style than they were prior to participating in the training? Cross-site evaluation data will be collected on an annual basis throughout the five-year funding period. Pre-test and follow-up versions of the survey are expected to require approximately 10 to 15 minutes to complete. Estimated response time for the follow-up survey includes time for respondents to access the Web-based survey, complete the survey online, and electronically submit the survey. Respondents will not need to implement a recordkeeping system or compile source data in order to complete the survey. Where possible, fields in the follow-up version of the survey will be pre-filled with static data from the respondents pre-test (*e.g.*, demographics, agency type) in order to further expedite completion of the survey and minimize respondent burden.

Respondents: Infant Adoption Awareness Program Trainees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
IAATP: Trainee Survey Pre-Test Administration	1,200	1	0.15	180
IAATP: Trainee Survey Follow-Up Administration	1,200	1	0.10	120

Estimated Total Annual Burden Hours: 300.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: October 1, 2008.

Janean Chambers,

Reports Clearance Officer.

Editorial Note: This document was received at the Office of the Federal Register on January 5, 2009.

[FR Doc. E9–100 Filed 1–7–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0464] (formerly Docket No. 2005N–0403)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing

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.

DATES: Fax written comments on the collection of information by February 9, 2009.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0045. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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 on Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing; Availability; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution—(OMB Control Number 0910–0045—Amendment)

Description of Respondents: Respondents to this collection of information are foreign and domestic owners and operators of establishments that engage in the manufacture, preparation, propagation, compounding, or processing (which includes, among other things, repackaging and relabeling) of a drug or drugs[1] and that are not exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act (the act) or subpart B of part 207 (21 CFR part 207) (registrants).

A. Reporting Burden

The draft guidance describes how to electronically create and submit Structured Product Labeling (SPL) files using defined code sets and codes for establishment registration and drug listing information (including labeling). Most information is already required to be submitted under section 510 of the act, section 351 of the Public Health Service Act, and part 207.

Drug establishment registration and drug listing information and updates to such information, required under part 207, and certain additional recommended information are currently submitted in paper form using Form FDA 2656 (Registration of Drug

[1] Means both human, including biological products, and animal drugs.

Establishment/Labeler Code Assignment), Form FDA 2657 (Drug Product Listing), and Form FDA 2658 (Registered Establishments Report of Private Label Distributors) (collectively referred to as FDA Forms; 72 FR 67733, November 30, 2007).

In addition to the information collected by the FDA Forms (72 FR 67733, November 30, 2007), the draft guidance addresses electronic submission of other required information as follows:

- For registered foreign drug establishments, the name, address, and telephone number of its U.S. agent (§ 207.40(c));
- The name of each importer that is known to the establishment (the U.S. company or individual in the United States that is an owner, consignee, or recipient of the foreign establishment's drug that is imported into the United States. An importer does not include the consumer or patient who ultimately purchases, receives, or is administered the drug, unless the foreign establishment ships the drug directly to the consumer or the patient) (section 510(i)(1)(A) of the act); and
- The name of each person who imports or offers for import (the name of each agent, broker, or other entity, other than a carrier, that the foreign drug establishment uses to facilitate the import of their drug into the United States) (section 510(i)(1)(A) of the act).

FDA also is recommending the voluntary submission of the following additional information, when applicable:

- To facilitate correspondence between foreign establishments and FDA, the e-mail address for the U.S. agent, and the telephone number(s) and e-mail address for the importer and person who imports or offers for import their drug;
- A site-specific D-U-N-S® Number[2] for each entity (e.g., the registrant, establishments, U.S. agent, importer);
- The National Drug Code product code for the source drug that is repacked or relabeled;
- Distinctive characteristics of certain listed drugs, i.e., the flavor, the color, and image of the actual solid dosage form; and
- Registrants may indicate that they view as confidential the registrant's business relationship with an establishment, or an inactive ingredient.

[2] D&B® D-U-N-S® Number is a unique nine-digit sequence recognized as the universal standard for identifying and keeping track of over 100 million businesses worldwide. Submitting the site-specific D-U-N-S® Number for an entity would provide by reference to the number certain business information for that entity, e.g., address, parentage.

In addition to the collection of information, there is additional burden for the following activities:

- Preparing a standard operating procedure (SOP) for the electronic submission of drug establishment registration and drug listing information;
- Creating the SPL file, including accessing and reviewing the technical specifications and instructional documents provided by FDA (accessible at *http://www.fda.gov/oc/datacouncil/spl.html*);
- Reviewing and selecting appropriate terms and codes used to create the SPL file (accessible at *http://www.fda.gov/oc/datacouncil/spl.html*);
- Obtaining the digital certificate used with FDA's electronic submission gateway (ESG) and uploading the SPL file for submission (accessible at *http://www.fda.gov/esg/default.htm*); and
- Requests for waivers from the electronic submission process as described in the draft guidance.

B. Burden Estimates

Reporting Burden—The estimates for the number of respondents, annual frequency per response, and total annual responses indicated in table 1 of this document are based on our current estimates of the number of registrants and the number of submissions using the FDA Forms (OMB Control No. 0910–0045). FDA estimates that it would take an additional 2 hours per response (in addition to the estimated 2.5 hours per response for registering, labeler code requests, listing, and providing updates to the information approved under OMB Control No. 0910–0045) for the collection of information not currently submitted using the FDA Forms, and to create and upload the SPL file. FDA anticipates that the hours per response will decrease over time due to the flexibility of submitting information for registering multiple establishments or listing multiple drugs in one SPL file instead of submitting individual FDA Forms, and increasing familiarity with the use of the standards and code sets and codes for creating the SPL file.

In certain cases, if it is unreasonable to expect a person to submit registration and listing information electronically, FDA may grant a waiver from the electronic format requirement. Because registrants will only need a computer and access to the Internet, FDA envisions few instances in which electronic submission of registration and listing information will not be reasonable for the person requesting the waiver and, thus, is estimating that FDA would grant one waiver annually. We estimate that a one-time burden for requesting a waiver would be an hour of time for a mid-level manager to draft, approve, and mail a letter.

Recordkeeping Burden—In table 2 of this document, FDA estimates that 3,295 (39 + 3,256) respondents would expend a one-time burden of approximately 40 hours in preparing, reviewing, and approving an SOP for creating and uploading the SPL file; and an estimated 1 hour annually to maintain the SOP as needed.

In the **Federal Register** of July 11, 2008 (73 FR 39964), FDA published a notice of availability of the draft guidance document providing a 60-day public comment period on the information collection provisions. Nineteen comments were received of which four remarked on the information collection. Thereafter, in the **Federal Register** of October 23, 2008 (73 FR 63158), FDA published a 30-day notice responding to the comments submitted on the proposed collection of information and announced that the proposed collection of information had been submitted to OMB. In response to a request by OMB, FDA is republishing the 30-day notice responding to comments and announcing the submission of the proposed collection of information to OMB.

(Comment 1) On the topic whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have a practical utility, one comment agreed that the proposed collection of information is necessary for us to perform its functions and is consistent with the provisions of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85). The comment continued to say that the information is also necessary to support the transition from paper format to electronic format, and that the additional information requested by us is logical and reasonable and is not an undue burden.

(Response) We appreciate the support and concurrence of the comment.

(Comment 2) On the topic whether the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used, one comment stated that we underestimated the effort to prepare, review, approve, implement and maintain internal SOPs for electronic submission of drug establishment registration and drug listing information because of the following reason. Particularly for most large companies, drug establishment registration and drug listing information (currently submitted in paper format under 21 CFR 207.22)

and content of labeling (currently submitted in electronic format under 21 CFR 314.50(l)(1)(i)) are handled by completely different functional experts and/or departments in the companies. To coordinate these processes, additional time is needed to define new procedures and interactions that cross functional departments and possibly international groups. Therefore, large companies will expend more than 40 hours to prepare, review, approve, implement and maintain SOPs.

Another comment asserts that the hours per response in table 1 are underestimated if the estimate accounts for the time required to become familiar with the Structured Product Labeling (SPL) standard.

(Response) In estimating hours per record in table 2 of this document, we considered the various sizes of entities affected and proposed an average number of hours per activity. For example, the estimated 40 hours per record are based on smaller entities requiring approximately 20 hours per record and larger entities requiring approximately 60 hours per record. Therefore, because the comment did not provide a revised estimate, we are maintaining an estimate of 40 hours per record, which is consistent with preparing SOPs for paper format submissions and also includes coordination efforts.

Regarding the comment on underestimating the hours per response in table 1, the software designed to create the SPL files, the step-by-step instructions in the technical guides, and our technical assistance email address are provided by us for the purpose of minimizing the need to learn the SPL standard before submitting information electronically.

In this document, we are correcting an error in table 1 under the hours per response column. Although the written description of the burden added 2 hours to the existing 2.5 hours approved by OMB under Control Number 0910–0045 (for a total of 4.5 hours), 4.5 hours was not correctly reproduced in table 1. The total hours column is also adjusted to reflect this correction.

(Comment 3) On the topic of ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology, one comment encouraged us to continue the availability of Xforms at no cost for industry to use as a software tool for the creation of SPL. The comment also requested that we continue this practice as technology evolves and provide support for this tool.

(Response) We appreciate the encouragement of the comment and will consider the request to continue the practice and provide support as technology evolves.

(Comment 4) Two comments did not agree with our statement that there are no capital or operating and maintenance costs associated with the collection of information. The comments explained that some companies may choose alternative tools to the Xform software or work with external conversion providers, which may involve the purchase and maintenance of software plus the use of internal information technology personnel for installation, configuration and maintenance. These comments further stated that these costs are significant and need to be considered in the overall cost for industry to comply with the electronic submission requirement.

(Response) As the comments stated, companies may choose to use alternative tools or work with external conversion providers. We do not disagree. However, we have made every effort to eliminate costs to industry to comply with the statutory requirement to electronically submit drug establishment registration and drug listing information.

We also received comments that were specifically related to the technical documents referenced in the draft guidance. Although these comments are not directly related to the draft guidance document that contains the information collection, we will consider the comments when reviewing the technical documents for revision.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
New registrations, including new labeler code requests	39	14.72	574	4.5	2,583
Annual updates of registration information	3,256	2.99	9,735	4.5	43,807.5
New drug listings	1,567	6.57	10,295	4.5	46,327.5
New listings for private label distributors	146	10.06	1,469	4.5	6,610.5
June and December updates of all drug listing information	1,677	11.21	18,799	4.5	84,595.5
Waiver requests	1	1	1	1	1
Total					183,924

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
One-time preparation of SOP	3,295	1	3,295	40	131,800

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
SOP maintenance	3,295	1	3,295	1	3,295
Total					135,095

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

C. Costs Associated With Electronic Submission

There are no capital costs or operating and maintenance costs associated with the transition from paper to electronic submissions. To create an SPL file and submit it to FDA, a registrant would need the following tools: A computer, appropriate software, access to the Internet, knowledge of terminology and standards, and access to FDA's ESG.

Registrants (and most individuals) have computers and Internet access available for their use. If a business does not have an available computer or access to the Internet, free use of computers and Internet are usually available at public facilities, e.g., a community library; or they may request a waiver from submitting the information electronically. Software is necessary to create a ''document.'' The SPL file or ''document'' may be created internally by a business with experience with SPL, or a business may use a user-friendly software (XForms)[3] available at no cost for industry use. In addition to the software, FDA also provides technical assistance, and other resources, code sets and codes, and data standards regarding SPL files.[4]

Once the SPL file is created, the registrant would upload the file through the ESG. A digital certificate is needed to use the ESG. The digital certificate binds together the owner's name and a pair of electronic keys (a public key and a private key) that can be used to encrypt and sign documents. However, a small fee of up to $20.00 is charged for the digital certificate and the registrant may need to renew the certificate not less than annually. FDA is not calculating this small fee as cost of doing business because it is less than or equal to the biannual courier costs the registrant incurs for paper submissions.

[3] See *http://www.fda.gov/oc/datacouncil/xforms.html.*

[4] See http://www.fda.gov/oc/datacouncil/spl.html.

Dated: December 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–108 Filed 1–7–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[Funding Announcement Number: HHS–2009–IHS–NIHB–0001]

Office of Tribal Program; Announcement Type: Competing Continuation

Catalog of Federal Domestic Assistance Numbers (s): 93.933

Key Dates: Application Deadline Date: January 9, 2009

Review Date: January 16, 2009

Results Notification: January 21, 2009

Earliest Anticipated Start Date: February 1, 2009

I. Funding Opportunity Description

Authority: The Indian Health Service (IHS) announces that a Single Source cooperative agreement is open for receipt of an application from the National Indian Health Board. This program is authorized under Public Health Service Act, 42 U.S.C. 301. This program is described at 93.933 in the Catalog of Federal Domestic Assistance (CFDA). Purpose: The Office of Tribal Programs (OTP) has designated funds for the Single Source National Indian Health Board (NIHB) to further health program objectives in the American Indian/Alaska Native (AI/AN) community with outreach and education efforts in the interest of improving Indian health care. The NIHB is the only national Indian organization with expertise on the variety of issues related to the provision of health care to Indian people.

The NIHB represents all 562–Federally recognized tribes: including Tribal governments operating their own health care delivery systems through self-determination agreements with the IHS and tribes that continue to receive health care directly from the IHS. The NIHB is governed by twelve elected Tribal Government Officials who represent each of the twelve IHS Areas and the HHS regions where Federally recognized Tribes exist. The NIHB is the only national organization with an expertise in health policy and health programs, and the only national organization with the designated authority to represent all AI/AN tribes and villages. The NIHB has a national constituency and clearly supports critical services and activities within the IHS mission of quality health care for AI/AN people. The NIHB provides policy analysis and development, program assessment and development, regional and national meeting coordination, consultation and health care advocacy to IHS and HHS based on tribal input through a broad based consumer network. Furthermore, the NIHB also provides planning and technical assistance to Tribes, Area Health Boards, and other Tribal organizations through the cooperative agreement with the IHS.

II. Award Information

Type of Award: Cooperative Agreement. A cooperative agreement will be awarded as the OTP staff will have substantial programmatic involvement with the recipient in carrying out the project as noted in the following delineated roles of involvement to further IHS' health program objectives in the AI/AN community with outreach and education efforts in the interest of improving Indian health care.

Cooperative Agreement—Involvement of Parties

This project is a cooperative agreement between the IHS and the NIHB.

Selected entity is responsible for the following:

1. To provide technical advice in the area of health care policy analysis and program development on which IHS needs to take action;

2. To provide consultation that is representative of all Tribal governments in the area of health care policy analysis and program development;

3. To assure that health care advocacy is based on Tribal input through a broad based consumer network involving the Area Indian Health Boards or Health