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WRITER'S DIRECT NUMBER
(212) 839-5621

WRITER'S E-MAIL ADDRESS
dmccenroe@sidley.com

August 18, 2005

By Facsimile and Federal Express

Robert E. Brackett, Ph.D.
Director
Center for Food Safety and Applied Nutrition
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Use of Ultrafiltration in Food Manufacturing

Dear Dr. Brackett:

We are writing on behalf of our client Daisy Brand of Garland, Texas. Daisy Brand currently markets no- and low-fat sour cream products manufactured using ultrafiltration technology. According to CFSAN's Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS), Daisy Brand may use ultrafiltration, but must disclose its use in ingredient labeling. Daisy Brand is concerned that, if its sour cream products are labeled in accordance with ONPLDS's position, consumers could be misled as to the ingredients Daisy Brand uses in its sour cream products. This issue is therefore of great importance to Daisy Brand.

It is also of great importance to the entire food industry. Ultrafiltration has been used in food manufacturing for nearly twenty years. Five years ago, the National Cheese Institute, the National Food Processors Association (NFPA), and the Grocery Manufacturers of America (GMA) jointly filed a citizen petition requesting that the Commissioner of Food and Drugs amend the cheese standards of identity to recognize explicitly that ultrafiltration can be used in the manufacture of all standardized cheeses, including those that for historical reasons lack alternate make procedure provisions. The amendments sought by the petition would also make clear that ultrafiltration need not be declared in ingredient labeling. Despite promises to act on the petition and a recent Federal Register notice pledging to modernize food standards (70 Fed. Reg. 29,214 (May 20, 2005)), FDA has yet initiated no regulatory process to ensure that food standards appropriately recognize use of ultrafiltration. Nor has FDA taken action to address generally the proper labeling of foods in which ultrafiltration is used.

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Instead, food manufacturers are currently subject to a product-by-product approach. ONPLDS has issued letters stating that manufacturers of standardized Cheddar and mozzarella cheeses may use ultrafiltration and need not disclose its use in ingredient labeling. At the same time, ONPLDS has said that manufacturers of Swiss cheese products and Daisy Brand may use ultrafiltration but must declare it in ingredient labeling. Wells Dairy has a temporary marketing permit authorizing it to use ultrafiltration in the manufacture of its cottage cheese products, but those products must disclose the use of ultrafiltration in ingredient labeling. According to the NCI/NFPA/GMA petition, it is unclear whether manufacturers of cheeses governed by standards of identity lacking alternate make procedure provisions may lawfully use ultrafiltration in manufacturing, and FDA has issued no comprehensive guidance on whether or how use of this process must be declared in labeling. The regulatory environment is thus incoherent, to the substantial detriment of food manufacturers considering whether to use this technology, and of consumers, who must navigate this tangled web of regulatory requirements to comprehend food composition and labeling.

We believe the current product-by-product approach should be jettisoned in favor of a comprehensive approach. Specifically, CFSAN should address ingredients made through the use of ultrafiltration, the use of ultrafiltration during the manufacturing process, and the proper labeling of foods in which ultrafiltration is used in a single proceeding. The obvious vehicle would be FDA's response to the pending NCI/NFPA/GMA citizen petition, which squarely presents both questions in the context of standardized cheeses. Daisy Brand believes that, in responding to this petition, FDA should address ultrafiltration not only in that context but also for other foods, including sour cream. Whether the citizen petition or some other vehicle is selected, Daisy Brand believes that the agency should use notice-and-comment rulemaking so that it and all other interested parties would have a meaningful opportunity to participate in the development of the comprehensive regulatory regime for ultrafiltration in food manufacturing.

There are signal advantages to our proposed approach. First, it would advance FDA's objective of ensuring that food standards effectively prevent consumer confusion by providing an open, public process for considering issues relating to ultrafiltration. Second, it would facilitate consumer access to a greater variety of food products. Third, it would ensure that food manufacturers receive consistent information on the regulatory requirements relating to ultrafiltration, thereby facilitating compliance. Fourth, it would enable CFSAN to use its finite resources more efficiently than if the Center were to either continue the product-by-product approach or initiate a separate rulemaking to address the use and labeling of ultrafiltration in other categories of foods. Fifth, it would provide a public forum for manufacturers to raise with FDA important issues relating to ultrafiltration, including the implications of requiring food manufacturers to disclose trade secret manufacturing processes in ingredient labeling.

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Daisy Brand recognizes that ONPLDS believes that ultrafiltration must be disclosed in ingredient labeling of some products. We appreciate very much the time and attention ONPLDS has devoted to assisting Daisy Brand in resolving issues relating to ultrafiltration, and we are not seeking a definitive CFSAN or FDA ruling at this stage that ONPLDS's position is incorrect. Rather, Daisy Brand simply requests that the use and proper labeling of food in which ultrafiltration is used be addressed comprehensively for all foods through notice-and-comment rulemaking in which Daisy Brand and all other interested members of the public would have an opportunity to participate.

We are enclosing documents to assist in your consideration of this issue: (1) copies of previous ONPLDS correspondence with Daisy Brand and other companies regarding the permissibility and proper labeling of foods in which ultrafiltration is used; and (2) a copy of the pending NCI/NFPA/GMA citizen petition and selected related correspondence.

We thank you very much for your attention to this matter and look forward to hearing from you after you have had the opportunity to review these materials. If you need any additional information, please contact me. We are not at this point requesting a meeting with CFSAN, but would, of course, be happy to meet with you or anyone you designate if such a meeting would be helpful.

Respectfully yours,



Diane C. McEnroe

Enclosures

cc: Lester M. Crawford, D.V.M., Ph.D. (HF-1)
Scott Gottlieb, M.D. (HF-21)
Murray M. Lumpkin, M.D. (HF-3)
Janet Woodcock, M.D. (HF-2)

TAB

1

B. Three to five focused questions on the topic to be addressed;

C. Plans for rapid translation of the evidence reports and technology assessments into clinical guidelines, performance measures, educational programs, or other strategies for strengthening the quality of health care services, or plans to inform development of reimbursement or coverage policies;

D. Plans for use and/or dissemination of these derivative products, e.g., to membership if appropriate; and,

E. Process by which the nominating organization will measure the use of these products and impact of such use.

6. Topic Selection

Factors that will be considered in the selection of topics for AHRQ evidence, report and technology assessment topics include:

A. Burden of disease including severity, incidence and/or prevalence or relevance of organizational/financial topic to the general population and/or AHRQ's priority populations;

B. Controversy or uncertainty about the topic and availability of scientific data to support the systematic review and analysis of the topic;

C. Total costs associated with a condition, procedure, treatment, technology, or organization/financial topic taking into account the number of people needing such care, the unit cost of care, and related or indirect costs;

D. Potential for achieving clinically significant variations in the prevention, diagnosis, treatment, or management of a disease or condition; or in changing the use of a procedure or technology; informing and improving patient and/or provider decisionmaking; improving health outcomes; and/or reducing costs;

E. Relevance to the needs of the Medicare, Medicaid and other Federal health care programs; and,

F. Nominating organization's plan to disseminate derivative products, measure use and impact of these products on outcomes, or otherwise incorporate the report into its managerial or policy decisionmaking.

7. Submission of Nominations

Topics nominations should be submitted to Kenneth Fink, MD, MGA, MPH, Director, Evidence-based Practice Centers (EPC) Program, Center for Outcomes and Evidence, AHRQ, 540 Gaither Road, Rockville, MD 20850. Electronic submissions to epc@ahrq.gov are preferred.

Dated: November 30, 2004.

Carolyn M. Clancy,

Director.

[FR Doc. 04-27058 Filed 12-8-04; 8:45 am]

BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004P-0519]

Cottage Cheese Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Wells' Dairy, Inc., to market test cottage cheese that deviates from the U.S. standard of identity for cottage cheese. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

DATES: This permit is effective for 15 months, beginning on the date the permit holder introduces or causes the introduction of the test product into interstate commerce, but not later than March 9, 2005.

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: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Wells' Dairy, Inc., 1 Blue Bunny Dr., P.O. Box 1310, Le Mars, IA 51031.

The permit covers limited interstate marketing tests of these products:

1. Blue Bunny Brand
 - "Cottage cheese, 4% milkfat, homestyle, large curd" 24 ounces (oz);
 - "Cottage cheese, 4% milkfat, original, small curd" 32 oz;
 - "Cottage cheese, 4% milkfat, original, small curd" 24 oz;
 - "Cottage cheese, 4% milkfat, original, small curd" 12 oz;

- "Cottage cheese, 2% milkfat, reduced fat" 24 oz;
 - "Cottage cheese, 2% milkfat, reduced fat" 12 oz;
 - "Cottage cheese, 1% milkfat, lowfat" 24 oz;
 - "Cottage cheese, 1% milkfat, lowfat" 12 oz; and
 - "Cottage cheese, Health Smart, fat free" 24 oz.
2. Great Value Brand
 - "Cottage cheese, 4% milkfat, large curd" 24 oz;
 - "Cottage cheese, 4% milkfat, large curd" 16 oz;
 - "Cottage cheese, 4% milkfat, small curd" 24 oz;
 - "Cottage cheese, 4% milkfat, small curd" 16 oz;
 - "Cottage cheese, 1% milkfat, lowfat, small curd" 24 oz;
 - "Cottage cheese, 1% milkfat, lowfat, small curd" 16 oz; and
 - "Cottage cheese, fat free, small curd" 24 oz.
 3. ShurFresh Brand
 - "Cottage cheese, 4% milkfat, small curd" 24 oz.

These cottage cheese products may deviate from the U.S. standard of identity for cottage cheese (21 CFR 133.128) in that the products are formulated using fluid ultrafiltered (UF) skim milk. Fluid UF skim milk is obtained by subjecting skim milk to a physical separation process called ultrafiltration using a membrane with a pore size of 10,000 Daltons molecular weight cutoff, resulting in the partial loss of lactose, minerals, water-soluble vitamins, and water present in skim milk. The casein-to-whey protein ratio of skim milk is not altered during the ultrafiltration process. The moisture content of fluid UF skim milk so obtained is about 80 percent. Fluid UF skim milk is added to skim milk at a level needed to increase the total solids of the cheese milk by 5 to 25 percent. The physical, chemical, and sensory properties characteristic of cottage cheese are not altered in the test product. The fluid UF skim milk will be declared in the ingredient statement of the finished cottage cheese as "ultrafiltered skim milk." The test product meets all the requirements of the standard with the exception of the use of fluid UF skim milk. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

This permit provides for the temporary marketing of a total of 15 million pounds (6.8 million kilograms) of the test product. The test products will be manufactured by Wells' Dairy,

Inc., at 12th and Lincoln Sts. SW., Le Mars, IA 51031. The test products will be distributed by Wells' Dairy, Inc., throughout the States of Iowa, Minnesota, Wisconsin, Missouri, Nebraska, Oklahoma, Kansas, South Dakota, North Dakota, Arkansas, and Colorado. Each of the ingredients used in the food must be declared on the labels as required by the applicable sections of part 101 (21 CFR part 101). The information panel of the labels will bear nutrition labeling in accordance with § 101.9. This permit is effective for 15 months, beginning on the date the permit holder introduces or causes the introduction of the product into interstate commerce, but not later than March 9, 2005.

Dated: November 29, 2004.

Barbara Schneeman,
Director, Office of Nutritional Products,
Labeling and Dietary Supplements, Center for
Food Safety and Applied Nutrition.
[FR Doc. 04-26996 Filed 12-8-04; 8:45 am]
BILLING CODE 4160-01-5

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 13, 2005, from 9 a.m. to 5 p.m.

Location: Hilton Washington DC North, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Geretta Wood, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8320, ext. 143, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation on the FDA Critical Path Initiative. The committee will also discuss, make recommendations, and vote on a premarket approval application for a thoracic endoprosthesis intended for endovascular repair of the descending thoracic aorta.

Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 5, 2005. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 5, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, at 301-594-1283, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 1, 2004.

Sheila Dearybury Walcott,
Associate Commissioner for External
Relations.

[FR Doc. 04-26994 Filed 12-8-04; 8:45 am]
BILLING CODE 4160-01-5

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Nonprescription Drugs Advisory Committee (NDAC) and the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC).

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 13, 2005, from 8 a.m. to 5 p.m., and January 14, 2005, from 8 a.m. to 3 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Cathy A. Groupe, or Hilda F. Scharen, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, Rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail GroupeC@cder.fda.gov or scharenh@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 3014512541 and 3014512536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On both days, the committees will consider the safety and efficacy of new drug application (NDA) 21-213, proposing over-the-counter (OTC) use of MEVACOR (lovastatin), 20 milligrams a day, Merck & Co., Inc., to help lower LDL "bad" cholesterol, which may prevent a first heart attack. The background material will become available no later than the day before the meeting and will be posted under the NDAC or the EMDAC Docket site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> (click on the year 2005 and scroll down to NDAC or EMDAC).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written



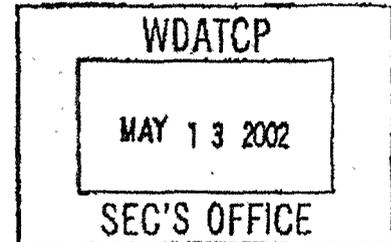
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 07 2002

Food and Drug Administration
Washington DC 20204

James E. Harsdorf
Secretary
Department of Agriculture, Trade and Consumer Protection
2811 Agriculture Drive
Post Office Box 8911
Madison, Wisconsin 53708-8911



Dear Mr. Harsdorf:

Thank you for your March 8, 2002 letter addressed to Lester Crawford, D.V.M., Ph.D., Deputy Commissioner, Food and Drug Administration (FDA), in which you describe your concerns about the use of milk protein concentrate (MPC) in standardized cheese. You specifically noted your concern about the use of MPC in "pasteurized process cheese food," which is a standardized cheese.

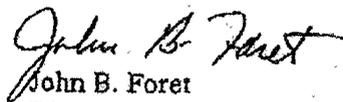
Standardized cheese products such as pasteurized process cheese food are governed by standards of identity under Title 21 Code of Federal Regulations (21 CFR) Part 133. Among other things, the standards specify the ingredients permitted in the manufacture of these foods. MPC is not included as an optional ingredient in any of the cheeses covered by the above standards of identity. Therefore, cheeses and related cheese products that are covered by a standard under Part 133 may not contain MPC as an ingredient. However, we have not objected to fluid ultra filtered (UF) milk under specific circumstances. In addition, foods that do not meet a defined standard of identity must be named by a common or usual name of the food other than a name in a standard, or in the absence of a common or usual name, an appropriately descriptive term.

The Center for Food Safety and Applied Nutrition (CFSAN) establishes priorities to make the most efficient use of available resources, i.e., the "CFSAN Program Priorities." Current priorities focus on bioterrorism, food allergens and food safety. To date the use of MPC ingredients in standardized cheese has not been highlighted for enforcement because it is not considered a food safety priority. However, in response to the growing concern over the use of MPC in standardized cheese, CFSAN is drafting an assignment to our FDA field offices to conduct inspections at specific cheese manufacturing sites to determine compliance with the cheese standards and to document the use of MPC in standardized cheese. Based on the results of this assignment, CFSAN will evaluate whether enforcement action, i.e., warning letter, seizure, or injunction, is appropriate. In addition, our fiscal year 2002 CFSAN Program Priorities include the development of a proposed rule to amend the definition for "milk" in cheese standards to provide for the use of fluid UF milk.

Page 2- James E. Harsdorf

Please do not hesitate to contact us if we can provide further assistance to you.

Sincerely yours,



John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 13, 2003

Mr. E. Linwood Tipton
President and Chief Operating Officer
International Dairy Foods Association
1250 H Street NW
Suite 900
Washington, D.C. 20005

Dear Mr. Tipton:

Thank you for your kind words about my participation in the Dairy Forum 2003. I enjoyed the opportunity to address the group and am pleased that your members were impressed with my presentation. Your letter also asks the Food and Drug Administration (FDA) to expedite making a decision on the National Cheese Institute's petition to permit the use of fluid filtered milk in standardized cheeses and related cheese products.

In June 2000, the National Cheese Institute, the Grocery Manufacturers of America, Inc., and the National Food Processors Association submitted a joint petition requesting that FDA provide for the use of fluid filtered milk in standardized cheese. In addition, the American Dairy Products Institute submitted a petition in December 1999 requesting that FDA provide for the use of fluid UF milk in standardized cheese. Taking action on these petitions was not included in CFSAN's Program Priorities for either FY 2000 or FY 2001 given other food safety priorities. Taking action on these petitions, however, was listed in CFSAN's FY 2002 priorities and, accordingly, CFSAN has been developing a proposed rule related to these petitions.

With respect to the request for a temporary marketing permit related to this issue, in August 2002, FDA received a request from a dairy processor for a temporary marketing permit to use UF milk in cottage cheese. However, the initial application did not provide all the necessary information, as required by 21 CFR 130.17. The company provided the missing pieces of information in January 2003 and the request is currently being reviewed by the agency.

Thank you for your interest in this issue. If I can be of further assistance, please let me know.

Sincerely,

Lester M. Crawford, D.V.M., Ph.D.
Deputy Commissioner



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD

FEB 6 2004

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Dean A. Sommer
Cheese and Food Technologist
Wisconsin Center for Dairy Research
1605 Linden Drive
Babcock Hall
Madison, Wisconsin 53706

Dear Mr. Sommer:

This is in response to your letter dated December 3, 2003, to the Food and Drug Administration (FDA) regarding the use of filtered milk in standardized cheeses, particularly Swiss cheese. You stated that it has been recently brought to your attention that there is a question concerning the use of filtered milk in Swiss cheese. You provided some data from trials conducted at the Center for Dairy Research (CDR) and maintained that these data and results of other studies conducted by CDR demonstrate that the composition and sensory characteristics of Swiss cheese made with milk that is supplemented with filtered milk are not significantly different from Swiss cheese made with only milk. In fact, you stated the flavor of Swiss cheese made using filtered milk was superior to that of the cheese made without using filtered milk. You further stated that the manufacturing procedure for making Swiss cheese using filtered milk is essentially the same as the standard "make" procedure used in the industry.

We thank you for your interest in this issue and for providing us with the information from your trials. As you may be aware, FDA has received two petitions, one from the American Dairy Products Institute (the ADPI petition; Docket No. 99P-5198/CP 1) and another filed jointly by the National Cheese Institute (NCI), the Grocery Manufacturers of America, and the National Food Processors Association (the NCI petition; 00P-0586/CP 2), requesting the amendment of Title 21 Code of Federal Regulations section 133.3 to include fluid filtered milk in the definition of milk and nonfat milk.

FDA has reviewed the ADPI petition and concluded that it did not present reasonable grounds to support the requested amendments. However, because the issues raised in the ADPI petition are clearly covered under the NCI petition, FDA closed the ADPI petition and converted it to a comment to the NCI petition. ADPI was informed of FDA's action in a letter dated February 26, 2003.

FDA also conducted a review of the NCI petition and the issues surrounding the use of fluid filtered milk in standardized cheeses and related cheese products. The development of a proposal to amend section 133.3 to provide for the use of fluid ultrafiltered milk in standardized cheeses and related cheese products was an A-list activity in FY2003 Center for

00P-0586

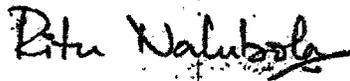
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Page 2 – Dean A. Sommer

Food Safety and Applied Nutrition's Program Priorities, and is likely to be a priority during FY2004. Accordingly, we are making progress on this issue. We encourage you and any food manufacturers you may collaborate with to provide comments on our proposed amendments when the proposed rule is published in the Federal Register. We have forwarded your letter to the Division of Dockets Management for inclusion in Docket No. 00P-0586. Please be assured that we will consider all comments received before making a final decision on this issue.

Should you have additional questions, do not hesitate to contact us.

Sincerely yours,



Ritu Nalubola, Ph.D.
Food Labeling
and Standards Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR 6 2005

Clay Hough
General Counsel and Senior Vice President
Regulatory Affairs
International Dairy Foods Association
1250 H Street, N.W.
Suite 900
Washington, D.C. 20005

Dear Mr. Hough:

This is in response to your letter dated October 15, 2004, to the Food and Drug Administration (FDA) regarding the use of ultrafiltered (UF) milk in Swiss cheese. Your letter was in further reference to FDA's letter dated February 23, 2004, to North American Milk Products, in which FDA requested additional information to demonstrate that the basic nature and essential characteristics of Swiss cheese are not altered by the use of UF milk as an ingredient. In your current submission, you provided analytical data, including those taken from published literature, that show that Swiss cheese made using fluid UF milk has the same chemical, nutritional, and sensory characteristics as Swiss cheese made in accordance with the current standard of identity in Title 21 of the Code of Federal Regulations (21 CFR) section 133.195. In light of these data, you asked that the agency consider granting regulatory discretion for the use of fluid UF milk in Swiss cheese.

We thank you for providing the data and factual information we requested to demonstrate that the basic nature and essential characteristics of Swiss cheese are maintained in the use of fluid UF milk in the making of Swiss cheese. FDA has reviewed the information you submitted and agrees that fluid UF milk may be used in Swiss cheese without adversely affecting the essential chemical characteristics, nutritional properties, or sensory attributes of Swiss cheese. Therefore, based on our review of the information provided, we do not object to the use of fluid UF milk as an ingredient in the manufacture of Swiss cheese at this time.

The following provides details about the ingredient, fluid UF milk, its processing, and its use in Swiss cheese. While you refer to the ingredient as "filtered" milk, the data submitted previously by Mr. Robert Fassbender (letter dated November 26, 2003, to Felicia Satchell) and Mr. Dean Sommers (letter dated December 3, 2003, to Felicia Satchell) as well as the data included in your current submission (Johnson 2004 and published literature) specifically refer to the ingredient as "UF" milk and/or clearly describe the process of ultrafiltration in the making of Swiss and other cheeses. Therefore, the agency's review in response to your current submission is limited to the use of fluid UF milk only and does not include other types of filtered milks. For example, we did not review your submission for the use of milk processed by microfiltration as an ingredient in the making of Swiss cheese. Providing for the use of fluid UF milk, but not other types of filtered milks, in the manufacture of Swiss cheese is also consistent with the agency's previous decision to grant regulatory discretion for the use of fluid UF milk in Cheddar and mozzarella cheeses.

Page 2 – Mr. Clay Hough

With respect to the process that will be employed to obtain the ingredient fluid UF milk, ultrafiltration, which retains macromolecules and particles larger than about 0.001-0.02 micrometers (Reference: Cheryan M. 1998. Ultrafiltration and Microfiltration Handbook, second edition. CRC Press LLC, Boca Raton, Florida), results in the partial loss of lactose, minerals, water-soluble vitamins, and water present in milk while the casein to whey protein ratio of milk is unaffected. In addition, as you noted, fluid UF milk typically is used in amounts of 5 to 7 percent of the volume of liquid milk in the cheese vat.

With respect to labeling, fluid UF milk that is used as an ingredient in Swiss cheese should be declared as "ultrafiltered milk" (or "ultrafiltered skim milk," as appropriate) in the ingredient statement of the finished food, Swiss cheese. Although we did not make this labeling declaration a condition as part of our enforcement discretion in the case of Cheddar and mozzarella cheeses, the agency's thinking and policy with respect to the declaration of fluid UF milk have evolved since that time. Milk that has undergone ultrafiltration is distinctly different from the starting ingredient milk. Ultrafiltration is a mechanical filtration process that typically results in the loss of some of the water, lactose, minerals, and water-soluble vitamins that are present in milk. The resulting ultrafiltered milk, therefore, is distinctly different from the starting ingredient milk and, therefore, cannot be called simply "milk." Rather, in accordance with 21 CFR 102.5, it must be described by a term that adequately and accurately describes its basic nature or characterizing properties. While an appropriate term to describe such ultrafiltered milk could be a name that identifies all the substances in milk that have been either reduced or removed (for example, "lactose, minerals, and vitamins reduced concentrated milk"), we believe that such a name would be cumbersome for the purposes of ingredient labeling. However, an alternative adequate and accurate descriptor is "ultrafiltered milk." A recently issued temporary marketing permit for the use of fluid UF skim milk in cottage cheese notes the agency's determination that this ingredient is appropriately declared on the finished food label as "ultrafiltered skim milk" (See 69 FR 71418, December 9, 2004).

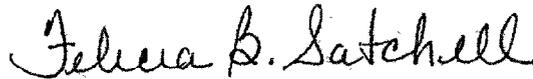
Finally, as you may be aware, the publication of a proposal to amend 21 CFR 133.3 to provide for the use of fluid UF milk in standardized cheeses and related cheese products is an A-list activity in CFSAN's FY2005 Program Priorities. Accordingly, we intend to publish a proposal on this issue during this fiscal year. We encourage you and the manufacturers you represent to provide comments on this proposal when it is published. During this rulemaking process and pending issuance of a final

Page 3 – Mr. Clay Hough

rule permitting fluid UF milk as an ingredient in standardized cheeses and related cheese products, based on the information you have provided, the use of fluid UF milk as described above in the manufacture of Swiss cheese is not an enforcement priority for FDA at this time.

Should you have additional questions, do not hesitate to contact us.

Sincerely yours,



Felicia B. Satchell
Director
Food Labeling
and Standards Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
College Park, MD 20740

JUL 29 2005

Diane C. McEnroe
Sidley Austin Brown & Wood LLP
787 Seventh Avenue
New York, New York 10019

Dear Ms. McEnroe:

In a letter dated June 24, 2004, Felicia B. Satchell, Director of the Food Labeling and Standards Staff (FLSS) of the Office of Nutritional Products, Labeling and Dietary Supplements, stated that the agency would not object to your client's use of ultrafiltered skim milk in its Light and No Fat sour cream products, but that the ultrafiltered skim milk must be declared in the ingredient statement of the finished foods as "ultrafiltered skim milk." Later, on January 10, 2005, in response to your follow-up letter dated August 23, 2004, Ms. Satchell reiterated that ultrafiltered skim milk used in the manufacturing of the above mentioned Daisy Brand sour cream products cannot be declared as simply "skim milk." Rather, it must be identified in the ingredient statement of the finished foods as "ultrafiltered skim milk."

You subsequently requested, in a conversation with Ms. Geraldine June of the FLSS, that the Food and Drug Administration (FDA) reconsider its position with respect to your client's desire to use ultrafiltered skim milk in its products without the label declaration required by FDA regulation. You also requested that we conduct a legal review of our determination regarding the appropriate labeling of ultrafiltered skim milk used in Daisy Brand sour cream products. You did not, in that conversation or subsequently, provide us with any new or additional information in support of your contention that our decision regarding the label declaration of ultrafiltered skim milk that is used in the manufacturing of Daisy Brand Light and No Fat Sour Cream products is incorrect. Therefore, as explained more fully in this letter, although we did reconsider the matter, we do not see any reason to change our position. Furthermore, we provided a copy of this letter to FDA's Office of General Counsel prior to its issuance.

In the remainder of this letter I explain again FDA's position with respect to the labeling of your client's product. Based on the information you have previously provided, it is our understanding that Daisy Light and No Fat Sour Cream products are made using skim milk that is processed using a membrane filtration (pore size of 0.01 micron) where the volume of the milk is reduced by about 60 percent and the protein content of the milk is increased. This ultrafiltered skim milk is then blended with cream and other ingredients (such as vitamin A palmitate, modified food starch, and carrageenan, as needed) at appropriate levels to achieve the desired end product fat content and the mixture is pasteurized and homogenized and culture is added for the fermentation process. It is also our understanding that the ultrafiltered skim milk with its increased protein content functions as a stabilizer in the Daisy Light and No Fat Sour Cream products resulting in an end product that possesses performance characteristics (viscosity, body, and texture) similar to those of regular sour cream.

Page 2 - Ms. Diane C. McEnroe

FDA does not object to your client's use of ultrafiltered milk, which is added at appropriate levels to cream prior to culturing to produce its Light and No Fat sour creams. Sour cream is a standardized food governed by the standard of identity in Title 21 of the Code of Regulations (21 CFR) section 131.160, which states that sour cream results from souring cream with lactic acid producing bacteria. Per 21 CFR 131.3(a), cream means the liquid milk product high in fat separated from milk which may have been adjusted by adding milk, skim milk, or their concentrated and dried forms. Sour cream may be modified to produce lower fat versions of the food under the provisions of 21 CFR 130.10, which specifies requirements for foods that use the name of a standardized food in their statement of identity but that do not comply with the standard because of a deviation that is described by an expressed nutrient content claim. Among other provisions, this regulation allows the use of safe and suitable ingredients, which are not specifically provided for in the relevant standard of identity, so that the product is not inferior in performance characteristics to the standardized food (see section 130.10(d)). In light of these regulations and based on the information you submitted, we stated that we do not object to your client's use of ultrafiltered milk to produce the above mentioned sour cream products.

However, we do not agree that your client's products are labeled appropriately. FDA regulation 21 CFR 101.4 requires ingredients of a food to be declared by their specific common or usual name in the ingredient statement of the finished food. This regulation permits the use of a collective term in the case of a few specific ingredients. For example, skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk may be declared as "skim milk" or "nonfat milk" (see section 101.4(b)(3)). This specific provision, however, does not extend to include ultrafiltered skim milk. Therefore, when used in foods, ultrafiltered skim milk must be declared by its specific common or usual name, i.e., "ultrafiltered skim milk." Accordingly, the labels you provided for your client's Light and No Fat sour creams, which declare ultrafiltered skim milk as simply "skim milk," are not appropriate. The ingredient that is used in the making of Daisy Brand sour cream products is not skim milk, but skim milk that has been subsequently processed (i.e., ultrafiltered) to obtain a liquid milk product that would provide the intended technical function (i.e., as a stabilizer) in the sour cream products. Therefore, although ultrafiltered skim milk is obtained from skim milk, the ingredient that is used in the manufacturing of the Daisy Brand sour cream products is ultrafiltered skim milk, not skim milk.

Milk that has undergone ultrafiltration is distinctly different from the starting ingredient milk in that ultrafiltration typically results in the loss of some of the water, lactose, minerals, and water-soluble vitamins that are present in milk. The resulting ultrafiltered milk, therefore, is distinctly different from the starting ingredient milk and cannot be called simply "milk." Rather, in accordance with 21 CFR 102.5, it must be described by a term that adequately and accurately describes its basic nature or characterizing properties. While an appropriate term to describe such ultrafiltered milk could be a name that identifies all the substances in milk that have been either reduced or removed (for example, "lactose, minerals, and vitamins reduced concentrated milk"), we believe that such a name would be cumbersome for the purposes of ingredient labeling. An alternative adequate and accurate descriptor is "ultrafiltered milk."

In sum, as Ms. Satchell's supervisor, I have reevaluated FDA's previous determination in response to your latest request for reconsideration and for a legal review of this issue. This position was first provided to you in writing more than a year ago, on June 24, 2004, and reiterated in a second written response on January 10, 2005. Upon reevaluation, and in the absence of any new information, I have reached the same conclusion as that previously communicated to you by Ms. Satchell—that the

Page 3 - Ms. Diane C. McEnroe

appropriate name for ultrafiltered milk that is used in the manufacturing of Daisy Brand sour cream products is "ultrafiltered skim milk," not simply "skim milk."

We consider this matter resolved.

Sincerely yours,



Barbara O. Schneeman, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copy to:
Office of General Counsel
Food and Drug Administration
Food and Drug Division

TAB

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COVINGTON & BURLING

1301 PENNSYLVANIA AVENUE NW WASHINGTON, DC
WASHINGTON, DC 20004-2401 NEW YORK
TEL 202.682.6000 LONDON
FAX 202.682.6291 BRUSSELS
WWW.COV.COM SAN FRANCISCO

June 9, 2000

BY HAND

Ms. Jennie C. Butler
Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 00P-0586/CP 1

5754 100 JUN -9 13:37

Dear Ms. Butler:

Enclosed for filing please find the original and three copies of a Citizen Petition submitted on behalf of the National Cheese Institute, Grocery Manufacturers of America, Inc., and National Food Processors Association. Kindly date-stamp the fourth copy and return it to me via the awaiting messenger.

The enclosed petition supersedes the petition filed by these organizations on February 10, 2000, and assigned the above docket number. That petition is hereby withdrawn pursuant to 21 C.F.R. § 10.30(g).

Thank you for your attention to this matter.

Sincerely yours,

Sarah E. Taylor
Coleen E. Klasmeier

Petitioners' Counsel

00P-0586

WDL1



International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

June 9, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION

The undersigned National Cheese Institute (NCI), joined by the Grocery Manufacturers of America, Inc. (GMA) and the National Food Processors Association (NFPA), submits this petition under sections 401 and 701(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. §§ 341 and 371(e), to request the Commissioner of the Food and Drug Administration (FDA) to amend section 133.3 of FDA regulations to recognize formally that filtered milk is a form of milk encompassed by the terms "milk" and "nonfat milk" under the standards of identity for cheese and cheese products (21 C.F.R. Part 133). This petition conforms with the requirements for citizen petitions set forth in FDA regulations. See 21 C.F.R. § 10.30.

Founded in 1927, NCI is affiliated with the International Dairy Foods Association and represents manufacturers, marketers, processors, and distributors of a wide variety of cheese and cheese products. Its 95 member companies market approximately 80 percent of the natural and processed cheese and cheese products sold in the United States and would be affected by the amendments proposed in this petition.

00P-0586

CP2

Dockets Management Branch

June 9, 2000

Page 2

GMA is the world's largest association of food, beverage, and consumer product companies. With U.S. sales of more than \$450 billion, GMA members employ more than 2.5 million workers in all 50 States. The organization applies legal, scientific, and political expertise from its member companies to vital food, nutrition, and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers at the state, federal, and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency, and growth in the food, beverage, and consumer products industry. GMA counts among its members a number of companies whose product lines include dairy products which would be affected by the amendments proposed in this petition.

NFPA is the voice of the \$460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical, and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications, and crisis management support for the Association's U.S. and international members, who produce processed and packaged foods, drinks, and juices, including a variety of dairy products. NFPA represents more than 40 companies whose product lines include dairy foods and thus would be affected by the amendments proposed in this petition.

Over the past 20 years, cheese manufacturers have widely adopted the use of milk filtration technology and the resulting filtered milk products in the manufacture of cheese under the alternate make procedures provisions in FDA's standards of identity for cheese. Milk

filtration technology is used to remove from milk the water phase constituents which otherwise are removed when whey is separated from the cheese curd in traditional cheesemaking procedures. The use of filtered milk in standardized cheese enhances product consistency and production efficiencies, which yields cost savings that can be passed on to consumers. Milk filtration also allows for more efficient transportation of milk, which helps stabilize milk supplies. Because milk filtration removes the same water phase constituents that otherwise are removed from milk in the separation of "whey" from curd, the finished cheese has the same physical, chemical, and nutritional characteristics as cheese made from other forms of milk expressly permitted under existing standards. This petition proposes to amend section 133.3 of FDA regulations to recognize explicitly that filtered milk is encompassed within the definitions of "milk" and "nonfat milk," as used in Part 133 of FDA regulations, and may be used in standardized cheese products like other forms of milk encompassed within the "milk" and "nonfat milk" definitions, to the extent permitted under applicable varietal cheese standards.

These amendments are consistent with the well-established and widespread use of milk filtration as part of the alternate make procedures for manufacturing standardized cheese, and would explicitly recognize that filtered milk products are interchangeable with other forms of milk for purposes of cheese manufacturing. The amendments would extend the authorized use of filtered milk to cheese varieties subject to standards of identity that, for historical reasons, do not include alternate make procedures, to the extent that filtered milk can feasibly be used under the traditional make procedures specified in these standards. The amendments also would facilitate administration of the cheese manufacturing plant inspection requirements associated with the USDA cheese grading service.

B. Action Requested

This petition requests that the Commissioner of Food and Drugs amend 21 C.F.R. § 133.3 (a) and (b) by adding the underscored language below specifying that "filtered milk" and "filtered skim milk" are acceptable forms of milk and nonfat milk respectively for use in standardized cheese and cheese products, and by adding a new subsection (c) as set forth below defining "filtered milk" for this purpose.

- (a) *Milk* means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, which may be clarified and may be adjusted by separating part of the fat therefrom; concentrated milk, filtered milk, reconstituted milk, and dry whole milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms of milk, may be added.
- (b) *Nonfat milk* means skim milk, concentrated skim milk, filtered skim milk, reconstituted skim milk, and nonfat dry milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms of nonfat milk, may be added.
- (c) *Filtered milk* means the liquid milk product produced by a physical separation technique in which raw or pasteurized milk is passed over one or more semipermeable membranes to partially remove the water phase and its constituents, including water, lactose, whey proteins, and minerals. Either before or after filtration, fat may be separated to produce filtered skim milk. After filtration, water may be partially removed by means of evaporation to produce more concentrated forms of filtered milk.

See Attachment A.

C. Statement of Grounds

1. Introduction

FDA's standards of identity for most cheese and cheese products contain "alternate make procedure" provisions which expressly permit cheesemakers to use either the traditional cheese manufacturing process described in the standard or an alternate procedure that

yields a finished cheese with the same physical and chemical properties. The standards in Part 133 that include alternate make procedure provisions are listed in Attachment B. The alternate make procedure provisions historically have enabled cheesemakers to embrace advances in cheese manufacturing technology that yield economic efficiencies and enhance quality while maintaining the character of cheese made using the traditional procedures. The alternate make procedure provisions have helped limit lengthy and expensive regulatory proceedings to amend the standards of identity for cheese to cover only those changes in cheese manufacturing procedures that produce a material change in the finished product. The alternate make procedure provisions have helped maintain the established high quality of standardized cheese while fostering the adoption of new technologies, including milk filtration. The extensive use of filtration technologies under the alternate make procedure provisions has produced significant benefits by improving product consistency and manufacturing efficiency, and expanding milk sourcing options enabling cheesemakers to respond more effectively to regional disruptions in the fluid milk supply, such as those caused by adverse weather conditions.

Although the petitioners believe that the alternate make procedure provisions of FDA's cheese standards provide an ample legal basis for the continued use of filtered milk in the manufacture of standardized cheese, we seek the proposed amendments to the definitions section of Part 133 to recognize explicitly that filtered milk and filtered skim milk produced using mechanical filtration are encompassed by the terms "milk" and "nonfat milk" in section 133.3. We believe that these amendments are needed for two reasons. First, by explicitly recognizing filtered milk products as "milk" and "nonfat milk" for purposes of cheese manufacturing, the proposed amendments would allow cheese manufacturers to expand the use of filtration

technologies and the resulting filtered milk in cheese manufacturing. The use of filtered milk would be permitted in standardized cheeses which are governed by standards of identity that, for historical reasons, do not include alternate make procedure provisions, to the extent feasible under the traditional make procedures specified in the existing standards. This would allow greater use of filtered milk to help manage seasonal imbalances in milk supplies and demand for cheese, including for smaller cheese manufacturers, which do not always have direct or consistent access to milk filtration facilities. This would expand the range of cheese manufacturers able to achieve the production efficiencies offered by filtered milk and the resulting cost savings that ultimately could be passed on to consumers.

Second, the proposed amendments would assist the USDA Office of Dairy Programs in administering plant inspection requirements associated with its voluntary cheese grading service by specifying that filtered milk products are encompassed within the meanings of "milk" and "nonfat milk" as used in Part 133 and may be used in the manufacture of standardized cheese. The proposed amendments also would help USDA inspectors distinguish filtered milk products used as ingredients in standardized cheeses from other milk isolates (such as chemically derived caseinates) that are produced through other separation processes which never have been encompassed by the alternate make procedure provisions for standardized cheeses.

2. The Use of Filtered Milk in Cheese Manufacturing

Mechanical filtration has been used extensively to process skim, reduced fat, and whole milk in cheese manufacturing in the United States for the past 20 years. We estimate that filtration techniques have been used to manufacture billions of pounds of cheese in the United States alone since this process was introduced. The history of use of milk filtration by European

cheesemakers is even longer, predating its use by U.S. manufacturers by at least ten years. For many years, the International Dairy Federation (IDF) has promoted milk filtration as a basic process for cheesemaking internationally, holding numerous symposia to educate cheesemakers on the technology and use of filtered milk in cheese manufacturing.

In general, the term "mechanical filtration" describes one of several membrane filtration techniques used by the food industry. In filtration, a pressurized fluid stream is passed over a semipermeable membrane which separates the liquid into two effluent streams. The "permeate" is the water phase stream that has passed through the membrane, while the "retentate" is the solids stream that has not passed through the membrane. See Attachment C. The size of the pores in the membrane and the number of membranes the fluid is passed over determine the concentration (e.g., 2x to 6x) of the retentate and the proportion of the water phase that has been removed as permeate. The membrane pore sizes vary between .0001 and .20 microns. This confines the composition of the permeate to the water phase constituents of fluid milk—the same constituents that otherwise would be removed as whey in the traditional cheesemaking process.

In traditional cheesemaking, water, lactose, protein, and ash (minerals) are removed from cheese curd in the form of whey through a draining procedure known as whey syneresis. Syneresis occurs at several steps in the cheese manufacturing process, resulting in a significant reduction in these constituents as compared to fluid milk. Similarly, in mechanical filtration, raw or pasteurized milk is separated into permeate, which consists of water and water soluble constituents including lactose, non-protein nitrogen, whey proteins, and ash; and retentate, which contains butterfat and casein in addition to the remaining water phase

constituents. The retentate is used instead of or in combination with milk, nonfat dry milk, or cream to make cheese. See Attachment D.

Because mechanical filtration removes only those constituents that are removed by whey syneresis in traditional cheesemaking, it functions effectively to rearrange the steps in the cheesemaking process to permit the water phase constituents to be removed from fluid milk. To produce a cheese using filtered milk that is equivalent physically, chemically, and nutritionally to a cheese made using traditional procedures, there is no need to add back any constituent lost to the permeate in the filtration process. A cheese that conforms with the moisture and solids requirements of the applicable FDA standard is necessarily equivalent when made directly from filtered milk in simple combination with other dairy ingredients that are already specifically permitted under the standard. The long history and widespread use of filtration technology and the resulting filtered milk under the alternate make procedure provisions have clearly established the equivalence of standardized cheese made from filtered milk and cheese made from other forms of milk already explicitly authorized under section 133.3. See Attachment F and pages 14-17, infra.

The ability of cheesemakers essentially to remove water phase constituents from fluid milk by means of mechanical filtration offers several distinct advantages. Cheesemakers are able to work with a smaller volume and more concentrated form of milk which facilitates standardization of formulation and production, promoting more consistent quality and yields. Since mechanical filtration is more effective than whey syneresis at retaining nutritionally valuable milk proteins, cheese yields may be greater in batches using filtered milk. This

conservation of desirable proteins also results in a corresponding decrease in whey disposal costs.

Mechanical filtration operations in cheese manufacturing originally were based in the same plant as other steps in the cheese manufacturing process. However, the benefits of economies of scale increasingly have caused cheese processors to rely on centralized milk filtering operations.

Larger cheese manufacturers frequently are able to centralize mechanical filtration operations in a single plant supplying multiple manufacturing facilities. Milk may now be filtered at or near the raw milk source and the filtered milk shipped to other facilities for further processing at lower refrigeration and hauling costs. In addition, the lower hauling costs for filtered milk have enabled cheesemakers to source milk from more distant regions, enabling them to meet milk demands for cheese manufacturing more effectively, particularly when there are disruptions in regional fluid milk supplies from serious drought or other adverse conditions, as occurred during 1999. Smaller cheese manufacturers—who are disproportionately affected by seasonal milk supply imbalances—can benefit from similar economies of scale through cooperative arrangements or contracts with third party suppliers of filtration services and filtered milk, including dairy farmers using filtration to concentrate raw milk at the farm. Centralizing milk filtering operations, like centralizing cheese aging and shredding operations, allows manufacturers to realize processing efficiencies through lower hauling, capital equipment, and labor costs. These efficiencies create cost savings that can ultimately be passed on to consumers.

3. The NCI/GMA/NFPA Proposal Is Consistent with Established FDA Policy

The amendments proposed by NCI, GMA, and NFPA to formally recognize that filtered milk and nonfat milk are acceptable forms of milk and nonfat milk respectively for use in standardized cheese are entirely consistent with existing FDA policy. Most FDA standards of identity for natural cheeses contain alternate make procedure provisions which state that the cheese may be manufactured according to a specified traditional procedure or "by any other procedure which produces a finished cheese having the same physical and chemical properties." See 21 C.F.R. Part 133. See also Attachment B. The alternate make procedure provisions historically have provided the legal basis for the use of milk filtration and the resulting filtered milk in cheesemaking. Nothing in the alternate make procedure provisions requires that all cheesemaking procedures be accomplished in a single manufacturing facility or by a single firm. Mechanical filtration of fluid milk is merely an interim step in the manufacture of cheese, regardless of whether such processing occurs in the same plant as other cheesemaking procedures or in a centralized filtration facility.

FDA has acknowledged that the use of mechanically filtered milk to manufacture Cheddar cheese is covered by the alternate make procedure provision of the Cheddar cheese standard, including when filtration occurs in a separate centralized facility. In a letter to a third party supplier of filtered milk, FDA stated:

"Cheddar cheese is one of the standardized cheeses for which 'alternate make procedures' have been provided Under alternate make procedures, Cheddar cheese may be prepared by any procedure which produces a finished cheese having the same physical and chemical properties as the cheese prepared by the traditional cheesemaking process [I]t is our understanding that the Cheddar cheese produced from the retentate that results when milk is subjected to processing in an ultrafiltration system is

nutritionally equivalent to and is physically and chemically identical to the Cheddar cheese prepared by the procedures set forth in the standard Based on this understanding, we would not object at this time to the use of this retentate in the manufacture of Cheddar cheese"

Letter from Dr. Margaret E. Cole, FDA Office of Food Labeling, to Mr. Ted Jacoby (October 21, 1996) (Attachment E). FDA's letter specifically recognized that, while "retentate is produced solely in-house by other companies as a step in the manufacture of various cheeses," the sale of retentate by one manufacturer to another for use in the manufacture of cheese "conforms with the requirements of the alternate make procedure."

The rationale stated in the FDA letter is consistent with the industry's longstanding position and supports the use of mechanical filtration in the manufacture of all standardized cheeses produced using an alternate make procedure. To amend section 133.3 of the FDA cheese standards as the petitioners propose would effectively codify this policy and extend it to those cheeses that, for historical reasons, are subject to standards that lack alternate make procedure provisions. Formally recognizing that filtered milk products qualify as "milk" and "nonfat milk" for cheesemaking also is consistent with the policy underlying the earlier amendments to section 133.3 which recognized that "milk" and "nonfat milk" encompass forms of milk that function as alternatives to fluid milk in cheese manufacturing.

These amendments to section 133.3 authorized the use of alternate forms of milk as substitutes for fluid milk in cheesemaking because these forms of milk may be used in place of fluid milk to produce a finished cheese that is equivalent physically and chemically to the traditional cheese made using fluid milk. The proposal specifically recognized the consistency

of these amendments with the policy underlying the alternate make procedure provisions. The preamble to the 1978 proposed amendments states:

"The existing cheese standards specify that the basic ingredient for cheese manufacture is fluid cow's milk which may have the fat of [sic] solids-not-fat levels adjusted by removing milkfat or adding cream, nonfat milk, concentrated skim milk or nonfat dry milk. The Commissioner believes that, technologically, alternate forms of milk, nonfat milk, and cream, i.e., concentrated, dried, and reconstituted forms, can be used to produce the same cheese as produced from fluid cow's milk. Further, he is of the opinion that provision for alternate forms of these milk products would be consistent with the provision in the existing standards for alternate manufacturing procedures that do not adversely affect the physical and chemical properties of the cheese. . . . While cheese must contain forms of milk, nonfat milk or cream, the manufacturer has the option of choosing, within specific classes of milk products, those forms he prefers to use."

43 Fed. Reg. 42127, 42128 (1978); see also 21 C.F.R. § 133.3(a). The amendments the petitioners propose to section 133.3 with respect to filtered milk are fully consistent with the basis and rationale for these earlier amendments expanding the scope of forms of milk recognized as "milk" for cheesemaking.

The flexible approach FDA has taken to allow alternate forms of milk to be treated interchangeably under section 133.3 where they can be used in accordance with the applicable standard to yield an equivalent finished cheese is consistent with the broader policy to recognize the comparable functionality of dairy ingredients, including those made by mechanical filtration, in dairy foods. FDA's standards of identity for dairy products permit manufacturers to use modified whey products, including mechanically-filtered whey in the form of whey protein concentrate, instead of milk, so long as such use does not materially affect the total nonfat milk

cream and frozen custard); 21 C.F.R. § 131.200(d) (yogurt). Whey protein concentrate is made by physically separating the minerals, lactose, and water from whey through filtration. See 21 C.F.R. § 1979c. This is essentially the same process used to make filtered milk.

FDA's food labeling regulations also acknowledge the interchangeability of dairy ingredients. FDA's general food labeling regulations specify that the generic term "milk" may be used in ingredient labeling rather than the more specific terms, "concentrated milk," "reconstituted milk," and "dry whole milk." See 21 C.F.R. § 101.4(b)(4). Moreover, in amending the cheese standards to permit alternate milk ingredients, FDA stood by its generic labeling policy, rejecting comments suggesting that the alternate milk forms be listed by specific name. FDA justified its approach emphasizing that "differences in the form of the dairy ingredients used . . . have no perceptible effect on the final [cheese] product." See 48 Fed. Reg. 2736, 2738 (1983).

4. Cheese Made With Filtered Milk Is Nutritionally Equivalent To Traditional Cheese

Cheese made using filtered milk is nutritionally equivalent to cheese made using other forms of "milk" or "nonfat milk" already recognized in section 133.3. FDA regulations specify that a food is "nutritionally inferior" to the reference food when there is "any reduction in the content of an essential nutrient that is present in a measurable amount" compared with the reference food. See 21 C.F.R. § 101.3(e)(4)(i). A "measurable" reduction is defined as two percent or more of the Daily Value of the essential nutrient for the finished product. See 21 C.F.R. § 101.3(e)(4)(ii). See also 61 Fed. Reg. 58991, 58997 (1996) ("foods having significantly less essential nutrients" are nutritionally inferior). Mechanical filtration of milk using membranes with pore sizes between .0001 and .20 microns removes the water phase constituents,

which otherwise would be removed in the traditional cheesemaking process as whey. Milk consists of a solid phase (fat and colloidal protein) and a water phase (water, soluble protein, lactose, minerals, and some water soluble vitamins). In traditional cheesemaking, the fat and the colloidal protein coagulate, resulting in almost 100 percent retention of these components in the cheese and significant loss of the water phase constituents in the form of whey. By filtering milk with membranes, cheese manufacturers can remove the constituents of the water phase in the same proportion as these constituents would otherwise be removed in whey. As a result, the cheese produced using filtered milk is nutritionally equivalent to cheese made using other forms of milk.

Notably, under FDA regulations, nutritional variations that involve an increase in essential nutrients relative to the reference food do not render the modified food nutritionally inferior. Such increases are acceptable provided they are disclosed in nutrition labeling. See 21 C.F.R. § 101.9(c), (g). With respect to filtered milk in cheese, the retentate may actually contain slightly greater concentrations of valuable constituents (e.g., whey proteins) than the cheese curd that remains after syneresis in traditional cheesemaking. Under existing FDA policy, cheese made with filtered milk is not "nutritionally inferior" to cheese made using traditional procedures, and any material increases in nutritional value in the finished cheese (e.g., protein content) would be reflected in nutritional labeling.

Indeed, cheeses made using even relatively large quantities of filtered milk exhibit the same natural variations in moisture, protein, fat, and ash content as cheeses made using traditional procedures. Two large cheese manufacturers have undertaken extensive research comparing the concentrations of protein, total fat, and key vitamins and minerals in Cheddar

cheese made using filtered milk with those in Cheddar cheese made using traditional procedures. Data from these studies indicate that Cheddar cheese made from filtered milk contains protein, fat, and key vitamins and minerals in concentrations that lie squarely within the range exhibited naturally in Cheddar cheese made using traditional procedures. Similarly, data published in 1981 from 14 experiments demonstrate that the mean concentrations of key constituents (fat, calcium, phosphorus, and protein) in hard cheeses made from filtered milk also were within the range permitted by USDA standards. See Attachment F.

The data supporting the nutritional equivalence of Cheddar cheese made with filtered milk with traditional versions is extensive, and represents a category of cheese for which any potential opportunity for filtered milk to affect nutritional quality would be greatest. First, filtered milk is used in Cheddar cheese under alternate make procedures, which means the cheese can be formulated with a significant proportion of filtered milk, and an amount substantial enough to display nutritional inferiority, if that would result from the use of filtered milk. Second, the Cheddar cheese standard specifies that the finished cheese must have a moisture content that is relatively low compared to other varieties. See 21 C.F.R. § 133.113(a)(1). This means that Cheddar cheese can readily be made with significant amounts of the more concentrated forms of filtered milk (e.g., 6x), in which nutrient losses in the water phase would be greatest because of the greater proportion of the water phase constituents removed through filtration. The data demonstrating the nutritional equivalence of Cheddar cheese made from filtered milk with traditional Cheddar cheese lend strong support for the nutritional equivalence of cheeses made from filtered milk generally.

Moreover, the nutritional equivalence of standardized cheese made with filtered milk to traditional cheese is assured by the limitations imposed on the use of filtered milk by the make procedures and ingredients already specified in the cheese standards. First, for cheeses for which alternate make procedures are not permitted, the rigid parameters of the traditional make procedures themselves, coupled with the moisture and solids requirements and other specifications, sharply limit the amount of filtered milk that could be used under the proposed amendments and assures that the use of filtered milk would have no material effect on the nutrient levels of the finished cheese.

Second, for those cheese varieties subject to standards which include alternate make procedure provisions and in which filtered milk can be used in more significant amounts, the alternate make procedure provisions themselves provide that cheese made using an alternate procedure must be physically and chemically equivalent to cheese made using the traditional procedure. See, e.g., 21 C.F.R. § 133.113(a) (stating that cheese may be manufactured under the traditional make procedure or "any other procedure which produces a finished cheese having the same physical and chemical properties."). Under existing FDA policy, the requirement that a cheese have the same "chemical properties" encompasses those chemical entities with nutritional value, and thus requires nutritional equivalence. See, e.g., supra page 11 (excerpt of letter from Dr. Margaret Cole, FDA Office of Food Labeling). The proposed amendments would make no change in this nutritional equivalence requirement. Under the proposed amendments, filtered milk in any form could only be used to the extent the finished cheese is nutritionally equivalent to cheese made under the traditional procedure.

5. The NCI/GMA/NFPA Proposal Is
Consistent With The Codex Standard For
Cheese

Consistent with section 410(c) of the FDA Modernization Act of 1997 (codified at 21 U.S.C. § 383(c)) and FDA's international harmonization policy (60 Fed. Reg. 53078 (1995)), it has been an FDA priority to promote international harmonization of regulatory requirements, including through FDA participation in the activities of the Codex Alimentarius Commission relating to food standards. The Codex standard of identity for cheese, Standard A-6-1978 (revised in January 1999), provides:

"Cheese is the ripened or unripened soft or semi-hard, hard and extra hard product, which may be coated, and in which the whey protein-casein ratio does not exceed that of milk, obtained by:

- (a) coagulating wholly or partly the following raw materials: milk and/or products obtained from milk, through the action of rennet or other suitable coagulating agents, and by partially draining the whey resulting from such coagulation; and/or
- (b) processing techniques involving coagulation of milk and/or products obtained from milk which give an end-product with similar physical, chemical and organoleptic characteristics as the product defined under (a)."

The Codex standard also provides that cheese must contain "milk and/or products obtained from milk." Under Codex Standard 206-1999, a "milk product" is "a product obtained by any processing of milk . . ." (emphasis added). The Codex standard encompasses mechanical filtration technology, provided the finished cheese meets applicable requirements for physical and chemical properties, which would include nutritional and organoleptic properties. The petitioners' proposal thus is consistent with FDA efforts aimed at international harmonization of cheese standards.

6. The Proposal Would Advance President Clinton's
"Reinventing Government" Initiative

On March 4, 1995, as part of the Administration's "Reinventing Government" initiative, President Clinton issued a memorandum directing agencies to take four steps designed to improve the federal regulatory system. See Memorandum on Regulatory Reform, 31 WEEKLY COMP. PRES. DOC. 363 (March 6, 1995). The President noted that, while all Americans want the benefits of effective regulation, too often federal regulations are drafted with unnecessary restrictions that undermine the objectives they seek to achieve. In response to the initiative, FDA identified food standards as prime candidates for reform because of their "potential to limit technological advances," and endorsed the notion that food manufacturers should have greater flexibility to adopt new technologies so long as the character of the finished standardized food remains the same:

"[T]he agency recognizes that food standards may serve as an impediment to the food industry to the degree to which they fail to reflect advances in food science and technology. New ingredients and plant varieties that allow manufacturers to enhance a food's organoleptic or functional properties, alter its nutritional profile, or extend its shelf life, are being developed and used in nonstandardized food products. Incorporation of these advances into standardized foods may be difficult or impossible without laborious amendment of the relevant standard. FDA believes that manufacturers of standardized foods should have the ability to make use of advances in food technology, provided the basic nature of the food remains essentially the same."

See 60 Fed. Reg. 67492, 67499 (1995).

In recent years, FDA has made a number of amendments to food standards to give manufacturers greater flexibility to take advantage of new technologies and expand ingredient options. See, e.g., 21 C.F.R. § 130.10 (establishing a "generic" standard of identity for

nutritionally modified foods and authorizing expanded processing methods and ingredients); 59 Fed. Reg. 47072, 47077 (1994) (amending ice cream standard to permit lactose reduction by new technologies); 57 Fed. Reg. 23989 (1992) (amending standards of identity for chocolate products to permit use of any "safe and suitable" optional ingredient in a functional category).

The amendments proposed by NCI, GMA, and NFPA are consistent with the standards reform objectives articulated by FDA under the "Reinventing Government" initiative. The proposed amendments would facilitate the continued adoption of milk filtration technology in cheese manufacturing, enabling manufacturers to produce standardized cheese that is equivalent physically, chemically, and nutritionally to cheese made with the milk ingredients already listed in section 133.3, while gaining economic benefits of filtration technology.

D. Environmental Impact

An environmental assessment is not required for a petition to amend a food standard. See 21 C.F.R. § 25.32(a).

E. Certification

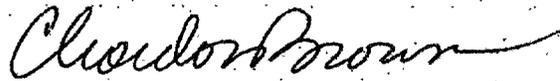
The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

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June 9, 2000
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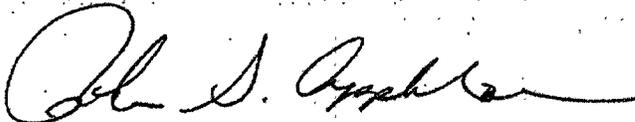
F. Conclusion

For the foregoing reasons, we request that the agency adopt the amendments to section 133.3 proposed by NCI, GMA, and NFPA.

Respectfully submitted,



Gordon Brown, Ph.D.
Senior Vice President of Scientific and Regulatory Affairs
NATIONAL CHEESE INSTITUTE



Rhona S. Applebaum, Ph.D.
Executive Vice President, Scientific and Regulatory Affairs
NATIONAL FOOD PROCESSORS ASSOCIATION
1350 I Street, NW
Washington DC 20005
(202) 639-5958



Stacey A. Zewel, Ph.D.
Vice President, Scientific and Regulatory Policy
GROCERY MANUFACTURERS OF AMERICA, INC.
1010 Wisconsin Avenue, NW
Washington DC 20007
(202) 295-3943

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08/25/2005

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3.		
4.		
5.		

<input checked="" type="checkbox"/> Action	<input type="checkbox"/> File	<input type="checkbox"/> Note and Return
<input type="checkbox"/> Approval	<input type="checkbox"/> For Clearance	<input type="checkbox"/> Per Conversation
<input type="checkbox"/> As Requested	<input type="checkbox"/> For Correction	<input type="checkbox"/> Prepare Reply
<input type="checkbox"/> Circulate	<input type="checkbox"/> For Your Information	<input type="checkbox"/> See Me
<input type="checkbox"/> Comment	<input type="checkbox"/> Investigate	<input type="checkbox"/> Signature
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REMARKS

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MICHAEL M. LANDA DEPUTY DIRECTOR FOR REGULATORY AFFAIRS, HFS-1	Phone No. (301) 436-1600

5041-102

OPTIONAL FORM 41 (Rev. 7-78)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

Dear Mr. Bass,

We are adding the letter to the docket, as a comment on the citizen petitions.

Michael M. Landa August 24, 2005

Michael M. Landa
Deputy Director, Regulatory Affairs
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Voice: 301.436.1600
Fax: 301.436.2668

-----Original Message-----

From: Bass, I. Scott [mailto:sbass@Sidley.com]
Sent: Friday, August 19, 2005 10:59 AM
To: 'mlanda@cfsan.fda.gov'
Subject:

Dear Mr. Landa,

Confirming your voicemail message, we are requesting on behalf of Daisy Brand that you treat the letter to Dr. Brackett as an addition to the pending citizen petitions. Kindly confirm that this is acceptable to FDA. Thank you for your response.

Scott Bass