industry entitled ''Submission of Summary Bioequivalence Data for ANDAs.'' The draft guidance is intended to assist abbreviated new drug application (ANDA) applicants in complying with the new requirements in the final rule on the submission of bioequivalence data published in the **Federal Register** in January 2009. The final rule requires ANDA applicants to submit data from all bioequivalence studies (BE studies) the applicant conducts on a drug product formulation submitted for approval, including both studies that demonstrate and studies that fail to demonstrate that a generic product meets the current bioequivalence criteria. The draft guidance provides recommendations to applicants planning to include BE studies for submission in ANDAs, and is applicable to BE studies conducted during both preapproval and postapproval periods.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by July 16, 2009.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Aida L. Sanchez, Center for Drug Evaluation and Research (HFD–650), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5847.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 29, 2003 (68 FR 61640), FDA published a proposed rule to require an ANDA applicant to submit data from all BE studies that the applicant conducts on a drug product formulation submitted for approval. The agency's final rule amending its bioequivalence regulations was published in the **Federal Register** on January 16, 2009 (74 FR 2849). All BE studies conducted on the same drug product formulation, including studies that demonstrate and studies that fail to demonstrate that a generic product meets the current bioequivalence criteria, must be submitted to the agency. Information from all BE studies is important to the agency for the following reasons:

- Data contained in any BE study could be important to FDA's assessment of bioequivalence for a specific product; and
- Even when additional BE studies are not critical to the agency's bioequivalence determination for the specific product being reviewed, the data provide valuable scientific information that increases the agency's knowledge and understanding of bioequivalence and generic drug development and promotes further development of science-based bioequivalence policies.

II. The Draft Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Submission of Summary Bioequivalence Data for ANDAs.'' The draft guidance provides recommendations to applicants planning to include BE studies for submission in ANDAs. The draft guidance provides information on the following subjects:

- The types of ANDA submissions covered by the new regulations on BE studies;
- A recommended format for summary reports of BE studies; and
- What formulations FDA considers the ''same drug product formulation'' for different dosage forms based on differences in composition.

The draft guidance is applicable to BE studies conducted for ANDAs during both preapproval and postapproval periods.

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 summary bioequivalence data reports to be submitted in ANDAs. 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.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding 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.

IV. Paperwork Reduction Act of 1995

The draft guidance refers to 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 collections of information in 21 CFR 314.94(a)(7), 314.96(a)(1), and 314.97 have been approved under OMB control number 0910–0630.

V. Electronic Access

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

Dated: April 9, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–8833 Filed 4–16–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Nursing Research.

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 Council for Nursing Research.

Date: May 19–20, 2009.

Open: May 19, 2009, 1 p.m. to Adjournment.

Agenda: Discussion of Program Policies and Issues.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6C, Room 6, Bethesda, MD 20892.

Closed: May 20, 2009, 9 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6C, Room 6, Bethesda, MD 20892.

Contact Person: Mary E. Kerr, FAAN, RN, PhD, Deputy Director, National Institute of Nursing, National Institutes of Health, 31 Center Drive, Room 5B–05, Bethesda, MD 20892–2178. 301/496–8230. *kerrme@mail.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.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

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

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: April 10, 2009.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–8899 Filed 4–16–09; 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 Closed Meeting

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 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 of Mental Health Special Emphasis Panel, NIMH/ARMY RFA Project.

Date: May 1, 2009.

Time: 2 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call)

Contact Person: David I. Sommers, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892–9606, 301–443–7861, *dsommers@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: April 10, 2009.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–8892 Filed 4–16–09; 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 Closed Meeting

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 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 of Mental Health Special Emphasis Panel. Biobehavioral Research Awards for Innovative New Sciences.

Date: May 14, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC 20037.

Contact Person: Megan Libbey, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9609, Rockville, MD 20852–9609. 301–402–6807. *libbeym@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: April 13, 2009.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–8891 Filed 4–16–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Disease Control and Prevention (CDC)

Board of Scientific Counselors, Coordinating Office for Terrorism Preparedness and Emergency Response (BSC, COTPER)

Correction: This notice was published in the **Federal Register** on March 20, 2009, Volume 74, Number 53, Page 11958. The time and date, place, status, and matters to be discussed for the aforementioned meeting have been changed to the following:

Time and Date: 2 p.m.–4:30 p.m., April 27, 2009.

Place: Web Conference. Please contact the BSC Coordinator (see Contact Person for More Information) to obtain further instructions on how to participate by phone and online. Members of the public may also attend this meeting in person at CDC, 1600 Clifton Road, NE., Global Communications Center, Building 19, Room 245/246, Atlanta, Georgia 30333.

Status: This Web conference will be open to the public, limited only by the public meeting space available for individuals participating in person. The public meeting room accommodates