

Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.).

Maxxam Analytics\*, 6740 Campobello Road, Mississauga, ON, Canada L5N 2L8, 905-817-5700, (Formerly: Maxxam Analytics Inc., NOVAMANN (Ontario), Inc.).

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651-636-7466/800-832-3244.

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503-413-5295/800-950-5295.

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612-725-2088.

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661-322-4250/800-350-3515.

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888-747-3774, (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory).

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800-328-6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory).

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509-755-8991/800-541-7891x7.

Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121, 858-643-5555.

Quest Diagnostics Incorporated, 3175 Presidential Dr., Atlanta, GA 30340, 770-452-1590/800-729-6432, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610-631-4600/877-642-2216, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).

Quest Diagnostics Incorporated, 7600 Tyrone Ave., Van Nuys, CA 91405, 866-370-6699/818-989-2521, (Formerly: SmithKline Beecham Clinical Laboratories).

S.E.D. Medical Laboratories, 5601 Office Blvd., Albuquerque, NM 87109, 505-727-6300/800-999-5227.

South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 574-234-4176 x1276.

Southwest Laboratories, 4625 E. Cotton Center Boulevard Suite 177, Phoenix, AZ 85040, 602-438-8507/800-279-0027.

St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St.,

Oklahoma City, OK 73101, 405-272-7052.

STERLING Reference Laboratories, 2617 East L Street, Tacoma, Washington 98421, 800-442-0438.

Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 573-882-1273.

Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305-593-2260.

US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755-5235, 301-677-7085.

The following laboratory will be voluntarily withdrawing from the National Laboratory Certification Program on December 1, 2009:

Clendo Reference Laboratory, Avenue Santa Cruz #58, Bayamon, Puerto Rico 00959, 787-620-9095.

\*The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 13, 2004 (69 FR 19644). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Dated: December 1, 2009.

**Elaine Parry,**

*Director, Office of Program Services, SAMHSA.*

[FR Doc. E9-29360 Filed 12-8-09; 8:45 am]

**BILLING CODE 4160-20-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2006-D-0362] (Formerly Docket No. 2006-D-0044)

### Guidance for Industry on Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (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 patient-reported outcome (PRO) instruments used to measure treatment benefit in medical product clinical trials. It also provides recommendations on how sponsors can use study results measured by PRO instruments to support claims in approved medical product labeling. This guidance finalizes the draft guidance published on February 3, 2006.

**DATES:** Submit written or electronic 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; or 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; or Office of Communication, Education, and Radiation Programs, Division of Small Manufacturers, International and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850-4307. Send one self-addressed adhesive label to assist in processing your requests. Submit written comments on the 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 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]

**BILLING CODE 4160-01-S**

**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](mailto: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