4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-5128]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

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 information collection relating to human drug compounding.

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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-2026-N-5128 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act." 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.

1. 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: Anne Taylor, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-402-5683, 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/reinstatement 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.

Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910-0800 – Revision

This information collection helps support the implementation of sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a and 353b); *Pharmacy Compounding and Outsourcing Facilities*. 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. Although compounded drugs can serve an important medical need for certain patients, they may also present risks. Our compounding program aims to protect patients from unsafe, ineffective, and poor-quality compounded drugs, while preserving access to lawfully-marketed compounded drugs for patients who have a medical need for them.

Respondents to the information collection are those engaged in the practice of human drug compounding. The information collection is intended to account for burden attributable to activities pertaining to the registration of outsourcing facilities and reporting of drugs, as established in sections 503B(b)(1) through 503B(b)(3) of the FD&C Act. The information collection is also intended to account for burden attributable to certain activities associated with the submission of adverse event reports, as required under section 503B(b)(5) of the FD&C Act. Additionally, the information collection is intended to account for burden attributable to certain activities associated with the documentation of clinical need of a compounded drug product as described in the revised draft guidance entitled "Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act". Finally, the information collection is intended to account for burden attributable to activities associated with States entering into memoranda of understanding with the Secretary, as described in section 503A(b)(3) of the FD&C Act.

To help respondents understand statutory requirements applicable to compounding activities governed by the FD&C Act, we have developed the following topical guidance documents:

- "*Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*" (January 3, 2017), available on our website at https://www.fda.gov/media/90173/download. The guidance is intended for entities that compound human drugs and elect to register as outsourcing facilities under section 503B of the FD&C Act. Once an entity has elected to register as an outsourcing facility, it must submit reports identifying the drugs compounded by the outsourcing facility. The guidance describes who must report, the format of the report, the content to include in each report, when to report, how outsourcing facilities may submit reports to FDA, and the consequences of outsourcing facilities' failure to submit reports.
- "*Adverse Event Reporting (AER) for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*" (October 8, 2015), available at Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act | FDA. The guidance document is intended for firms that have registered with FDA under section 503B of the FD&C Act as human drug compounding outsourcing facilities (outsourcing facilities). Under section 503B(b)(5) of the FD&C Act, an outsourcing facility must submit adverse event reports to FDA "in accordance with 21 CFR 310.305(e)(1)." The guidance document explains that, under 21 CFR 310.305(c)(1), manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved new drug or abbreviated new drug application must submit to FDA serious and unexpected adverse event reports within 15 calendar days of receiving the information and must submit follow-up reports within 15 calendar days of receipt of new information about the serious adverse event, or as requested by FDA. Also, under §310.305(f), entities must maintain for 10 years the records of all adverse events required to be reported

under § 310.305. The guidance document also explains that, in accordance with regulatory requirements, adverse event reports must be submitted in an electronic format that FDA can process, review, and archive (collection of information is submitted via Form FDA 3500A (MedWatch), approved under OMB control number 0910-0291). A copy of the current labeling of the compounded drug product must be provided in the report.

- "*Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act*" (October 2021, Revision 1), available at https://www.fda.gov/media/97353/download. A condition under section 503A(b)(2) of the FD&C Act, is a drug product must be compounded by a licensed pharmacist or a licensed physician that "does not compound regularly or in inordinate amounts (as defined by [FDA]) any drug products that are essentially copies of a commercially available drug product. Pursuant to section 503A(b)(2) of the FD&C Act, a compounded drug product is not essentially a copy of a commercially available drug product if a change is made to the commercially available drug product for an identified individual patient, and the prescribing practitioner has determined that the change will produce a significant difference for that patient. As described in the FDA's 503A copies guidance, if a compounder intends to rely on such a determination to establish that a compounded drug is not essentially a copy, the compounder should ensure that the determination is documented on the prescription. The guidance explains that FDA generally would not intend to take action against a hospital or health system pharmacy that is not an outsourcing facility for compounding a drug product regularly or in inordinate amounts that is essentially a copy of commercial available drug product, if the compounded drug product is administered only to patients within the hospital or health system and the pharmacy obtains from the prescriber a statement that: (1) Specifies a change between the

compounded drug product and the commercially available drug product; (2) indicates that the compounded drug product will be administered only to patients for whom a change produces a significant difference from the commercially available drug product; and (3) describes the intended patient population for the compounded drug product. The guidance also specifies that the statement would be maintained in the hospital or health system pharmacy to address routine orders for patients whom the change produces a significant difference, and a statement would be on file for each prescriber that covers each drug product that is compounded.

We maintain a searchable database on our website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents that includes other topical guidance pertaining to human drug compounding. Guidance documents are issued consistent with FDA's good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time. Please see 21 CFR 10.115(f) for instruction on how to participate in the development and issuance of FDA guidance documents.

In the Federal Register of February 23, 2026 (91 FR 8495), we published a 30-day notice announcing that we had submitted this collection to OMB for review and clearance under the PRA to extend OMB approval. With this notice we are announcing a revision to this collection. We are revising the information collection to include reporting activities related to a human drug compounding cross-sector stakeholder group. As part of its efforts under FDA’s Compounding Quality Center of Excellence, FDA seeks to better understand the challenges and barriers that compounders, outsourcing facilities, and other stakeholders encounter related to the purchasing, production, distribution, and use of compounded drugs, as well as opportunities for education and growth in these areas. The Agency also seeks to gain further insight into any issues that the compounding sector faces in fully complying with relevant policies, laws, and regulatory oversight. A comprehensive understanding of the compounding sector—its challenges and

successes—is essential to the growth and success of FDA's endeavors to protect the public health.

The cross-sector stakeholder group will be comprised of up to 30 stakeholders, including entities such as outsourcing facilities with different business models, hospitals, health systems, physician groups, and suppliers of drug ingredients and components. The purpose of these meetings will be to gather individual perspectives on topics such as demand and patient need, quality, drug shortages, the current and future roles of 503B outsourcing facilities, education, and messaging about the 503B outsourcing facility industry, or other cross-cutting issues germane to human drug compounding. The goals of the meetings are to improve FDA's understanding of complex issues relevant to compounding and to foster cross-disciplinary discussion within the compounding sector. An existing limited iteration of the cross-sector stakeholder group has discussed topics such as drug shortages, educating stakeholders about the outsourcing facility industry, compounding in outsourcing facilities, the future role of outsourcing facilities, drug approval pathways, and drug compendia databases. Individual perspectives shared by group members during meetings of the existing small group have been instrumental in understanding challenges faced by the industry as well as potential opportunities to catalyze solutions that improve the quality of compounded drugs, safeguarding patients. It is based on the success of this initiative that we want to continue and expand the Cross-Sector Stakeholder group.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1, 2]

Information Collection Activity in Sections 503A and 503B of the FD&C Act	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
503B AERs	55	1	55	1.10	61
503B Recordkeeping AERs	55	1	55	16	880
503A Reporting	45	197.3111	8,879	0.87	7,725
503A Recordkeeping	45	2	90	1	90
503A Disclosure (MOU)	1	1	1	1	1
Outsourcing facility drug product reporting under 503B(b)	75	108.1467	8,111	0.025 (1.5 mins)	203
Cross-sector stakeholder group meeting planning, participation, and follow up	30	9	270	2	540
Total			17,461		9,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Figures have been rounded.

As shown in Table 1, we estimate an increase in reporting burden hours and annual responses associated with the cross-sector stakeholder group. We have otherwise retained our currently approved reporting burden estimates. We base our estimates on our experience with compounding related activities. We estimate that 30 respondents will participate in the cross-sector stakeholder group. We anticipate that respondents will engage in approximately 9 various meeting preparation and planning, meeting participation, and meeting follow up activities. We anticipate that these activities will take respondents approximately two hours per response, on average.

Our estimated reporting burden for the information collection reflects an increase of 540 hours and a corresponding increase of 270 responses. We attribute this increase to activities associated with the cross-sector stakeholder group.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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