ADDRESSES: 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 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written requests for single copies of the 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. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. 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: H. Gregg Claycamp, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301–827–6505; Albinus D Sa, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–9044; Anna M. Flynn, Center for Biologics Evaluation and Research (HFM–610), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6201; or Diana J. Kolaitis, Office of Regulatory Affairs (HFR–NE1), Food and Drug Administration, 158–15 Liberty Ave., Jamaica, NY 11433, 718–662–5612.

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 August 8, 2005 (70 FR 45722), FDA published a notice announcing the availability of a draft tripartite guidance entitled ''Q9 Quality Risk Management.'' The notice gave interested persons an opportunity to submit comments by October 7, 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 November 2005.

The guidance provides recommendations for a systematic approach to quality risk management. The guidance is intended to support other ICH quality documents, complement existing quality practices and standards, and enable regulators and industry to make more effective and consistent risk-based decisions.

The guidance includes principles and examples of tools for quality risk management that can be applied to different aspects of pharmaceutical quality throughout the lifecycle of drug substances, drug products, and biological and biotechnological products. These aspects include development, manufacturing, distribution, inspection, and submission/review processes (including the use of raw materials, solvents, excipients, packaging and labeling materials in drug products and biological and biotechnological products). The guidance is not intended to create any new expectations beyond current regulatory requirements.

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 or electronic comments on the guidance at any time. 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. The guidance and 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: May 23, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–8573 Filed 6–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Neurological Sciences and Disorders A, June 22,

2006, 8 a.m. to June 23, 2006, 6 p.m. The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037, which was published in the **Federal Register** on May 3, 2006, 71, FR: 06–4149.

This meeting was scheduled for June 22–23, 2006 and has been changed to a one day meeting on June 22, 2006; 8 a.m. to 6 p.m. The meeting is closed to the public.

Dated: May 25, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–5061 Filed 6–1–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Disorders; 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 purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for type 1 diabetes. The outcome of the evaluation will be a decision whether NIDDK should support the request and make available contract resources for development of the potential therapeutic to improve the treatment or prevent the development of type 1 diabetes and its complications. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Type 1 Diabetes—Rapid Access to Intervention Development Special Emphasis Panel, National Institute of Diabetes and Digestive and Kidney Diseases.

Date: June 22, 2006.

Time: 11:30 a.m. 2 p.m.

Agenda: To evaluate requests for preclinical development resources for potential new therapeutics for type 1 diabetes and its complications.

Place: 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Dr. Myrlene Staten, Senior Advisory, Diabetes Translation Research, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK, NIH, 6707 Democracy Boulevard, Bethesda, MD 20892–5460. 301 402–7886.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 98.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: May 25, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–5068 Filed 6–1–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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 of Child Health and Human Development Initial Review Group; Population Sciences Subcommittee.

Date: June 15–16, 2006.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Carla T. Walls, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health, and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892. (301) 435–6898. *wallsc@mail.nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Energy Dysregulation.

Date: June 15, 2006.

Time: 8:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Rita Anand, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health, and Human Development, NIH, 6100 Executive Blvd. Room 5B01, Bethesda, MD 20892. (301) 496–1487. *anandr@mail.nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Youth Weight and Obesity: Gender and Racial Disparities.

Date: June 16, 2006.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Michele C. Hindi-Alexander, PhD, Division of Scientific Review, National Institutes of Health, National Institute for Child Health, and Human Development, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20812–7510. (301) 435–8382. *hindialm@mail.nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Function, Integration, and Rehabilitation Sciences Subcommittee.

Date: June 19, 2006.

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

Agenda: To review and evaluate grant applications.

Place; Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: Anne Krey, Scientific Review Administrator, Division of Scientific Review, National Institutes of Child Health, and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892. (301) 435–6908. *ak41o@nih.gov..*

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Obstetrics and Maternal-Fetal Biology Subcommittee.

Date: June 19, 2006.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place; Holiday Inn—Gaithersburg, 2 Montgomery Village Avenue, Gaithersburg, MD, 20879.

Contact Person: Gopal M. Bhatnagar, PhD, Scientific Review Administrator, National Institutes of Child Health, and Human Development, National Institutes of Health, 6100 Bldg Rm 5B01, Rockville, MD 20852. (301) 435–6889. *bhatnagg@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)