Pharmaceuticals.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance provides recommendations on nonclinical testing approaches to identify compounds that have the potential to be immunotoxic and guidance on a weight-of-evidence decisionmaking approach for immunotoxicity testing. The guidance is intended to provide recommendations on nonclinical testing for immunotoxicity induced by human pharmaceuticals. The guidance applies to unintended immunosuppression and immunoenhancement, excluding allergenicity or drug-specific autoimmunity.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD, 20857. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Kenneth L. Hastings, Center for Drug Evaluation and Research (HFD–024), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6480, Silver Spring, MD 20993–0002, 301–796–0169.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health, Labour, and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH steering committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of February 8, 2005 (70 FR 6697), FDA published a notice announcing the availability of a draft tripartite guidance entitled ''S8 Immunotoxicity Studies for Human Pharmaceuticals.'' The notice gave interested persons an opportunity to submit comments by April 11, 2005. After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH steering committee and endorsed by the three participating regulatory agencies in August 2005.

The guidance provides the following information: (1) Recommendations on nonclinical testing approaches to identify compounds which have the potential to be immunotoxic, and (2) guidance on a weight-of-evidence decisionmaking approach for immunotoxicity testing. The guidance is intended to provide recommendations on nonclinical testing for immunotoxicity induced by human pharmaceuticals. The guidance applies to immunosuppression and immunoenhancement, excluding allergenicity or drug-specific autoimmunity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: April 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5495 Filed 4–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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.

The meeting 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 of Biomedical Imaging and Bioengineering Special Emphasis Panel, ZEB1 OSR–A M2 S–NIBIB Conference Grants.

Date: May 1, 2006.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: NIBIB/NIH/OSR, Democracy II, 6707 Democracy Boulevard, 2nd Floor Conference Room, Bethesda, MD 20892.

Contact Person: David George, Ph.D., Director, Office of Scientific Review, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Blvd., Suite 920, Bethesda, MD 20892, 301–496–8633, *georged1@mail.nih.gov*.

Dated: April 4, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–3514 Filed 4–12–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; 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 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 of Dental and Craniofacial Research Special Emphasis Panel, 06–74, Review R21.

Date: May 5, 2006.

Time: 10 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Sooyoun (Sonia) Kim, MS, Associate SRA, 45 Center Dr., 4An 32B, Division of Extramural Research, National Inst. of Dental & Craniofacial Research, National Institutes of Health, Bethesda, MD 20892, (301) 594–4827, *kims@email.nidr.nih.gov*.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel, 06–81, Review R21.

Date: May 18, 2006.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Sooyoun (Sonia) Kim, MS, Associate SRA, 45 Center Dr., 4An 32B, Division of Extramural Research, National Inst. of Dental & Craniofacial Research, National Institutes of Health, Bethesda, MD 20892, (301) 594–4827, *kims@email.nidr.nih.gov*.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel, 06–75, Review of U01s and R21.

Date: July 19, 2006.

Time: 1 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Yujing Liu, MD, PhD., Scientific Review Administrator, National Institute of Dental & Craniofacial Res., 45 Center Drive, Natcher Building, Rm 4AN38E, Bethesda, MD 20892, (301) 594–3169, *yujing_liu@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: April 4, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–3515 Filed 4–12–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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.

The meeting 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 of General Medical Sciences Special Emphasis Panel, Conference Grants.

Date: May 1, 2006.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room 3AN12, Bethesda, MD 20892. (Virtual Meeting).

Contact Person: Arthur L. Zachary, PhD, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN–12, Bethesda, MD 20892. (301) 594–2886. *zacharya@nigms.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: April 4, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–3516 Filed 4–12–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 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