the risks and about protective measures allows consumers to more accurately assess how much they would pay for reductions in this risk, but more importantly, it also informs the consumer as to what the risks are and how they can protect themselves. This information is important since the consumer is the last line of defense in the campaign against foodborne illnesses. The total burden hours are 1,000.

Instrument	Number of respondents	Number of responses/ respondent	Hours per response
Mail survey	3,000	1	20/60

Dated: October 28, 2003.

Gaylon D. Morris,

Acting Director, Executive Secretariat, Centers for Disease Control and Prevention.

[FR Doc. 03–27796 Filed 11–4–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999N–1852]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; ''Draft Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997''

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by December 5, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Draft Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997

FDA is requesting OMB approval under the PRA (44 U.S.C. 3507) for the reporting requirements contained in the draft guidance for industry entitled ''Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997.'' The draft guidance provides recommendations on these topics:

- Procedures, content, and format for submitting a postmarketing study status report for an approved human drug or licensed biological product;
- Timeframes for FDA's review of postmarketing studies; and
- Information about postmarketing studies that will be available to the public.

The draft guidance is intended to assist applicants in meeting the requirements of section 130 of the Food and Drug Administration Modernization Act of 1997. Section 506B ''Reports of Postmarketing Studies'' of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 356b) provides FDA with additional authority for monitoring the progress of postmarketing studies that drug and biologics applicants have made a commitment to conduct. Postmarketing studies are those studies conducted after approval to gather information about approved drug or biologics products. Such studies are used to gather additional information about product safety, efficacy, or optimal use.

Under 506B(a) of the act, an applicant who has entered into an agreement with FDA to conduct a postmarketing study is required to provide the agency with an annual report on the status of the study until the study is completed or terminated. The annual report must address the progress of the study or the reasons for the failure of the applicant to conduct the study. Section 506B(c) of the act directs FDA to develop and publish annually in the **Federal Register** a report on the status of postmarketing studies that applicants have made a commitment to conduct and for which status reports have been submitted. In the **Federal Register** of October 30, 2000 (65 FR 64607), the agency published a final rule to implement section 506B of the act. The final rule made several changes to the regulations for approved human drugs and licensed biological products.

The draft guidance is intended to provide information on the following topics: (1) Procedures concerning the submission of postmarketing study status reports; (2) the content and format of a postmarketing study status report; (3) timeframes for FDA's review of postmarketing study reports; and (4) information about postmarketing studies that will be available to the public. The draft guidance applies to postmarketing studies for approved human drug products and licensed biological products that meet the definition of ''drug'' under the act. It does not apply to biological products that meet the definition of medical ''device'' under the act, or to veterinary drug products, which will be addressed separately.

In addition to the information collection provisions covered by the October 30, 2000, final rule, the guidance recommends an additional reporting requirement. The draft guidance proposes that applicants with postmarketing study commitments submit with their annual report a redacted version of each status report that already has been formatted and completed for submission. The draft guidance requests that applicants redact complete reports to the extent necessary to protect trade secrets or to conceal individual patient identifiers. FDA will use this redacted report for release to the public on its Web site and in the report on the status of postmarketing studies required under section 506B(c) of the act. FDA will accept the redacted version of the applicant's status report either in an electronic format compatible with FDA's electronic database or in hard copy.

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.

[FR Doc. 03–27717 Filed 11–4–03; 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) 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