DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–4348]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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 March 25, 2026.

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 0910–0800. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

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

OMB Control Number 0910–0800—Extension

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 also present risk. 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 pharmacy 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. Additionally, the information collection is 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. 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 submit to FDA 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 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.

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 November 24, 2025 (90 FR 52965), we published a 60-day notice soliciting comment on the proposed collection of information. Five comments have been posted to the docket, which we have subsequently evaluated. All commenters appear to recognize the practical utility of the collection activities in supporting FDA's public health protection goals, but asked for increased transparency regarding specific elements. We appreciate this

feedback and remind interested readers that FDA published its 60-day notice in compliance with requirements of the PRA, as administered by OMB, and uses the notice as way to help us with the ongoing evaluation of our existing collection inventory. Toward that end, we have updated explanatory text that accompanies our burden estimate figures. At the same time, we have made no adjustments to our estimated annualized burden.

With regard to comments pertaining to certain AER follow-up information, it is our understanding that provision in 5 CFR 1320.3(h)(5) excepts this collection activity from what an Agency must consider in its calculation of burden to respondents. For the benefit of our stakeholders, however, we note that the majority of burden attributable to information collection activities associated with AER and FDA's MedWatch program is currently approved in OMB control number 0910–0291. Also, other postmarketing AER information collection activity for drugs is accounted for in OMB control number 0910–0230. We have therefore confined our calculation of burden for this information collection to those activities we believe may be attributable to tasks recommended in specific FDA guidance. Established in 2015 to account for burden associated with guidance pertaining to AER for certain facilities as referenced above in this notice, the information collection has evolved to include burden that may be attributable to FDA guidance pertaining to the electronic submission of information, previously approved and included in OMB control number 0910–0827.

Relatedly, we note three other currently approved information collections that account for burden attributable to statutory requirements in sections 503A and 503B: (1) OMB control number 0910–0776, *Registration of Human Drug Compounding Outsourcing Facilities under section 503B of the FFDCA and Associated fees under section 744K,* established in 2014 to account for burden that may be attributable to FDA guidance discussing applicable fees; (2) OMB control number 0910–0858, *Human Drug Compounding, Repackaging, and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act,* established in 2018 to account for burden that may be attributable to FDA guidance discussing various respective compounding activities; and (3) OMB control number 0910–0883, *Obtaining Information to Understand and Challenges and Opportunities Encountered by Compounding Outsourcing Facilities,* established in 2020 to account for burden that may be attributable to FDA efforts undertaken to help inform us how best to utilize our limited resources toward ensuring the safety of human drug compounding. We note, also, comment on the latter collection, currently pending OMB review and approval under the PRA.

With regard to comments on burden estimates associated with States entering into memoranda of understanding with the Secretary, as described in section 503A(b)(3) of the FD&C Act, we again remind readers our 60-day notice was published in compliance with requirements of the PRA. Acknowledging no current activity in this regard, the figure of ''1'' is proffered in accordance with FDA's understanding of requirements in 5 CFR 1320.5(a), as a minimum placeholder for potential activity and in acknowledgement of any burden associated with informal inquiry, as described in 5 CFR 1320.3(b)(1)(5).

With regard to comments pertaining to the accuracy of FDA's estimate of both the number of respondents and amount of effort for requisite tasks, we appreciate the need for greater clarity. As FDA has communicated in previous notices, there are challenges in determining the precise number of respondents to the various information collection tasks, as well as in determining what specific activities are subject to review and approval by OMB under the PRA. Some activities may be considered usual and customary (5 CFR 1320.3(b)(2)) and therefore not subject to such review and approval. For this reason we have retained our currently approved estimates, but continue to consider public comment regarding the number of potential respondents to the collection activities as well as the corresponding annualized burden.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

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	8,879	0.87	7,968
503A Recordkeeping	45	2	90	1	90
503A Disclosure (MOU)	1	1	1	1	1
Outsourcing facility reporting under 503B(b)	75	~108	8,111	0.2	214
Total			17,191		9,214

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

While we have retained our currently approved burden estimates, we have corrected an inadvertent omission from our 60-day notice in row 6 of Table 1 reflecting the number of estimated responses and average burden per response.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–03448 Filed 2–20–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

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