



January 23, 2026

[Submitted electronically to www.reginfo.gov]

Docket Management Staff (HFA-305)
c/o Lowell M. Zeta,
Acting Deputy Commissioner for Policy, Legislation, and International Affairs.
Food and Drug Administration (FDA)
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: [\[Docket No. FDA-2025-N-4348\]](#) Agency Information Collection Activities; Proposed Collection; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

Dear Acting Deputy Commissioner Zeta,

The American Pharmacists Association (APhA) is pleased to submit comments to FDA and the Department of Health and Human Services (HHS) on the “Agency Information Collection Activities; Proposed Collection; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act” notice.

APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

[OMB Control Number 0910-0800–Extension](#) (FR 52966)

Within this notice, FDA and HHS note this “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.”¹ FDA and HHS also state this “information collection is intended to account for burden

¹ Agency Information Collection Activities; Proposed Collection; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act, 90 Fed. Reg. 52965, 52966 (Nov. 24, 2025). Available at: <https://www.federalregister.gov/d/2025-20773/p-19>.

attributable to activities associated with States entering into memoranda of understanding with the Secretary, as described in section 503(A)(b)(3) of the FD&C Act.”² Table 1 provides the estimated average burden per response for the following:³

Excerpts from Table 1 – Estimated Annual Reporting Burden

Section 503B of the FD&C Act	Average Burden Per Response
503B AERS	1.10
503B Recordkeeping AERs	16
503A Reporting	0.87
503A Recordkeeping	1
503A Disclosure (MOU)	1
Total	19.97

APhA’s Compounding Community finds that FDA has underestimated the annual reporting burden. Accordingly, APhA asks FDA and HHS to reevaluate the estimated time burdens presented within Table 1 of the notice. FDA and HHS estimate to receive responses from only 55 individuals related to 503B AERs and 503B Recordkeeping AERs, and 45 individuals on the 503A Reporting and 503A Recordkeeping. Given the anticipated respondents to this “information collection are those engaged in the practice of pharmacy compounding,”⁴ APhA believes this estimate is low, as the number of pharmacists and entities involved in compounding under both 503A and 503B, combined, is in the thousands. As such, APhA encourages FDA and HHS to update this estimate and to better incorporate feedback from the pharmacy compounding community to understand the impact of these reporting and recordkeeping requirements.

Additionally, in reviewing this notice, FDA and HHS include links to the [Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry](#) document and the [Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry](#) document. These documents review certain reporting requirements and the corresponding processes; however, these processes need to be streamlined and updated to eliminate any potential redundancies with existing reporting requirements. APhA respectfully asks FDA and HHS to honor their commitment to health care providers, including our nation’s compounding pharmacists, under the [May 13, 2025, deregulatory initiative](#) to spend more time on patient care, including addressing drug shortages and providing personalized medicines, rather than being bogged down by unnecessary overregulation.

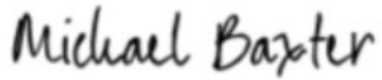
² *Id.*

³ *Id.* at 52967. Available at: <https://www.federalregister.gov/d/2025-20773/p-24>.

⁴ *Id.* at 52966. Available at: <https://www.federalregister.gov/d/2025-20773/p-19>.

Thank you for the opportunity to submit comments on this notice. If you have any questions or would like to meet with APhA and our nation's pharmacists, including those within APhA's Compounding Community, please contact Corey Whetzel, APhA's Senior Manager, Regulatory Affairs, at cwhetzel@aphanet.org.

Sincerely,

A handwritten signature in black ink that reads "Michael Baxter". The script is cursive and fluid.

Michael Baxter
Vice President, Government Affairs