Proposed Rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

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; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Advanced notice of proposed rulemaking, reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 45 days the comment period for an advanced notice of proposed rulemaking (ANPRM) published in the Federal Register of July 11, 2003 (68 FR 41507), in which FDA is requesting 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. Since publication of the ANPRM on July 11, 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.” FDA is reopening the comment period to receive comments that consider the information in the IOM/NAS report 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.

DATES: Submit written or electronic comments by April 15, 2004.


SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 11, 2003 (68 FR 41507), FDA issued 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 (FDA) 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.

Since the end of the previous comment period, the IOM/NAS issued a report entitled “Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification.” The 2003 report recognizes that trans fat and saturated fat are chemically distinct and acknowledges that research demonstrates different physiological effects among the fatty acids; however, both trans fat and saturated fat raise total and low density lipoprotein (LDL) cholesterol levels, which are potential contributors to coronary heart disease risk. We are requesting comment about the development of a joint DV for saturated and trans fats. If a joint DV for saturated and trans fats is pursued, we are requesting comment about the use of the same approach that the 2003 report recommended for establishing a DV for trans fat (noted previously) to establish a new DV for saturated fat that would then be added to the DV for trans fat to establish a new combined DV. Alternatively, to directly establish a joint DV for saturated and trans fats. Additionally, we are requesting

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We are also requesting comment 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 CHD. 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 do the following: (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 percent DV for saturated and trans fat in the nutrition facts panel to assist consumers in maintaining healthy dietary practices. At a later date, we will solicit comment on the remaining parts of the 2003 report.

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 text or PDF at http://www.gpoaccess.gov/fr/index.html by browsing the “Table of Contents from Back Issues” and select the publication date of Friday, July 11, 2003.

IV. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but is not responsible for subsequent changes to the Web sites after this document publishes in the Federal Register.


Jeffrey Shuren,
Assistant Commissioner for Policy.

FOR FURTHER INFORMATION CONTACT:
Concerning the proposed regulations, Charles J. Magee, (202) 622–3110; concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Robin Jones, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

Temporary regulations in the rules and regulations section of this issue of the Federal Register amend 26 CFR part 1 relating to section 168 of the Internal Revenue Code (Code). The temporary regulations provide guidance under section 168 on how to depreciate MACRS property acquired in a like-kind exchange under section 1031 or as a result of an involuntary conversion under section 1033 when both the acquired and relinquished property are subject to MACRS in the hands of the acquiring taxpayer. The text of those temporary regulations also serves as the text of these proposed regulations. This document also provides notice of a public hearing on these proposed regulations and a partial withdrawal of proposed regulations (REG–139499–02) published July 21, 2003.

DATES: Written or electronic comments must be received by June 1, 2004. Outlines of topics to be discussed at the public hearing scheduled for June 3, 2004, at 10 a.m. must be received by May 13, 2004.

ADDRESSES: Send submissions to CC:PA:PR (REG–106590–00), room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Alternatively, submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:PR (REG–106590–00), Courrier’s Desk, Internal Revenue Service, 1111 Constitution Ave., NW., Washington, DC, or sent electronically, via the IRS Internet site at http://www.irs.gov/regs. The public hearing will be held in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.