(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: October 15, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–26915 Filed 10–16–96; 12:37 pm]

BILLING CODE 4160–01–F

[Docket No. 95S–0181]

Mutual Recognition Agreement (MRA); Public Meeting; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and availability of draft document.

SUMMARY: The Food and Drug Administration (FDA) (Office of External Affairs, Office of International Affairs; Office of Policy; Office of Operations, Office of Regulatory Affairs; and the Centers for Biologics Evaluation and Research, Drug Evaluation and Research, and Veterinary Medicine) is announcing a public meeting to provide information about discussions with the European Union (EU) related to a possible agreement to exchange inspectional information on good manufacturing practices and quality controls for human biologicals and human and animal drugs. At a meeting held on March 31, 1995, FDA committed to keeping the public informed about the progress of these negotiations and to receiving comments on FDA's proposal for an MRA. FDA is also announcing the availability of the document entitled ''FDA Proposal for an Agreement With the European Union Concerning the Mutual Recognition of Inspections to Determine Adherence to Good Manufacturing Practices for Pharmaceuticals Including Biologicals.''

DATES: The public meeting will be held on Wednesday, October 30, 1996, from 9 a.m. to 1 p.m. Those persons interested in attending this meeting must fax their registration, including name(s), firm/organization name, address, and telephone and fax number by October 25, 1996, to Nathaniel L. Geary (address below). Those persons interested in making a presentation at this meeting must contact Nathaniel L. Geary (address below) by October 25, 1996. There is no registration fee for this meeting, but advance registration is required. Space is limited and all interested parties are encouraged to register early. Written comments may be submitted at any time.

ADDRESSES: The public meeting will be held at the Parklawn Bldg., conference room E, 5600 Fishers Lane, Rockville, MD 20857.

Submit written requests for single copies of ''FDA Proposal for an Agreement With the European Union Concerning the Mutual Recognition of Inspections to Determine Adherence to Good Manufacturing Practices for Pharmaceuticals Including Biologicals'' to Walter M. Batts or Merton V. Smith (address below). Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on ''FDA Proposal for an Agreement With the European Union Concerning the Mutual Recognition of Inspections to Determine Adherence to Good Manufacturing Practices for Pharmaceuticals Including Biologicals'' to Merton V. Smith (address below). 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. A copy of ''FDA Proposal for an Agreement with the European Union Concerning the Mutual Recognition of Inspections to Determine Adherence to Good Manufacturing Practices for Pharmaceuticals Including Biologicals'' and received comments may be seen at the Dockets Management Branch between 9 a.m and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

For information regarding registration: Nathaniel L. Geary, Industry and Small Business Liaison Staff (HF–50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3375, FAX 301–443–5153.

For information regarding comments: Walter M. Batts or Merton V. Smith, Office of International Affairs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480, FAX 301–443–0235.

SUPPLEMENTARY INFORMATION: Joint discussions between the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, and the FDA with the EU, were disclosed in a public meeting held in Washington, DC on March 31, 1995. FDA is interested in the views of industry and other interested parties on its approach to negotiating an MRA with the EU. It would be useful for FDA to receive comments on the following issues: What effect will such an agreement have upon importation and exportation of those drug and biological products which would be covered by an MRA? What effect on product safety or other product-related matters, if any, do industry and other interested parties perceive to result from entering into an MRA?

Interested persons may submit written comments on ''FDA Proposal for an Agreement With the European Union Concerning the Mutual Recognition of Inspections to Determine Adherence to Good Manufacturing Practices for Pharmaceuticals Including Biologicals'' to Merton V. Smith (address above). 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. A copy of ''FDA Proposal for an Agreement With the European Union Concerning the Mutual Recognition of Inspections to Determine Adherence to Good Manufacturing Practices for Pharmaceuticals Including Biologicals'' and received comments may be seen at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m.

Dated: October 16, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–26914 Filed 10–17–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Eye Institute; Notice of Meeting of Board of Scientific Counselors

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Eye Institute, December 9 and 10, 1996 in Building 31, Room 6A35, National Institutes of Health, Bethesda, Maryland.

This meeting will be open to the public on December 9 from 9 a.m. until approximately 4 p.m. for general remarks by the Director, Intramural Research Program, National Eye Institute (NEI), on matters concerning the intramural program of the NEI. Attendance by the public will be limited to space available.

In accordance with provisions set forth in sec. 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92–463, the meeting will be closed to the public on December 9 from approximately 4 p.m. until recess and on December 10 from 8:30 a.m. until adjournment for the review, discussion, and evaluation of individual projects conducted by the Laboratory of Retinal Cell and Molecular Biology. These evaluations and discussions could reveal personal information concerning individuals associated with the projects, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Marie Watkins, Committee Management Officer, NEI, EPS/350, Bethesda, Maryland 20892, (301) 496–5301, will provide a summary of the meeting, roster of committee members, and substantive program information upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Watkins in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.867, Vision Research; National Institutes of Health)

Dated: October 10, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–26690 Filed 10–17–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: October 24, 1996.

Time: 1 p.m.

Place: Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Phyllis L. Zusman, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–1340.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

Dated: October 11, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–26689 Filed 10–17–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Child Health and Human Development; Notice of Meeting of the National Advisory Board on Medical Rehabilitation Research

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 United States Code Appendix 2), notice is hereby given of the meeting of the National Advisory Board on Medical Rehabilitation Research, National Institute of Child Health and Human Development, November 18–19, 1996, Radisson Mark Plaza Hotel, 5000 Seminary Road, Alexandria, Virginia.

The meeting will be open to the public from 8:30 a.m. to 5:00 p.m. on November 18 and 8:30 a.m. to adjournment on November 19. Attendance by the public will be limited to space available. Board topics will include: (1) A report on fiscal issues concerning the National Center for Medical Rehabilitation Research (Center) and the Institute; (2) reports on program activities of the Center; (3) a discussion of general priority areas of research for the Center; (4) a discussion of support for medical rehabilitation research by government agencies; and (5) development of a conference to define the structure for clinical trials in medical rehabilitation.

Ms. Debbie Welty, Board Secretary, NICHD, 6100 Building, Room 2A03, National Institutes of Health, Bethesda, Maryland 20892, Area Code 301–402–2242, will provide a summary of the meeting and a roster of Advisory Board members as well as substantive program information. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Welty.

Dated: October 10, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–26691 Filed 10–17–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Neurological Disorders and Stroke; Division of Extramural Activities; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting:

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel.

Date: November 6, 1996.

Time: 8:00 a.m.

Place: Federal Building, Conference Room 6B08 7550 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Dr. Katherine Woodbury-Harris, Scientific Review Administrator National Institutes of Health, 7550 Wisconsin