4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 133

[Docket No. FDA-2017-D-4713]

Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled "Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products: Guidance for Industry." The guidance advises manufacturers who wish to use ultrafiltered milk (UF milk) or ultrafiltered nonfat milk (UF nonfat milk) in the production of standardized cheeses and related cheese products that, pending completion of a rulemaking regarding the use of UF milk in the production of these products, we intend 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. We also intend to exercise enforcement discretion regarding the declaration of ingredients in the labeling of standardized cheeses and related cheese products when fluid UF milk and fluid UF nonfat milk are used as ingredients.

DATES: The announcement of the guidance is published in the Federal Register on [Insert date of publication in the Federal Register]. Submit either electronic or written comments on FDA guidance at any time.

ADDRESSES: You may submit comments as follows:

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-2017-D-4713 for "Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products: Guidance for Industry." Received comments 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 dockets, see 80 FR 56469, September 18, 2015,

or access the information at: *https://www.gpo.gov/fdsys/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.

Submit written requests for single copies of the guidance to the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Terri Wenger, Center for Food Safety and Applied Nutrition (HFS-800), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2373.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled "Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products: Guidance for Industry." We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

Our regulations specify the standards of identity for cheeses and related cheese products in part 133 (21 CFR part 133). The general provisions within part 133, in part, define "milk" and "nonfat milk" that may be used in the manufacture of cheeses and related cheese products. The definitions for "milk" and "nonfat milk" in § 133.3(a) and (b), respectively, list different forms of milk and nonfat milk, including concentrated, reconstituted, and dried forms, that may be used in the making of cheeses and related cheese products. However, fluid or dried filtered forms of milk obtained through mechanical filtration of milk or nonfat milk are not included within these definitions. Therefore, while current regulations permit the use of concentrated, reconstituted, and dried forms of milk and nonfat milk as basic dairy ingredients (i.e., the only difference in these ingredients is the amount of water), they do not provide for the use of fluid or dried filtered milk or fluid or dried filtered nonfat milk as basic dairy ingredients in standardized cheeses and related cheese products.

Mechanical filtration technologies available for milk processing include ultrafiltration. For purposes of this guidance, we consider filtration to be a process whereby milk is passed over a series of semipermeable membranes with varying pore sizes. Ultrafiltration retains macromolecules and particles larger than about 0.001-0.02 micrometers. In dairy processing, ultrafiltration is typically used to retain all protein components of milk, including casein and whey proteins, while some of the lactose, minerals, and water soluble vitamins present in milk are lost along with water.

For purposes of the guidance, UF milk means raw or pasteurized milk that is passed over one or more semipermeable membranes to partially remove water, lactose, minerals, and water-soluble vitamins without altering the casein::whey protein ratio of the milk and resulting in a

liquid product. UF nonfat milk is defined similarly, except that raw or pasteurized nonfat milk is used.

In the *Federal Register* of October 19, 2005 (70 FR 60751), we issued a proposed rule that would amend our regulations to provide for the use of fluid UF milk in the manufacture of standardized cheeses and related cheese products. We tentatively concluded that the proposed rule, if finalized, would promote honesty and fair dealing in the interest of consumers and, to the extent practicable, achieve consistency with existing international standards of identity for cheeses and related cheese products.

While we have not completed the rulemaking as of August 2017, we are aware of issues regarding UF milk in the United States. In brief, due to recent developments in the export market, the United States dairy industry is experiencing an oversupply of and pricing challenges with domestically produced UF milk (Refs. 1 and 2). Additionally, we have received requests to exercise enforcement discretion while the rulemaking is pending, in part to mitigate the impact on U.S. companies producing UF milk (Ref. 3).

FDA believes that food standards should provide for flexibility in manufacturing procedures and ingredients, provided that the basic nature and essential characteristics of the food are preserved. Given the oversupply of UF milk and the pending rulemaking, through this guidance we are announcing 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 under part 133, in addition to the other required dairy ingredients, provided that the physical, chemical, and organoleptic properties of the cheese or cheese product are not affected. FDA is also announcing its intent to exercise enforcement discretion with respect to the labeling of standardized cheeses and related cheese products, when, in addition to milk or nonfat

milk, fluid UF milk or fluid UF nonfat milk is used as an ingredient, but is not declared in the ingredient statement, provided that milk or nonfat milk is declared in the ingredient statement. We are exercising 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 encourage industry to identify these ingredients as "ultrafiltered milk" and "ultrafiltered nonfat milk" to the extent feasible and appropriate. We intend to exercise enforcement discretion until we have completed a rulemaking process amending our regulations with respect to the issues covered by this guidance, or announce in the *Federal Register* our determination not to proceed with such a rulemaking.

We are issuing this guidance without prior public comment under 21 CFR 10.115(g)(2) because we have determined that prior public participation is not feasible or appropriate, as this guidance implements a temporary enforcement policy to address an oversupply of UF pending the completion of rulemaking regarding the use of UF milk in the production of standardized cheeses and related cheese products. The oversupply of UF milk would be worsened if we deferred exercising of enforcement discretion regarding the matters in the guidance while providing an opportunity for prior public comment. (We also note that, as we stated in the preamble to the 2005 proposed rule, we tentatively conclude that fluid UF milk can be used in standardized cheeses while maintaining the essential characteristics of those cheeses specified in the individual standards of identity in part 133 (see 70 FR 60751 at 60756 through 60757).) However, as with all Agency guidances, the public may comment on the guidance at any time. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov*. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

III. References

The following references are on display in the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov*. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. Letter from Senator Amy Klobuchar, Senator Al Franken, Representative Collin Peterson, and Representative Tim Walz, to President Donald J. Trump, accessed on the Web at *https://www.klobuchar.senate.gov/public/index.cfm/2017/4/klobuchar-franken-peterson-walz-urge-administration-to-support-minnesota-dairy-farmers-through-strong-enforcement-of-our-trade-laws-with-canada*.

2. Congressional Research Service, "New Canadian Dairy Pricing Regime Proves Disruptive for U.S. Milk Producers," dated April 20, 2017, accessed on the Web at *https://www.everycrsreport.com/reports/IN10692.html*.

3. Letter from Michael D. Dykes, D.V.M., President and CEO, International Dairy Foods Association, to Stephen Ostroff, M.D., Deputy Commissioner for Foods and Veterinary Medicine, Food and Drug Administration, dated June 22, 2017.

Dated: August 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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