electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Laurie B. Burke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6462, Silver Spring, MD 20993–0002, 301–796–0900; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210; or Sahar Dawisha, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0717.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims.'' This guidance describes how FDA reviews and evaluates PRO instruments used to measure treatment benefit in medical product clinical trials. A PRO instrument (e.g., questionnaire, diary, plus all the information and documentation that support its use) is a means to capture PRO data. This guidance also describes FDA's current thinking on how sponsors can use study results measured by PRO instruments to support claims in approved medical product labeling. It does not address the use of PRO instruments for purposes beyond evaluation of treatment benefit claims made about a drug or medical product in labeling.

By explicitly addressing the review issues identified in this guidance, sponsors can increase the efficiency of their discussions with FDA during the medical product development process, streamline FDA's review of PRO instrument adequacy, and provide optimal information about the patient's perspective for use in making conclusions about treatment benefit at the time of medical product approval.

A draft version of this guidance was made available for public comment in the **Federal Register** of February 3, 2006 (71 FR 5862). All of the public comments we received have been considered and the guidance has been revised as appropriate.

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 the use of PRO measures in medical product clinical trials. 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 guidance contains information collection that is 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 information collection has been approved under OMB Control Numbers 0910–0001, 0910–0338, and 0910–0231. The information requested in the guidance is currently submitted to FDA to support the medical product's effectiveness and to support claims in approved medical product labeling (see 21 CFR 314.50(d)(5), 314.126(b)(6), 601.2, and part 814).

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. 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*, *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*, or *http://www.regulations.gov*.

Dated: December 3, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–29273 Filed 12–8–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; 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: Biomedical Library and Informatics Review Committee.

Date: March 4–5, 2010.

Time: March 4, 2010, 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

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

Time: March 5, 2010, 8 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Arthur A. Petrosian, PhD, Chief Scientific Review Officer, Division of Extramural Programs, National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892–7968, 301–496–4253, *petrosia@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: December 2, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–29231 Filed 12–8–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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