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 a Food and Drug Administration 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.

The Drug Quality and Security Act of 2013 created "outsourcing facilities" – a new type of drug compounder, regulated under Section 503B of the Federal Food, Drug, and Cosmetic Act, that is held to higher quality standards for drug production to protect patient health. Outsourcing facilities are intended to offer a safer, more reliable supply of compounded drugs needed by hospitals, clinics, and other health care providers to administer to patients. Six years since its creation, this domestic industry is still relatively small (approximately 70 entities), is experiencing growth challenges, and is not yet fulfilling its potential to supply high-quality, needed drugs for patients. Outsourcing facilities have encountered barriers that limit entry and advancement, and FDA continues to find quality and safety problems during inspections that raise public health concerns.

FDA seeks to engage in research to analyze and better understand perspectives on challenges and opportunities faced by outsourcing facilities as they attempt to supply safe, high-quality drug products needed by patients. The agency currently lacks information in this area and the information is not available through other entities. FDA seeks to obtain this information through use of targeted surveys.

This is an extension of research that began last year. We have learned about barriers and opportunities encountered by outsourcing facilities in several areas. These include: operational barriers and opportunities related to the outsourcing facility market and business viability; knowledge and operational barriers and opportunities related to compliance with federal policies and good quality drug production; and barriers and opportunities related to outsourcing facility interactions with FDA. We need to extend this information collection for two reasons: 1. Based on what we learned, we will want to ask some follow up questions in these areas. 2. We received a low response rate and need to reach the rest of the outsourcing facility industry. We only managed to obtain completed surveys from approximately one third of respondents. Only 45% of outsourcing facilities provided any response to the survey. Therefore, over half of outsourcing facilities did not respond to our survey and we were unable to obtain their viewpoints.

2. Purpose and Use of the Information Collection

The results of this research will be used by FDA to develop a comprehensive understanding of the outsourcing facility sector, its challenges, and opportunities for advancement. The information

will be essential to help identify knowledge and information gaps, operational barriers, and views on interactions with FDA. The research results will inform FDA's future approaches to communication, education, training, and other engagement with outsourcing facilities to address challenges and support advancement of the industry in its ability to produce high-quality drug products that are safe for patients.

3. Use of Improved Information Technology and Burden Reduction

An electronic survey will be used to administer the survey. The electronic survey will use standardized questions submitted as part of this package. Skip patterns will be applied to tailor the survey questions to the respondent in order to reduce burden.

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 one-time collection in the Spring of 2021 with the potential for occasional repeat surveys, as needed. 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 needed by patients.

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

There are no special circumstances for this collection of information.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *Federal Register* of June 18, 2020 (85 FR 36857). FDA received four comments. Although four comments were received, three were not responsive to the four collection of information topics solicited and therefore will not be discussed in this document. The other comment included a number of suggested questions to expand upon the questions posed in the 60-day notice and therefore can be considered ways to enhance the quality, utility, and clarity of the information to be collected. While the questions will not be included verbatim in our survey instrument, FDA will give the questions due consideration as the Agency proceeds with this study.

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

This ICR does not collect personally identifiable information (PII) or information of a personal nature. This information collection supports a Food and Drug Administration, 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 name 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 the 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

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

The following is a calculation of the annualized reporting burden for this information collection. FDA updated this calculation from its 30-day notice, decreasing the estimated total hours given a refined estimate of the number of respondents.

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Survey	300	2	600	1	600

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

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 (visited November 05, 2019).

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

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

14. Annualized Cost to the Federal Government

The annualized cost to the federal government has been calculated by multiplying the total number of responses – 600 – by the cost to process each response – $23.70 – to get a total labor cost to the government of $14,220. The cost to process each response was calculated by multiplying the hourly wage of worker's processing the responses – $94.80 – 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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

Select information collected as part of this survey may be published as part of FDA's future approaches to communication, education, training, and other engagement with outsourcing facilities to address challenges and support advancement. The collection and tabulation of the results will be combined 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) is as follows:

Activity	Estimated Start Date	Estimated End Date
OMB review of PRA package	1-15-2021	3-19-2021
Issue survey(s) to registered outsourcing facilities and collect results	4-01-2021	4-01-2023

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

There are no exceptions to the certification.