public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive “In Vitro Diagnostic 2009 H1N1 Tests for Use in the 2009 H1N1 Emergency,” you may either send an e-mail request to dsmsca@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1706 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, Federal Register reprints on premarket submissions (including lists of approved applications and manufacturers’ addresses), small manufacturer’s assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at http://www.fda.gov/cdrh. A search capability for all CDRH guidance documents is available at http://www.fda.gov/cdrh/guidance.html. Guidance documents are also available at http://www.regulations.gov.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance documents. 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 part 814 have been approved under OMB Control No. 0910–0231; the collections of information in 21 CFR part 807 Subpart E have been approved under OMB Control No. 0910–0120; the collections of information in 21 U.S.C. 360bbb–3(b) have been approved under OMB Control No. 0910–0584; the collections of information in 21 CFR part 812 have been approved under OMB Control No. 0910–0078; the collections of information in 21 CFR part 56 have been approved under OMB Control No. 0910–0130; the collections of information in Section 564(b)(1) of the FD&C Act have been approved under OMB Control No. 0910–0595; the collections of information in 21 CFR part 820 have been approved under OMB Control No. 0910–0073; and the collections of information in 21 CFR 809.10 have been approved under OMB Control No. 0910–0485.

V. 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.

Dated: November 2, 2009.

David Horowitz,
Assistant Commissioner for Policy.

[FR Doc. E9–26737 Filed 11–5–09; 8:45 am]
BILLING CODE 4160–01–S

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). The Mandatory Guidelines were first published in the Federal Register on April 11, 1988 (53 FR 11970), and subsequently revised in the Federal Register on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

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 the 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://www.workplace.samhsa.gov and http://www.drugfreeworkplace.gov.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 2–1042, One Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. Subpart C of the Mandatory Guidelines, “Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,” sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens 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 undergo 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 described 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 dated April 13, 2004 (69 FR 19644), the following laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:


Aegis Analytical Laboratories, 345 Hill Ave., Nashville, TN 37210, 615–255–2400. (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc.).

Baptist Medical Center-Toxicology Laboratory, 9601 I–630, Exit 7, Little
Rock, AR 72205–7290, 501–202–2783,
(Formerly: Forensic Toxicology
Laboratory Baptist Medical Center).
Clendo Reference Laboratory, Avenue
Santa Cruz #58, Bayamon, Puerto Rico
00950, 787–620–9095.
Clinical Reference Lab, 8433 Quivira
Road, Lenexa, KS 66215–2802, 800–
445–6917.
Doctors Laboratory, Inc., 2906 Julia
Drive, Valdosta, GA 31602, 229–671–
2281.
DrugScan, P.O. Box 2969, 1119
Means Road, Warminster, PA 18974,
DynALIFE Dx *, 10150–102 St., Suite
66219, 913–888–3927/800–873–8845,
(Formerly: Dynacare Kasper Medical
Laboratories).
ElSohly Laboratories, Inc., 5 Industrial
Park Drive, Oxford, MS 38655, 662–
236–2609.
Gamma-Dynacare Medical
Laboratories*, A Division of the
Gamma-Dynacare Laboratory
Partnership, 245 Pall Mall Street,
London, ONT, Canada N6A 1P4, 519–
679–1630.
Kroll Laboratory Specialists, Inc., 1111
Newton St., Gretna, LA 70053, 504–
361–8989/800–433–3823, (Formerly:
Laboratory Specialists, Inc.), Kroll
Laboratory Specialists, Inc., 450
Southlake Blvd., Richmond, VA
23236, 804–378–9130, (Formerly: Scien-
tific Testing Laboratories, Inc.;
Kroll Scientific Testing Laboratories,
Inc.).
Laboratory Corporation of America
Holdings, 7207 N. Gessner Road,
Houston, TX 77040, 713–856–8288/
800–800–2387.
Laboratory Corporation of America
Holdings, 69 First Ave., Raritan, NJ
08869, 908–526–2400/800–437–4986,
(Formerly: Roche Biomedical
Laboratories, Inc.).
Laboratory Corporation of America
Holdings, 1904 Alexander Drive,
Research Triangle Park, NC 27709,
919–572–6900/800–833–3984,
(Formerly: LabCorp Occupational
Testing Services, Inc.;
CompuChem Laboratories, Inc.;
CompuChem Laboratories, Inc., A Subsidiary
of Roche Biomedical Laboratory; Roche
CompuChem Laboratories, Inc., A Member of the Roche Group).
Laboratory Corporation of America
Holdings, 1120 Main Street,
Southaven, MS 38671, 666–827–8042/
800–233–6339, (Formerly: LabCorp
Occupational Testing Services, Inc.;
MedExpress/National Laboratory
Center).
LabOne, Inc. d/b/a Quest Diagnostics,
10101 Renner Blvd., Lenexa, KS
66219, 913–888–3927/800–873–8845,
(Formerly: Quest Diagnostics
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, 402 W.
County Road D, St. Paul, MN 55112,
MetroLab Legacy Laboratory Services,
1225 NE. 2nd Ave., Portland, OR
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,
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,
800–326–6942, (Formerly: Centinela
Hospital Airport Toxicology
Laboratory).
Pathology Associates Medical
Laboratories, 110 West Cliff Dr.,
Spokane, WA 99204, 509–755–59219/
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, 480
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,
866–370–6969/819–989–2521,
(Formerly: SmithKline Beecham
Clinical Laboratories).
S.E.D. Medical Laboratories, 5601 Office
Bld., Albuquerque, NM 87109, 505–
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
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.
Elaine Parry,
Director, Office of Program Services,
SAMHSA.
[FR Doc. E9–26796 Filed 11–5–09; 8:45 am]
BILLING CODE 4160–20–P
DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Allergy and Infectious Diseases; 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,
* 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 the 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 16944). 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.