the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record).[1] This draft guidance addresses one of these goals with the creation of a guidance document that addresses the ''imaging standards for use as an endpoint in clinical trials.'' This draft guidance also follows the April 13, 2010, public workshop ''Standards for Imaging Endpoints in Clinical Trials'' cosponsored by FDA, the Society of Nuclear Medicine, and the Radiological Society of North America.[2]

This draft guidance outlines the major considerations for standardization of image acquisition, image interpretation methods, and other procedures to help ensure imaging data quality. The draft guidance describes two categories of image acquisition and interpretation standardization, a medical practice standard and a clinical trial standard, and provides guidance on the role of each standard in a clinical trial. With a medical practice standard, the image acquisition and interpretation methods in the trial do not exceed those used in medical practice. In contrast, a clinical trial standard involves imaging methods that exceed those used in medical practice. The draft guidance focuses on the methods important for image acquisition and interpretation and provides a detailed outline of other procedures important for optimizing clinical trial imaging data quality.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on standards for clinical trial imaging endpoints. 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. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.egulations.gov.*

Dated: August 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21244 Filed 8–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine 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 a meeting of the Board of Scientific Counselors, National Center for Biotechnology Information.

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 as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for review, discussion, and evaluation of individual intramural programs and projects conducted by the National Library of Medicine, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Center for Biotechnology Information.

Date: November 8, 2011.

Open: 8:30 am to 12:00 pm.

Agenda: Program Discussion.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD. 20892.

Closed: 12:00 pm to 2:00 pm.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Library of Medicine, Building 38, 2nd Floor, Board, Room, 8600 Rockville Pike, Bethesda, MD 20892.

Open: 2:00 pm to 3:00 pm.

Agenda: Program Discussion.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: David J. Lipman, MD, Director, National Center of Biotechnology Information, National Library of Medicine, Department of Health and Human Services, Building 38A, Room 8N805, Bethesda, MD 20892, 301–435–5985, *dlipman@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.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS).

Dated: August 15, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–21238 Filed 8–18–11; 8:45 am]

BILLING CODE 4140–01–P

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[1] See ''Section A: PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 Through 2012'' (*http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm*).

[2] See *http://www.rsna.org/snm/index.html.*