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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-8690]

Agency Information Collection Activities; Proposed Collection; 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 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 the information collection pertaining to the registration of human drug compounding outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and associated fees.

DATES: Either electronic or written comments on the collection of information must be submitted 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. 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 received 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 NoFDA-2026-N-8690 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the

FD&C Act and Associated Fees Under Section 744K." 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, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-1244, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), 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.

Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the 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 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 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.

B. Registration Fees

Upon registration, and in accordance with section 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, 2026, to qualify for a reduction in the FY 2027 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 titled "Outsourcing Facilities for Human Drug Compounding: Small Business Establishment Fee Reduction Request." The completed form should be submitted via email to FDAUserFees@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 titled "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 titled "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 at FDAUserFees@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 to FDA, Division of User Fee Management, 10903 New Hampshire Ave., Bldg. 32, Room 4245, Silver Spring, MD 20993.

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	100	1	100	4.5	450
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	90	1	90	0.5 (30 minutes)	45
Request for Small Business Reduction (Form FDA 3908)	8	1	8	25	200
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			213		704

[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 100 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 90 registrants will remit annual establishment fees and assume this task requires 30 minutes per respondent. We estimate that 8 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	8	1	8	0.5 (30 minutes)	4

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

We estimate that annually 8 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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