4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3077]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Obtaining Information to Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0883. Also include the FDA docket number found in brackets in the heading of this document.

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, 301-796-7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

OMB Control Number 0910-0883--Extension

This information collection supports Agency-sponsored research. Drug compounding is generally the practice of combining, mixing, or altering ingredients of a drug to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients when an approved drug is not medically appropriate, they also present a risk to patients. Compounded drugs are not FDA-approved. Therefore, they do not undergo premarket review by FDA for safety, effectiveness, and quality. Since compounded drugs are subject to a lower regulatory standard than approved drugs, Federal law places conditions on compounding that are designed to protect the public health.

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 protect patient health. Outsourcing facilities are intended to offer a more reliable supply of compounded drugs needed by hospitals, clinics, and other providers. Seven years since its creation, this domestic industry is still relatively small and is experiencing growth and market challenges. In addition, FDA continues to find concerning quality and safety problems during inspections.

To help this industry meet its intended function, FDA intends to engage in several initiatives to address challenges and support compliance and advancement. One initiative includes conducting in-depth research to understand better the challenges and opportunities encountered by the outsourcing facility sector in a number of different 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.

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 percent 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. 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.

Researchers will engage pharmacists, staff, and management from outsourcing facilities and similar compounding businesses. Researchers may use surveys, interviews, and focus groups to obtain information concerning challenges and opportunities encountered by outsourcing facilities. Within this context, the following questions or similar, related questions may be posed:

1. What financial and operational considerations inform outsourcing facility operational and business model decisions?
2. What factors impact the development of a sustainable outsourcing facility business?

3. What financial and operational considerations inform outsourcing facility product decisions?
4. Do outsourcing facilities understand the Federal legislative and regulatory policies that apply to them? What, if any, knowledge gaps need to be addressed?
5. What challenges do outsourcing facilities face when implementing Federal current good manufacturing practice (CGMP) requirements?
6. How do outsourcing facilities implement quality practices at their facilities?
7. How is CGMP and quality expertise developed by outsourcing facilities? How do they obtain this knowledge, and what training do they need?
8. What are the economic consequences of CGMP noncompliance/product failures for outsourcing facilities?
9. What are outsourcing facility management and staff views on current interactions with FDA? How do they want the interactions to change?
10. What are outsourcing facilities' understanding of how to engage with FDA during and following an inspection?

In the *Federal Register* of June 18, 2020 (85 FR 36857), FDA published a 60-day notice requesting public comment on the proposed collection of information. 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.

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

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
Surveys, focus groups, and interviews	300	2	600	1	600

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

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

Dated: November 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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