

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pulmonary-Allergy Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Pulmonary-Allergy Drugs Advisory Committee. This meeting was announced in the **Federal Register** of May 11, 2004 (69 FR 26169). The amendment is being made to reflect a change in the location portion of the meeting, a clarification in the agenda portion of the meeting, and a change in the procedure portion regarding the time for the open public hearing session. There are no other changes.

FOR FURTHER INFORMATION CONTACT:

Shalini Jain, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, or e-mail: jains@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512545. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 11, 2004, FDA announced that a meeting of the Pulmonary-Allergy Drugs Advisory Committee will be held on June 10, 2004. On page 26170, in the first column, the location, agenda, and procedure portions of the meeting are amended to read as follows:

Location: Holiday Inn, Two Montgomery Village Ave., Gaithersburg, MD.

Agenda: The committee will discuss whether the use of chlorofluorocarbons (CFCs) as propellants in albuterol metered-dose inhalers (MDIs) is no longer an essential use under the criteria as set forth in the Code of Federal Regulations (21 CFR § 2.125(g)).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 24, 2004. Oral presentations from the public will be scheduled between approximately 12:30 p.m. to 2:30 p.m. Time allotted for each presentation may be limited. Those

desiring to make formal oral presentations should notify the contact person by May 24, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

This notice is given under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: May 25, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) published in the **Federal Register** on April 11, 1988 (53 FR 11970), and revised in the **Federal Register** on June 9, 1994 (59 FR 29908) and on September 30, 1997 (62 FR 51118). A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from HHS' National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at <http://workplace.samhsa.gov> and <http://www.drugfreeworkplace.gov>.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersch or Dr. Walter Vogl, Division of Workplace Programs, 5600

Fishers Lane, Rockwall 2, Room 815, Rockville, Maryland 20857; 301-443-6014 (voice), 301-443-3031 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100-71. Subpart C of the Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards that laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection.

To maintain that certification, a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines, the following laboratories meet the minimum standards set forth in the Mandatory Guidelines:

ACL Laboratories 8901 W. Lincoln Ave.
West Allis, WI 53227

414-328-7840 / 800-877-7016
(Formerly: Bayshore Clinical Laboratory)

ACM Medical Laboratory, Inc.
160 Elmgrove Park
Rochester, NY 14624
585-429-2264

Advanced Toxicology Network
3560 Air Center Cove, Suite 101
Memphis, TN 38118
901-794-5770 / 888-290-1150

Aegis Analytical Laboratories, Inc.
345 Hill Ave.
Nashville, TN 37210
615-255-2400

Baptist Medical Center-Toxicology
Laboratory

9601 I-630, Exit 7
Little Rock, AR 72205-7299
501-202-2783

(Formerly: Forensic Toxicology Laboratory
Baptist Medical Center)

Clinical Reference Lab
8433 Quivira Rd.
Lenexa, KS 66215-2802
800-445-6917

Diagnostic Services Inc., dba DSI
12700 Westlinks Dr.
Fort Myers, FL 33913
239-561-8200 / 800-735-5416

DrugProof, Division of Dynacare/Laboratory
of Pathology, LLC
1229 Madison St., Suite 500, Nordstrom
Medical Tower