



APR 26 2002

Food and Drug Administration
College Park, MD 20740

Howard I. Bernstein
J. H. Chapman Group, L.L.C.
9700 Higgins Road
Rosemont, Illinois 60018

Dear Mr. Bernstein:

Your letter of March 26, 2002 to Secretary Thompson urging the Food and Drug Administration to issue a final rule on the labeling of *trans* fatty acids has been forwarded to me for response. Secretary Thompson has placed a high priority on health promotion and disease prevention, and we agree that consumers need this information to assist them in maintaining healthy dietary practices and reducing the risk of coronary heart disease.

As you may know, FDA initially had planned to publish a final rule by the end of 2001, but the process has been delayed due to the numerous comments on the proposed rule that FDA received, and the lack of a daily allowance and upper limit for *trans* fat. FDA is continuing to evaluate as quickly as possible the more than 2,700 comments we received that address the scientific, economic, policy and legal underpinnings of the proposed rule. In addition, when developing the current food label, FDA used recommendations from the Institute of Medicine at the National Academy of Sciences (IOM/NAS) as a basis for establishing daily values (DVs) and claims derived from DVs (e.g., nutrient content claims and disqualifying levels for health claims). FDA believes that similarly, IOM/NAS recommendations for *trans* fat may provide support for some of the labeling requirements that FDA believes would be useful information for consumers about *trans* fat. The Department of Health and Human Services (DHHS) has contracted with IOM/NAS to review current knowledge of macronutrient nutrition and to make recommendations regarding dietary intakes for macronutrients, including *trans* fat. IOM/NAS estimates that it will deliver its report to DHHS this summer. Due to the close timing, the Center for Food Safety and Applied Nutrition (CFSAN) intends to wait for this report to allow us to consider the IOM/NAS recommendations as we finalize the rule.

Accordingly, CFSAN has placed this completion of this regulation on the B* list of its 2002 Program Priorities. Activities are assigned either an A, B*, or a B classification. Our plan is to complete fully at least 90 percent of the A list items by the end of the current fiscal year, September 30, 2002. Activities on the B* list are those we plan to complete during the next fiscal year, which ends on September 30, 2003. B* activities that are not completed in this fiscal year are candidates for the A list next year.

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I hope this information helps you understand the current status of this project and assures you of our commitment to complete this rulemaking as soon as possible once the IOM/NAS issues its report. Thank you for your interest.

Sincerely yours,

Susan Thompson

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