This guidance represents FDA's current thinking on ''Control of Nitrosamine Impurities in Human Drugs.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 312 pertaining to investigational new drug applications, including meetings at the ''pre-NDA'' stage, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to new drug applications, abbreviated new drug applications, amendments and supplemental applications, and formal meetings with FDA about drug development programs have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to biologics license applications have been approved under OMB control number 0910–0338. The collections of information pertaining to over-the-counter monograph drug products have been approved under OMB control number 0910–0340. The collections of information pertaining to meetings related to generic drug development, including controlled correspondences, have been approved under OMB control number 0910–0727.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: August 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19883 Filed 9–4–24; 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; Proposed Collection; 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 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 information collection associated with FDA research in obtaining information from pharmacists and other management at outsourcing facilities and related human prescription drug compounding businesses. The research supports a comprehensive analysis of the outsourcing facility sector that informs ongoing FDA work in this area.

DATES: Either electronic or written comments on the collection of information must be submitted by November 4, 2024.

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 November 4, 2024. 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. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–3762 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Obtaining Information to Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the

claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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.

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.

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	0.75 (45 mins)	188
Total			500		209

[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 anticipate a slight reduction in burden hours to 45 minutes (0.75 hour) per survey response from our previous estimate of 1 hour per response. We estimate that approximately 250 respondents will spend 45 minutes completing the survey, for a total of 187.5 burden hours per year, rounded to 188 hours.

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 391 hours and a corresponding decrease of 100 responses. We have also reduced our estimated burden per survey response from 1 hour to 45 minutes.

Dated: August 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19870 Filed 9–4–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Allergy, Immunology, and Transplantation Research Committee.

Date: October 24–25, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G51, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Thomas F. Conway, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G51, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G51, Rockville, MD 20892, 240–507–9685, *thomas.conway@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)