100 mg/mL in 5 mL vials to Canada. The firm does have an approved new drug application for this product, but has requested a change in the manufacturing site. Haldol® (haloperidol) Decanoate is intended for use in the management of patients requiring prolonged parenteral antipsychotic therapy. The application was received and filed in the Center for Drug Evaluation and Research on May 13, 1994, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by July 5, 1994, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: June 15, 1994.

David B. Barr,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 94–15436 Filed 6–23–94; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

MEETINGS: The following advisory committee meetings are announced:

National Mammography Quality Assurance Advisory Committee

Date, time, and place. July 12, 1994, 1:30 p.m., and July 13, 14, and 15, 1994, 9 a.m., Gaithersburg Holiday Inn, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Holiday Inn. Attendees requiring overnight accommodations must contact the hotel at 301–948–8900 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open public hearing, July 12, 1994, 1:30 p.m. to 2:30 p.m., unless public participation does not last that long; open committee discussion, 2:30 p.m. to 5:30 p.m.; open committee discussion, July 13 and 14, 1994, 9 a.m. to 5 p.m.; open committee discussion, July 15, 1994, 9 a.m. to 3:30 p.m.; Charles K. Showalter, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1901 Chapman Ave., Rockville, MD 20857, 301–594–3311.

General function of the committee. The committee advises on developing appropriate quality standards and regulations for the use of mammography facilities.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before July 8, 1994, 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 required to make their comments.

Open committee discussion. The committee will discuss the interim final standards for accreditation bodies and the interim final standards for facilities. Specific topics to be discussed include: Sanctions, suspensions, revocations and injunction procedures, quality control and quality assurance standards, x-ray equipment standards, and accreditation bodies standards.

National Task Force on AIDS Drug Development

Date, time, and place. July 18 and 19, 1994, 8:30 a.m., Sheraton National Hotel, South Ballroom, 900 South Orme St., Arlington, VA.

Type of meeting and contact person. Open task force discussion, July 18, 1994, 8:30 a.m. to 4:30 p.m.; open public hearing, 4:30 p.m. to 5:30 p.m., unless public participation does not last that long; open task force discussion, July 19, 1994, 8:30 a.m. to 11:30 a.m.; Jean H. McKay, Office of AIDS and Special Health Issues (HF–12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–0104.

General function of the task force. The National Task Force on AIDS Drug Development shall identify any barriers and provide creative options for the rapid development and evaluation of treatments for human immunodeficiency virus (HIV) infection and its sequelae. It also advises on issues related to such barriers and provides options for the elimination of these barriers.

Open task force discussion. The task force will present, hear, and discuss issues on the barriers to acquired immune deficiency syndrome (AIDS) drug discovery from the perspective of task force members, members of the Federal Government, and the public. The task force will determine how to proceed with overcoming the barriers to AIDS drug discovery.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the task force. Those desiring to make formal presentations should notify the contact person before July 8, 1994, 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 required to make their comments.

Nonprescription Drugs Advisory Committee

Date, time, and place. July 27, 1994, 2 p.m., Parklawn Bldg., conference rms. D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 2 p.m. to 3 p.m., unless public participation does not last that long; open committee discussion, 3 p.m. to 6 p.m.; Maé Brooks or Lee L. Zwanziger, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the

contact person before July 20, 1994, 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 required to make their comments.

Open committee discussion. The committee will discuss the new drug application (NDA) 19–501, The Upjohn Co., to switch Rogaine® (minoxidil 2% topical solution) for use as a hair growth stimulant for persons with androgenetic alopecia, from prescription to over-the-counter marketing status.

Antiviral Drugs Advisory Committee

Date, time, and place. July 29, 1994, 8 a.m., Parklawn Bldg., conference rms. G, H, I, and J, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open committee discussion, 8 a.m. to 11 a.m.; open public hearing, 11 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 4 p.m.; Lee L. Zwanziger or Valerie Mealy, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of AIDS, AIDS-related complex (ARC), and other viral, fungal, and mycobacterial infections.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify a contact person before July 20, 1994, 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 required to make their comments.

Open committee discussion. The committee will discuss data submitted in support of supplementary new drug applications (NDA's) 19–655 (supplement 023), 19–910 (supplement 011), and 19–951 (supplement 003) for zidovudine (Retrovir®, Burroughs Welcome) for use as prophylaxis against maternal to fetal transmission of HIV infection.

Joint Meeting of the Gastrointestinal Drugs and the Nonprescription Drugs Advisory Committees

Date, time, and place. July 29, 1994, 9 a.m., Parklawn Bldg., conference rms. D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 3 p.m.; Joan C. Standaert, Center for Drug Evaluation and Research (HFD–180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419–259–6211, or Lee Zwanziger or Valerie M. Mealy, 301–443–4695.

General function of the committees. The Gastrointestinal Drugs Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in gastrointestinal diseases. The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Those desiring to make formal presentations should notify the contact person before July 15, 1994, 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 required to make their comments.

Open committees discussion. The committees will discuss NDA 20–325, Pepcid (famotidine), Merck and Co., for treatment and prevention of episodic heartburn.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing; (2) an open committee discussion; (3) a closed presentation of data; and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.