relationship of any nutrient of the type required to be in the label or labeling of the food to a disease or a health related condition only where that statement meets the requirements of the regulations promulgated by the Secretary of Health and Human Services to authorize the use of such a health claim. Section 101.82 (21 CFR 101.82) of FDA's regulations authorizes a health claim for food labels about soy protein and the risk of coronary heart disease. To bear the soy protein/coronary heart disease health claim, foods must contain at least 6.25 grams of soy protein per reference amount customarily consumed. Analytical methods for measuring total protein can be used to quantify the amount of soy protein in foods that contain soy as the sole source of protein. However, at the present time there is no validated analytical methodology available to quantify the amount of soy protein in foods that contain other sources of protein. For these latter foods, FDA must rely on information known only to the manufacturer to assess compliance with the requirement that the food contain the qualifying amount of soy protein. Thus, FDA requires manufacturers to have and keep records to substantiate the amount of soy protein in a food that bears the health claim and contains sources of protein other than soy, and to make such records available to appropriate regulatory officials upon written request. The information collected includes nutrient databases or analyses, recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates the ratio of soy protein to total protein.

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Part	No. of Record-keepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
101.82(c)(2)(ii)(B)	25	1	25	1	25

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

Based upon the agency's experience with the use of health claims, FDA estimates that only about 25 firms would be likely to market products bearing a soy protein/coronary heart disease health claim and that only, perhaps, one of each firm's products might contain nonsoy sources of protein along with soy protein. The records required to be retained by § 101.82(c)(2)(ii)(B) are the records, e.g., the formulation or recipe, that a manufacturer has and maintains as a normal course of its doing business. Thus, the burden to the food manufacturer is that involved in assembling and providing the records to appropriate regulatory officials for review or copying.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: October 15, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–25336 Filed 10–22–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0464]

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 November 24, 2008.

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 at 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 or subpart B of 21 CFR part 207 (part 207) (registrants).

A. Reporting Burden

The draft guidance describes how to electronically create and submit Structured Product Labeling (SPL) files using defined terminology for establishment registration and drug

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

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 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;
- In providing the labeling as specified under § 207.25, for manufacturers with a Web site for voluntary reporting of adverse drug reactions, the manufacturer's telephone number and URL address that appear on the label under 21 CFR 201.57(a)(11);
- 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;
- A reference drug if used as a basis for the strength of the listed drug;
- 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.

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 terminology 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 draft notice of availability requesting public comment on the information collection provisions. Nineteen comments were received of which 4 remarked on the information collection.

(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,

[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.

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 of this document are underestimated if the estimate accounts for the time required to become familiar with the 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 e-mail address are provided by us for the purpose of minimizing the need to learn the SPL standard before submitting information electronically.

(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.

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	2	1,148
Annual updates of registration information	3,256	2.99	9,735	2	19,470
New drug listings	1,567	6.57	10,295	2	20,590
New listings for private label distributors	146	10.06	1,469	2	2,938
June and December updates of all drug listing information	1,677	11.21	18,799	2	37,598
Waiver requests	1	1	1	1	1
Total					81,745

[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
SOP maintenance	3,295	1	3,295	1	3,295

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

Activity	No. of Recordkeepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record	Total Hours
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, terminology, 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: October 15, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–25338 Filed 10–22–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Development of Mutations Useful for Attenuating Dengue Viruses and Chimeric Dengue Viruses

Description of Technology: Although flaviviruses cause a great deal of human suffering and economic loss, there is a shortage of effective vaccines. This invention relates to dengue virus mutations that may contribute to the development of improved dengue vaccines. Site directed and random mutagenesis techniques were used to introduce mutations into the dengue virus genome and to assemble a collection of useful mutations for incorporation in recombinant live attenuated dengue virus vaccines. The resulting mutant viruses were screened for several valuable phenotypes, including temperature sensitivity in Vero cells or human liver cells, host cell restriction in mosquito cells or human liver cells, host cell adaptation for improved replication in Vero cells, and attenuation in mice or in mosquitoes. The genetic basis for each observed phenotype was determined by direct sequence analysis of the genome of the mutant virus. Mutations identified through these sequencing efforts have been further evaluated by re-introduction of the identified mutations, singly, or in combination, into recombinant dengue virus and characterization of the resulting recombinant virus for phenotypes. In this manner, a menu of attenuating and growth promoting mutations was developed that is useful in fine-tuning the attenuation and growth characteristics of dengue virus vaccine candidates. The mutations promoting growth in Vero cells have usefulness for the production of live or inactivated dengue virus vaccines.

Inventors: Stephen S. Whitehead, Brian R. Murphy, Kathryn A. Hanley, Joseph E. Blaney (NIAID).

Patent Status: U.S. Patent No. 7,226,602 issued 05 Jun 2007 (HHS Reference No. E–120–2001/0–US–04); U.S. Patent Application No. 11/446,050 filed 02 Jun 2006 (HHS Reference No. E–120–2001/0–US–10).

Licensing Contact: Peter A. Soukas, J.D.; 301–435–4646; *soukasp@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases, Laboratory of Infectious Diseases, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize these vaccines. Please contact Dr. Brian Murphy at 301–594–1616 or *bm25f@nih.gov* for more information.

Dengue Tetravalent Vaccine Containing a Common 30 Nucleotide Deletion in the 3′-UTR of Dengue Types 1, 2, 3, and 4

Description of Technology: The invention relates to a dengue virus