4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-3007]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration of Human Drug Compounding Outsourcing Facilities Under the Federal Food, Drug, and Cosmetic Act and Associated Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 0910-0776. 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.

Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and Associated Fees Under Section 744K

OMB Control Number 0910-0776--Extension

This information collection helps to support implementation of section 503B of the FD&C Act (21 U.S.C. 353b) and the assessment and remission of user fees under section 744K of the FD&C Act (21 U.S.C. 379j-62).

A. Registration

Under section 503B of the FD&C Act a facility that compounds drugs may elect to register with FDA as an outsourcing facility. Upon electing to do so, outsourcing facilities must register annually between October 1 and December 31, providing information that includes its name, place of business, a unique facility identifier, and a point of contact's email address and phone number. The outsourcing facility must also indicate: (1) whether it intends to compound, within the next calendar year, a drug that appears on our drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) and (2) whether it compounds from bulk drug substances and, if so, whether it compounds sterile or nonsterile drugs from bulk drug substances. Registered outsourcing facilities must submit a drug product report upon initial registration under section 503B of the FD&C Act and twice each year in June and December for drug products produced during the previous 6-month period. We require this data be submitted electronically, unless a waiver is granted, in structured product labeling (SPL) format.

Drug products compounded in a registered outsourcing facility can qualify for exemptions from the FDA-approval requirements in section 505 of the FD&C Act (21 U.S.C. 355), 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)), and the requirements for drug supply chain security in section 582 of the FD&C Act (21 U.S.C. 360eee-1) if the requirements in section 503B of the

FD&C Act have been met. We provide general information and resources on our website at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding, including a list of currently registered outsourcing facilities as required under section 503B of the FD&C Act.

B. Registration Fees

Upon registration, and in accordance with sections 503B and 744K of the FD&C Act, facilities are assessed an establishment fee and receive an annual invoice from FDA with instructions for remitting payment. Until payment is made for each given fiscal year (FY), an establishment is not considered to be registered as an outsourcing facility. In accordance with section 744K of the FD&C Act, certain outsourcing facilities may qualify for a small business reduction in the amount of the annual establishment fee. To qualify for this reduction, an outsourcing facility must submit a written request to FDA certifying that the entity meets the requirements for the reduction. For each FY a firm seeks to qualify as a small business and receive the fee reduction, it must submit to FDA a written request by April 30 of the preceding FY. For example, an outsourcing facility must have submitted a written request for the small business reduction by April 30, 2023, to qualify for a reduction in the FY 2024 annual establishment fee.

Section 744K of the FD&C Act also requires an outsourcing facility to submit written requests for a small business reduction in a specified format: Form FDA 3908 entitled "Outsourcing Facilities for Human Drug Compounding: Small Business Establishment Fee Reduction Request." The completed form should be submitted via email to CDERCollections@fda.hhs.gov. Form FDA 3908 is available from our website at: https://www.fda.gov/media/90740/download. In response to the submission of a small business reduction request, FDA will send a notification letter of its decision and recommends that applicants retain the notification.

C. Reinspection Fees

In accordance with section 503B of the FD&C Act, outsourcing facilities are subject to inspection and, in accordance with section 744K of the FD&C Act, subject to reinspection fees. A reinspection fee will be incurred for each reinspection and is intended to reimburse FDA when a particular outsourcing facility requires reinspection because of noncompliance identified during a previous inspection. After a reinspection is conducted, FDA will send an invoice to the email address indicated in the facility's registration file. The invoice contains instructions for remitting the reinspection fee. For further information on human drug compounding outsourcing facility fees, please visit our website at https://www.fda.gov/industry/fda-user-fee-programs/human-drug-compounding-outsourcing-facility-fees.

D. Dispute Resolution

Agency regulations under § 10.75 (21 CFR 10.75) provide for internal Agency review of decisions. Accordingly, an outsourcing facility may request reconsideration of an FDA decision related to the fee provisions of section 744K of the FD&C Act. Requests for reconsideration should include the facility's rationale for its position that FDA's decision was in error and include any additional information that is relevant to the outsourcing facility's assertion. The denial of a request for reconsideration may be appealed by submitting a written request to FDA, consistent with § 10.75.

To assist respondents with the information collection provisions, we have developed Agency guidance documents. The guidance document entitled "Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act (November 2014)" describes the process for electronic submission of establishment registration information for outsourcing facilities and provides information on how to obtain a waiver from submitting registration information electronically. The guidance document entitled "Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act (November 2014)" (Fees for Human Drug Compounding Outsourcing Facilities guidance) describes the types and amounts of fees that outsourcing facilities must pay, the adjustments to

fees required by law, how outsourcing facilities can submit payment to FDA, the consequences of outsourcing facilities' failure to pay fees, and how an outsourcing facility can qualify as a small business to obtain a reduction in fees. The guidance documents were issued consistent with our good guidance practice regulations (21 CFR 10.115), which provide for public comment at any time, and are available on our website at https://www.fda.gov/media/87570/download and https://www.fda.gov/media/136683/download, respectively.

All requests for dispute resolution should be sent via email to the Division of User Fee Management and Budget Formulation at CDERCollections@fda.hhs.gov. If an outsourcing facility does not have email access, it can mail a request to FDA via the carrier of its choice. For the most updated physical mailing address, visit this website: https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm382846.htm.

In the *Federal Register* of August 15, 2023 (88 FR 55464), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

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

Activity; 21 CFR Section; Guidance or Associated FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Electronic Submission of Registration Information Using the SPL Format; 207.61; Section III. of the "eDRLS"[2] guidance	79	1	79	4.5	355
Waiver Request from Electronic Submission of Registration Information; 207.65; Section VI. of the "eDRLS"[2] guidance	1	1	1	1	1
Remission of Annual Establishment Fee from FDA Invoice; Section E.1. of the Fees for Human Drug Compounding Outsourcing Facilities guidance	76	1	76	0.5 (30 minutes)	38
Request for Small Business Reduction (Form FDA 3908)	18	1	18	25	450
Reinspection Fees; Section C. of the Fees for Human Drug Compounding Outsourcing Facilities guidance	12	1	12	0.5 (30 minutes)	6
Reconsideration Requests; Section V.B.1. of the Fees for Human Drug Compounding Outsourcing Facilities guidance	1	1	1	1	1
Appeal of Reconsideration Denials; Section V.B.2. of the Fees for Human Drug Compounding Outsourcing Facilities guidance	1	1	1	1	1
Total			188		852

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] "Providing Regulatory Submissions in Electronic Format--Drug Establishment Registration and Drug Listing" (May 2009; available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-drug-establishment-registration-and-drug-listing).

We estimate 79 respondents annually will submit outsourcing facility registrations using the SPL format as specified in Agency guidance and assume each registration will require 4.5 hours to prepare and complete. We expect no more than one waiver request from the electronic submission requirement annually and assume each waiver request will require 1 hour to prepare and submit. We estimate each of the 76 registrants will remit annual establishment fees and assume this task requires 30 minutes per respondent. We estimate that 18 of those respondents will request a small business reduction in the amount of the annual establishment fee using Form FDA 3908.

We estimate 12 outsourcing facilities annually will remit reinspection fees and assume this will require 30 minutes. We also estimate that we will receive one request for

reconsideration and one appeal of a denial of a request for reconsideration and assume 1 hour per respondent for this activity.

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

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Retention of Small Business Designation Notification Letter	18	1	18	0.5 (30 minutes)	9

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

We estimate that annually 18 outsourcing facilities will maintain a copy of their small business designation letter and that maintaining each record will require 30 minutes. These estimates reflect a slight increase in the number of annual registrations, but a decrease in reinspection fee submissions.

Dated: November 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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