

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2003N-0076]

Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements; Extension of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Advanced notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending for 60 days the comment period for an advanced notice of proposed rulemaking (ANPRM) published in the **Federal Register** of July 11, 2003 (68 FR 41507). FDA reopened the comment period in the **Federal Register** of March 1, 2004. Since reopening the comment period, FDA has scheduled a Food Advisory Committee (FAC) Nutrition Subcommittee meeting for April 27 and 28, 2004. The outcome of this meeting may help determine the course of action for trans fat labeling. FDA is extending the comment period to receive comments that consider the information resulting from this upcoming FAC Nutrition Subcommittee meeting specific to this ANPRM and trans fat labeling. Information and data obtained from comments to this ANPRM may be used to help draft a proposed rule on trans fat labeling.

DATES: Submit written or electronic comments by [*insert date 60 days after the date of publication in the Federal Register*].

ADDRESSES: You may submit comments, identified by Docket No. 2003N–0076, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2003N–0076 in the subject line of your e-mail message.
- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]:
Division of Dockets Management, 5630 Fishers Lane, rm. 1061,
Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/dockets/ecomments*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “How to Submit Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Julie Schrimpf, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1450, FAX 301–436–2636.

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of July 11, 2003 (68 FR 41507), FDA published an ANPRM to solicit information and data that potentially could be used to establish new nutrient content claims about trans fatty acids (trans fat); to establish qualifying criteria for trans fat in current nutrient content claims for saturated fatty acids (saturated fat) and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids; and, in addition, to establish disclosure and disqualifying criteria to help consumers make heart-healthy food choices. We also requested comments on whether we should consider statements about trans fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the nutrition facts panel or as a disclosure statement in conjunction with claims to enhance consumers' understanding about such cholesterol-raising lipids and how to use the information to make healthy food choices. The comment period was open until October 9, 2003.

In December 2003, the Institute of Medicine of the National Academy of Science (IOM/NAS) issued a report entitled "Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification" (the 2003 report) in which the overarching goal was to have updated nutrition labeling that consumers can use to make informed dietary choices. The IOM/NAS's Dietary Reference Intake (DRI) 2002 report on macronutrients did not establish an estimated average requirement (EAR), an adequate intake (AI), or an acceptable macronutrient distribution range (AMDR) for trans fat because the presence in the diet meets no known nutritional need, hence there are no DRI values that can be readily used as the basis for a trans fat daily value (DV). Therefore,

to establish a DV for trans fat, the 2003 report suggested an approach to estimate minimum trans fat intakes within a nutritionally adequate North American diet and use this value to establish a DV for trans fat. The 2003 report also recommended that saturated fat and trans fat amounts be listed on separate lines, but that one numerical value for the percent DV (%DV) be included in the nutrition facts panel for these two nutrients together. In response to requests received in this docket, FDA reopened the comment period on March 1, 2004 (69 FR 9559), to allow interested persons the opportunity to consider the 2003 report and its discussion specific to trans fat labeling in comments submitted on the ANPRM.

Recently, FDA has scheduled a FAC Nutrition Subcommittee meeting for April 27 and 28, 2004 (see the notice of meeting in the **Federal Register** of March 29, 2004 (69 FR 16275), or <http://www.fda.gov/OHRMS/DOCKETS/>), to discuss, in part, the current scientific evidence for determining a maximal daily intake value of trans fat and how trans fat compares to saturated fat with respect to reducing coronary heart disease risk. The outcome of this meeting may help determine the course of action for trans fat labeling. We believe it is necessary to extend the comment period to allow stakeholders time to consider the new information when commenting in this docket. Using this new information will provide a stronger science base for a subsequent proposal. Therefore, we are requesting comment on whether the available scientific evidence, as will be discussed in the FAC Nutrition Subcommittee meeting, supports listing the %DV for saturated fat and trans fat together or separately on the nutrition facts panel and what the maximal daily intake of trans fat may be. A transcript of the subcommittee meeting is expected to be placed in Docket 2003N-0076 by May 14, 2004.

We are continuing to request comments on whether a DV for trans fat or joint DV for saturated and trans fats would eliminate the necessity for considering a disclosure statement, in conjunction with nutrient content or health claims, concerning levels of saturated fat, trans fat, or cholesterol in a food or in the diet, or a message about the role of such cholesterol-raising lipids in increasing the risk of coronary heart disease. Further, we are requesting comment on whether a DV for trans fat or a joint DV for saturated and trans fats would eliminate the need for a footnote about trans fat, either alone or in combination with saturated fat and cholesterol.

Information and data obtained from comments and from consumer studies may be used to help draft a proposed rule on trans fat to: (1) Establish criteria for certain nutrient content or health claims; (2) require the use of a footnote, or other labeling approach, about one or more cholesterol-raising lipids in the nutrition facts panel; and (3) develop a DV for trans fat either alone or in combination with saturated fat for use with a joint %DV for saturated and trans fat on the nutrition label to assist consumers in maintaining healthy dietary practices.

II. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this ANPRM. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the ANPRM at *http://www.gpoaccess.gov/fr/index.html* by browsing the “Table of Contents from Back Issues” and selecting the publication date of Friday, July 11, 2003.

Dated: April 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S