

2401 PENNSYLVANIA AVE., NW SECOND FLOOR WASHINGTON, DC 20037 PHONE (202) 337-9400 FAX (202) 337-4508 www.gmabrands.com

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

ANPR COMMENTS

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. 68 FR 41507, July 11, 2003

The Grocery Manufacturers of America (GMA)¹ appreciates this opportunity to offer comments concerning the Food and Drug Administration (FDA) Advanced Notice Proposed Rulemaking (ANPR) on *trans* fatty acids in nutrition labeling. This ANPR will explore consumer research to consider nutrient content and health claims and possible footnote or disclosure statements.

GMA agrees with the Agency's recognition that the Institute of Medicine/National Academy of Sciences (NAS) Committee on Uses of Dietary Reference Intakes (DRIs) in Nutritional Labeling report will play an important role in determining the final regulations on *trans* fat nutrient content claims and health claims, and commends the Agency's decision to re-open the comment period once the Committee issues its report. GMA believes it is virtually impossible to address nutrient content claims and disqualifying or disclosure levels for health claims until we have had the opportunity to read the Committee's Report. Until the NAS report is released, GMA has decided to wait to submit comments to FDA on the use of *trans* fat in labeling schemes.

¹ GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than \$500 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers and sales agencies at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

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The Relationship of Trans Fat to Nutrient Content Claims

GMA has already begun to explore the relationship of *trans* fat to several nutrient content claims including "*trans* fat free", "no cholesterol", "reduced *trans* fat", "reduced saturated fat" and "low saturated fat". Once we have had the opportunity to read the NAS report we will be in a much better position to submit specific criteria for each of these nutrient content claims. GMA believes the most up-to-date research on *trans* fat and total nutrition should be used to develop regulations, and we will rely on the NAS report to provide critical guidance to our comments at that time.

The Relationship of Trans Fat to Health Claims

Disqualifying Level for Coronary Heart Disease Health Claims GMA fully recognizes that the amount of fat, including the amount of *trans* fat, in a food needs to be addressed before health claims pertaining to coronary heart disease (e.g.; foods low in fat can help reduce the risk of heart disease, etc.) can be made. GMA urges the agency to build a disqualifying level into each of these types of health claims. For the same reasons cited previously, GMA will submit specific criteria after we have had the opportunity to read the NAS report.

Trans Fat Footnote

GMA strongly believes additional mandatory labeling (i.e., a footnote) beyond the current final rule on *trans* fat is completely unnecessary.

GMA strongly opposes the proposed use of a footnote advising consumers to limit their intake of *trans* fat, saturated fat and/or cholesterol regardless of the wording selected. A footnote represents an unnecessary and inappropriate policy shift in the type of information provided within the Nutrition Facts panel. GMA does not believe that a footnote is needed to provide guidance to consumers when using the quantitative information to help maintain healthy dietary practices. The basis for requiring quantitative information is well established for a recognized nutrient of nutritional significance, including *trans* fatty acids. Where sufficient information is available, the basis for establishing a reference value, (i.e., Daily Reference Value or Reference Daily Intake) is similarly well established. A textual footnote of the type FDA is proposing, however is not as simple, clear, or useful as a statement of percent Daily Value, nor is it all clear that consumer will react to the proposed footnote in the manner that FDA anticipates. In a recent consumer research study conducted by IFIC, funded by GMA and others, results demonstrated that a footnote about *trans* fat tended to focus consumer attention on *trans* fat to the exclusion of all other nutrients.²

² Cogent Research, Impact of Trans Fat Label Information on Consumer Food Choices (2003).

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A simple, consistent, and uncluttered format is the best way for nutrition information to be presented and comprehended. For the following reasons, GMA believes the proposed footnote statement will be confusing to consumers by hindering comprehensive consumer understanding of the Nutrition Facts panel information.

First, information of several types and forms (e.g. quantitative declarations, Daily Values, cautionary footnotes, etc) could confuse or frustrate consumers to the point that they avoid using any of the provided information because they do not understand the differences or why multiple forms of information are used.

As it has for other nutrients that lack a DRV or RDI, FDA should require declaration of the amount of *trans* fat but leave the Percent Daily Value declaration blank. This approach is sound from both a legal and a policy standpoint because FDA historically has not required a Percent Daily Value declaration where there exist insufficient data to establish a DRV (e.g., monounsaturated fat, sugars) or other reasons make such a declaration unnecessary in certain circumstances (i.e., protein).

Second, the terminology "diets low in saturated fat, *trans* fat, and cholesterol" used in some of the proposed footnote statements is open to variable interpretation. For example, what is a consumer suppose to do with this piece of information as cholesterol is listed in milligrams and is likely to have a number close to a hundred or in the hundreds against saturated fat and *trans* fat that are listed in grams and is likely to have much smaller numbers? Many foods that make important contributions to meeting micronutrient requirements could potentially be demonized by one of these proposed footnote statements. It simply is not feasible or realistic to provide characterizing nutritional advice, in the form of a textual statement, on the nutrition label for *trans* fat or any other nutrient for which dietary guidance would be beneficial for consumers.

Third, the nutrition label cannot, by itself, provide all the information important to maintaining healthy dietary practices. Complex dietary guidance in the Nutrition Facts box is not prudent. A mandatory footnote for *trans* fat would inappropriately emphasize this issue over all other dietary guidance. The role of the nutrition label should be to provide factual, product-specific quantitative information that will benefit all consumers. Broader dietary guidance should be provided through off-label activities of public and private health and nutrition education programs. In some cases, individuals should seek individualized health and dietary counseling by a professional registered dietitian.

Consumers are already learning about *trans* fat through information on manufacturers' web sites as well as the media. FDA has launched their consumer education campaign on *trans* fat. FDA has developed consumer messages on how consumers can keep their intake of saturated fat, *trans* fat, and cholesterol low: "Look at the Nutrition Facts panel when comparing products. Choose foods low in the combined amount of saturated fat and *trans* fat and low in cholesterol as part of Dockets Management Branch (HFA-305) October 9, 2003 Page 4

a nutritionally adequate diet." In a relatively short period of time, consumers will be educated about *trans* fat and feel confident in making product selections with mandatory declaration of the quantitative amount of *trans* fat as a separate line entry in the Nutrition Facts box. GMA strongly believes additional mandatory labeling (i.e., a footnote) beyond the current final rule on *trans* fat is completely unnecessary.

CONCLUSION

GMA looks forward to working with the Agency to meet the needs of consumers concerning *trans* fat. In order to do this, however, the approach must be based on sound science and adequate consumer research data to ensure that the nutrition information on our food products is appropriate and meaningful to consumers. GMA has not made a decision on whether we will pursue additional consumer research on *trans* fat. Before we can make this determination, we need to learn of FDA's plans for consumer research on *trans* fat. The food and beverage industry may identify areas that they feel need additional consumer research particularly as it pertains to a footnote statement. In addition, the report of the IOM Committee on Use of Dietary Reference Intakes in Nutrition Labeling may also provide additional ideas for consumer research.

Respectfully submitted,

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Alison J. Kretser MS, RD Director, Scientific and Nutrition Policy