

(i) If no indications of incorrect fit, damage or wear are found, no further action is required by this AD.

(ii) If any incorrect fit, damage or wear is found, before next flight, do related investigative actions and applicable corrective actions in accordance with the Accomplishment Instructions of the service bulletin.

(2) When incorrect fit, damage or wear is found, within 30 days after the inspection or within 30 days after the effective date of the AD, whichever occurs later, report the findings to Fokker Services B.V., Technical Services Dept., P.O. Box 231, 2150 AE Nieuw-Vennep, The Netherlands.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM-116, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-1137; fax (425) 227-1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

Related Information

(h) Refer to MCAI Dutch Airworthiness Directive NL-2005-013, dated October 17, 2005, and Fokker Service Bulletin SBF100-53-101, dated September 30, 2005, for related information.

Issued in Renton, Washington, on November 30, 2007.

Stephen P. Boyd,

Assistant Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7-23950 Filed 12-10-07; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 133

[Docket No. 2000P-0586 (Formerly Docket No. 00P-0586)]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until February 11, 2008, the comment period for the proposed rule published in the *Federal Register* of October 19, 2005 (70 FR 60751), (herein after referred to as the 2005 proposed rule). In that document, FDA proposed to amend its regulations to provide for the use of fluid ultrafiltered (UF) milk in the manufacture of standardized cheeses and related cheese products. FDA received a number of comments that were opposed to the proposed requirement to declare fluid UF milk, when used, as "ultrafiltered milk" or "ultrafiltered nonfat milk," as appropriate, in the ingredient statement of the finished cheese. FDA is reopening the comment period on the 2005 proposed rule to seek further comment only on two specific issues raised by the comments concerning the proposed ingredient declaration.

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

ADDRESSES: You may submit comments, identified by Docket No. 2000P-0586, by any of the following methods:
Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

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 or the agency Web site, 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.fda.gov/ohrms/dockets/default.htm>, 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.fda.gov/ohrms/dockets/default.htm> 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. The 2005 Proposed Rule

In the 2005 proposed rule, 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.

FDA proposed these amendments principally in response to two citizen petitions, one submitted by the American Dairy Products Institute (Docket No. 1999P-5198 (formerly

Docket No. 99P-5198)) and another submitted jointly by the National Cheese Institute, the Grocery Manufacturers of America, Inc., and the National Food Processors Association (the NCI petition; Docket No. 2000P-0586 (formerly Docket No. 00P-0586)). In the 2005 proposed rule, FDA explained the scientific and legal basis for its tentative conclusion to permit the use of fluid UF milk as an ingredient and provided a tentative definition of fluid UF milk. In addition, FDA tentatively concluded that fluid UF milk, as defined, is significantly different in its composition from the starting material "milk" and, therefore, proposed that fluid UF milk must be declared as "ultrafiltered milk" in the ingredient statement of the finished cheese. FDA requested comments on the 2005 proposed rule by January 17, 2006.

II. Comments to the 2005 Proposed Rule

The agency received about 24 responses (letters and e-mails), each containing 1 or more comments, in response to the 2005 proposed rule. A majority of the comments were from industry, including cheese manufacturers and milk producers and processors, while other comments were from farmers or groups representing farmers, individual consumers, foreign governments, a research institution, and a member of Congress. 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 is seeking public comment only with respect to two of their reasons that: (1) Due to economic and logistical burdens, it would be impracticable for cheese manufacturers to comply with the labeling requirement; and (2) 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. In section III of this document, the agency discusses the primary arguments that the comments presented with respect to each of these reasons.

Comments also opposed other tentative conclusions that the agency stated in the 2005 proposed rule. The agency has considered those comments and intends to respond to all issues raised by the comments in any subsequent final rule. However, at this time, the agency is not seeking further comment on any topic other than the two related to the labeling provision, as described in section III of this document.

III. Request for Comments

By way of background, section 403(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343), which governs the labeling of ingredients in foods, requires, with few exceptions, the declaration of all ingredients by their individual common or usual names. Section 403(i) of the act also provides that to the extent that compliance with this requirement "is impracticable, or results in deception or unfair competition," FDA shall establish regulations for exemptions from this requirement.

As noted in section II of this document, FDA received comments from industry opposing the proposed requirement to declare fluid UF milk as "ultrafiltered milk" or "ultrafiltered nonfat milk" in the ingredient statement of the finished cheese in which these ingredients are used. FDA is seeking comments with respect to two of the reasons that these comments cited in support of their opposition to the proposed labeling provision, i.e., that it would be impracticable for industry to comply with the proposed labeling requirement and that declaring fluid UF milk as "ultrafiltered milk" would be misleading to consumers.

Comments previously submitted to the Division of Dockets Management do not need to be and should not be resubmitted. All comments previously submitted to the docket number found in brackets in the heading of this document, and comments submitted in response to this limited reopening of the comment period, will be considered in any final rule to the 2005 proposed rule.

A. *Impracticability*

Some comments stated that the proposed labeling requirement would be impracticable for the cheese industry to implement in a cost-effective way. They stated that the cost of complying with the proposed labeling requirement would outweigh any economic benefits provided by the use of fluid UF milk in cheesemaking. They further maintained that cheese manufacturers have long used UF milk in cheddar and mozzarella cheeses without declaring it

as "ultrafiltered milk." Another comment emphasized that "outsourced UF milk" (a term the comments used to refer to milk that is ultrafiltered at a facility other than the plant where the cheese is produced) is widely used in today's marketplace and labeling changes at this time would reduce or eliminate the currently realized economic benefits of using UF milk. The comments contained several arguments in support of their claim of impracticability.

(Comment 1) Some comments stated that cheese manufacturers do not use "outsourced UF milk" on a consistent basis and that they use milk and "outsourced UF milk" interchangeably as needed and economically practical and, therefore, it would be economically and logistically burdensome to monitor the use of UF milk.

(Response) The agency questions the basis for this argument. The 2005 proposed rule provides for optional (not mandatory) use of fluid UF milk and, therefore, manufacturers have the option to use fluid UF milk as an ingredient only if it is economically practical. Cost considerations would factor into a firm's decision to use fluid UF milk, as with any other ingredient. Furthermore, it is FDA's understanding that fluid UF milk is likely to be used simultaneously, not interchangeably, with milk. As FDA explained in the 2005 proposed rule (70 FR 60751 at 60759), most cheeses are amenable to the use of fluid UF milk, not in lieu of milk, but as a supplement to milk to produce a protein-standardized milk and thus increase cheese yield. In addition, the petitioners acknowledged that fluid UF milk is economically beneficial to cheese manufacturers because it increases cheese yield, decreases production time, and decreases costs associated with shipping of raw materials and disposal of whey (a byproduct of cheesemaking) (pp. 8-9, the NCI petition).

(Comment 2) According to a trade association, cheese manufacturers do not have information technology systems in place to track and measure the presence of "outsourced UF milk" and tracking "outsourced UF milk" becomes even more unmanageable as the cheese is further processed into other products, such as shredded cheese blends. Further, the comment indicated that suppliers often do not provide information on whether the cheese product is made from UF milk and to do so would mean more logistical difficulties and added costs. The comment also argued that a cheese processor has no way to test a product from a supplier to determine if UF milk

was used and thus ensure that the correct label was affixed to the finished food.

(Response) It is the agency's understanding that most cheesemaking production lines are fully automated and allow manufacturers to track raw materials from receiving docks through to finished products. Published literature, including articles in trade journals, indicate that computer-integrated manufacturing systems are used to control ingredient feeders and maintain detailed records of the combination of ingredients used and results of laboratory analyses of ingredients and product formulations (Refs. 1 and 2). Another publication indicated that automation in the dairy industry enables manufacturers to track every batch of cheese that is produced, including the combination of ingredients that are fed into each batch (Ref. 3). Moreover, food manufacturers would have to monitor the ingredients that are used to manufacture the food they market in order to comply with the ingredient declaration provisions of § 101.4 (21 CFR 101.4). Therefore, it is unclear to the agency why a cheese supplier would not provide information about the ingredients (including fluid UF milk, when used) that are used to produce the cheese. With respect to the cost argument, the 2005 proposed rule provides for optional (not mandatory) use of fluid UF milk and, therefore, manufacturers have the option to weigh any associated costs against benefits to determine whether it would be economically beneficial to use fluid UF milk in cheese.

(Comment 3) The trade association also estimated that, in order to comply with the labeling requirement, cheese manufacturers will, at a minimum, need to triple their label inventory. According to this comment, associated costs that will also increase include:

- Producing more labels (estimated at \$985,000 to \$2.7 million);
- Carrying additional packaging inventory, risk of obsolete packaging, and additional storage space (estimated at doubling or tripling of current costs);
- Increasing raw material inventory (estimated at \$470,000 to \$5.8 million);
- Additional personnel (estimated at \$240,000 to \$900,000); and
- Administrative and logistical problems (estimates of \$5.4 million and \$72 million).

(Comment 4) Another comment stated that the proposed labeling requirement would result in costs to modify tracking systems, update specifications, and update quality control programs as well as costs associated with increased inventory of raw materials, packaging,

and finished goods. This comment estimated the cost of complying with the labeling requirement to be about \$23 million.

(Response) The comments did not provide a detailed or itemized breakdown of the estimation of these costs sufficient to enable the agency to conduct any meaningful analysis of these figures. FDA requests that interested persons submitting comments on this issue provide such data. It is FDA's current understanding that cheese manufacturing facilities are already equipped with systems that can handle multiple ingredients and combinations of ingredients in the manufacture of a cheese product and, therefore, can easily adapt to the introduction of a single, new ingredient. Indeed, manufacturers routinely adjust existing product formulations or introduce new ones based on supply and availability of ingredients and market demand. Thus, FDA questions the additional cost described in the comments associated with the labeling of this new ingredient given the extensive monitoring systems already in place.

(Comment 5) The trade association also asserted that under the proposed labeling requirement, operational efficiencies would decline, cheese plants would lose up to an hour a day changing packaging, and additional time would be spent auditing labels to ensure proper labeling.

(Response) It seems possible to FDA that declines in operational efficiencies can be avoided by proper planning of the production run. Further, any decrease in efficiency due to the labeling requirement is likely to be offset by increased yield, increased through-put (decreased time between coagulation and cutting phases), and increased overall production efficiency. Moreover, the provision for fluid UF milk, as stated in the 2005 proposed rule, is optional and, if finalized as proposed, would not limit manufacturers' ability to weigh different cost considerations to determine whether it would be economical to use fluid UF milk in their cheese production.

FDA is interested in factual information or data that would enable the agency to fully evaluate claims in these comments that it would be impracticable for the cheese industry to comply with the proposed labeling requirement. In particular, FDA seeks information on the following questions:

1. What systems do cheese plants use to monitor ingredients received and ingredients used in different cheeses and related cheese products?

2. How extensively are cheese plants automated with respect to tracking the use of different ingredients?

3. What types of costs are associated with introducing a new ingredient into cheesemaking?

4. How are costs associated with the use of fluid UF milk different from those associated with the use of any other new ingredient or other reformulation of a cheese product?

5. Are the costs associated with the labeling of UF milk that are estimated by the two comments noted previously reasonable? Explain.

6. What mechanisms do manufacturers of cheese-based products (for example, cheese spreads, processed cheeses, shredded cheese blends) currently employ to ensure that the ingredients used in their products, including the sub-ingredients of the cheeses used in their products, are accurately declared? Why are these same mechanisms inadequate to accurately identify fluid UF milk when it is a sub-ingredient of a cheese ingredient?

B. Misleading Ingredient Declaration

Comments that opposed the proposed labeling requirement stated that this requirement would lead to consumer confusion and deception. They stated that consumers would be misled by special ingredient labeling of UF milk, given that the finished cheeses made with or without UF milk are indistinguishable and that there are no differing consequences of use or allergen-related concerns between the two cheeses. One comment also stated that the use of UF milk is not material information because cheeses made with or without UF milk are the same. In addition, comments from Kraft and those submitted jointly by the International Dairy Foods Association (IDFA) and the National Milk Producers Federation (NMPF) included consumer research, which they claim indicates that consumers, when shown cheese labels that declare either "milk," "ultrafiltered milk," or "milk and ultrafiltered milk" in the ingredient statement, believe that the cheeses are different with respect to taste, healthfulness, and quality. Based on these results, these two comments stated that it would be misleading to consumers to declare UF milk as "ultrafiltered milk" because it would lead them to believe that the cheeses are "different" when, in fact, cheeses made with or without UF milk are "identical." These comments urged the agency to remove the proposed labeling requirement from any final rule on this issue such that ultrafiltered milk and

ultrafiltered nonfat milk, when used as ingredients in standardized cheeses and related cheese products, would be declared as simply "milk" and "nonfat milk," respectively, in the ingredient statement of the finished food.

With respect to the consumer research information that Kraft and IDFA/NMPF submitted, the agency reviewed these submissions and notes several limitations in the design of the surveys and interpretation of the results from these surveys (Refs. 4 and 5). In the case of the IDFA-commissioned consumer research (IDFA study; n=672), as an Internet study, the survey sample cannot be considered representative of the population as a whole. The study is essentially a survey with a key measure being forced comparisons between two product labels. However, a substantial limitation of the study is that the forced comparison questions (in which respondents are directed to examine specific label information) are not reliable indicators of what consumers are likely to do in realistic product selection situations (in which consumers may or may not review or consider such information in making their choices). A more useful and appropriate research method would be an experimental study, which looks to establish cause-effect relationships between changes in label information and consumers' judgments and inferences. The results of the IDFA study suggest that some study participants whose attention is directed to the "ultrafiltered milk" in a product's ingredient list may infer that the product may be different somehow from a product that does not have that specific ingredient listed. However, this conclusion is likely to be more a product of the logical deduction that something that is labeled differently must be different than it is to any understanding of what "ultrafiltered milk" is or how this ingredient may affect the product. The IDFA study demonstrates that when study participants notice or are directed to notice a single ingredient difference between two otherwise similar product labels, some will believe the products differ in some way. Of the attributes tested, healthfulness of the product was believed to differ by the largest minority (45 percent). For taste and quality fewer expected a difference (38 percent and 35 percent respectively).

The Kraft consumer research is nearly identical to the IDFA study. It is an Internet panel study, with a smaller sample size (n=301), conducted among individuals who reported that they were cheese product consumers. Like the IDFA study, the Kraft study sample

cannot be considered representative of the population as a whole or of all consumers of cheese products. As did the IDFA study, the Kraft study focuses narrowly on the question of whether disclosing "milk" or "ultrafiltered milk" in the ingredient list of a cheese product affects study participants' perceptions of the product, and the Kraft study suffers from the same shortcomings as does the IDFA study. Kraft's study demonstrates that when study participants noticed or were directed to notice the ingredient difference between two otherwise identical product labels, some inferred that the products differ in some way. Of the attributes tested, healthfulness of the product was believed to differ by nearly half (48 percent) of the respondents. For taste and quality fewer respondents expected a difference (32 percent and 42 percent respectively).

Because of the limitations in the design of these studies as noted previously, FDA tentatively concludes that the findings from both the IDFA study and the Kraft study fail to provide sufficient support for their assertion that labeling fluid UF milk on cheese products as "ultrafiltered milk" would be deceptive to consumers.

With respect to the recommendation of some comments that fluid UF milk and fluid UF nonfat milk should be permitted to be declared by the collective terms "milk" and "nonfat milk," respectively, the agency seeks comment on the need for and appropriateness of such declaration. The existing provisions for the use of the collective terms "milk" and "nonfat milk" in § 101.4(b) are relatively narrow and limited to those forms of milk and nonfat milk from which only water is removed to varying degrees. For example, concentrated milk, reconstituted milk, and dry whole milk are all permitted as basic ingredients in standardized cheeses and § 101.4(b)(4) permits these ingredients to be declared as "milk." However, the agency is being asked to consider extending this collective declaration provision to fluid UF milk. The petitioners and a number of comments in response to the petitions and to the 2005 proposed rule have noted that several substances present in milk (such as lactose, minerals, and water-soluble vitamins) are lost during the ultrafiltration process. The agency also explained the process of ultrafiltration and its effect on milk composition based on its own review of the scientific literature in the 2005 proposed rule (70 FR 60751 at 60752). Unlike concentrated milk, reconstituted milk, and dry whole milk, all of which differ from milk only with respect to their moisture content (and which are

permitted under § 101.4 to be declared by the generic term "milk"), fluid UF milk, as defined in the 2005 proposed rule, has a composition that is significantly different from that of milk.

Another factor that should be considered is that fluid UF milk is not the standardized food "milk" as defined 21 CFR 131.110. Given that there is currently no provision in § 101.4 for fluid UF milk to be declared as "milk" in the ingredient statement of a finished food, and that fluid UF milk does not comply with the standard of identity for "milk," current regulations do not permit fluid UF milk to be declared as "milk." In such instances, consistent with 21 CFR 101.3, the agency generally applies the principles of common or usual name regulations in 21 CFR 102.5 to determine an appropriate name that accurately identifies or describes the basic identity of the food. Consequently, in the 2005 proposed rule, the agency proposed "ultrafiltered milk" as the appropriate declaration of this ingredient. In addition, in response to the petitions, the agency previously received comments from consumers who requested that, if ultrafiltered milk is permitted as an ingredient, cheeses made with this ingredient should be clearly labeled to distinguish them from cheeses made with only milk. The agency seeks public comment on the need for, and appropriateness of, declaring fluid UF milk (or fluid UF nonfat milk) as simply "milk" (or "nonfat milk") when used as an ingredient in standardized cheeses and related cheese products.

Under certain conditions, FDA has previously permitted the use of "or," "and/or," or "contains one or more of the following:" in the declaration of ingredients to accommodate relevant concerns related to ingredient supply and availability. For example, § 101.4(b)(23) provides that when manufacturers are unable to adhere to a constant pattern of fish species ingredient(s) in the manufacture of processed seafood products containing fish protein, due to seasonal or other limitations of species availability, the common or usual name of each individual fish species need not be declared in descending order of predominance, and fish species not present in the fish protein product may be listed if they are sometimes used in the product. This provision permits the declaration of such ingredients using the terms "or," "and/or," or "contains one or more of the following:" to indicate to consumers that all of the listed ingredients may not be present or that they may not be present in the listed descending order of

predominance. For example, the provision allows for the declaration “fish protein (contains one or more of the following: Pollock, cod, and/or pacific whiting).” Given the concerns that industry has expressed with respect to impracticability of the agency’s proposed labeling requirement (see section III.A of this document), we seek comment on the need for and appropriateness of a similar provision for the labeling of fluid UF milk that is used interchangeably with milk, as needed and when economically and logistically practical, in the manufacture of standardized cheeses and related cheese products.

The agency seeks public comment on whether the labeling requirement that the agency proposed would be misleading or deceptive to consumers. Specifically, the agency seeks comment on the following questions:

1. Considering that the products of ultrafiltration, as defined in proposed § 133.3(f) and (g) in the 2005 proposed rule, are significantly different in composition from milk and nonfat milk, is it or is it not appropriate to require that they must be identified by a common or usual name other than “milk” and “nonfat milk,” respectively?

2. If it is appropriate to permit fluid UF milk and fluid UF nonfat milk to be declared by the collective terms “milk” and “nonfat milk,” respectively, when used in standardized cheeses and related cheese products, what is the scientific and legal justification?

3. Is there a need to consider the declaration of fluid UF milk and fluid UF nonfat milk by a term(s) other than their specific, individual common, or usual names when they are used as ingredients in standardized cheeses and related cheese products? Should this consideration be extended to fluid UF milk and fluid UF nonfat milk when they are used as ingredients in other foods? If they are required to be declared by different terms when used in standardized cheeses as compared to other foods, what would be the scientific and legal basis for the different labeling requirements?

4. Is there a need for the agency to consider providing for “and/or” labeling (similar to such provisions in § 101.4(b)) when fluid UF milk or fluid UF nonfat milk are used as ingredients in standardized cheeses and related cheese products? What is the scientific and legal justification for such a provision?

IV. 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 in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

V. References

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

1. Johnson, M.E. and J.A. Lucey, “Major Technological Advances and Trends in Cheese,” *Journal of Dairy Science*, 89:1174–1178, 2006.

2. Dudlicek, J., “Cutting Edge: Innovative Processes Keep Dairy Manufacturing Moving,” in the February 2006 ed. of *Dairy Field* (<http://www.dairyfield.com/content.php?s=DF/2006/02&p=10>), accessed July 2, 2007.

3. Tamime, A.Y. and B.A. Law (Eds.), *Mechanisation and Automation in Dairy Technology*, pp. 1–29 and 204–295, Sheffield Academic Press Ltd., Sheffield, England, 2001.

4. Derby, B.M., Memorandum to Nalubola, R., Consumer Research on Ultrafiltered Milk Labeling, February 10, 2006.

5. Derby, B.M., Memorandum to Nalubola, R., Kraft Consumer Research on Ultrafiltered Milk Labeling, August 16, 2006.

Dated: December 3, 2007.

Leslye M. Fraser,

Director, Office of Regulations and Policy, Center for Food Safety and Applied Nutrition. [FR Doc. E7–23981 Filed 12–10–07; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R05–OAR–2007–0957; FRL–8504–1]

Approval and Promulgation of Implementation Plans and Designation of Areas for Air Quality Planning Purposes; Wisconsin; Redesignation of Kewaunee County Area to Attainment for Ozone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to make a determination under the Clean Air Act (CAA) that the nonattainment area of Kewaunee County has attained the 8-hour ozone National Ambient Air Quality Standard (NAAQS). This determination is based on quality-assured ambient air quality monitoring data for the 2004–2006 ozone seasons that demonstrate that the 8-hour ozone NAAQS has been attained in the area. Preliminary monitoring data for 2007 continue to show monitored attainment of the NAAQS.

EPA is proposing to approve a request from the State of Wisconsin to redesignate the Kewaunee County area to attainment of the 8-hour ozone NAAQS. The Wisconsin Department of Natural Resources (WDNR) submitted this request on June 12, 2007. In proposing to approve this request EPA is also proposing to approve, as a revision to the Wisconsin State Implementation Plan (SIP), the State’s plan for maintaining the 8-hour ozone NAAQS through 2018 in the area. EPA also finds adequate and is proposing to approve the State’s 2012 and 2018 Motor Vehicle Emission Budgets (MVEBs) for the Kewaunee County area.

DATES: Comments must be received on or before January 10, 2008.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2007–0957, by one of the following methods:

1. *www.regulations.gov*: Follow the on-line instructions for submitting comments.

2. *E-mail*: mooney.john@epa.gov.

3. *Fax*: (312) 886–5824.

4. *Mail*: John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand delivery*: John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77