

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Current Good Manufacturing Practices for Blood and Blood Components: Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Margaret R. Wolff, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of December 27, 1996 (61 FR 68268), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). OMB has now approved the information collection and has assigned OMB control number 0910-0336. The approval expires on February 28, 2000. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Dated: March 19, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97-7726 Filed 3-26-97; 8:45 am]

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### 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:

#### Nonprescription Drugs Advisory Committee

*Date, time, and place.* April 15, 1997, 8 a.m.; Holiday Inn—Gaithersburg, Goshen Room, Two Montgomery Village Ave., Gaithersburg, MD.

*Type of meeting and contact person.* Open committee discussion, 8 a.m. to 1:30 p.m.; open public hearing 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 p.m.; closed committee deliberations, 5 p.m. to 6 p.m.; Andrea G. Neal, 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. Please call the hotline for information concerning any possible changes.

*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 April 1, 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 committee will discuss a possible association between vaginal douching and adverse consequences. FDA is aware of a number of case-control epidemiologic studies in the literature that suggest a possible association between vaginal douching and several conditions, such as pelvic inflammatory disease, ectopic pregnancy, and cervical

cancer (letter from D. Bowen, FDA, to R. W. Soller, Nonprescription Drug Manufacturers Association, LET 105, Docket No. 75N-0183, Dockets Management Branch). The committee's discussion will include issues relating to behavioral, epidemiological, and microbiological aspects of vaginal douching. Regulatory issues related to over-the-counter vaginal-douche drugs, cosmetics, and devices (douching equipment) will also be addressed.

*Closed committee deliberations.* The committee will review trade secret and/or confidential commercial information relevant to pending investigational new drugs applications (IND's) or new drug applications (NDA's). This portion of the meeting will be closed to permit discussion of this information. (5 U.S.C. 552b (c)(4)).

#### Dermatologic and Ophthalmic Drugs Advisory Committee

*Date, time, and place.* April 17 and 18, 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, April 17, 1997, 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 5:30 p.m.; closed presentation of data, April 18, 1997, 8:30 a.m. to 11 a.m.; closed committee deliberations, 11 a.m. to 1 p.m.; Tracy Riley or Angie Whitacre, 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), Dermatologic and Ophthalmic Drugs Advisory Committee, code 12534. Please call the hotline for information concerning any possible changes.

*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 dermatologic and ophthalmic 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 April 11, 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.* On April 17, 1997, the committee will hear presentations and discuss the teratogenicity and labeling issues regarding approved NDA 19-821 for Soriatane (acitretin capsules, Hoffman-LaRoche, Inc.) for use in treating severe psoriasis.

*Closed presentation of data.* On April 18, 1997, the committee will hear trade secret and/or confidential commercial information relevant to pending IND's or NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

*Closed committee deliberations.* On April 18, 1997, the committee will review trade secret and/or confidential commercial information relevant to pending IND's and/or NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above 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. The dates and times reserved for the separate 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, 5600 Fishers Lane, rm. 12A-16, 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.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

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: March 21, 1997.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 97-7790 Filed 3-26-97; 8:45 am]

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## Health Resources and Services Administration

### Special Project Grants; Traumatic Brain Injury Demonstration Grants

**AGENCY:** Health Resources and Services Administration (HRSA).

**ACTION:** Notice of availability of funds.

**SUMMARY:** The HRSA announces that approximately \$2.8 million in fiscal year (FY) 1997 funds will be available for demonstration projects to improve access to health and other services for people who have sustained a traumatic brain injury (TBI). Discretionary grants