Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 or FAX 301–443–8818.

SUPPLEMENTARY INFORMATION:

I. Background

The United States and the European Community (EC) exchanged letters on October 30, 1998, which brought the MRA into force on December 7, 1998. FDA published a final rule on the MRA on November 6, 1998 (63 FR 60122).

In the MRA negotiations, FDA led the negotiations on the Annex to the MRA between the United States and the EC. These negotiations resulted in the drafting of the MRA, which includes a special section pertaining to medical devices that is referred to as the Annex. The Annex provides for a 3-year transition period. After the transition period FDA and the EC may normally endorse premarket and quality system evaluation reports provided by equivalent third parties, the CAB's.

In order to establish confidence in the conformity assessment process, CAB's will be required to participate in rigorous joint exercises to demonstrate their proficiency to conduct evaluations. Upon implementation of this program, CAB evaluations will be exchanged and normally endorsed by both FDA and the EC for the marketing of medical devices.

FDA is using the National Voluntary Conformity Assessment System Evaluation (NVCASE) administered by the National Institute of Standards and Technology (NIST) of the U.S. Department of Commerce to recognize one or more accreditation bodies that, in turn, will accredit potential U.S. CAB's seeking to be designated under the Annex to evaluate medical devices produced for the EC market. FDA has considered the recommendations made by the NIST under NVCASE and has designated the U.S. CAB's that meet criteria for technical competence established in the Annex, for possible participation in transition activities.

In the **Federal Register** of July 2, 1998 (63 FR 36247), FDA published information regarding the process for CAB's to become eligible for designation under the Annex. On the same date, the agency announced the availability of a draft guidance on the third party program (63 FR 3621). The agency received three comments on the draft guidance. FDA has reviewed these comments and has made no significant revisions in the guidance in response to these comments. The agency has, however, included additional information regarding conflicts of interest, including additional examples of situations that would indicate a potential conflict of interest.

II. Significance of Guidance

This guidance represents the agency's current thinking on ''Guidance for Staff, Industry, and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community.'' 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) that 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 is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so using the World Wide Web. CDRH maintains an entry on the World Wide Web 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 the ''Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA),'' device safety alerts, access to **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''.

IV. Comments

Interested persons may, at any time, submit written comments regarding this guidance to the contact person listed above. Such comments will be considered when determining whether to amend the current guidance.

Dated: January 19, 1999.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 99–2509 Filed 2–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

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

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: February 3, 1999.

Time: 1:00 PM to 3:00 PM.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 2055 Harbor Boulevard, Ventura, CA 93001, (Telephone Conference Call).

Contact Person: Paul K. Strudler, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4100, MSC 7804, Bethesda, MD 20892, (301) 435–1716.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Endocrinology and Reproductive Sciences Initial Review Group Reproductive Biology Study Section.

Date: February 8–9, 1999.

Time: 8:30 AM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Dennis Leszczynski, PHD, Scientific Review Administrator, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, (301) 435–1044.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel ZRG1–SSS–W(17).

Date: February 8–10, 1999.

Time: 6:00 PM to 1:00 PM.

Agenda: To review and evaluate grant applications.

Place: Sheraton Hotel, 36th & Chestnut, Philadelphia, PA 19104.

Contact Person: Dharam S. Dhindsa, DVM, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5126, MSC 7854, Bethesda, MD 20892, (301) 435–1174, dhindsad@csr,nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Musculoskeletal and Dental Sciences Initial Review Group, Oral Biology and Medicine Subcommittee 1.

Date: February 9–10, 1999.

Time: 8:30 AM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Old Town Alexandria, Alexandria, VA 22314.

Contact Person: Priscilla B. Chen, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4104, MSC 7814, Bethesda, MD 20892, (301) 435–1787.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Oncological Sciences Initial Review Group Pathology B Study Section.

Date: February 10–12, 1999.

Time: 8:00 AM to 6:00 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, 2101 Wisconsin Ave, Washington, DC 20007.

Contact Person: Martin L. Padarathsingh, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7804, Bethesda, MD 20892, (301) 435–1717.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Initial Review Group Visual Sciences C Study Section.

Date: February 10–11, 1999.

Time: 8:30 AM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Georgetown Inn, 1310 Wisconsin Ave., N.W., Washington, DC 20007.

Contact Person: Carole L. Jelsema, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5222, MSC 7850, Bethesda, MD 20892, (301) 435–1249, jelsemac@drg.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–2564 Filed 2–2–99; 8:45am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

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 meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individual associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness in CHF Patients (Escape).

Date: February 9, 1999.

Time: 9:00 AM to 3:00 PM.

Agenda: To review and evaluate contract proposals.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Louise P. Corman, PhD, Scientific Review Administrator, Review Branch, NIH, NHLBI, Rockledge Building II, 6701 Rockledge Drive, Suite 7180, Bethesda, MD 20892–7924, (301) 435–0270.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Stem Cell Transplantation to Establish Allochimerism.

Date: February 24, 1999.

Time: 8:30 AM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: David T. George, PhD, Scientific Review Administrator, NIH, NHLBI, DEA, Review Branch, Rockledge Building II, Room 7188, 6701 Rockledge Drive, Bethesda, MD 20892–7924, 301/435–0288.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 29, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–2570 Filed 2–2–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

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 meetings.

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

Name of Committee: National Institute on Aging Special Emphasis Panel, Discovery of Novel Drugs for Alzheimer's Disease.

Date: February 11, 1999.

Time: 1:00 PM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: University of Florida, Gainesville, FL 32610.

Contact Person: Louise L. Hsu, PhD, Scientific Review Administrator, The Bethesda Gateway Building, 7201 Wisconsin Avenue/Suite 2C212, Bethesda, MD 20892, (301) 496–9666.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Aging Initial Review Group, Clinical Aging Review Committee.

Date: February 28–March 1, 1999.

Time: 7:00 PM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Chevy Chase Holiday Inn, Terrace Room, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: William A. Kachadorian, PhD, SRA, The Bethesda Gateway Building, 7201 Wisconsin Avenue/Suite 2C212, Bethesda, MD 20892, (301) 496–9666.

Name of Committee: National Institute on Aging Special Emphasis Panel, Pepper Center Applications.

Date: March 2–4, 1999.