of over-the-counter antiplaque-antigingivitis drug products. On May 29, 1998, the subcommittee will discuss recommended therapeutic combinations for antiplaque-antigingivitis drug products.

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 May 20, 1998. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 12 m. on May 27, 28, and 29, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 20, 1998, 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.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 24, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–11742 Filed 5–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0191]

Testing for Skin Sensitization to Chemicals in Latex Products; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Testing for Skin Sensitization to Chemicals in Latex Products.'' This draft guidance is intended to provide alternative claims for medical devices containing natural rubber latex to the ''hypoallergenic'' claim that no longer will be acceptable after September 30, 1998. The draft guidance, which is not in effect at this time, is being issued for comment. This draft guidance was reviewed by the General Hospital and Personal Use Devices Panel in September 1997, and it will be posted on the Internet.

DATES: Written comments concerning this guidance must be received by August 3, 1998.

ADDRESSES: Written comments concerning the draft guidance must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for singles copies of the draft guidance to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION:

I. Background

This is the second draft of the guidance entitled ''Testing for Skin Sensitization to Chemicals in Latex Products,'' and it replaces the July 28, 1997, version that was posted on the Internet and distributed by DSMA to manufacturers of medical devices made of natural rubber to consumer groups and other agencies of the Federal Government for comment. This draft guidance was also discussed during the General Hospital and Personal Use Devices Advisory Panel meeting on September 15, 1997. This second draft incorporates comments received from the General Hospital and Personal Use Devices Advisory Panel meeting, consumer groups, and medical device manufacturers. This draft guidance is intended to provide alternative claims for medical devices containing natural rubber latex to replace the ''hypoallergenic'' claim. The ''hypoallergenic'' claim will no longer be acceptable after September 30, 1998, which is the effective date of the final rule on medical devices containing natural-rubber that published in the **Federal Register** of September 30, 1997 (62 FR 51021). This draft guidance also includes test methods for supporting these claims. When this draft guidance becomes final, the manufacturers of latex containing medical devices may use it to address label options and what tests FDA regards as appropriate to support statements that replace the current ''hypoallergenic'' statement.

II. Significance of Guidance

The draft guidance represents the agency's recommended tests to support label claims for reduced chemical sensitivity during use of latex products and label options. 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 applicable statute, regulations, or both. The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is being issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance entitled ''Testing for Skin Sensitization to Chemicals in Latex Products'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (944) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes ''Testing for Skin Sensitization to Chemicals in Latex Products,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The draft guidance entitled ''Testing for Skin Sensitization to Chemicals in Latex Products'' will be available at http://www.fda.gov/cdrh/ode/ed—rp.html.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 1–800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press

Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

IV. Comments

Interested persons may, on or before August 3, 1998, submit to the Dockets Management Branch written comments regarding this guidance document. Two copies of any 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 guidance document and received comments may be in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 14, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–11683 Filed 5–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

John E. Fogarty International Center for Advanced Study in the Health Sciences; Notice of Meeting of the Fogarty International Center Advisory Board

Pursuant to Public Law 92–463, as amended, notice is hereby given of the thirty-eighth meeting of the Fogarty International Center (FIC) Advisory Board, May 19, 1998, in the Lawton Chiles International House (Building 16) at the National Institutes of Health. The Research Awards Subcommittee will meet on May 18 in the FIC Conference Room, Building 31, Room B2C07, from 1:00 p.m. to approximately 4:00 p.m., and will be closed to the public.

The meeting of the Board will be open to the public from 8:30 a.m. to approximately 12:00 noon.

In addition to a report by the Director, FIC, the agenda will include presentations on FIC Evolution and Long-Range Planning; the Status of FIC International Training and Research Programs; ICD-Wide Initiatives in Support of International Relations; and FIC International Policy Support to NIH and other Government Agencies.

In accordance with the provisions of sections 552b(c)(4) and 552b(c)(6), Title 5, United States Code and section 10(d) of Public Law 92–463, as amended, the entire meeting of the Research Awards Subcommittee on May 18 will be closed to the public from 1:00 p.m. to approximately 4:00 p.m., and the Board meeting on May 19 will be closed to the public from 1:00 p.m. to adjournment for the review of applications for awards under the Senior International Fellowship and International Fellowship Programs; and the Fogarty International Research Collaboration Awards and HIV, AIDS and Related Illnesses Collaboration Awards.

Paula Cohen, Committee Management Officer, Fogarty International Center, National Institutes of Health, Building 31, Room B2C08, 31 CENTER DR MSC 2220, Bethesda, Maryland 20892–2220, telephone: 301–496–1491, will provide a summary of the meeting and a roster of the committee members upon request.

Irene Edwards, Executive Secretary, Fogarty International Center Advisory Board, Building 31, Room B2C08, telephone: 301–496–1491, will provide substantive program information.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Cohen at least 2 weeks in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.989, Senior International Fellowship Awards Programs; and 93.934, Fogarty International Research Collaboration Award)

Dated: April 24, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–11676 Filed 5–1–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting of the National Cancer Advisory Board and Its Subcommittees

Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given of the meeting of the National Cancer Advisory Board (Board), National Cancer Institute (NCI), and its Subcommittees on May 11–13, 1998. The meeting of the Board and its Subcommittees will be open to the public as indicated below. Attendance by the public will be limited to space available.

A portion of the Board meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552(c)(4) and 552(c)(6), Title 5 U.S.C. and section 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications and for discussion of issues pertaining to programmatic areas and/or NCI personnel. These applications and discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning the individuals associated with the applications or programs, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The Committee Management Office, National Cancer Institute, National Institutes of Health, Executive Plaza North, Room 609, 6130 Executive Boulevard, MSC 7410, Bethesda, Maryland 20892–7410, (310) 496–5708 will provide summaries of the meetings and rosters of the Board members, upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Mrs. Linda Quick-Cameron, Committee Management Officer, at (301) 496–5708 in advance of the meetings.

Name of Committee(s): Subcommittee on Activities and Agenda, Subcommittee on Cancer Centers, Subcommittee on Clinical Investigations, Subcommittee on Planning and Budget.

Date: May 11, 1998.

Time: 7:00 p.m.—Adjournment.

Place: Hyatt Regency Bethesda, One Bethesda Metro, Bethesda, Maryland 20814.

Agenda(s): See NCI Homepage/Advisory Board and Groups,

http://deainfo.nci.nih.gov/ADVISORY/boards.htm

Tentative agenda available 10 working days prior to meetings;

Final agenda available 5 working days prior to meetings.

Contact Person: Dr. Marvin R. Kalt, Executive Secretary, National Cancer Institute, NIH, Executive Plaza North, Room 600, 6130 Executive Blvd., MSC 7405, Bethesda, MD 20892–7405, (301) 496–5147.

Name of Committee: National Cancer Advisory Board.

Dates: May 12–13, 1998.

Place: Building 31C, Conference Room 10, National Institutes of Health, 3100 Center Drive, Bethesda, MD. 20892.

Open: May 12—9:00 a.m. to 4:00 p.m.; May 13—9:00 a.m. to 12:20 p.m.

Agenda: Program reports and presentations; business of the Board. For a