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GENERAL MILLS

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October 9, 2003

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

Docket No. 03N-0076 Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements; Advance notice of proposed rulemaking 68 Federal Register 41507, July 11, 2003.

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, refrigerated dough products, cake and other dessert mixes, soups, vegetables, snacks and numerous other products.

We have been committed to nutrition labeling for over 25 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 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.

General Mills previously filed comments on the presentation of *trans* fat information on the nutrition label in Docket No. 94P-0036, the docket resulting in the *trans* fat labeling final rule. General Mills fully intends to comply with that rule, and has begun the process of evaluating our many products and revising labels as necessary. General Mills submits these comments to provide input on the issues raised by the Food and Drug Administration (FDA) in its request for additional information regarding *trans* fat labeling.

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Extension of Comment Period

General Mills supports the several requests for extension of the comment period submitted in this docket to allow time for the Institute of Medicine Committee on Uses of Dietary Reference Intakes in Labeling to issue its report. Without this crucial information, it is difficult to properly address nutrient content claims and disqualifying or disclosure levels for *trans* fat labeling. We note that FDA indicated an intention to conduct consumer research on the proposed footnote statements. General Mills believes it is premature to comment on footnote language prior to the release of the results of the government-sponsored research. As FDA has not granted these extension requests, General Mills requests that FDA reopen the comment period in this docket after the IOM Committee issues its report and after the release of the government-sponsored research on the footnote language to allow an opportunity for additional comment based on that important information.

Trans Fat Footnote

At the present time, there has not been sufficient research into the effects any of the proposed footnote options might have on consumers. Unless consumer data shows that a footnote statement is necessary, the potential is great for consumer confusion and misunderstanding, leading to health decisions based on a misunderstanding of the information presented with any of the proposed footnotes. It is possible that consumers could perceive any footnote as a warning statement regarding the consumption of *trans* fat, leading them to focus too much attention on *trans* fat levels. At the least, it would seem to draw particular attention to *trans* fat, at the expense of the other useful information in the Nutrition Facts box. Currently, there is not enough known about the impact on consumers' knowledge and behavior for any footnote statement to be required on the label.

At some point in the future, it may be demonstrated that a footnote would be useful to consumers in making sound decisions for a healthy diet. In that event, FDA should ensure that the language in the footnote is consistent with governmental dietary guidance regarding *trans* fat intake, including both that from the Dietary Guidelines and the IOM Committee report. FDA should also ensure that the language is not misleading in any way, and that the footnote language does not isolate *trans* fat from the other fatty acids that may have an adverse impact on consumers. FDA should reopen the comment period to allow for industry and consumer input into any proposed language.

It is also possible that in the future, consumer knowledge will be sufficient such that no footnote is required.

Nutrient Content Claims

General Mills believes it is reasonable, within the general claims framework established by FDA, to set criteria for the following specific nutrient descriptor claims: "*trans* fat free", "reduced *trans* fat" and "low *trans* fat." It is important to establish these claims, as doing so will provide useful information to consumers to allow them to make healthier choices in their diet, particular regarding the fat content of the foods they consume. Also, providing definitions for these claims, established at realistic and attainable levels, should encourage food manufacturers to reformulate their products to have a healthier nutritional profile to qualify for the claims.

For all claims, saturated fat and *trans* fat content should be linked, as these fats share a unique relationship from both food functionality and health perspectives. For example, it is possible to reduce *trans* fat content in foods by increasing the saturated fat content. Thus, unless the two are linked for purposes of claims, the food selected by the consumer may not be necessarily a nutritionally better choice, even though it now purports to be, for example, "*trans* fat free." Clearly, this is not the intent of the *trans* fat nutrient content claims. To prevent this, nutrient content claims for *trans* fat should include criteria for saturated fat and conversely those for saturated fat should include criteria for *trans* fat.

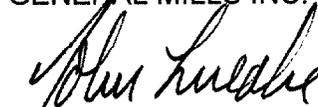
Although it is premature at this point to establish disqualifying or disclosure levels of *trans* fat for purposes of health claims, General Mills believes it is important to consider establishing these levels in the context of cardiovascular health claims. It is incomplete to address only saturated fat and cholesterol levels without also considering *trans* fat levels in the context of heart health.

Coordinated Label Changes

The soon-to-be-released IOM Committee report will have significant impact on all areas of *trans* fat labeling. Given the uncertainty regarding the footnote language, disclosure or disqualifying levels for *trans* fat, and *trans* fat nutrient content claims, it is not yet appropriate for FDA to require or define these statements for nutrition labeling. Should FDA set requirements for any of these label statements in the future, however, General Mills requests that the agency do so in a coordinated fashion, such that all required label changes can be made at one time, rather than serially. The cost both in terms of dollars and personnel resources associated with the current revisions underway to comply with the *trans* fat labeling rule are enormous, and incurring those costs repeatedly would be an unnecessary burden, particularly on small manufacturers. Accordingly, FDA should postpone further required labeling changes until its position on all these issues has been resolved.

Respectfully submitted,

GENERAL MILLS INC.



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Counsel