



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 133

[Docket No. FDA-2008-P-0086]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the proposed rule, published in the *Federal Register* of October 19, 2005, entitled “Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk.” The proposed rule would amend our regulations to provide for the use of fluid ultrafiltered (UF) milk in the manufacture of standardized cheeses and related cheese products. FDA is reopening the comment period to update comments and to receive any new information.

DATES: FDA is reopening the comment period on the proposed rule published on October 19, 2005 (70 FR 60751), for which we had reopened the comment period as recently as December 30, 2019 (84 FR 71834). The reopened comment period ended on March 30, 2020. Through this document, we are reopening the comment period again. Submit either electronic or written comments by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before

[INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2008-P-0086 for “Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions--**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as

“confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public docket, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jessie Zhao, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of October 19, 2005, we proposed to amend our regulations to provide for the use of fluid UF milk in the manufacture of standardized cheeses and related cheese products. Specifically, the proposed rule, if finalized, for standardized cheeses and related cheese products, would: (1) amend the definitions of “milk” and “nonfat milk” in § 133.3 (21 CFR 133.3) to provide for ultrafiltration of milk and nonfat milk and (2) define ultrafiltered milk and ultrafiltered nonfat milk in § 133.3 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. FDA also proposed that the name of such treated milk be “ultrafiltered milk” or “ultrafiltered nonfat milk,”

as appropriate. Consequently, when this type of milk is used, it would be declared in the ingredient statement of the finished food as “ultrafiltered milk” or “ultrafiltered nonfat milk.”

This proposal was issued in response to citizen petitions from the American Dairy Products Institute and the National Cheese Institute, the Grocery Manufacturers of America, Inc., and the National Food Processors Association. Interested persons were originally given until January 17, 2006, to comment. We subsequently reopened the comment period to seek further comment on two specific issues raised by the comments concerning the proposed ingredient declaration (72 FR 70251, December 11, 2007); the reopened comment period was scheduled to end on February 11, 2008. In the *Federal Register* of February 11, 2008 (73 FR 7692), we extended the comment period until April 11, 2008.

In the *Federal Register* of August 14, 2017 (82 FR 37815), we announced the availability of a guidance for industry entitled “Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products.” In the guidance, we notified manufacturers who wish to use UF milk or UF nonfat milk in the production of standardized cheeses and related cheese products of our intent to exercise enforcement discretion regarding the use of fluid UF milk and fluid UF nonfat milk in the production of standardized cheeses and related cheese products, provided that the physical, chemical, and organoleptic properties of the cheese or cheese product are not affected. We also stated our intent to exercise enforcement discretion with respect to the labeling of fluid UF milk and fluid UF nonfat milk in recognition of the costs and logistics involved in label changes; however, we encouraged industry to identify these ingredients as “ultrafiltered milk” and “ultrafiltered nonfat milk” to the extent feasible and appropriate. We further explained that we intend to exercise enforcement discretion until we have completed a

rulemaking process amending our regulations with respect to the issues covered by the guidance or announced our determination not to proceed with such a rulemaking.

In the *Federal Register* of December 30, 2019, we announced another reopening of the comment period to receive information and further comment on current industry practices regarding the use of fluid UF milk and fluid UF nonfat milk in the manufacture of standardized cheeses and related cheese products, and the declaration of fluid UF milk and fluid UF nonfat milk when used as ingredients in standardized cheeses and related cheese products. The reopened comment period ended on March 30, 2020.

Following publication of the December 30, 2019, document reopening the comment period for the proposed rule, we received requests to allow interested persons additional time to comment. In conjunction with the requests, we are providing an additional 120 days for persons to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues. Therefore, we are reopening the comment period until [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Dated: April 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-07749 Filed: 4/14/2020 8:45 am; Publication Date: 4/15/2020]