Food and Drug Administration

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:

Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. October 21, 1996, 8:30 a.m., Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel at 301–590–0044 or 800–228–9290 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Shirley Meeks, Conference Management, 301–594–1283, ext. 113. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Closed committee deliberations, 8:30 a.m. to 9:30 a.m.; open public hearing, 9:30 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 5 p.m.; Alfred W. Montgomery, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Obstetrics and Gynecology Devices Panel, code 12524. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

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 October 11, 1996, 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 and vote on a premarket approval application for a silicone barrier contraceptive device.

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial information regarding medical devices used in obstetrics and gynecology that are currently being evaluated by FDA. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Biological Response Modifiers Advisory Committee

Date, time, and place. October 21, 1996, 10 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I, II, and III, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, 10 a.m. to 10:40 a.m., unless public participation does not last that long; open committee discussion, 10:40 a.m. to 1:30 p.m.; closed committee deliberations, 1:30 p.m. to 2:30 p.m.; open committee discussion, 2:30 p.m. to 3 p.m.; closed committee deliberations, 3 p.m. to 5 p.m.; open public hearing, 5 p.m. to 5:30 p.m., unless public participation does not last that long; William Freas, Pearline K. Muckelvene, or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Biological Response Modifiers Advisory Committee, code 12388. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data relating to the safety, effectiveness, and appropriate use of biological response modifiers which are intended for use in the prevention and treatment of a broad spectrum of human 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 October 14, 1996, 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: (1) FDA oncology initiative; (2) standards for approval of therapies for non-Hodgkin's Lymphoma; and (3) intramural research program for the Laboratory of Cell Biology, Laboratory of Immunobiology, and the Laboratory of Cell and Viral Regulation in the Office of Therapeutics Research and Review of the Center for Biologics Evaluation and Research.

Closed committee deliberations. On October 21, 1996, the committee will discuss trade secret and/or confidential commercial information relevant to pending investigational new drug applications (IND's) in the Center for Biologics Evaluation and Research. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)). The committee will also discuss the intramural scientific program. This portion of the meeting will be closed to prevent disclosure of personal information concerning individuals associated with the research program, disclosure of which would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)).

Cardiovascular and Renal Drugs Advisory Committee

Date, time, and place. October 24, 1996, 9 a.m., Woodmont Building II, conference room F, 5th floor, 1451 Rockville Pike, 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; closed committee deliberations, 10 a.m. to 5:30 p.m.; Joan Standaert, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419–259–6211, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Cardiovascular and Renal Drugs Advisory Committee, code 12533. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use 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 October 10, 1996, 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.

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

Vaccines and Related Biological Products Advisory Committee

Date, time, and place. October 29 and 30, l996, 8 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Closed committee deliberations, October 29, l996, 8 a.m. to 8:30 a.m.; open committee discussion, 8:30 a.m. to 5 p.m.; open committee discussion, October 30, l996, 8 a.m. to 1:30 p.m.; closed committee deliberations, 1:30 p.m. to 2:30 p.m.; open public hearing, 2:30 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 5:15 p.m.; Nancy Cherry or Sandy Salins, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Vaccines and Related Biological Products Advisory Committee, code 12388. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human 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 October 22, 1996, 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 October 29, 1996, the committee will review safety and efficacy data pertaining to diphtheria/tetanus/acellular pertussis vaccines manufactured by Amvax, Inc., and Lederle Laboratories. On October 30, 1996, the committee will review the possibility of using animal challenge studies (and the design of such studies), in addition to human neutralizing antibody data, to support the efficacy of the botulinum toxoid vaccine. The committee will also hear a briefing on a research program in the Division of Viral Products and a briefing on a new Points to Consider document on Plasmid DNA Vaccines for Preventive Infectious Disease Indications.

Closed committee deliberations. On October 29, l996, the committee will review trade secret and/or confidential commercial information relevant to pending IND's or product licensing applications. These portions of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)). On October 30, l996, the committee will also review data of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(6)).

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 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, 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: September 19, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–24755 Filed 9–26–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4086–N–53]

Office of the Assistant Secretary for Public and Indian Housing; Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: November 26, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Mildred M. Hamman, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451-7th Street, SW., Room 4238, Washington, DC 20410–5000.

FOR FURTHER INFORMATION CONTACT: Mildred M. Hamman, (202) 708–0846, extension 4128, (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques of other forms of information technology.

This Notice also lists the following information:

Title of Proposal: Family Report and Family Self-Sufficiency Addendum.

OMB Control Numbers: 2577–0083 and 2577–0184.

Description of the need for the information and proposed use: Collection of this information is authorized by the U.S. Housing Act of 1937 (42 U.S.C. 1437, et seq.), Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d), the Fair Housing Act (42 U.S.C. 3601–19), and Section 214 of the Housing and Community Development Act of 1980. Public Housing Agencies (PHAs) and Indian Housing Authorities (IHAs) administering public, Indian Housing and the Section 8 Rental Certificate, Rental Voucher and Moderate Rehabilitation Programs must submit family information to assist HUD in managing and monitoring HUD-assisted programs. HUD will use the information to (1) monitor program participants' compliance with requirements, (2) provide demographic information describing tenants' characteristics, (3) participate in income matching to detect fraud, and (4) plan for future use of the housing inventory with emphasis on the housing needs of special groups. The Forms HUD–50058 and HUD–50058–FSS are being revised to reflect legislative changes and requirements. Initially, PHAs/IHAs will need ½ hour to input the data into each Form HUD–50058. After a three-year period, average input time should be reduced to 15 minutes per form. The reduction in time will be due to the pre-entering of key information on the form (i.e., income changes, change in family composition, etc.). PHAs/IHAs