4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry on Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled "Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." The draft guidance addresses new provisions in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Drug Quality and Security Act (DQSA), and sets forth an interim electronic submission method for human drug compounders that choose to register as outsourcing facilities (outsourcing facilities).

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on a draft guidance describing the updated format for long-term use, submit either electronic or written comments on this draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].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comments concerning the collection of information proposed in the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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, Drug Registration and Listing Team, 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 draft guidance for industry entitled "Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." The draft guidance is being issued to implement new provisions added to the FD&C Act in the DQSA. In the newly enacted legislation, Congress created a new statutory category of "outsourcing facilities" that compound drugs. New section 503B of the FD&C Act (21 U.S.C. 353b) allows compounders to register with FDA as

outsourcing facilities and, among other things, imposes reporting requirements on these entities if they choose to register. The draft guidance is intended to assist registered outsourcing facilities in implementing drug reporting. The draft guidance describes how an outsourcing facility should provide interim electronic reports while FDA modifies its existing electronic drug registration and listing system to accommodate reporting of product information by registered outsourcing facilities under section 503B of the FD&C Act. When the Agency has modified its current electronic submission system to allow outsourcing facilities to submit information electronically through a Structured Product Labeling file, FDA intends to issue a draft guidance describing the updated format for long-term use. When such guidance is issued in final form, it will specify the form of reporting that outsourcing facilities are to follow from that point forward.

The draft guidance 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.

Elsewhere in this issue of the Federal Register, the Agency is making available for comment a draft 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 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 draft guidance, registered outsourcing facilities should submit to FDA a report identifying all drugs compounded by the facility during the previous 6-month period. This product report should be submitted upon initial registration as an outsourcing facility and once during the months of June and December of each year. The report should include the following information for all drugs compounded by 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 drug);

- 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; and
- The NDC number of the final product, if assigned.

Product reports should be submitted to FDA electronically using an Excel spreadsheet and via an email attachment, as described in the draft guidance. Outsourcing facilities may 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.

Because human drug compounders are not required to register and report as outsourcing facilities, it is difficult to anticipate the number of outsourcing facilities that will participate in the process. We estimate that a total of approximately 20 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 by the facility. We also estimate that these outsourcing facilities will submit a total of approximately 20 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 10 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 20 outsourcing facilities ("number of respondents" in table 2, row 1) will annually submit to FDA a report identifying all drugs compounded by the facility. We estimate that these outsourcing facilities will submit a total of approximately 20 reports in June and 20 reports in December containing the information specified in the draft guidance ("total annual responses" in table 2, row 1). We estimate that preparing and submitting this information electronically will take approximately 10 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	20	1	20	10	200
Waiver Request from Electronic Submission of Initial Product Report	1	1	1	1	1
Total					201

[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 June Product Report	20	1	20	10	200
Submission of December Product Report	20	1	20	10	200
Waiver Request from Electronic Submission of Product Reports	1	1	1	1	1
Total					401

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

III. Comments

Interested persons may 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 may be seen in 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 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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