

Respondents to this information collection are applicants holding approved applications for human drugs and licensed biological products that are required or have committed to conduct postmarketing studies.

Based on agency data, there are approximately 152 drug applicants who are required or who have committed to conduct approximately 935 postmarketing studies, and approximately 44 applicants holding approved biologics license applications who are required or who have

committed to conduct approximately 223 postmarketing studies. The agency assumes that all of the estimated 196 respondents would voluntarily submit approximately 1,158 redacted versions of each study in their annual status reports. Based on FDA experience, the agency estimates that an applicant would expend a total of 0.5 hours preparing a redacted version of each study in the status report that already has been formatted and completed for submission.

In the **Federal Register** of April 4, 2001 (66 FR 17912), FDA announced the availability of the draft guidance and requested comments for 60 days on the information collection. No comments were received that pertained to information collection estimates.

FDA estimates the burden of this collection of information as shown in table 1 of this document. The estimates have been updated from the April 4, 2001, notice to reflect current data.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

Title	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
Center for Drug Evaluation and Research	152	approx. 6	935	0.5	467.50
Center for Biologics Evaluation and Research	44	approx. 5	223	0.5	111.50
Total					579

Dated: October 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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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 Hersh 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 Public Law 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.
Alliance Laboratory Services, 3200 Burnet Ave., Cincinnati, OH 45229, 513-585-6870 (Formerly: Jewish Hospital of Cincinnati, 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).
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, Seattle, WA 98104, 206-386-2661/800-898-0180

- (Formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.).
- DrugScan, Inc., P.O. Box 2969, 1119 Mearns Rd., Warminster, PA 18974, 215-674-9310.
- Dynacare Kasper Medical Laboratories*, 10150-102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2, 780-451-3702/800-661-9876.
- ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 662-236-2609.
- Express Analytical Labs, 3405 7th Ave., Suite 106, Marion, IA 52302, 319-377-0500.
- Gamma-Dynacare Medical Laboratories*, A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall St., London, ONT, Canada N6A 1P4, 519-679-1630.
- General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608-267-6225.
- Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504-361-8989/800-433-3823 (Formerly: Laboratory Specialists, Inc.).
- LabOne, Inc., 10101 Renner Blvd., Lenexa, KS 66219, 913-888-3927/800-873-8845 (Formerly: Center for Laboratory Services, a Division of LabOne, Inc.).
- Laboratory Corporation of America Holdings, 7207 N. Gessner Rd., 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 Dr., 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, 10788 Roselle St., San Diego, CA 92121, 800-882-7272 (Formerly: Poisonlab, Inc.).
- Laboratory Corporation of America Holdings, 1120 Stateline Rd. West, Southaven, MS 38671, 866-827-8042/800-233-6339 (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center).
- Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave., Marshfield, WI 54449, 715-389-3734/800-331-3734.
- MAXXAM Analytics Inc.*, 5540 McAdam Rd., Mississauga, ON, Canada L4Z 1P1, 905-890-2555 (Formerly: NOVAMANN (Ontario) Inc.).
- MedTox Laboratories, Inc., 402 W. County Rd. D, St. Paul, MN 55112, 651-636-7466/800-832-3244.
- MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503-413-5295/800-950-5295.
- Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Dr., Minneapolis, MN 55417, 612-725-2088.
- National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661-322-4250/800-350-3515.
- Northwest Drug Testing, a division of NWT Inc., 1141 E. 3900 S., Salt Lake City, UT 84124, 801-293-2300/800-322-3361 (Formerly: NWT Drug Testing, NorthWest Toxicology, Inc.).
- One Source Toxicology Laboratory, Inc., 1705 Center St., Deer Park, TX 77536, 713-920-2559 (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory).
- Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440-0972, 541-687-2134.
- 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, 509-755-8991/800-541-7891 x8991.
- PharmChem Laboratories, Inc., 4600 N. Beach, Haltom City, TX 76137, 817-605-5300 (Formerly: PharmChem Laboratories, Inc., Texas Division; Harris Medical Laboratory).
- Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913-339-0372/800-821-3627.
- 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, 4770 Regent Blvd., Irving, TX 75063, 800-824-6152 (Moved from the Dallas location on 03/31/01; Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).
- Quest Diagnostics Incorporated, 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119-5412, 702-733-7866/800-433-2750 (Formerly: Associated Pathologists Laboratories, Inc.).
- Quest Diagnostics Incorporated, 400 Egypt Rd., Norristown, PA 19403, 610-631-4600/877-642-2216 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).
- Quest Diagnostics Incorporated, 506 E. State Pkwy., Schaumburg, IL 60173, 800-669-6995/847-885-2010 (Formerly: SmithKline Beecham Clinical Laboratories; International Toxicology Laboratories).
- Quest Diagnostics Incorporated, 7600 Tyrone Ave., Van Nuys, CA 91405, 818-989-2520/800-877-2520 (Formerly: SmithKline Beecham Clinical Laboratories).
- Scientific Testing Laboratories, Inc., 450 Southlake Blvd., Richmond, VA 23236, 804-378-9130.
- Sciteck Clinical Laboratories, Inc., 317 Rutledge Rd., Fletcher, NC 28732, 828-650-0409.
- 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, 2727 W. Baseline Rd., Tempe, AZ 85283, 602-438-8507/800-279-0027.
- Sparrow Health System, Toxicology Testing Center, St. Lawrence Campus, 1210 W. Saginaw, Lansing, MI 48915, 517-377-0520 (Formerly: St. Lawrence Hospital & Healthcare System).
- St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405-272-7052.
- Sure-Test Laboratories, Inc., 2900 Broad Ave., Memphis, TN 38112, 901-474-6026.
- Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 2703 Clark Lane, Suite B, Lower Level, Columbia, MO 65202, 573-882-1273.
- Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305-593-2260.
- US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755-5235, 301-677-7085.
- The following laboratory's certification was suspended on October 6, 2003:
- Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31602, 912-244-4468.

* 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 June 9, 1994 (59 FR 29908), and on September 30, 1997 (62 FR 51118). 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.

Dated: October 30, 2003.

Anna Marsh,

Acting Executive Officer, SAMHSA.

[FR Doc. 03-27797 Filed 11-4-03; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA-2003-16345]

Notice Requesting Comment on the Imposition of the Aviation Security Infrastructure Fee

AGENCY: Transportation Security Administration (TSA), DHS.

ACTION: Notice; request for comments.

SUMMARY: TSA seeks comment on possible changes to the way it sets the Aviation Security Infrastructure Fee (ASIF), which is a fee imposed on air carriers and foreign air carriers to help pay the Government's costs of providing civil aviation security services. Beginning in fiscal year 2005, TSA may set the per-carrier fee based on each carrier's market share or other appropriate factors. TSA seeks comments on issues such as how to impose the ASIF, and whether, when, and how often the ASIF should be adjusted.

DATES: Submit comments by January 5, 2004.

ADDRESSES: *Comments Submitted by Mail or In Person:* Address written,

signed comments to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590-0001.

Comments that include trade secrets, confidential commercial or financial information, or sensitive security information (SSI) should not be submitted to the public regulatory docket. Please submit such comments separately from other comments. Comments containing trade secrets, confidential commercial or financial information, or SSI should be appropriately marked as containing such information and submitted by mail to the individual listed in **FOR FURTHER INFORMATION CONTACT**.

Comments Filed Electronically: You may also submit comments through the Internet at <http://dms.dot.gov>. Please be aware that anyone is able to search the electronic form of all comments received into any of these dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the applicable Privacy Act Statement in the **Federal Register** published on April 11, 2000, (65 FR 19477) or you may visit <http://dms.dot.gov>.

Reviewing Comments In the Docket: All submissions to the public docket may be viewed in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Dockets Office is on the plaza level of the NASSIF Building at the Department of Transportation at the above address. Also, you may review public dockets on the Internet at <http://dms.dot.gov>.

See **SUPPLEMENTARY INFORMATION** for format and other information about comment submissions.

FOR FURTHER INFORMATION CONTACT: Randall Fiertz, Office of Revenue, Transportation Security Administration Headquarters, West Building, Floor 5, TSA-14, 601 South 12th Street, Arlington, VA 22202; e-mail: TSA-Fees@dhs.gov, telephone: 571-227-2323.

SUPPLEMENTARY INFORMATION:

Comments Invited

The TSA invites interested persons to submit written comments, data, or views on the issues described in this notice, including comments relating to the economic, environmental, energy, or federalism impacts. See **ADDRESSES** above for information on where to submit comments.

Do not submit to the public regulatory docket any comments that you believe include trade secrets, confidential commercial or financial information, or sensitive security information (SSI) governed by 49 CFR part 1520. Such comments should be appropriately marked as containing such information and submitted by mail to the individual listed in **FOR FURTHER INFORMATION CONTACT**. When a commenter properly designates and submits confidential commercial or financial information or information the submitter considers to be a trade secret, TSA does not place it in the public docket and TSA will handle it in accordance with applicable safeguards and restrictions on access. TSA will hold it in a separate file to which the public does not have access, and place a note in the public docket that TSA has received such materials from the commenter. If TSA receives a request to examine or copy this information, TSA would treat the request as any other request under the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the Department of Homeland Security's FOIA regulation found in 6 CFR part 5.

With each comment, please include your name and address, identify the docket number at the beginning, and give the reason for each comment, including any supporting data. You may submit comments and material electronically, in person, or by mail as provided under **ADDRESSES**, but please submit your comments and material by only one means. If you submit comments by mail or delivery, submit them in two copies, in an unbound format, no larger than 8.5 by 11 inches, suitable for copying and electronic filing.

If you want the TSA to acknowledge receipt of your comments, include with your comments a self-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it to you.

Except for comments properly submitted as containing confidential information or SSI, we will file in the public docket all comments we receive. The docket is available for public inspection before and after the comment closing date.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late to the extent practicable.

Document Availability

You can get an electronic copy using the Internet by—

(1) Searching the Department of Transportation's electronic Docket