any interested person may petition FDA, on or before July 7, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 25, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 97–138 Filed 1–3–97; 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.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Joint Meeting of the Nonprescription Drugs and Anti-Infective Drugs Advisory Committees

Date, time, and place. January 22, 1997, 8:30 a.m., Holiday Inn—Gaithersburg, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Ermona B. McGoodwin or Danyiel A. D'Antonio, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Nonprescription Drugs Advisory Committee, code 12541, or Anti-Infective Drugs Advisory Committee, code 12530. Please call the hotline for information concerning any possible changes.

General function of the committee. 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. The Anti-Infective Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

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 January 13, 1997, 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 joint committees will discuss issues relating to a health-care continuum model. In the Federal Register of June 17, 1994 (59 FR 31402 through 31452) the agency published a proposed rule for OTC health-care antiseptic drug products, i.e., patient preoperative skin preparations, surgical hand scrubs, and health-care personnel and antiseptic handwashes. In response to the proposed rule, the agency received a number of requests to consider a health-care continuum as a model for the regulation of OTC health-care antiseptic drug products. The proposed model defines six drug product categories (preoperative skin preparation, surgical hand scrub, health-care personnel handwash, food handler handwash, antimicrobial handwash, and antimicrobial body wash) and proposes testing requirements, key characteristics, and labeling for each of the categories. The model also proposes that the public health impact of these products is the lowest for consumer use products and continuously increases through the model as follows: Antimicrobial hand washes, antimicrobial body washes, food handler handwash, health-care personnel handwash, surgical hand scrub, and preoperative skin preparation. Conversely, the model proposes that the size of the population impacted by these products continuously decreases from consumer use products to professional use products. FDA is seeking an evaluation of the model's impact on public health in light of the isolation of pathogenic bacteria-bearing plasmids encoding for both topical antiseptic and multiple antibiotic resistance and is soliciting the advice and opinions from the advisory committees on this issue. The agency encourages investigators, academicians, and manufacturers of these products to respond to this notice with information bearing on this issue and to present their views on this issue before the committees.

A Joint Meeting of the Nonprescription Drugs Advisory Committee and the Cardiovascular and Renal Drugs Advisory Committee

Date, time, and place. January 23, 1997, 8:30 a.m., Holiday Inn—Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Tracy K. Riley or Joan C. Standaert, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Nonprescription Drugs Advisory Committee, code 12541, or Cardiovascular and Renal Drugs Advisory Committee, code 12533. Please call the hotline for information concerning any possible changes.

General function of the committee. 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. The Cardiovascular and Renal Drugs Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for used in cardiovascular and renal disorders.

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 January 8, 1997, 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 committees will jointly discuss issues relevant to professional labeling indications for aspirin. A citizen petition requested that the Commissioner of Food and Drugs approve various vascular professional labeling indications for aspirin. FDA has already acted on some of the issues raised, while others have not been resolved. FDA is now soliciting advice and opinions from the advisory committees regarding the use of aspirin for expanded professional labeling indications for aspirin. Issues to be discussed include the use of aspirin in patients deemed to be at elevated risk of cardiovascular events due to some form of vascular disease or other conditions implying an increased risk of occlusive vascular disease (i.e., patients undergoing coronary, cerebral, or peripheral arterial revascularization procedures; patients with chronic nonvalvular atrial fibrillation; patients requiring hemodialysis access with a fistula or shunt; patients with chronic stable angina; and other patients deemed to be at elevated risk). The agency encourages investigators, academicians, and members of the pharmaceutical industry with information about the use of aspirin in patients at increased risk of cardiovascular events to respond to this notice.

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 the meeting(s) 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, 12420 Parklawn Dr., rm. 1–23, 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.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: December 20, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–92 Filed 1–3–97; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

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MEETING: The following advisory committee meeting is announced: