4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0577]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in the requirements for the submission of labeling for human prescription drugs and biologics in electronic format.

DATES: Submit either electronic or written comments on the collection of information by (INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER).

ADDRESSES: 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 (HFA-305), Food and Drug Administration, 5630 Fishers

Lane., rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150-400B, Rockville, MD 20850, 301-796-7726, Ila.mizrachi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), 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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites 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.

Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format--(OMB Control Number 0910-0530)--Extension

FDA is requesting that OMB extend approval under the Paperwork Reduction Act (44 USC 3501-3520) for the information collection resulting from the requirement that the content of labeling for prescription drug products be submitted to FDA electronically in a form that FDA can process, review, and archive. This requirement was set forth in the final rule entitled "Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format" (December 11, 2003; 68 FR 69009), which amended FDA regulations governing the format in which certain labeling is required to be submitted for FDA review with new drug applications (NDAs) (21 CFR 314.50(l)(1)(i)), including supplemental NDAs, abbreviated new drug applications (ANDAs) (21 CFR 314.94(d)(1)(ii)), including supplemental ANDAs, and annual reports (21 CFR 314.81(b)(2)(iii)(b)) (the final rule also applied to certain BLAs, but the information collection for these requirements is not part of this OMB approval request).

This OMB approval request is only for the burden associated with the electronic submission of the content of labeling. The burden for submitting labeling as part of NDAs, ANDAs, supplemental NDAs and ANDAs, and annual reports, has been approved by OMB under control number 0910-0001.

We estimate that it should take applicants approximately 1.25 hours to convert the content of labeling from Word or PDF to structured labeling format (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 which 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 the past few years, we estimate that approximately 5,750 content of labeling submissions are made annually with original NDAs, ANDAs, supplemental NDAs and ANDAs, and annual reports by approximately 500 applicants. Therefore, the total annual hours to convert the content of labeling from Word or PDF to SPL format would be approximately 7,187.50 hours.

Concerning costs, we conclude 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 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), has been approved by OMB under control number 0910-0045. As discussed in the January 8, 2009, Federal Register 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 "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 8, 2009, Federal Register 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 this extension 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 Annual Reporting Burden[1]

Content of labeling submissions in NDAs, ANDAs, supplemental NDAs and ANDAs, and annual reports	No. of Respondents	No. of Responses per Response	Total Annual Responses	Average Burden per Response	Total Hours
	500	11.50	5750	1.25	7,187.50

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

Dated: May 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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