INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Chi-wan Chen, Center for Drug Evaluation and Research (HFD–830), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2001; or Andrew Shrake, Center for Biologics Evaluation and Research (HFM–345), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1148, 301–402–4635.

Regarding the ICH: Janet J. Showalter, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

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 (EU), 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 (WHO), Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedure for publishing ICH guidances. Beginning April 2000, we no longer include the text of ICH guidances in the **Federal Register**. Instead, we publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance will be placed in the docket and can be obtained through regular agency sources (see **ADDRESSES**). Draft guidances are left in the original ICH format. The final guidance is reformatted to conform to the GGP style before publication.

In February 2002, the ICH Steering Committee agreed that a draft guidance entitled ''Q1F Stability Data Package for Registration in Climatic Zones III and IV'' should be made available for public comment. The draft guidance is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

This draft guidance, an annex to an ICH guidance entitled ''Q1A(R) Stability Testing of New Drug Substances and Products'' (66 FR 56332, November 7, 2001), defines an approach for broader use of Q1A(R) for territories in climatic zones III and IV.

There are four climatic zones in the world that are distinguished by their characteristic prevalent annual climatic conditions, based on the concept described by P. Schumacher (*Pharmazeutische Zeitung*, 119:321–324, 1974). The Q1A(R) guidance defines the stability data package for the ICH tripartite regions (the EU, Japan, and the United States), which are in climatic zones I or II. The WHO has published a guideline entitled ''Stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms'' (WHO technical report series, no. 863, annex 5), updated in the ''Report of the thirty-seventh meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations,'' Geneva, October 22–26, 2001. The WHO guideline defines stability testing recommendations, including storage conditions for all four climatic zones.

Harmonized global stability testing recommendations have been established in this draft guidance based on Q1A(R) and the WHO guideline. For territories in climatic zones III and IV, the data package as described in Q1A(R) can be considered applicable except for the defined long-term storage condition. The draft guidance recommends the long-term storage condition for a stability data package for registration of drug substances and products intended to be marketed in climatic zones III and IV.

When this draft guidance is finalized, Q1A(R) will be revised to harmonize the intermediate storage condition for zones I and II with the long-term storage condition for zones III and IV.

This draft guidance, when finalized, will represent the agency's current thinking on a stability data package for registration in climatic zones III and IV. 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 statues and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance by August 20, 2002. 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. The guidance and received comments may be seen in the office above 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: June 6, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–14999 Filed 6–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Gene and Environment.

Date: June 24–25, 2002.

Time: 7 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: William J. Johnson, Scientific Review Administrator, NHLBI Review Branch, Division of Extramural Affairs, Two Rockledge Centre, Room 7184, MSC7924, 6701 Rockledge Drive, Bethesda, MD 20892, 301/435–0275; *johnsonw@nhlbi.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. 93.233, 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: June 7, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–15018 Filed 6–13–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health 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: Environmental Health Sciences Review Committee.

Date: July 18–19, 2002.

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

Agenda: To review and evaluate grant applications.

Place: Nat. Institute of Environmental Health Sciences, South Campus, Building 101 Conference Room, Research Triangle Park, NC 27709.

Contract Person: Linda K. Bass, PhD, Scientific Review Administrator, Nat'l Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–24, Research Triangle Park, NC 27709, (919) 541–1307.

(Catalogue of Federal Domestic Assistance Program Nos. 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences, National Institutes of Health, HHS)

Dated: June 7, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–15019 Filed 6–13–02; 8:45 am]

BILLING CODE 4140–01–M

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 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: Immunological Sciences Integrated Review Group, immunobiology Study Section.

Date: June 20–21, 2002.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Grand, 2350 M Street NW., Washington, DC 20037.

Contact Person: Betty Hayden, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4206, MSC 7812, Bethesda, MD 20892. (301) 435–1223.

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–Y (01).

Date: June 20, 2002.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge 2, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Michael R. Schaefer, PhD., Genetic Sciences IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6166, MSC 7890, Bethesda, MD 20892. (301) 435–2477, *schaefem@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: Center for Scientific Review Special Emphasis Panel, SBIR Special Study Section Meeting-3 (10).

Date: June 24–25, 2002.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Gopal C. Sharma, DVM, MS, PhD, Diplomat American Board of Toxicology, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2184, MSC 7818, Bethesda, MD 20892. (301) 435–1783. *sharmag@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: Center for Scientific Review Special Emphasis Panel, ZRG1 MEP (04) Leukemia virus.

Date: June 27, 2002.

Time: 5:30 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge 2, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Angela Y. Ng, PhD, MBA, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7804, (For courier delivery, use MD 20817), Bethesda, MD 20892. 301–435–1715. *nga@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 SSS–3 (04).