

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 94P-0036]

DMB

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Certifier	S. Reese

**Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Reopening of the Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; reopening of the comment period.

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**SUMMARY:** The Food and Drug Administration (FDA) is reopening to [*insert date 45 days after date of publication in the Federal Register*], the comment period for a document published in the **Federal Register** of November 17, 1999 (64 FR 62746). In that document, FDA proposed to amend its regulations on nutrition labeling to require that the amount of *trans* fatty acids present in a food, including dietary supplements, be included in the amount and percent Daily Value declared for saturated fatty acids. FDA also proposed that, wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure or disqualifying levels, the amount of *trans* fatty acids be limited as well. Finally, FDA proposed to define the nutrient content claim “*trans* fat free.” FDA is taking this action in response to comments on the November 17, 1999, proposal to ensure that interested parties have an adequate opportunity to comment on the issue of whether the agency should define the nutrient content claims “reduced *trans* fat” and “reduced saturated and *trans* fats.”

**DATES:** Submit written comments on nutrient content claims for “reduced *trans* fat” and “reduced saturated and *trans* fats” by [*insert date 45 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may also send comments to the Dockets Management Branch at the following e-mail address:

FDADockets@oc.fda.gov or via the Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>.

**FOR FURTHER INFORMATION CONTACT:** Susan Thompson, Center for Food Safety and Applied Nutrition (HFS-832), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5587.

**SUPPLEMENTARY INFORMATION:**

**I. Reopening of Comment Period**

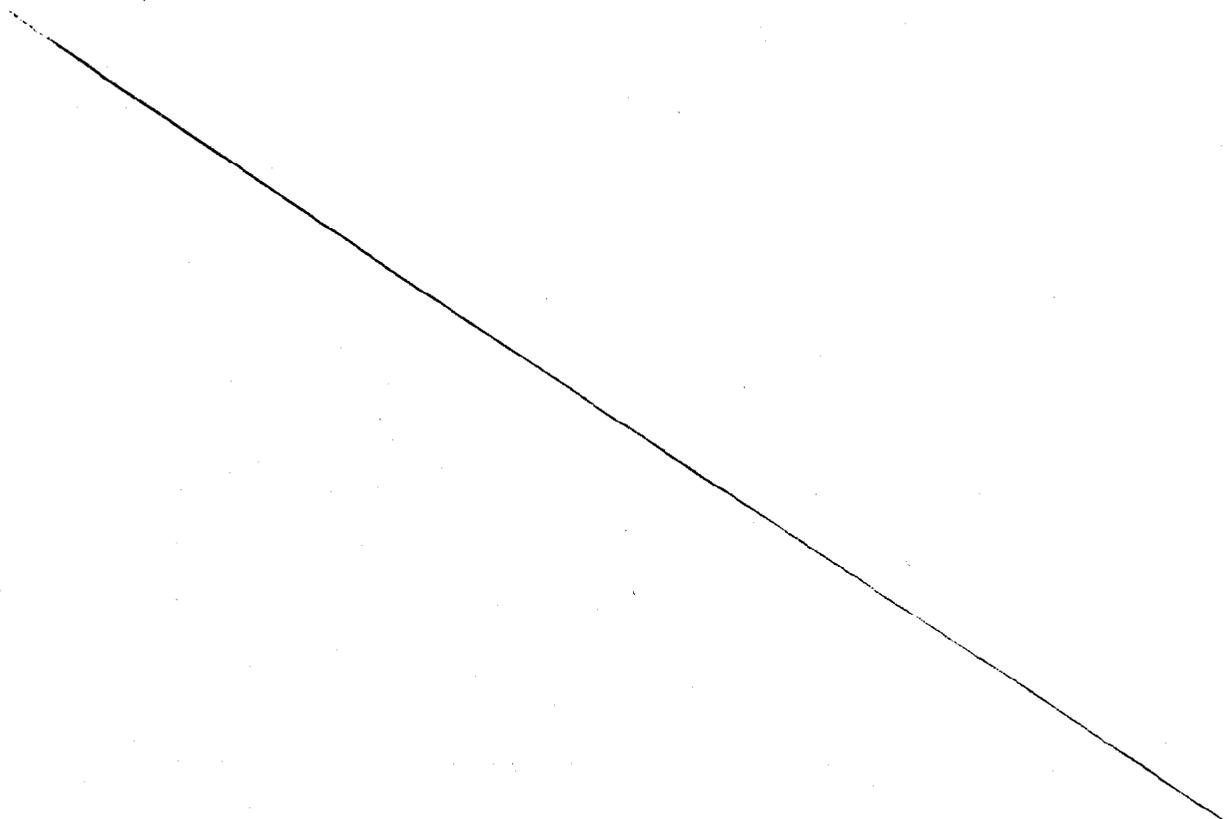
In the **Federal Register** of November 17, 1999 (64 FR 62746), FDA (we) proposed to amend our regulations on nutrition labeling to require that the amount of *trans* fatty acids present in a food, including dietary supplements, be included in the amount and percent Daily Value declared for saturated fatty acids. We also proposed that, wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure or disqualifying levels, the amount of *trans* fatty acids be limited as well. Finally, we proposed to define the nutrient content claim “*trans* fat free.” In that document, we requested comments on the proposal by February 15, 2000. In the **Federal Register** of February 16, 2000 (65 FR 7806), we extended the comment period to April 17, 2000.

Ten comments responding to the proposal (see Docket 94P-0036, Comment numbers 1776, 2113, 2117, 2125, 2128, 2133, 2135, 2138, 2139, and EMC 475) requested that the final rule define the nutrient content claim “reduced *trans* fat.” We had not proposed a definition for this claim, and had suggested that persons who believe that such a claim is useful could petition the agency under § 101.69 (21 CFR 101.69) (64 FR 62746 at 62760). Other comments (see Docket 94P-0036, Comment numbers 2136 and 2139) suggested a criterion (i.e., 25 percent less saturated fat and *trans* fat combined) for the claim “reduced saturated fat” that we believe may be more appropriate as a criterion for the claim “reduced saturated and *trans* fats.”

We have considered these comments and believe that some members of the public may not have anticipated these issues and thus did not address them in comments. To ensure that all interested parties have had an opportunity to comment on whether the final rule should define the claims “reduced *trans* fat” and “reduced saturated and *trans* fats,” we are reopening the comment period for the November 17, 1999, proposed rule for a period of 45 days. Comments submitted during this period are to be limited to those that directly address the two claims identified above. We are not requesting comments on any other issue, and we do not intend to consider such comments if submitted.

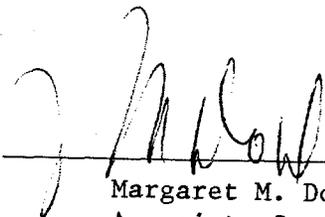
## II. How to Submit Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments by [*insert date 45 days after date of publication in the Federal Register*]. You may also send comments to the Dockets Management Branch at the following e-mail address: [FDADockets@oc.fda.gov](mailto:FDADockets@oc.fda.gov), or via the Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>. You must submit two copies of comments, identified with the



docket number found in brackets in the heading of this document, except that you may submit one copy if you are an individual. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11-29-06  
November 29, 2000.

  
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Margaret M. Dotzel,  
Associate Commissioner for Policy.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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