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 021030004 and the account number is 75060099. 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Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Electrocardiograph Electrodes; Availability; Correction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 The document announced the availability of a draft guidance entitled “Class II Special Controls Guidance Document: Electrocardiograph Electrodes.”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.

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 16444). 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 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).

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 Main 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 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:

- ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016. (Formerly: Bayshore Clinical Laboratory)
- Aegis Sciences Corporation, 345 Hill Ave., Nashville, TN 37210, 615–255–2400. (Formerly: Aegis Analytical Laboratories, Inc.)
- 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)
- DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974, 215–674–9310.
- Kroll Laboratory Specialists, Inc., 1111 Newton St., Greta, LA 70053, 504–361–8989 / 800–433–3823. (Formerly: Laboratory Specialists, 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, 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 98112, 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, 1626 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, 913–888–3927 / 800–873–8845. (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)
- MAXXAM Analytics Inc.,* 6740 Campus Boulevard, Mississauga, ON, Canada L5N 2L8, 905–817–5700. (Formerly: NOVAMANN (Ontario), Inc.)
- Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2008.
- 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, 509–755–8991/800–541–7891X.
- Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121, 858–643–5555.
- Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216. (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline BioScience Laboratories)
- Quest Diagnostics Incorporated, 7600 Tyrone Ave., Van Nuys, CA 91405, 866–370–6699 818–989–2521. (Formerly:}
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 (HSINAC) 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 below by October 20, 2007. Comments must be identified by DHS–2007–0069 and may be submitted by one of the following methods:
- E-mail: elliott.langer@dhs.gov. Include the docket number in the subject line of the message.
- Fax: 202–282–8191.


Instructions: All submissions received must include the words “Department of Homeland Security” and the docket number for this action. Comments received will be posted without alteration at www.regulations.gov, including any personal information provided.

Docket: For access to the docket to read background documents or comments received by the Homeland Security Information Network Advisory Committee, go to http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–463). The mission of the HSINAC is to identify issues and provide independent advice and recommendations for the improvement of HSIN to senior leadership of the Department, in particular the Director of Operations Coordination. The agenda for the first meeting will consist of a briefing on the development of HSIN and identifying overarching strategic issues concerning HSIN development as well as user operational requirements. In addition, discussions will provide an opportunity for initial discussion to identify issues and concerns held by state, local, tribal and private sector users.

Procedural
This meeting is open to the public. Please note that the meeting may close early if all business is finished.
Participation in HSINAC deliberations is limited to committee members, Department of Homeland Security officials, and persons invited to attend the meeting for special presentations.
All visitors to Bolger Center will have to pre-register to be admitted to the building. Please provide your name, telephone number by close of business on October 20, 2007, to Elliott Langer (202–282–8978) (elliott.langer@dhs.gov).

Information on Services for Individuals With Disabilities
For information on facilities or services for individuals with disabilities or to request special assistance at the