4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 electronic drug product reporting for human drug compounding outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

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

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m.

Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2013-N-1428 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in

accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@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.

Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910-0827--Extension

The Drug Quality and Security Act added section 503B to the FD&C Act (21 U.S.C. 353b) creating a category of entities called "outsourcing facilities." Outsourcing facilities, as defined in section 503B(d)(4) of the FD&C Act, are facilities that must meet all the requirements described in section 503B, including registering with FDA as an outsourcing facility and submitting regular reports identifying the drugs compounded by the outsourcing facility during the previous six-month period. The first of these reports must be submitted upon initial registration as an outsourcing facility. Thereafter, semiannual product reports must be submitted, once during the month of June and once during the month of December, for as long as an establishment remains registered as an outsourcing facility.

In addition, drug products compounded in an outsourcing facility can qualify for exemptions from the FDA approval requirements in section 505 of the FD&C Act (21 U.S.C. 355)

and the requirement to label products with adequate directions for use under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) if the requirements in section 503B are met.

To help respondents understand the statutory requirements, how we interpret them, and the associated information collection, we developed the guidance document entitled, "Guidance for Industry; Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." The guidance explains that, once an entity has elected to register as an outsourcing facility, it must submit reports identifying the drugs compounded by the outsourcing facility. The guidance also communicates who must report, the format of the report, the content to include in each report, when to report, how reports are submitted to FDA, and the consequences of outsourcing facilities' failure to submit reports.

Based on current data for outsourcing facilities, we estimate that 75 outsourcing facilities will submit an initial report identifying all drugs compounded in the facility in the previous six months. For the purposes of this estimate, each product's structured product labeling (SPL) submission is considered a separate response, and therefore each facility's product report will include multiple responses. Taking into account that a particular product that is compounded into different strengths from different sources of active ingredient can be reported in a single SPL response, we estimate that each facility will average 76 products. Our estimate is based on current product reporting data.

We expect each product report will consist of multiple SPL responses per facility and estimate that preparing and submitting this information electronically may take up to 2 hours for each initial SPL response. We also estimate that the 75 registered outsourcing facilities will

submit a report twice each year identifying all drugs compounded at the facility in the previous six months.

As stated above, we estimate on average 76 SPL responses per facility and that preparing and submitting this information electronically will take approximately 30 minutes per response. We have reduced our burden estimate for semiannual product submissions since outsourcing facilities can save each SPL response once initially created and submitted. For subsequent reports, an outsourcing facility may resubmit the same file(s) after changing the RootID and version number (both SPL metadata), effective date (to identify the reporting period), and the number of units produced, along with other data as appropriate, to appropriate values for the reporting period. Furthermore, if a product was not compounded during a particular reporting period, no SPL response needs be sent for that product during that reporting period.

We expect to receive no more than one waiver request, each, from the electronic submission process for initial product reports and semiannual reports, and that each waiver request will take 1 hour to prepare and submit.

We therefore estimate the burden of the information collection as follows:

Table 1.--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
Initial product reports	75	1.01	76	2	152
Waiver request from electronic submission of initial product reports	1	1	1	1	1
June product reports	75	1.01	76	.5	38
December product reports	75	1.01	76	.5	38
Waiver request from electronic submission of product reports	1	1	1	1	1
TOTAL					230

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

Based on submissions we have received, we have reduced the number of responses significantly since our original estimate establishing the collection. This results in an overall reduction to the information collection by 36,072 hours.

Dated: July 9, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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