Dated: December 28, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021–28474 Filed 1–3–22; 8:45 am]

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## 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, Agency, or we) 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 February 3, 2022.

**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 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 to 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) (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''—a new industry sector of drug compounders held to higher quality standards to 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 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 for 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 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, (4) stability and beyond use dates, (5) requirements for outsourcing facility guides, and (6) 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) barriers and opportunities related to outsourcing facility interactions with FDA.

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.

Researchers engage with pharmacists, staff, management from outsourcing facilities, similar compounding businesses, and related stakeholders and may use surveys, interviews, and focus groups to obtain information about outsourcing facilities' challenges and opportunities. Within this context, we may pose the following questions or similar, related questions:

1. What financial and operational considerations inform outsourcing facility operational and business model decisions?
2. What factors impact developing a sustainable outsourcing facility business?
3. What financial and operational considerations inform outsourcing facility product decisions?
4. Do outsourcing facilities understand the Federal laws and policies that apply to them? What, if any, knowledge gaps do we need to address?
5. What are outsourcing facilities' challenges when implementing Federal CGMP requirements?
6. How do outsourcing facilities implement quality practices at their facilities?
7. How do outsourcing facilities develop CGMP and quality expertise? How do they obtain this knowledge, and what training do they need?
8. What are the economic consequences of CGMP noncompliance and 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 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 stated 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity | Number of respondents | Number 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.

Our original request for the information collection was approved January 21, 2020; however, the subsequent public health emergency inhibited our ability to administer the requested survey. We have therefore made no adjustments to our current burden estimate.

Dated: December 28, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Statement of Organization, Functions, and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Recourses and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 86 FR 48737–48743 dated August 31, 2021).

This reorganization updates the functions of the HIV/AIDS Bureau's Division Policy and Data (RVA).

**Chapter RVA—Division of Policy and Data**

*Section RVA.20 Function*

Delete the functional statement for the Division of Policy and Data (RVA) in its entirety and replace with the following:

**Division of Policy and Data (RVA)**

The Division of Policy and Data serves as the Bureau's focal point for program data collection and analysis, development of policy guidance, advancement of implementation science, and analyses of data for reports for dissemination, coordination of program and clinical performance activities, and technical assistance and training internally and externally. The division directs and manages the portfolio of recipients and programs funded under Special Projects of