Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans," published elsewhere in this issue of the **Federal Register**.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 28, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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; or the Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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 Submit electronic comments on the draft guidance to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Janet Norden, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6324, Silver Spring, MD 20993–0002, 301–796–2500; or Laura Rich, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and investigators entitled "Safety Reporting Requirements for INDs and BA/BE Studies." This draft guidance is intended to help sponsors and investigators comply with the new requirements for investigational new drug applications (IND) safety reporting and safety reporting for bioavailability (BA) and bioequivalence (BE) studies.

In the **Federal Register** of March 14, 2003 (68 FR 12406), FDA published a proposed rule to revise its regulations governing pre- and postmarket safety reporting for human drug and biological products. To make rulemaking more manageable, the Agency decided to issue revisions to the pre- and postmarket safety reporting regulations in two separate rulemakings. The final rule, entitled "Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans," published elsewhere in this issue of the **Federal Register**, revises the premarket regulations. The revisions in the final rule will improve the utility and quality of safety reports, expedite and strengthen FDA's ability to review critical safety information, improve safety monitoring of human drug and biological products, better protect human subjects enrolled in clinical trials, and harmonize safety reporting internationally. The new requirements revise the definitions used for IND safety reporting, make clear when to submit IND safety reports, and subject BA and BE studies to safety reporting requirements.

The draft guidance was developed to accompany the publication of the final rule. The draft guidance provides examples and explanations of the definitions used for IND safety reporting, makes recommendations for determining when and how to submit a safety report, and provides advice on other safety reporting issues that have generated questions from sponsors and investigators.

The 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 safety reporting requirements for INDs and BA/BE studies. 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. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection(s) of information in the draft guidance are estimated in section "VII. Paperwork Reduction Act of 1995" of the final rule entitled, "Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans" published elsewhere in this issue of the **Federal Register**.

IV. 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: September 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–24295 Filed 9–28–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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: National Cancer Institute Special Emphasis Panel; Basic and Translational Oncology P01.

Date: September 30–October 1, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Shakeel Ahmad, PhD, Scientific Review Officer, Research Programs

Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8137, Bethesda, MD 20892–8328, (301) 594–0114, *ahmads@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

Name of Committee: National Cancer Institute Special Emphasis Panel; Cancer Prevention Research Small Grant Program (R03).

Date: October 28–29, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington, DC DuPont Circle Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Contact Person: Irina Gordienko, PhD, Scientific Review Officer, Scientific Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Rm. 7073, Bethesda, MD 20892, 301–594–1566, *gordienkoiv@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 22, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–24414 Filed 9–28–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of an Interagency Autism Coordinating Committee (IACC) meeting.

The purpose of the IACC meeting is to listen to presentations on various aspects of autism spectrum disorder research and services and to discuss plans for the annual update of the IACC Strategic Plan for Autism Spectrum Disorders Research. The meeting will be open to the public and will be accessible by webcast and conference call.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of meeting: Open meeting.

Date: October 22, 2010.

Time: 10 a.m. to 5 p.m.* Eastern *Time* *—Approximate end time.

Agenda: Invited speakers will give presentations on various aspects of autism spectrum disorder research and services and the IACC will discuss plans for the annual update of the IACC Strategic Plan for Autism Spectrum Disorder Research.

Place: The National Institutes of Health, Main Campus, William H. Natcher Conference Center, 45 Center Drive, Conference Rooms E1/E2, Bethesda, MD 20892.

Webcast Live: http://videocast.nih.gov/.

Conference Call Access: Dial: 1–888–577–8995; Access code: 1991506.

Cost: The meeting is free and open to the public.

Registration: http://www.acclaroresearch.com/oarc/10-22-10_IACC. Pre-registration is recommended to expedite check-in. Seating in the meeting room is limited to room capacity and on a first come, first served basis.

Deadlines: Notification of intent to present oral comments: October 14th by 5 p.m. ET.

Submission of written/electronic statement for oral comments: October 15th by 5 p.m. ET.

Submission of written comments: October 18th by 5 p.m. ET.

Access: Metro accessible—Medical Center Metro (Red Line).

Contact Person: Ms. Lina Perez, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Room 8200, Bethesda, MD 20892–9669. Phone: 301–443–6040. E-mail: *IACCPublicInquiries@mail.nih.gov.*

Please Note: Any member of the public interested in presenting oral comments to the Committee must notify the Contact Person listed on this notice by 5 p.m. ET on Thursday, October 14, 2010 with their request to present oral comments at the meeting. Interested individuals and representatives of organizations must submit a written/electronic copy of the oral statement/comments including a brief description of the organization represented by 5 p.m. ET on Friday, October 15, 2010. Statements submitted will become a part of the public record. Only one representative of an organization will be allowed to present oral comments and presentations will be limited to three to five minutes per speaker, depending on number of speakers to be accommodated within the allotted time. Speakers will be assigned a time to speak in the order of the date and time when their request to speak is received, along with the required submission of the written/electronic statement by the specified deadline.

In addition, any interested person may submit written comments to the IACC prior to the meeting by sending the comments to the Contact Person listed on this notice by 5 p.m. ET, Monday, October 18, 2010. The comments should include the name and when applicable, the business or professional affiliation of the interested person. All written comments received by the deadlines for both oral and written public comments will be provided to the IACC for their consideration and will become part of the public record.

The meeting will be open to the public through a conference call phone number and webcast live on the Internet. Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. If you experience any technical problems with the webcast live or conference call, please e-mail *IACCTechSupport@acclaroresearch.com.*

Individuals who participate in person or by using these electronic services and who need special assistance, such as captioning of the conference call or other reasonable accommodations, should submit a request to the Contact Person listed on this notice at least 7 days prior to the meeting.

To access the webcast live on the Internet the following computer capabilities are required: (A) Internet Explorer 5.0 or later, Netscape Navigator 6.0 or later or Mozilla Firefox 1.0 or later; (B) Windows® 2000, XP Home, XP Pro, 2003 Server or Vista; (C) Stable 56k, cable modem, ISDN, DSL or better Internet connection; (D) Minimum of Pentium 400 with 256 MB of RAM (Recommended); (E) Java Virtual Machine enabled (Recommended).

NIH has instituted stringent security procedures for entrance onto the NIH campus. All visitors must enter through the NIH Gateway Center. This center combines visitor parking, non-commercial vehicle inspection and visitor ID processing, all in one location. The NIH will process all visitors in vehicles or as pedestrians. You will be asked to submit to a vehicle or personal inspection and will be asked to state the purpose of your visit. Visitors over 15 years of age must provide a form of government-issued ID such as a driver's license or passport. All visitors should be prepared to have their personal belongings inspected and to go through metal detection inspection.

When driving to NIH, plan some extra time to get through the security checkpoints. Be aware that visitor parking lots on the NIH campus can fill up quickly. The NIH campus is also accessible via the metro Red Line, Medical Center Station. The William H. Natcher Conference Center is a 5-minute walk from the Medical Center Metro Station.

Additional NIH campus visitor information is available at: *http://www.nih.gov/about/visitor/index.htm.*

As a part of security procedures, attendees should be prepared to present a photo ID at the meeting registration desk during the check-in process. Pre-registration is recommended. Seating will be limited to the room capacity and seats will be on a first come, first served basis, with expedited check-in for those who are pre-registered.

Meeting schedule subject to change.

Information about the IACC is available on the website: *http://www.iacc.hhs.gov.*

Dated: September 22, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–24403 Filed 9–28–10; 8:45 am]

BILLING CODE 4140–01–P