King, Sr., Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4150, Silver Spring, MD 20993–0002,301–796–1242; or

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1),Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

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In June 2008, the ICH Steering Committee agreed that a draft guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 4C: Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter'' should be made available for public comment. The draft guidance is the product of the Q4B Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Q4B Expert Working Group.

The draft guidance provides the specific evaluation results from the ICH Q4B process for the Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter harmonization proposal originating from the three-party PDG. This draft guidance is in the form of an annex to the core ICH Q4B guidance. Once finalized, the annex will provide guidance to assist industry and regulators in the implementation of the specific topic evaluated by the ICH Q4B process.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 or electronic comments on the draft guidance. 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

III. Electronic Access

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

Dated: July 28, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–17865 Filed 8–4–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given that the following committee will convene its fifty-ninth meeting.

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Times: September 24, 2008, 9 a.m.–4:30 p.m.; September 25, 2008, 8:45 a.m.–5:30 p.m.; September 26, 2008, 8:15 a.m.–10 a.m.

Place: Madden's on Gull Lake, 11266 Pine Beach Peninsula, Brainerd, MN 56401, Phone: 800–642–5363.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research, development and administration of health and human services in rural areas.

Agenda: Wednesday morning, at 9 a.m., the meeting will be called to order by the Chairperson of the Committee, the Honorable David Beasley. The first presentation will be an overview of rural Minnesota. The Committee will hear presentations on the three chosen Subcommittee topics. The first panel will focus on Workforce and Community Development. Jay Fonkert, with the Minnesota Office of Rural Health and Primary Care, and Valerie DeFor, Director of the Healthcare Education Industry Partnership, are confirmed speakers. The second panel of speakers will lead a discussion on Serving At-Risk Children with a representative from the Minnesota Early Childhood Comprehensive System. The final panel for the day is on the Medical Home Model, with Scott Leitz, Assistant

Commissioner of the Minnesota Department of Health, as a confirmed speaker. After the panel discussions, the Committee Chair will give an overview of the site visits. The Wednesday meeting will close at 4:30 p.m.

Tuesday morning, at 8:45 a.m., the Committee will break into Subcommittees and depart to the site visits. The Workforce and Community Development Subcommittee will learn about the Bridges to Excellence Program and a cross-training program for paramedics in Crosby, Minnesota. The Serving At-Risk Children Subcommittee will learn about child welfare, family support and prevention initiatives in rural Minnesota. The Medical Home Subcommittee will visit a medical home model at Lakewood Health System in Staples, Minnesota. Transportation to the site visits will not be provided to the public. At 4 p.m. the Subcommittees will arrive back at Madden's on Gull Lake for Subcommittee meetings. The Committee as a whole will reconvene at 4:45 p.m. There will be a review of the site visits and action items will be developed for the Committee members and staff. The meeting will be adjourned at 5:30 p.m.

The final session will be convened on Friday morning, at 8:15 a.m. Those available from the Committee will meet to discuss topic ideas for the next report. The Friday meeting will adjourn at 10 a.m.

For Further Information Contact: Anyone requiring information regarding the Committee should contact Jennifer Chang, MPH, Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 9A–55, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–0835, Fax (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Michele Pray-Gibson, Office of Rural Health Policy (ORHP), Telephone: (301) 443–0835. The Committee meeting agenda will be posted on ORHP(s Web site: *http://www.ruralhealth.hrsa.gov*.

Dated: July 29, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8–17850 Filed 8–4–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of 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 a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Advisory Environmental Health Sciences Council.

Date: September 9–10, 2008.

Open: September 9, 2008, 8:30 a.m. to 1 p.m.

Agenda: Discussion of program policies and issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: September 9, 2008, 1 p.m. to 5 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: September 10, 2008, 8:30 a.m. to 12 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Contact Person: Dennis R. Lang, PhD., Acting Director, Division of Extramural Research and Training, Nat. Inst. of Environmental Health Sciences, National Institutes of Health, P.O. Box 12233/EC–3431, 79 Alexander Drive, Research Triangle Park, NC 27709, (919) 541–7729, *lang4@niehs.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.niehs.nih.gov/dert/c-agenda.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 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; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: July 28, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–17728 Filed 8–4–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 on Drug Abuse Special Emphasis Panel: MIDARP.

Date: August 19, 2008.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Nadine Rogers, PhD., Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, 301–402–2105, *rogersn2@nida.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. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health HHS)

Dated: July 29, 2008.

Jennifer Spaeth

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–17819 Filed 8–4–08; 8:45 am]

BILLING CODE 4140–01–M