TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
514.87(a)–(e)—Annual Reports for Sponsors With Inactive Applications—Electronic Submission	10	17.9	179	2	358
Total					8,338

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

We base our estimate of the average burden per response on our recent experience with the existing antimicrobial animal drug distribution reports program. We base our estimate of the number of affected respondents reported in tables 1 and 2 and the average number of responses per respondent in table 1 on a review of our records of sponsors with active and inactive applications. We estimate sponsors with active applications, who submit an annual antimicrobial annual drug sales and distribution report on paper, will spend 62 hours to assemble the necessary information, prepare, and submit to FDA. We estimate sponsors with active applications, who submit an annual antimicrobial animal drug sales and distribution report electronically, will spend 52 hours to assemble the necessary information, prepare, and submit to FDA. We estimate that sponsors with inactive applications will spend 2 hours preparing their annual antimicrobial animal drug sales and distribution reports, whether electronically or on paper.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping required by section 512(l)(3) of the FD&C Act	23	1	23	2	46

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

Animal drug manufacturers are already required to maintain distribution records for their animal drug products to comply with FDA's current good manufacturing regulations for periodic drug reports under § 514.80(b)(4)(i) (21 CFR 514.80(b)(4)(i)), approved under OMB control number 0910–0284. Section 512(l)(3) of the FD&C Act differs from § 514.80(b)(4)(i) in that it requires that records include separate information for each month of the calendar year. In addition, under 21 CFR 211.196 (approved under OMB control number 0910–0139), manufacturers currently are required to maintain distribution records that include dosage form, and date drug is distributed. Based on these requirements, FDA believes that manufacturers already keep detailed records of the dates when antimicrobial drugs are distributed for marketing and recall purposes from which monthly reports can be prepared as part of usual and customary business practices. However, FDA estimates an additional recordkeeping burden of 46 hours for further compliance with section 512(l)(3), as detailed in table 2.

After a review of the information collection since our last request for OMB approval, we have adjusted our estimates based on our experience with the antimicrobial animal drug distribution reports program. Our estimated burden for the information collection reflects a decrease of 54 burden hours and a corresponding decrease of 27 total annual responses. We attribute this to respondents who submitted by paper in previous years and are now reporting electronically.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–07587 Filed 4–30–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3762]

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 June 2, 2025.

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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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 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 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) 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 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.

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.

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.

Researchers engage with pharmacists, staff, and management from outsourcing facilities and similar compounding businesses, and related stakeholders and use surveys 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?

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

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.

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

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

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 to 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.

Based on a review of the information collection since our last request for OMB approval, we have made adjustments to our burden estimate. Our estimated burden for the information collection reflects an overall decrease of 454 hours and a corresponding decrease of 100 responses. We have also reduced our estimated burden per survey response from 1 hour to 30 minutes.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0082]

Agency Information Collection Activities; Proposed Collection; Comment Request; Compounding Animal Drugs From Bulk Drug Substances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the recordkeeping provisions set forth in Guidance for Industry, GFI #256—Compounding Animal Drugs from Bulk Substances.

DATES: Either electronic or written comments on the collection of information must be submitted by June 30, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 30, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.