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