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 x276.

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 NW. 79th Ave., Miami, FL 33166. 305–593–2260.

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

*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.

Elaine Parry,

Director, Office of Program Services, SAMHSA.

[FR Doc. E9–15648 Filed 7–1–09; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0339]

Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices; 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 ''Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices.'' The Food and Drug Administration Amendments Act of 2007 (FDAAA) includes a requirement that FDA identify and periodically update susceptibility test interpretive criteria for antibacterial drug products and make those findings publicly available. This guidance describes how FDA will comply with the FDAAA requirement and procedures for application holders to update the labeling of antibacterial drug products and antimicrobial susceptibility testing (AST) devices.

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 the Division of Small Manufacturers 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 that office 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:

Regarding antibacterial drug products: Edward Cox, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6212, Silver Spring, MD 20993–0002, 301–796–1300; or

Regarding AST devices: Freddie Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0712.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices.'' Antibacterial susceptibility testing is used to determine if bacteria that are isolated from a patient with an infection are likely to be killed or inhibited by a particular antibacterial drug product at the concentrations of the drug that are attainable at the site of infection using the dosing regimen(s) indicated in the drug product's labeling. The results from antibacterial susceptibility testing generally categorize bacteria as ''susceptible,'' ''intermediate,'' or ''resistant'' to each antibacterial drug tested. When available, culture and susceptibility testing results are one of the factors that physicians consider when selecting an antimicrobial drug product for treating a

patient. The numerical values generated by susceptibility testing to determine whether a particular microorganism is susceptible to a particular antimicrobial drug—the antimicrobial susceptibility test interpretive criteria—are commonly referred to as breakpoints. These breakpoints are specified in the antimicrobial drug product's label. The antimicrobial susceptibility test interpretive criteria can be used to interpret results from either manual or automated AST devices.

On September 27, 2007, FDAAA (Public Law 110–85) was signed into law. Section 1111 of FDAAA requires FDA to identify and periodically update susceptibility test interpretive criteria for antibacterial drug products and to make those findings publicly available. By enacting section 1111 of FDAAA, Congress recognized the importance of maintaining updated susceptibility test interpretive criteria.

In the **Federal Register** of June 12, 2008 (73 FR 33438), FDA issued a draft guidance entitled ''Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices.'' The draft guidance described procedures for FDA, drug application holders, and AST device manufacturers to ensure that updated susceptibility test information is available to health care providers. The draft guidance explained that where appropriate, FDA intends to identify susceptibility test interpretive criteria, quality control parameters, and susceptibility test methods by recognizing annually, in a **Federal Register** notice, standards developed by one or more nationally or internationally recognized standard development organizations. The draft guidance described, for holders of applications for approved antibacterial drug products, the option of relying on such standards to update their product labeling. The draft guidance explained that the agency intends to make the updated information available by publicly posting changes to the drug product labeling within 30 days following approval of a supplement that includes a change to the *Microbiology* subsection of the product labeling. The draft guidance also described, for manufacturers of in vitro diagnostic AST devices, the process for updating the susceptibility test information in their labeling to conform with updated labeling for a relevant antibacterial drug product.

FDA has carefully reviewed comments received on the draft guidance (11 comments were submitted to the public docket). This final version of the guidance reflects our consideration of these comments, as well as our experience updating the labeling of susceptibility test information in systemic antibacterial drug products and AST devices. Most of the changes to the guidance were made to clarify statements in the draft guidance. The following changes in the final version of the guidance are noteworthy:

- The guidance clarifies that FDA is not imposing new requirements by recommending that drug application holders submit revised labeling or an explanation of why revisions are not needed within a specific time period after FDA recognizes a standard that is different from the information in the *Microbiology* subsection of the labeling for the application holder's drug product. (See 21 CFR 201.56(a)(2).)
- The agency revised the recommended time period for submitting revised labeling by extending the period from 60 days to 90 days.

Certain requests that the guidance provide greater detail regarding the procedures for updating in vitro AST devices have not been addressed in this guidance but will be addressed when FDA updates ''Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA.'' 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 this topic. 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**) 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.

III. Paperwork Reduction Act of 1995

This 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 of information in this guidance was approved under OMB control number 0910-0638.

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: June 26, 2009.

David Horowitz,

Assitant Commissioner for Policy

[FR Doc. E9–15682 Filed 7–1–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 Environmental Health Sciences Special Emphasis Panel; Research Conference Grants with an Environmental Health Focus.

Date: July 30, 2009.

Time: 2 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Keystone Building, 530 Davis Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Linda K. Bass, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709. (919) 541–1307. *bass@niehs.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund