United States Food and Drug Administration

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

OMB Control No. 0910-0883

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports FDA research in obtaining a range of information 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 risks to patients. Compounded drugs are not FDA-approved; they do not undergo FDA premarket review for safety, effectiveness, and quality.

Section 503A of the Federal Food, Drug, and Cosmetic Act (the 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) (21 U.S.C. 351(a)(2)(B)) (current good manufacturing practice (CGMP) requirements), (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (labeling of drugs with adequate directions for use), and (3) section 505 (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--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 for hospitals, clinics, and other providers.

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.

To help strengthen the outsourcing facility industry's ability to provide quality compounded drugs to patients who need them, the Center of Excellence offers training sessions and opportunities to develop manufacturing quality and other policies for outsourcing facilities, including current good manufacturing practices (CGMPs).

The Center of Excellence offers several training sessions (available at https://www.fda.gov/drugs/human-drug-compounding/compounding-quality-center-excellence-training-programs). Self-guided training sessions teach the following topics: (1) environmental monitoring, (2) sterile drug compounding, (3) cleanroom performance tests, and (4) conducting investigations and formulating corrective and preventive actions. Instructor-led sessions teach the regulatory framework for these topics: (1) human drug compounding, (2) airflow practices, (3) insanitary conditions and sterility, (3) stability and beyond use dates, (4) requirements for outsourcing facility guides, and (5) conducting investigations and formulating corrective and preventive actions. Management and staff from outsourcing facilities have attended the training sessions. Feedback on the training sessions has been positive, and interest in the sessions continues to grow.

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) challenges and opportunities related to other 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 conferences and 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 the Spring of 2021. 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 October 1, 2021 (86 FR 54450), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment from an industry association relating to the quality of questions previously posed to industry stakeholders concerning outsourcing facilities. Specifically, the commenter claimed that the proposed questions included in the 60-Day notice were insufficient to fully acquire information relating to the challenges and opportunities outsourcing facilities face. Accordingly, the commenter provided a number of additional questions for FDA to use, which the commenter believes will better solicit relevant information. FDA has considered the commenter's additional questions and will take them under advisement for possible inclusion in future studies. However, at this time FDA will not include the commenter's questions in this particular study because we believe the proposed questions listed in the 60-Day notice will sufficiently solicit the specific information we are currently seeking.

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

This ICR does not collect personally identifiable information (PII) or information of a personal nature. This information collection supports an FDA compounding program. Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.

FDA further determined that this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA (including vendors or service providers acting on behalf of FDA) does not use names or any other personal identifier to retrieve records from the information collected.

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate handling of information collected.

The survey will be distributed to a limited group who have already registered with FDA. Respondents to the survey will remain anonymous to provide assurances of privacy and non-attribution.

- No personally identifiable information (PII) is being collected as part of this data collection.
- A System of Record Notice (SORN) is not required for this collection because records are not retrievable by PII.
- A Privacy Impact Assessment (PIA) is not required for this collection because PII is not being collected electronically.
- A Privacy Act Statement is not required for this collection because we are not requesting individuals to furnish personal information for a system of records.

11. Justification for Sensitive Questions

This information collection does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Time (in hours) per Response	Total Hours
Surveys, focus groups, and interviews	300	2	600	1	600

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Outsourcing Facility Manager	600	$47.95	$28,770

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 600 responses by the $23.70 cost to process each response, which results in a total labor cost to the Federal government of $14,220. 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 $14,220.

Labor Cost to the Federal Government (Contract Costs)

a. Number of Total Annual Responses:	600
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:	$14,220 = (600*$23.70)

Overall Labor Burden to Federal Government

a. Total Number of Annual Responses:	600
b. Total Labor Burden:	$14,220

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:	$14,220
3. Total Cost to the Federal Government:	$14,220

15. Explanation for Program Changes or Adjustments

OMB approved our original request for the information collection January 21, 2020. We administered the survey to outsourcing facilities. The second annual survey administered in 2021 and was similar in length and content to the previous survey. We have made no adjustments to our current burden estimate.

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	1-15-2022	3-19-2022
Issue survey(s) to registered outsourcing facilities and collect results	4-01-2022	4-01-2024

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.