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

submissions may be made to the contact person by January 6, 2005. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 9:30 a.m. on January 14, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 6, 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 LaNise Giles 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. 04–26995 Filed 12–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0327]

Draft Compliance Guidance for Small Business Entities on Labeling Over-the-Counter Human Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft compliance guidance for small business entities entitled ''Labeling OTC Human Drug Products; Small Entity Compliance Guide.'' FDA has prepared this guidance in accordance with the Small Business Regulatory Enforcement Fairness Act. It is intended to help small businesses better understand the new over-the-counter (OTC) labeling requirements and to prepare new labeling within the prescribed implementation compliance dates.

DATES: Submit written or electronic comments on the draft compliance guidance by February 7, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft compliance guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft compliance guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft compliance guidance document.

FOR FURTHER INFORMATION CONTACT: Cazemiro R. Martin or Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft compliance guidance for small business entities entitled ''Labeling OTC Human Drug Products; Small Entity Compliance Guide.'' FDA has prepared this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act. This is one of several guidances the agency is developing to help manufacturers, packers, and distributors implement the final rule establishing standardized content and format requirements for the labeling of all OTC drug products. Once finalized, these guidances will supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final rule.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized content and format regulations for the labeling of OTC drug products. This regulation is intended to standardize labeling for all OTC drug products so consumers can easily read and understand OTC drug product labeling and use these products safely and effectively.

The regulation for this new standardized labeling requires manufacturers to present OTC drug labeling information in a prescribed order and format. The new format will require revision of all existing labeling and covers all OTC drug and drug-cosmetic products, whether marketed under a new drug marketing application (NDA), abbreviated new drug application (ANDA), or OTC drug monograph (or product not yet the subject of a final OTC drug monograph). To reduce the economic impact on small business entities, the new regulations provide an additional 1-year period to comply with § 201.66 (21 CFR 201.66) for OTC drug products with sales of less than $25,000 per year. You can find a copy of § 201.66 at the Division of Dockets Management Web site at *http://www.fda.gov/cder/otc/label/label-fr-reg.htm*.

Following issuance of the final rule, the agency received a number of inquires from manufacturers seeking guidance on how to present the labeling information for their OTC drug products using the new standardized content and format requirements. This draft guidance summarizes the new Drug Facts labeling requirements as set forth in § 201.66. The draft guidance also describes how to list those inactive ingredients that are different when a finished OTC drug product is obtained from multiple suppliers.

This draft guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). The draft compliance guidance, when finalized, will represent the agency's current thinking on how OTC drug monograph labeling finalized prior to or after the new requirements can be converted to the new OTC ''Drug Facts'' format labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

I. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft compliance guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft compliance guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.