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. Controvery 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 Filed12–8–04; 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–S

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 Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 04–26994 Filed 12–8–04; 8:45 am]

BILLING CODE 4160–01–S

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