

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In the **Federal Register** of April 4, 2001 (66 FR 17912), FDA announced the availability of the draft guidance and requested comments for 60 days on the information collection.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