Registration of Human Drug Compounding Outsourcing Facilities Under Section 503b of the Federal Food, Drug, and Cosmetic Act And Associated Fees Under Section 744k

OMB Control No. 0910-0776 - Extension

SUPPORTING STATEMENT **Part A: Justification:**

1. Circumstances Making the Collection of Information Necessary

This information collection helps to support the implementation of section 503B of the Federal - Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b) and the Drug Quality and Security Act (DQSA) regarding the registration of human drug compounding outsourcing facilities. This information collection also implements provisions applicable to registered outsourcing facilities and the assessment and remission of user fees under section 744K of the FD&C Act (21 U.S.C. 379j).

A. Registration

Under section 503B of the FD&C Act (21 U.S.C. 353b), 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 six-month period. We require this data be submitted electronically, unless a waiver is granted, in Structured Product Labeling (SPL) format in accordance with the FDA guidance for industry entitled "*Providing Regulatory Submissions in Electronic Format--Drug Establishment Registration and Drug Listing (eDRLS guidance) (May 2009*)." The guidance is available from our website at https://www.fda.gov/media/71146/download.

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 (21 U.S.C. 379j-62), 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, relevant information 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:

- *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; and

- *Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act (November 2014)* 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.

Both guidance documents were issued consistent with FDA's good guidance practice regulations (21 CFR 10.115), which provide for public comment at any time and are available at https://www.fda.gov/media/87570/download and https://www.fda.gov/media/136683/download, respectively.

Accordingly, we request Office of Management and Budget (OMB) approval of the information collection provisions applicable to the registration of outsourcing facilities as set forth in 503B of the FD&C Act, the remission of applicable fees and Form FDA 3908, and associated instruction found in the agency guidance documents discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The purpose of the information collection is to implement section 503B of the FD&C Act and assess and collect applicable fees under section 744K.

3. Use of Improved Information Technology and Burden Reduction

Consistent with statutory requirements, registration is completed electronically. Form FDA 3908 is submitted via email to CDERCollections@fda.hhs.gov with the subject line "Outsourcing Facility Small Business Reduction Request." When disputes arise between an outsourcing facility and FDA about an FDA decision related to the fee provisions of sections 503B and 744K of the FD&C Act, the outsourcing facility may request a reconsideration of that decision by directing reconsideration requests via email to the Director of the Division of User Fee Management and Budget Formulation at CDERCollections@fda.hhs.gov with the subject line "Request for Reconsideration of agency Decision–Outsourcing Facility Fee Determination." 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: http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm382846.htm. If a request is denied upon reconsideration, the outsourcing facility may choose to appeal the denial. Requests for appeals should be submitted via email to the Director of CDER's Office of Management at CDERCollections@fda.hhs.gov with the subject line "Appeal of agency's Decision at Reconsideration–Outsourcing Facility Fee Determination." These instructions are included in the referenced guidance documents developed to assist respondents with information collection.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

No undue burden is imposed on small entities. We estimate 32% of outsourcing facilities may qualify as small businesses. Entities that qualify as small businesses under section 744K(c)(4) of the FD&C Act are required to pay only one-third of the annual establishment fee. At the same time, we provide small businesses with assistance through resources available at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory requirements.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

There are no special circumstances relating to this information collection. (The submission of proprietary, trade secret, or other confidential information is addressed under section 10 below).

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice in the *Federal Register* of August 15, 2023 (88 FR 55464) requesting public comment on the proposed collection of information. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

Consistent with 5 CFR 1320.5(d)(2)(vii), data will be kept private to the extent allowed by law:

The Privacy Act of 1974

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3908 (Outsourcing Facilities for Human Drug Compounding Small Business Establishment Fee Reduction Request) is point of contact name, work phone number, and work email address. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

SUMMARY BURDEN TABLE NEXT PAGE

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

Reporting Activity; CFR citation, Guidance or Associated 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; 21 CFR 207.61; Section III. of the eDRLS guidance	79	1	79	4.5	355
Waiver Request from Electronic Submission of Registration Information; 21 CFR 207.65; Section VI. of the eDRLS guidance	1	1	1	1	1
Subtotal			80		356
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
Subtotal			108		496
Total			188		852

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

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 annually from the electronic submission requirement 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 will require 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 information collection.

We estimate that 18 outsourcing facilities annually will maintain a copy of their small business designation letter and that maintaining each record will require 30 minutes.

12b. Annualized Cost Burden Estimate

The industry burden estimate calculated above would result in labor costs. Labor hours for facilities managers are valued at the mean hourly wage rate of $70.21 as reported by the U.S. Department of Labor, Bureau of Labor Statistics, in its May 2022 National Industry–Specific Occupational Employment and Wage Estimates for Pharmaceutical and Medicine Manufacturing (NAICS, code 325400), available at https://www.bls.gov/oes/current/naics4_325400.htm. Wages are further adjusted for benefits and overhead for an average hourly labor cost of $140.42 ($70.21 x 2). Using this wage rate multiplied by the total hours calculated above for this information collection (861), we estimate approximately $120,901.62 in labor costs ($140.42 x 861).

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There is no capital, start-up, or operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Assuming 2,080 hours is expended annually to evaluate submissions and administer the information collection, and using a cost factor of $325,348 per one full time equivalent (salary plus overhead, full-time 40-hour week) we multiplied the total number of hours worked (2,080 hours) by the fully loaded wage rate $156 per hour to calculate the total cost to the Federal government to be **$312,000**.

15. Explanation for Program Changes or Adjustments

The information collection reflects an increase in the number of annual registrations, but a decrease in reinspection fee submissions. The adjustments result in an increase of 90 responses and 432 hours annually.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration data will be displayed where required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.