

ESTIMATED ANNUALIZED BURDEN HOURS

Forms	Respondent type	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden hours
Application for Training	Laboratorians, Doctors, Nurses	74,000	1	5/60	6167
Total	6167

Dated: October 22, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0355]

Draft Guidance for Industry and Reviewers on Structured Product Labeling Standard for Content of Labeling Technical Questions and Answers, Revision; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft revised guidance for industry and reviewers entitled “SPL Standard for Content of Labeling Technical Qs & As.” This draft guidance is intended to assist sponsors who submit the content of their product labeling to the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) using the Structured Product Labeling standard (SPL) in extensible markup language (XML). The draft guidance also provides information to CDER and CBRE staff who review and manage that product information using electronic systems. This draft guidance is being revised to reflect technological changes and changes resulting from the requirement in the Food and Drug Administration Amendments Act of 2007 to submit drug establishment registration and drug listing information electronically.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by December 28, 2009. Submit electronic or written comments

on the collection of information by December 28, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management. All comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lonnie Smith, Center for Drug Evaluation and Research (HFD-001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-0011.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 11, 2003 (68 FR 69009), FDA published final regulations requiring that the content of labeling be submitted to FDA electronically for new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain biologics license applications (BLAs), and annual reports (see 21 CFR 314.50(l), 314.94(d), 601.14(b), and 314.81(b), respectively) (the December 2003 regulations). The December 2003 regulations state that the content of labeling must be submitted to

FDA electronically and “in a form that FDA can process, review, and archive.”

Initially, CDER accepted electronic submissions of content of labeling in portable document format (PDF). Then, in September 2004, CDER announced that it would accept content of labeling in both PDF and SPL formats until the autumn of 2005. On October 21, 2005, CDER announced that effective October 31, 2005, CDER would no longer accept content of labeling submissions in PDF format and that applicants should use the SPL standard when submitting content of labeling to FDA in XML with original submissions, supplements, and annual reports. CBRE made a similar announcement on July 11, 2008, which went into effect on October 15, 2008. On July 10, 2008, CDER, CBRE, and the Center for Veterinary Medicine announced their intention to begin using the SPL standard for electronic drug establishment registration and drug product listing.

Since FDA began accepting content of labeling in SPL format for application submissions, we have received numerous questions about SPL submission requirements. Based on preliminary questions, and in an effort to provide easy access to common questions that were being raised, in December 2005 we published a final guidance for industry entitled “SPL Standard for Content of Labeling Technical Qs and As.” As a result of initial experience using the SPL format and as a result of changes to the system for receiving registration and listing information, FDA is revising its SPL Qs & As guidance to provide recommendations in response to additional technical questions. Because of the number of questions that have arisen as a result of the actions described in this section of the document, FDA is issuing this guidance as a draft to solicit input from the public on the recommendations.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on submitting content of labeling in the SPL format. It does not create or confer

any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Draft Guidance for Industry and Reviewers on SPL Standard for Content of Labeling Technical Qs & As, Revision

In the December 2003 regulations, FDA calculated the burden hours (see section V “Paperwork Reduction Act of 1995”) and the costs (see section VIII “Analysis of Economic Impacts”) resulting from the final regulations requiring that the content of labeling be submitted to FDA electronically for NDAs, ANDAs, certain BLAs, and annual reports. The information collection resulting from the final rule is approved by OMB under Control Number 0910–0530. The burden hours and costs that were calculated in the final rule were based on the submission

of the content of labeling in PDF. As discussed in section I of this notice and in the Background section of the draft guidance, CDER and CBER no longer accept content of labeling submissions in PDF and applicants should now use the SPL standard when submitting content of labeling in XML with original submissions, supplements, and annual reports. The burden hours and costs associated with making these submissions using the SPL standard are discussed in this section of the document.

We estimate that it should take applicants approximately 1.25 hours to convert the content of labeling from Word or PDF to SPL format. The main task involved in this conversion is copying the content from one document (Word or PDF) to another (SPL). Over the past few years, several enhancements have been made to SPL authoring software which significantly reduces the burden and time needed to generate well-formed SPL documents. SPL authors may now copy a paragraph from a Word or PDF document and paste the text into the appropriate section of an SPL document. In those cases where an SPL author needs to create a table, the table text may be copied from the Word or PDF document and pasted into each table cell in the SPL document, eliminating the need to retype any information. Enhancements have also been made to the software for conversion vendors. Conversion software vendors have designed tools that will import the Word version of the content of labeling and, within minutes, automatically generate the SPL document (a few formatting edits may have to be made).

Based on the number of content of labeling submissions received during 2006, 2007, and 2008, we estimate that approximately 5,000 content of labeling submissions are made with original submissions, supplements, and annual reports by approximately 450 applicants. Therefore, the total annual hours to convert the content of labeling from Word or PDF to SPL format would be approximately 6,250 hours. We note that in the future, applicants will not need to convert their content of labeling from Word or PDF to SPL, but will be able to prepare their content of labeling in SPL format.

Concerning costs, we have concluded that there are no capital costs or operating and maintenance costs associated with this collection of information. In May 2009, FDA issued a guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Listing” (the May 2009

guidance). The May 2009 guidance describes how to electronically create and submit SPL files using defined code sets and codes for establishment registration and drug listing information, including labeling. The information collection resulting from this guidance, discussed in the **Federal Register** of January 8, 2009 (74 FR 816) (the January 2009 notice), has been approved by OMB under Control Number 0910–0045. As discussed in the January 2009 notice, 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 electronic submission gateway (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 the Internet are usually available at public facilities, e.g., a community library. In addition, there should be no additional costs associated with obtaining the appropriate software. In 2008, FDA collaborated with GlobalSubmit to make available free SPL authoring software that SPL authors may utilize to create new SPL documents or edit previous versions. (Information on obtaining this software is explained in section IV.A of the guidance entitled “Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Listing.”) In addition to the software, FDA also provides technical assistance and other resources, code sets and codes, and data standards regarding SPL files.

After the SPL file is created, the registrant would upload the file through the ESG, as explained in the January 2009 notice. 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. A 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. We are not calculating this fee as a cost for the draft guidance because all applicants who submit content of labeling are also subject to the drug establishment registration and listing requirements and would have already acquired the digital certificate as a result of the May 2009 guidance on drug establishment registration and listing.

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

TABLE 1.—ESTIMATED REPORTING BURDEN¹

Guidance	No. of Respondents	Frequency per Response	Total Responses	Hours per Response	Total Hours
Draft Guidance for Industry and Reviewers on SPL Standard for Content of Labeling Technical Qs & As, Revision	450	11.11	5,000	1.25	6,250

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

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.regulations.gov>.

Dated: October 23, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Science Advisory Board to the National Center for Toxicological Research Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Science Advisory Board (SAB) to the National Center for Toxicological Research (NCTR).

General Function of the Committee: To provide advice and

recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 17, 2009, from 8:15 a.m. to 5 p.m. and on November 18, 2009, from 8:15 a.m. to 2 p.m.

Location: NCTR SAB Conference Room B-12, 3900 NCTR Dr., Jefferson, AR 72079.

Contact Person: Margaret Miller, Designated Federal Official (DFO), National Center for Toxicological Research (HFT-10), Food and Drug Administration, 5600 Fishers Lane, Room 9C-05, Rockville, MD 20857, 301-827-6693, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 301-451-2559. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On November 17, 2009, the NCTR Director will provide a Center-wide update on scientific endeavors and discuss prioritization, alignment, and the strategic focus of NCTR. The SAB will be presented with responses to the evaluations of the Division of Systems Toxicology and the Division of Genetic and Reproductive Toxicology. The evaluations were the product of an on-site review of the Division of Systems Toxicology in February 2009 and the Division of Genetic and Reproductive Toxicology in July 2009, and will address the issues raised and recommendations made by the site visit teams. On November 18, 2009, the SAB will be presented with the Division of Personalized Nutrition and Medicine site visit report. This report is the product of a site review of the Division of Personalized Nutrition and Medicine in August 2009 and will address the issues and recommendations made by the site visit teams.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: On November 17, 2009, from 8:15 a.m. to 5 p.m., and November 18, 2009, from 8:15 a.m. to 1 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 16, 2009. Oral presentations from the public will be scheduled November 17, 2009, between approximately 12:30 p.m. to 1:30 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 12, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 13, 2009.

Closed Committee Deliberations: On November 18, 2009, from approximately 1 p.m. to 2 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information