4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0030]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0800. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910-0800--Revision

This information collection helps support implementation of sections 503A (21 U.S.C. 353a) and 503B (21 U.S.C. 353b) of the Federal Food Drug and Cosmetic Act (FD&C Act), which govern requirements for pharmacy compounding and outsourcing facilities, respectively. For efficiency of Agency operations, we are revising the information collection to include related reporting activities currently approved under OMB control number 0910-0827. Specifically, upon electing and in order to become an outsourcing facility, respondents must register under section 503B of the FD&C Act and submit certain reports and updates to FDA. The information is required to be submitted by electronic means unless otherwise exempt, and prepared in such form and manner as the Secretary of the Department of Health and Human Services may prescribe through regulation or guidance.

In the guidance for industry entitled "Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act" (December 2016), available on our website at https://www.fda.gov/media/90173/download, we explain how facilities that elect to register with FDA as outsourcing facilities are to submit drug product reports, consistent with section 503B of the FD&C Act. The guidance document describes who must report and what information must be provided to FDA. The guidance document also explains that drug compounding reports must be submitted in structured product labeling (SPL) format using FDA's electronic submissions system and discusses the consequences of outsourcing facilities' failure to submit reports.

In the *Federal Register* of June 17, 2022 (87 FR 36507) we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

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

Section 503B of the FD&C Act	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Initial product reports	3	53	159	0.0833 (5 minutes)	13.25
Waiver request from electronic submission of initial product reports	1	1	1	1	1
June product reports	75	53	3,975	0.025 (1.5 minutes)	99.375
December product reports	75	53	3,975	0.025 (1.5 minutes)	99.375
Waiver request from electronic submission of product reports	1	1	1	1	1
Total					214

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

Respondents to this collection of information are outsourcing facilities. Based upon our evaluation of the information collection, we have adjusted our estimate downward by 16 hours (from 230 to 214) annually to reflect more recent Agency data. We estimate that each year three outsourcing facilities will submit a product report upon initial registration under section 503B of the FD&C Act. We estimate that twice each year 75 outsourcing facilities will submit a report identifying all human drugs compounded in the facility in the previous 6 months. For the purposes of this estimate, each product's SPL submission is considered a separate product response, and therefore each facility's product report will include multiple product responses. We estimate that each facility will average 53 product responses. We expect each product report will consist of multiple product responses per facility and estimate that preparing and submitting this information electronically may take up to 5 minutes for each initial product response.

Assuming an average of 53 product responses per facility, we estimate that, for semiannual reports, preparing and submitting this information electronically will take 1.5 minutes per product response. Our burden estimate for semiannual product report submissions is lower than for initial product reports because outsourcing facilities can save each product 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 product response would be sent for that product during that reporting period.

We expect to receive no more than one waiver request from the electronic submission process for initial product reports and semiannual reports, and that each waiver request will take 60 minutes to prepare and submit.

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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