4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1428]

Electronic Product Reporting for Human Drug Compounding Outsourcing Facilities; Draft Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a revised draft guidance entitled "Electronic Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." The revised draft guidance addresses provisions in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) added by the Drug Quality and Security Act (DQSA) and updates reporting instructions for drug compounders that choose to register as outsourcing facilities. Such compounders must report information on the drugs they have compounded in Structured Product Labeling (SPL) format using FDA's electronic submissions system. This revised draft guidance supersedes a draft guidance entitled "Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act."

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any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the Agency considers your comments on this revised draft guidance, submit either electronic or written comments on the revised draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic

or written comments concerning the collection of information proposed in the revised draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the revised draft guidance document to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the revised draft guidance.

Submit electronic comments on the revised draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lysette Deshields, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3100.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled "Electronic Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." In the Federal Register of December 4, 2013 (78 FR 72897), FDA issued a notice announcing the availability of an initial draft of this guidance entitled "Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." That

draft guidance addressed new provisions in the FD&C Act added by the DQSA and set forth an interim submission method for human drug compounders that choose to register as outsourcing facilities.

The comment period on the initial draft guidance ended on February 3, 2014. FDA received six comments on the draft. In response to received comments or on its own initiative, FDA made the following changes and updates in the revised draft guidance: (1) Modified the scope of the guidance to refer to product reports submitted in SPL format; (2) clarified the following elements required in a product report: "Strength of the active ingredient per unit," "package description," and "number of individual units produced"; (3) included language that discusses the time period during which outsourcing facilities must submit product reports; (4) included the appropriate SPL document type category for outsourcing facilities submitting a product report and a reference to detailed instructions on how to submit information using SPL; (5) clarified that reports submitted under section 503B(b)(2) of the FD&C Act (21 U.S.C. 353b(b)(2)) are exempt from inspection unless the Secretary finds that such an exemption would be inconsistent with the protection of the public health; and (6) made grammatical and other minor editorial changes for clarity.

In some cases, received comments raised issues that were not directly pertinent to the topics addressed in the draft. This revised draft guidance explains that registered outsourcing facilities must provide reports to FDA on compounded drugs in SPL format using FDA's electronic submissions system. It supersedes the draft guidance entitled "Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act."

Section 503B(b)(2)(B) of the FD&C Act provides that a facility that elects to register with FDA as an outsourcing facility is required to report to FDA information about the drugs compounded at that outsourcing facility in the form and manner as FDA may "prescribe by regulation or guidance." Congress gave FDA explicit statutory authority to establish binding requirements on this topic in guidance. Therefore, this guidance is not subject to the usual restrictions in FDA's good guidance practice regulations (e.g., the requirements that guidances not establish legally enforceable responsibilities and that guidances prominently display a statement of the document's nonbinding effect); see 21 CFR 10.115(d)(1)).

As provided in section 503B of the DQSA, this revised draft guidance explains the form and manner in which registered outsourcing facilities are required to submit drug reporting information. This revised draft guidance, when finalized, will prescribe the form and manner for submitting drug product reports to FDA under section 503B of the FD&C Act and will have binding effect under section 503B(b)(2)(B). Until this draft guidance is finalized, FDA will accept drug product reports submitted in accordance with the form and manner described in FDA's initial draft guidance on this subject. However, FDA strongly encourages outsourcing facilities to submit drug product reports as described in this revised draft guidance.

Elsewhere in this issue of the Federal Register, FDA is making available a final guidance on registration for human drug compounding outsourcing facilities under section 503B of the FD&C Act.

II. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (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 that 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 for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

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

Under the revised draft guidance, registered outsourcing facilities must submit to FDA a report identifying all drugs compounded by the facility during the previous 6-month period. The report must be submitted upon initial registration as an outsourcing facility, once in June, and once in December of each year. The report must include the following information for all drugs compounded at the outsourcing facility during the previous 6-month period:

- The active ingredient and strength of active ingredient per unit
- The source of the active ingredient (bulk or finished)
- The National Drug Code (NDC) number of the source drug or bulk active ingredient, if available

- The dosage form and route of administration
- The package description
- The number of individual units produced
- The NDC number of the final product, if assigned

Product reports must be submitted to FDA electronically in SPL format, as described in the revised draft guidance. Outsourcing facilities can request a waiver from the electronic submission process by submitting a written request to FDA explaining why the use of electronic means is not reasonable for them.

Based on our familiarity with outsourcing facilities, we estimate that annually a total of approximately 50 outsourcing facilities ("number of respondents" in table 1, row 1) will submit to FDA at the time of initial registration a report identifying all drugs compounded in the facility. We also estimate that these outsourcing facilities will submit a total of approximately 50 reports for compounded drugs containing the information specified in the draft guidance ("total annual responses" in table 1, row 1). We estimate that preparing and submitting this information electronically will take approximately 2 hours per report ("average burden per response" in table 1, row 1). We expect to receive no more than one waiver request from this electronic submission process ("total annual responses" in table 1, row 2), and each request should take approximately 1 hour to prepare and submit to us ("average burden per response" in table 1, row 2).

We also estimate that a total of approximately 50 outsourcing facilities ("number of respondents" in table 2, row 1) will submit to FDA a report twice each year identifying all drugs compounded at the facility. We estimate that these outsourcing facilities will submit a total of approximately 50 reports in December and 50 reports in June containing the information specified in the draft revised guidance ("total annual responses" in table 2, row 1). We estimate

that preparing and submitting this information electronically will take approximately 2 hours per report ("average burden per response" in table 2, row 1). We expect to receive no more than one waiver request from the electronic submission process ("total annual responses" in table 2, row 2), and each request should take approximately 1 hour to prepare and submit to us ("average burden per response" in table 2, row 2).

Table 1.--Estimated One-Time Reporting Burden[1]

Product Reporting for Compounding Outsourcing Facilities	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of Initial Product Report	50	1	50	2	100
Waiver Request from Electronic Submission of Initial Product Report	1	1	1	1	1
Total					101

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

Table 2.--Estimated Annual Reporting Burden[1]

Product Reporting for Compounding Outsourcing Facilities	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of December Product Report	50	1	50	2	100
Submission of June Product Report	50	1	50	2	100
Waiver Request from Electronic Submission of Product Reports	1	1	1	1	1
Total					201

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

III. Comments

Interested persons can submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments can be viewed at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

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

Dated: November 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014-27691 Filed 11/21/2014 at 8:45 am; Publication Date: 11/24/2014]