

United States Food and Drug Administration

Obtaining Information to Understand and Challenges and Opportunities Encountered by
Compounding Outsourcing Facilities

OMB Control No. 0910-0883 - Revision

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports FDA research to obtain information about challenges and opportunities pertaining to human prescription drug compounding by outsourcing facilities. Generally, drug compounding is the practice of combining, mixing, or altering ingredients of a drug to create a medication tailored an individual patient’s needs. Although compounded drugs can serve an important medical need for certain patients when an approved drug is not medically appropriate, compounded drugs also present a risk to patients. Compounded drugs are not FDA-approved; therefore, they do not undergo FDA premarket review for safety, effectiveness, and quality.

Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for compounded human prescription drug products to be exempt from certain sections of the FD&C Act: (1) section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (current good manufacturing practice (CGMP) requirements); (2) section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) (labeling of drugs with adequate directions for use); and (3) section 505 of the FD&C Act (21 U.S.C. 355) (approval of drugs under new drug applications or abbreviated new drug applications).

The Drug Quality and Security Act of 2013 (Pub. L. 113-54) created outsourcing facilities—a new industry sector of drug compounders held to higher quality standards to help protect patient health. Section 503B of the FD&C Act (21 U.S.C. 353b) describes the conditions that outsourcing facilities must satisfy for drug products compounded in an outsourcing facility by or under the direct supervision of a licensed pharmacist to be exempt from the certain sections of the FD&C Act. Outsourcing facilities are intended to offer a more reliable supply of compounded drugs that hospitals, clinics, and other providers need.

FDA continues to find concerning quality and safety problems during inspections of outsourcing facilities. FDA has implemented and will continue to implement programs to support compounding quality and compliance. One initiative is FDA’s Compounding Quality Center of Excellence (Center of Excellence), <https://www.fda.gov/drugs/human-drug-compounding/compounding-quality-center-excellence>, which was developed to focus on improving the quality of compounded human prescription drugs to promote patient safety. One of our top priorities is to help ensure that compounded drugs are safe by focusing on quality. FDA, state regulators, pharmacy associations, and compounders, including outsourcing facilities, share the responsibility of patient safety.

The Center of Excellence engages and collaborates with compounders, including outsourcing facilities, and other stakeholders to improve the overall quality of compounded drugs. Furthermore, the Center of Excellence promotes collaboration to help compounders implement robust quality management systems that are better for business and the safety of patients.

In addition, the Center of Excellence is conducting in-depth research to better understand outsourcing facilities' challenges and opportunities in different areas to help guide decisions regarding future training and other engagement. Outsourcing facilities encounter the following challenges and opportunities: (1) operational barriers and opportunities related to the outsourcing facility market and business viability; (2) knowledge and operational barriers and opportunities related to compliance with Federal policies and good quality drug production; and (3) barriers and opportunities related to outsourcing facility interactions with FDA.

We therefore request extension of OMB approval for the information collection that supports FDA research in obtaining a range of information about human prescription drug compounding by outsourcing facilities as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

FDA used previous research results under this information collection to develop an understanding of the outsourcing facility sector, the sector's challenges, and opportunities for advancement. The information collected was an essential tool to help FDA identify knowledge and information gaps, operational barriers, and views on interactions with FDA. FDA has presented this information in public settings such as stakeholder meetings. Continuing this collection will enable FDA to deepen our understanding of the outsourcing facility sector and increase our efficacy in developing a Center of Excellence that is responsive to outsourcing facilities' needs. The research results will inform FDA's future activities for the Center of Excellence in the areas of communication, education, training, and other engagement with outsourcing facilities to address challenges and support advancement.

3. Use of Improved Information Technology and Burden Reduction

We use an electronic survey to administer the survey. The electronic survey used standardized questions submitted as part of this package. To reduce burden on the respondent, we applied skip patterns to tailor the survey questions.

4. Efforts to Identify Duplication and Use of Similar Information

The information obtained through this collection is unique and is not already available for use or adaptation from another cleared source.

5. Impact on Small Businesses or Other Small Entities

This information collection does not impose a significant economic impact on a substantial number of small businesses or entities.

6. Consequences of Collecting the Information Less Frequently

The proposed survey represents a collection that will occur in 2025. Understanding the unique perspectives of outsourcing facilities is essential to developing effective future approaches to communication, education, training, and other engagement with outsourcing facilities to address challenges and support advancement of the industry as they attempt to supply safe, high-quality drug products that patients need.

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

No special circumstances are associated with this collection of information.

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

In the *Federal Register* of September 5, 2024 (89 FR 72410), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received four comment letters from trade organizations and industry, each containing one or more comments on the proposed collection of information.

(Comment 1) Several comments expressed appreciation for FDA's efforts in developing a comprehensive understanding of the outsourcing facility sector, its challenges, and opportunities for advancement. Other comments expressed appreciation for FDA's efforts to ensure that the survey questions capture the most important information from compounding outsourcing facilities and that the survey not place an undue burden on respondents.

(Response 1) We agree that the information being collected has utility for understanding of the outsourcing facility sector, its challenges, and opportunities for advancement and that we are making an effort to not place an undue burden on respondents.

(Comment 2) One comment suggested that certain questions focus on financial considerations and economic consequences and argued that they are not necessary for FDA's oversight of outsourcing facilities and are unrelated to FDA's public health mission and the quality and safety of compounded drugs.

(Response 2) We have considered the comments and disagree. As stated previously, the Center of Excellence is conducting this research to better understand outsourcing facilities' challenges and opportunities in different areas to help guide decisions regarding future training and other engagement. We think that an important component to understanding the challenges and opportunities that outsourcing facilities face includes gaining insight into the financial considerations that impact outsourcing facilities' operations and business models.

(Comment 3) Several comments proposed changes to existing questions or the inclusion of new questions.

(Response 3) We have considered the comments requesting that the agency update the questionnaire and disagree that certain questions should be modified or added. We believe

that the information sought from the proposed questions will be captured within the existing questions or elsewhere in our research.

9. Explanation of Any Payment or Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondents

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

This ICR will collect personally identifiable information (PII). The PII collected typically consists of name and contact information. PII is collected on behalf of the FDA by a contractor or vendor who conducts surveys. PII is collected to gather information on compounding pharmacies to support the FDA compounding program. Information collected by the vendor or contractor will be summarized into aggregate form, sent in aggregate to FDA (no PII will be included), and destroyed after the study has been completed. Collected PII is used to notify potential respondents of their selection and includes name and contact information. All information collected will be kept secure by the vendor or contractor. FDA and any vendor or contractor will disclose identifiable information only to the extent authorized by the individual or required by law. Contractors or vendors maintaining information will destroy it in accordance with applicable records retention and other requirements per contract terms after the aggregate information has been provided to FDA and the survey has been completed. In keeping with IRB/Human Subjects Research protocols, the FDA clearance process ensures that study data is appropriately secured (e.g., housed on the Contractor's servers, password protected, separate storage areas for each study, access controlled).

FDA determined that although PII is collected it 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 does not use name or any other personal identifier to retrieve records from the information collected.

11. Justification for Sensitive Questions

This information collection does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

Description of Respondents: Respondents to this information collection are employees at outsourcing facilities and related human prescription drug compounding businesses.

12a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
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Table 1.--Estimated Annual Reporting Burden

Survey Invitation	250	1	250	0.0833 (5 mins)	21
Survey Questionnaire	250	1	250	0.50 (30 mins)	125
Total			500		146

The universe of registered outsourcing facilities and related human prescription drug compounding businesses known to the Center of Excellence will be sent a survey invitation. We reduced our estimate of the number of respondents from 300 to 250. We estimate that approximately 250 respondents will receive an invitation to participate in the survey and will spend 5 minutes reading the invitation and considering whether to take the survey, for a total of 20.825 burden hours per year, rounded to 21 hours. Based on our historical experience, we anticipate that all those invited to participate in the survey will complete the survey. We estimate that respondents will spend 15-30 minutes to complete the revised survey. Using the upper-bound estimate, we report a reduction in burden hours to 30 minutes (0.50 hour) per survey response from our previous estimate of 1 hour per response. We estimate that approximately 250 respondents will spend 30 minutes completing the survey, for a total of 146 burden hours per year.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Outsourcing Facility Manager	146	\$53.21	\$7,770

The respondent hourly wage was determined by using the Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Medical and Health Services Managers, on the Internet at <https://www.bls.gov/ooh/management/medical-and-health-services-managers.htm>.

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

No capital, start-up, operating or maintenance costs are associated with this information collection.

14. Annualized Cost to the Federal Government

We calculated the annualized cost to the Federal Government by multiplying the total number of 500 responses by the \$23.70 cost to process each response, which results in a total labor cost to the Federal government of \$11,850. We calculated the cost to process each response by multiplying the \$94.80 hourly wage of worker's processing the responses by the number of hours needed to process each response, .25. There are no operational and maintenance costs to the government, so the total annualized cost to the Federal Government is \$11,850.

Labor Cost to the Federal Government (Contract Costs)

a. Number of Total Annual Responses:	500
b. Processing Time per Response:	.25 hours
c. Hourly Wage of Worker(s) Processing Responses:	\$94.80
d. Cost to Process Each Response:	\$23.70 = (\$94.80*.25)

e. Total Cost to Process Responses: \$11,850 = (500*\$23.70)

Overall Labor Burden to Federal Government

a. Total Number of Annual Responses: 500
b. Total Labor Burden: \$11,850

Operational and Maintenance Costs

a. Equipment: \$0
b. Printing: \$0
c. Postage: \$0
d. Software Purchases: \$0
e. Licensing Costs: \$0
f. Other: \$0
g. Total: \$0

1. Total Operational and Maintenance Costs: \$0
2. Total Labor Cost to the Federal Government: \$11,850
3. Total Cost to the Federal Government: \$11,850

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall decrease of 454 hours and a corresponding decrease of 350 responses. We revised the survey to improve clarity and simplify the experience for participants. We made grammatical, stylistic, format, and other editorial changes to the content. In doing so, we reduced the number of questions from 31 to 20. We anticipate a reduction in burden hours to 30 minutes (.50 hour) per survey response from our previous estimate of 1 hour per response.

16. Plans for Tabulation and Publication and Project Time Schedule

We may select information collected as part of this survey as part of FDA's future approaches to communication, education, training, and other engagement with outsourcing facilities to address challenges and support advancement. We will combine the collection and tabulation of the results with additional research to develop a comprehensive understanding of the outsourcing facility sector, its challenges and opportunities for advancement. The current schedule for the survey (and potential repeat surveys) follows:

Activity	Estimated Start Date	Estimated End Date
OMB review of PRA package	1-31-2025	3-28-2025
Issue survey(s) to registered outsourcing facilities and collect results	4-01-2025	4-01-2027

Upon completion of the internal FDA report, FDA will decide what portions, if any, should be published and included as part of communication, education, training, and engagement with outsourcing facilities.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification are associated with this information collection.