whether research studies must be conducted under an investigational new drug application (IND). It also offers answers to frequently asked questions on conducting research with radioactive drugs, and provides information on the membership, functions, and reporting requirements of a radioactive drug research committee approved by FDA.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Orhan Suleiman, Center for Drug Evaluation and Research, Food and Drug Administration, 10901 New Hampshire Ave., Bldg. 22, rm. 2202, Silver Spring, MD 20993–0002, 301–796–1471.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and researchers entitled "The Radioactive Drug Research Committee: Human Research Without an Investigational New Drug Application."

In a document published in the **Federal Register** on July 25, 1975 (40 FR 31298), FDA changed the conditions under which new radioactive drug and biological products could be used. First, the Agency terminated a 1963 order from the Commissioner of Food and Drugs (28 FR 183, January 8, 1963) that had exempted radioactive new drug and biological products for investigational use in humans from new drug requirements (21 CFR part 312), as long as they were shipped consistent with regulations issued by the then Atomic Energy Commission (AEC). FDA and AEC had agreed that all radioactive drugs and biological products should now become subject to the same requirements for investigational use as other new drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and section 351 of the Public Health Service Act (42 U.S.C. 262). Simultaneously, the Agency issued regulations (§ 361.1 (21 CFR 361.1)) explaining when radioactive drugs for basic science and medical research would not be subject to the same requirements for investigational use as other new drugs.

Today, research studies with a radioactive drug or biological product may be conducted in a number of ways: (1) Under an IND (part 312), (2) exempt from IND requirements (§ 312.2), or (3) under certain conditions, with the supervision and approval of an FDA-approved Radioactive Drugs Research Committee (RDRC) (§ 361.1).

This guidance discusses the conditions under which research with a radioactive drug may be conducted under § 361.1. Appendices to the guidance answer frequently asked questions about those conditions and provide additional information on RDRCs. Appendix A of the guidance answers questions on basic science research with radioactive drugs. Appendix B addresses approval by the RDRC and the information that must be submitted by investigators to the RDRC. Appendix C discusses the limits on the pharmacological dose, and Appendix D discusses the limits on the radiation dose. Each of these appendices also includes a summary of the regulations. Appendix E provides information on the membership, functions, and reports of an RDRC. The final appendix, Appendix F, is an RDRC review criteria checklist, indicating the areas on which the RDRC will focus when considering a proposed research study.

In the **Federal Register** of June 3, 2009 (74 FR 26703), FDA announced the availability of a draft guidance for industry and researchers entitled "The Radioactive Drug Research Committee: Human Research Without an Investigational New Drug Application." The notice gave interested persons an opportunity to comment by September 1, 2009. We received comments from seven institutions, organizations, and individuals. We have carefully considered the comments and, where appropriate, have made corrections, added information, or clarified the information in the guidance in response to the comments or on our own initiative.

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 determining whether human research with a radioactive drug can be conducted under a radioactive drug research committee. 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**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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 either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: July 27, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–18853 Filed 7–30–10; 8:45 am]

BILLING CODE 4160–01–S

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. App.), 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: Center for Scientific Review Special Emphasis Panel Member Conflict: AIDS Molecular Biology and Opportunistic Infections.

Date: August 12–13, 2010.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3200, MSC 7848, Bethesda, MD 20892, 301–435–1050, *freundr@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 PAR10–074: Crystallography Partnership.

Date: August 27–28, 2010.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nuria E. Assa-Munt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, *assamunu@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 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: July 23, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–18880 Filed 7–30–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Meeting; National Commission on Children and Disasters

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of Meeting.

DATES: The meeting will be held on Monday, August 23, 2010, from 9:30 a.m. to 3:30 p.m.

ADDRESSES: The meeting will be held at the Administration for Children and Families, 901 D Street SW., Washington, DC 20024. To attend either in person or via teleconference, please register by 5 p.m., Eastern Time, August 18, 2010. To register, please e-mail *jacqueline.haye@acf.hhs.gov* with "Meeting Registration" in the subject line, or call (202) 205–9560. Registration must include your name, affiliation, and phone number. If you require a sign language interpreter or other special assistance, please call Jacqueline Haye at (202) 205–9560 or e-mail *jacqueline.haye@acf.hhs.gov* as soon as possible and no later than 5 p.m. Eastern Time, August 9, 2010.

AGENDA: The Commission will: (1) Review and vote on the Final Report to the President and Congress; (2) Host panel discussion on the progress of children's working group activities and collaborations between Federal Emergency Management Agency, Assistant Secretary for Preparedness and Response and the Administration for Children and Families.

Written comments may be submitted electronically to *Juliana.Sadovich@ACF.hhs.gov* with "Public Comment" in the subject line. The Commission recommends that you include your name, mailing address and an e-mail address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment, and it allows the Commission to contact you if further information on the substance of the comment is needed or if your comment cannot be read due to technical difficulties. The Commission's policy is that the Commission will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment placed in the official record.

The Commission will provide an opportunity for public comments during the public meeting on August 23, 2010. Those wishing to speak will be limited to three minutes each; speakers are encouraged to submit their remarks in writing in advance to ensure their comment is received in case there is inadequate time for all comments to be heard on August 23, 2010.

Additional Information: Contact CAPT Juliana Sadovich, RN, Ph.D. Director, Office of Human Services Emergency Preparedness and Response, e-mail *Juliana.Sadovich@ACF.hhs.gov* or call (202) 401–9306.

SUPPLEMENTARY INFORMATION: The National Commission on Children and Disasters is an independent Commission that shall conduct a comprehensive study to examine and assess the needs of children as they relate to preparation for, response to, and recovery from all hazards, building upon the evaluations of other entities and avoiding unnecessary duplication by reviewing the findings, conclusions, and recommendations of these entities. The Commission shall then submit a report to the President and the Congress on the Commission's independent and specific findings, conclusions, and recommendations to address the needs of children as they relate to preparation for, response to, and recovery from all hazards, including major disasters and emergencies.

Dated: July 20, 2010.

David A. Hansell,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2010–18905 Filed 7–30–10; 8:45 am]

BILLING CODE 4184–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration (SAMHSA) National Advisory Council will meet on August 17–18 at the Omni Hotel at CNN Center, Atlanta, Georgia. The meeting is open to the public.

The SAMHSA National Advisory Council was established to advise the Secretary, Department of Health and Human Services (HHS), and the Administrator, SAMHSA, to reduce the impact of substance abuse and mental illnesses in American communities. The Agenda will include a report from the SAMHSA Administrator, updates on SAMHSA's strategic initiatives, and a panel discussion on health reform and the role of peers and families in behavioral health. In addition, Council members will participate in a listening session on September 18 at the Centers for Disease Control and Prevention's Fourth National Conference on Health Communication, Marketing, and Media.

Attendance by the public will be limited to space available. Public comments are welcome. The meeting can also be accessed via webstream. To obtain the call-in numbers and access codes, to submit written or brief oral comments, or to request special accommodations for persons with disabilities, please register on-line at *https://nac.samhsa.gov/Registration/meetingsRegistration.aspx*. You may also communicate with the SAMHSA National Advisory Council Designated Federal Officer, Ms. Toian Vaughn (*see* contact information below).

Substantive program information and a roster of Council members may be obtained either by accessing the SAMHSA Committee Web site, *https://nac.samhsa.gov/NACcouncil/index.aspx* or by contacting Ms.