VI. Implementation of Adjusted Fee Schedule

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application or supplement subject to fees under PDUFA that is received after September 30, 2007. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Please include the user fee ID number on your check. Your payment can be mailed to: Food and Drug Administration, P.O. Box 70963, Charlotte, NC 28272–0963.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: Wachovia Bank, Attn: Food and Drug Administration Lockbox 70963, 1525 West WT Harris Blvd., rm. NC0810, Charlotte, NC 28262. (Note: This Wachovia Bank address is for courier delivery only.)

Please make sure that the FDA post office box number (P.O. Box 70963) is written on the check. The tax identification number of the Food and Drug Administration is 53–0196965.

Wire transfer payment may also be used. The routing and transit number is 021000004 and the account number is 75060909. Please include, as the reference, the NDA/BLA number and the user fee ID number.

FDA is in the process of implementing alternate Web-based payment methods. For more information on these payment options and when they will be available, please visit FDA’s Web site at http://www.fda.gov, select the appropriate user fee type, and click on “User Fee Cover Sheet.”

B. Establishment and Product Fees

FDA will issue invoices for establishment and product fees for FY 2008 under the new fee schedule in October 2007. Payment will be due 30 days from the date of the invoice. FDA will issue invoices in November 2008 for any products and establishments subject to fees for FY 2008 that qualify for fees after the October 2007 billing.


Randall W. Lutter,
Deputy Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0309]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Electrocardiograph Electrodes; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of October 4, 2007 (72 FR 56771). The document announced the availability of a draft guidance entitled “Class II Special Controls Guidance Document: Electrocardiograph Electrodes.” The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce A. Strong, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. E7–19578, appearing on page 56771 in the Federal Register of Thursday, October 4, 2007, the following correction is made:

1. On page 56771, in the third column, in the heading of the document, “[Docket No. 2007D–0309]” is corrected to read “[Docket No. 2007D–0309].”


Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. E7–20183 Filed 10–11–07; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Draft Policy Documents for Comment

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Extension of requests for comments deadline.


Correction: In the Federal Register of August 29, 2007, FR Doc. E7–17092, on page 49724, in the first column, under DATES, the deadline for comments has been extended to October 19, 2007.


Dennis P. Williams,
Deputy Administrator.

[FR Doc. E7–20183 Filed 10–11–07; 8:45 am]

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.
Road, Lenexa, KS 66215
Laboratory Baptist Medical Center)
Laboratories, Inc.)
2400. (Formerly: Aegis Analytical
TN 38118, 901
2610 (fax).

SUPPLEMENTARY INFORMATION: The
Mandatory Guidelines were developed in
accordance with Executive Order
20857; 240
Cherry Road, Rockville, Maryland
SAMHSA/CSAP, Room 2
–
6917.

FOR FURTHER INFORMATION CONTACT:
Mrs. Giselle Hersh or Dr. Walter Vogl,
Division of Workplace Programs,
SAMHSA/CSAP, Room 2–1035, 1 Choke
Cherry Road, Rockville, Maryland
20857; 240–276–2600 (voice), 240–276–
2610 (fax).

This notice is also available on the
Internet at http://

Diagnostic Services, Inc., dba DSI,
12700 Westlinks Drive, Fort Myers, FL
Doctors Laboratory, Inc., 2906 Julia
Drive, Valdosta, GA 31602, 229–671–
2281.
DrugScan, Inc., P.O. Box 2969, 1119
Mearns Road, Warminster, PA 18974,
Dynacare Kasper Medical
Laboratories,* 10150–102 St., Suite 200,
Edmonton, Alberta, Canada T5J 5E2,
ElsOhly Laboratories, Inc.,
Industrial Park Drive, Oxford, MS
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,
(Formerly: Laboratory Specialists, Inc.)
Kroll Laboratory Specialists, Inc.,
450 Southlake Blvd., Richmond, VA 23236,
804–378–9130. (Formerly: Scientific
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
(Formerly: Roche Biomedical
Laboratories, Inc.)
Laboratory Corporation of America
Holdings, 1904 Alexander Drive,
Research Triangle Park, NC 27709, 919–
(Formerly: LabCorp Occupational Testing Services, Inc.;
Computichem Laboratories, Inc.;
Computichem Laboratories, Inc., A
Subsidiary of Roche Biomedical
Laboratory; Roche Computichem
Laboratories, Inc., A Member of the
Roche Group)
Laboratory Corporation of America
Holdings, 13112 Evening Creek Drive,
Suite 100, San Diego, CA 92128, 858–
668–3710/800–882–7272. (Formerly:
Poisonlab, Inc.)
Laboratory Corporation of America
Holdings, 550 17th Ave., Suite 300,
Seattle, WA 98122, 206–923–7020/800–
898–0180. (Formerly: DrugProof,
Division of Dynacare/Laboratory of
Pathology, LLC; Laboratory of Pathology
of Seattle, Inc.; DrugProof, Division
of Laboratory of Pathology of Seattle, Inc.)
Laboratory Corporation of America
Holdings, 2400 Grand Main Street, Southaven,
MS 38671, 866–827–8042/800–233–
6339. (Formerly: LabCorp Occupational
Testing Services, Inc.; MedExpress/
National Laboratory Center)
LabOne, Inc. d/b/a Quest Diagnostics,
10101 Renner Blvd., Lenexa, KS 66219,
(Formerly: Quest Diagnostics
Incorporated; LabOne, Inc.; Center for
Laboratory Services, a Division of
LabOne, Inc.)
Marshfield Laboratories, Forensic
Toxicology Laboratory, 1000 North Oak
Ave., Marshfield, WI 54449, 715–389–
3734/800–331–3734.
MAXXAM Analytics Inc.*, 6740
Campobello Road, Mississauga, ON,
Canada L5N 2L8, 905–817–5700.
(Formerly: NOVAMANN (Ontario), Inc.)
MedTox Laboratories, Inc., 402 W.
County Road D, St. Paul, MN 55112,
MetroLab-Legacy Laboratory Services,
1225 NE 2nd Ave., Portland, OR 97232,
Minneapolis Veterans Affairs Medical
Center, Forensic Toxicology Laboratory,
1 Veterans Drive, Minneapolis,
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)
Oregon Medical Laboratories, 123
International Way, Springfield, OR
97477, 541–341–8092.
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.
Physicians Reference Laboratory,
7800 West 110th St., Overland Park, KS
Quest Diagnostics Incorporated, 3175
Presidential Dr., Atlanta, GA 30340,
(Formerly: SmithKline Beecham
Clinical Laboratories; SmithKline Bio-
Science Laboratories)
Quest Diagnostics Incorporated, 400
Egypt Road, Norristown, PA 19403,
(Formerly: SmithKline Beecham
Clinical Laboratories; SmithKline Bio-
Science Laboratories)
SmithKline Beecham Clinical Laboratories.
South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 574–234–4176 x276.
Sparrow Health System, Toxilogy Testing Center, St. Lawrence Campus, 1210 W. Saginaw, Lansing, MI 48915, 517–364–7400. (Formerly: St. Lawrence Hospital & Healthcare System)
St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405–272–7052.
Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 573–882–1273.
U.S. 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 HHS National Laboratory Certification Program on October 12, 2007:
Meriter Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6225. (Formerly: General Medical Laboratories)
*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,
Acting Director, Office of Program Services, SAMHSA.
[FR Doc. E7–20203 Filed 10–11–07; 8:45 am]
BILLING CODE 4160–20–P
DEPARTMENT OF HOMELAND SECURITY
[Docket No. DHS–2007–0069]
Committee Name: Homeland Security Information Network Advisory Committee; Notice of Federal Advisory Committee Meeting
AGENCY: Department of Homeland Security.
ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.
SUMMARY: The Homeland Security Information Network (HSIN) Advisory Committee will meet on October 31, 2007, in Potomac, MD. The meeting will be open to the public.
DATES: The HSINAC will meet Wednesday, October 31, 2007, from 9 a.m. to 4:30 p.m. and on Thursday, November 1, 2007, from 8:30 a.m. to 12 p.m. Please note that the meeting may close early if the committee has completed its business.
ADDRESSES: The meeting will be held at Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854–4436. Send written material, comments, and requests to make oral presentations to Elliott Langer, Department of Homeland Security, 245 Murray Lane, SW., Bldg 410, Washington, DC 20528. Written materials, comments, and requests to make oral presentations at the meeting should reach the contact person listed below by October 20, 2007. Requests to have a copy of your material distributed to each member of the committee prior to the meeting should reach the contact person at the address above by October 20, 2007. Comments must be identified by DHS–2007–0069 and may be submitted by one of the following methods:
• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
• E-mail: elliott.langer@dhs.gov. Include the docket number in the subject line of the message.
• Fax: 202–282–8191.

For information on services for individuals with disabilities
For information on services or facilities for individuals with disabilities or to request special assistance at the