fat section of the Nutrition Facts panel. "Contains" should be used only in optional statements that indicate no trans fat is present, as "contains" could otherwise suggest to consumers that trans should be added to the declaration for total fat.

Rounding of Trans Fat Values

General Mills strongly supports the proposal that if the serving contains less than 0.5 gram of saturated fat and less than 0.5 gram of trans fat, the declared content shall be expressed as zero. This is consistent with the mandatory nutrition labeling regulations that indicate that 0.5 grams of either total fat or specific fatty acids represent trivial amounts of total fat and fatty acids and should be rounded to zero. Trans fat should be treated in the same manner as other fatty acid classes. Thus, both saturated fat and trans fat at levels below 0.5 grams per serving should be rounded to zero before they are included in the nutrition label.

II. Daily Reference Value

General Mills believes that there is no basis for establishing a Daily Reference Value for trans fat because the science is insufficiently developed at this time to support such value. A Daily Value (DV) for trans fat could confuse consumers and divert attention from both total and saturated fat information that is supported by existing scientific data and recent public health messages.

The recently convened Macronutrient DRI panel of the National Academy of Sciences will be evaluating the scientific data to determine whether a recommended intake level for trans fat can be made, either alone or in conjunction with saturated fat, in their final report that is due in 2001. If the DRI panel recommends an intake level for trans fat, FDA should take those recommendations under consideration, and if warranted, issue a new proposal related to this rulemaking and allow public comment prior to finalizing this rulemaking. A proposed DV for trans fat should undergo the same process for public comment that the other portions of the rule have undergone.

III. Proposed Nutrient Descriptor Claims and Requirements for Trans Fat

General Mills has comments on the following specific nutrient descriptor claims for trans fat and corresponding criteria.

Trans Fat Free and Saturated Fat Free

General Mills supports the proposed requirements for these claims that a product contains less than 0.5 grams trans fat and less than 0.5 grams saturated fat per RACC serving.

No Cholesterol/Cholesterol Free

This claim should be permitted for foods containing 2.5 grams or less of trans fat and saturated fat combined per RACC serving. This provides for additional fat over and above the current requirement of 2.0 grams for saturated fat alone.

Low Saturated Fat

General Mills believes that this claim should be permitted for foods containing 1.5 grams of trans and saturated fat combined per RACC serving. The proposed requirement of 1.0 gram saturated fat and less than 0.5 trans fat does not allow a product to contain any trans fat.

Low Trans Fat or Reduced Trans Fat

General Mills supports FDA's position that it is inappropriate to define either of these claims at this time because it is premature to establish a Daily Value for trans fat.

Reduced Saturated Fat

We believe the reduced saturated fat claim should be allowed by reducing trans fat by at least 25% and no accompanying increase in saturated fat compared to the reference food. There is no justification for requiring that both trans and saturated fat be reduced by at least 25%, but there is rationale for not permitting an increase in saturated fat. Similarly, a reduced saturated fat claim should meet the 25% reduction requirement and not allow an increase in trans fat. This allows the food manufacturer some flexibility concerning the approach by which a reduction can be achieved in a product when it contains both saturated and trans fat. Either of these claims triggers the trans fat footnote.

Low Saturated Fat

General Mills urges that the criteria for this nutrient descriptor should be 1.5 grams of trans and saturated fat combined, along with the requirement of no more than 15% of calories from saturated fat.

No Hydrogenated Oil

General Mills recommends that the requirements for this claim should be both that the food meets the definition of "trans fat free" and that the food contains no hydrogenated oil.

Analytical Methodology

General Mills recommends that AOAC Official Method of Analysis 996.06 for Fat be included as one of the approved analytical methods because it can accurately analyze the trans fat content of a complex food matrix. The methods identified in the proposed regulation work well for fats and oils but are less sensitive in a complex food matrix. AOAC Official Method of Analysis 996.06 for Fat (Total, Saturated, and Unsaturated) in Foods,

Hydrolytic Extraction Gas Chromatographic Method, Official First Action 1996, Revised First Action 2000 is of adequate selectivity and sensitivity to meet the analytical requirements of the proposed regulations with regard to the required labeling of *trans* fat content of foods and food products. When the system performance requirements of section B(b) of the method (i.e. adequate separation is obtained for the closely eluting pairs C18:3 and C20:1 as well the closely eluting triplet of peaks C22:1, C20:3, and C20:4) some 58 fatty acids including the food fatty acids with the double bond in the unconjugated *trans* configuration relevant to the labeling proposal can be resolved, identified, and quantitated (see table 996.96D of the method).

The proposed regulation calls for the labeling of unconjugated *trans* fat at levels greater than 0.5 g per serving. Fat is defined under NLEA as the sum of the fatty acids making up the defined component of the fat., therefore the *trans* fat per serving is the sum of the fatty acids containing a double bond in the unconjugated *trans* configuration in the sample. For a 100 g serving of food, this requires measurements of fatty acids down to 0.005 g/g (5.0 mg/g) of food. The gas chromatographic systems applicable and used for method 996.06 detect and quantitate individual fatty acids down to a level of 0.1 mg/g of food sample. Therefore the sensitivity level of the method is sufficient to analyze a *trans* fatty acid at 1/50th the level being proposed for labeling.

Effective Date

Compliance with the final regulation promulgated by FDA will require substantial resources and cost because many food labels will need to be redesigned and reprinted. For this reason, General Mills urges FDA provide that compliance with the final regulation be on or after the 2004 uniform effective date or two years following promulgation of the final regulation, whichever occurs later.

Respectfully submitted,

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