

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 133

[Docket No. FDA-2008-P-0086] (formerly Docket No. 2000P-0586)

Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk; Extension of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period until April 11, 2008, for a proposed rule that was published in the **Federal Register** of October 19, 2005 (70 FR 60751). FDA issued a **Federal Register** notice to reopen the comment period on this proposal on December 11, 2007 (72 FR 70251), to seek further comment on only two specific issues raised by the comments concerning the proposed ingredient declaration. The agency is extending this comment period in response to a request to give interested parties additional time to provide the information requested by FDA in that notice.

DATES: Submit written or electronic comments by April 11, 2008.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2008-P-0086, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the

instructions for submitting comments.

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Certifier L. CLAWSON
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Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]:

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

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “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.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ritu Nalubola, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of October 19, 2005 (70 FR 60751), FDA proposed to amend the definitions of “milk” and “nonfat” milk in § 133.3 (21 CFR 133.3) for cheeses and related cheese products to: (1) Provide for ultrafiltration of milk and nonfat milk; (2) define UF milk and UF nonfat milk as raw or pasteurized milk or nonfat milk that is passed over one or more semipermeable membranes to partially remove water, lactose, minerals, and water-soluble vitamins without altering the casein-to-whey protein ratio of the milk or nonfat milk and resulting in a liquid product; and (3) require that such treated milk be declared in the ingredient statement of the finished food as “ultrafiltered milk” and “ultrafiltered nonfat milk,” respectively.

The agency received about 24 responses, each containing one or more comments to the 2005 proposal. Most comments supported the proposed use of fluid UF milk in standardized cheeses and related cheese products and several comments encouraged the agency to adopt the definition of fluid UF milk as proposed. However, although they did not disagree that fluid UF milk is significantly different from “milk,” several comments opposed the proposed provision to require fluid UF milk or fluid UF nonfat milk to be declared as “ultrafiltered milk” or “ultrafiltered nonfat milk,” respectively. They cited several reasons for their opposition.

FDA reopened the comment period on the proposed rule on December 11, 2007 (72 FR 70251) to seek public comment only with respect to two issues raised in the comments that opposed the proposed provision to require fluid UF milk or fluid UF nonfat milk to be declared as “ultrafiltered milk” or “ultrafiltered nonfat milk,” respectively: (1) That, due to economic and

logistical burdens, it would be impracticable for cheese manufacturers to comply with the labeling requirement; and (2) that the proposed provision to declare fluid UF milk as “ultrafiltered milk” would be misleading to consumers in that consumers incorrectly believe that cheeses that declare “ultrafiltered milk” as an ingredient are different from those cheeses that declare “milk” as an ingredient or “milk and ultrafiltered milk” as ingredients.

The agency has received a request for an additional 60 days to respond to the questions FDA asked in its December 11, 2007, document. The request expressed concern that the reopening of the comment period did not allow adequate time to provide the data and information that FDA requested.

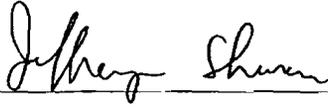
FDA has considered the request and is extending the request for an additional 60 days until April 11, 2008. The agency believes that this additional time will provide interested parties sufficient time to respond to the questions raised in the December 11, 2007, document.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: 2-6-08
February 6, 2008.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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