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January 23, 2026

Dockets Management Staff (HFA-305)
Food and Drug Administration
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

To Whom It May Concern:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is pleased to submit these comments in response to the Food and Drug Administration's ("FDA" or "the Agency") request for comments on the Agency Information Collection Activities on Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act ("comment request").

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

PhRMA members believe patients deserve rigorously tested medicines that are proven to be safe and effective. That principle is the foundation of the FDA's "gold standard" drug-review process, which is reinforced by the limited exceptions in the federal legal framework for compounding. As FDA has itself acknowledged, compounded drugs are not approved by FDA and are not subject to the same rigorous requirements as FDA-approved medicines.[1] Accordingly, to prevent patient exposure to serious health risks, FDA has recognized that "[c]ompounded drugs should only be used in patients whose medical needs cannot be met by an FDA-approved drug."[2] Over the last several years, however, there has been an explosion in mass compounding—far beyond what Congress intended when it enacted the limited exceptions to the FDA's "gold standard" drug approval framework for compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act ("FDCA"). This has resulted in American patients being exposed to substandard medicines on an enormous scale. Furthermore, lack of firm and decisive action by FDA has resulted in a vast quantity of unapproved and untested drugs contaminating the U.S. drug supply chain. This is evidenced by the more than 70,000 vials of compounded GLP-1 products that have been recalled, mostly due to lack of sterility.[3]

Our comments here focus on the comment request's solicitation of feedback on, among other things, the "accuracy of FDA's estimate of the burden of the proposed collection of information." The comment request includes several assumptions and estimates that do not accurately reflect the current legal and policy landscape for 503A and 503B compounders. Our comments here highlight these inaccuracies and the related patient safety risks.

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[1] FDA, Compounding and the FDA: Questions and Answers (accessed Jan. 5, 2026), https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.
[2] *Id.*
[3] *See* FDA, Recalls Dashboard, https://datadashboard.fda.gov/oii/cd/recalls.htm.

I. The Comment Request Fails to Reflect the Current Absence of Reporting and Recordkeeping of Adverse Events and Product Quality Issues for 503A Compounded Drugs

FDA inaccurately estimates the burden attributable to activities associated with states entering into memoranda of understanding ("MOU") with FDA under section 503A(b)(3) of the FDCA. For "503A Reporting" and "503A Recordkeeping," the comment request estimates 45 respondents with a total burden of 7,968 hours (for reporting) and 90 hours (for recordkeeping). The comment request also estimates one hour of estimated annual burden associated with "503A Disclosure (MOU)." These estimates do not reflect the current absence of reporting and recordkeeping by 503A compounders under section 503A(b)(3).

Section 503A(b)(3)(B) sets forth differing requirements for 503A compounders depending on whether or not the state in which the 503A compounding takes place has entered into a MOU with FDA that "addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State."[4] If the state in which the 503A compounding takes place has *not* entered into an MOU, then the 503A compounder can only "distribute[] . . . compounded drug products out of the State . . . in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy."[5]

In October 2020, FDA made a standard MOU available for signature by the states that would have required 503A compounders and the states to report and keep records concerning complaints of adverse drug experiences and product quality issues relating to human drug products compounded by an intrastate pharmacy and distributed interstate.[6] However, following litigation challenging the MOU, FDA suspended the MOU and extended its existing policy of enforcement discretion on the 5% limit until FDA completes rulemaking related to the MOU and 5% limit provisions.[7] FDA's current policy is that "FDA will not enter into new agreements with States based on the October 2020 standard MOU" and that the Agency "does not expect States that have signed the October 2020 standard MOU to carry out the activities described in the MOU."[8] Accordingly, **there are currently no information collection burdens for adverse events or product quality issues associated with compounded drug products under section 503A(b)(3)**.

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[4] FDCA § 503A(b)(3)(B)(i).
[5] *Id.* § 503A(b)(3)(B)(ii).
[6] FDA, Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State Board of Pharmacy or Other Appropriate State Agency and the Food and Drug Administration; Availability, 85 Fed. Reg. 68,074 (Oct. 27, 2020), https://www.federalregister.gov/documents/2020/10/27/2020-23687/memorandum-of-understanding-addressing-certain-distributions-of-compounded-human-drug-products; Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [insert State Board of Pharmacy or other appropriate state agency] and the U.S. Food and Drug Administration, https://www.fda.gov/media/143283/download?attachment.
[7] FDA, Extension of the Period Before the Food and Drug Administration Intends To Begin Enforcing the Statutory 5 Percent Limit on Out-of-State Distribution of Compounded Human Drug Products, 87 Fed. Reg. 63,947 (Oct. 21, 2022), https://www.federalregister.gov/documents/2022/10/21/2022-22876/extension-of-the-period-before-the-food-and-drug-administration-intends-to-begin-enforcing-the.
[8] *See* FDA, Memorandum of Understanding Addressing Certain Distributions of Compounded Drugs (accessed Jan. 5, 2026), https://www.fda.gov/drugs/human-drug-compounding/memorandum-understanding-addressing-certain-distributions-compounded-drugs

Moreover, there currently is no burden associated with disclosure related to the MOU in light of FDA's suspension of the 2020 MOU.

This, however, also means that there is no reporting by 503A compounding pharmacies pertaining to the scale and distribution of mass compounded products. This complete lack of any reporting and recordkeeping for adverse events and product quality issues associated with compounded drugs by 503A compounding pharmacies presents significant safety risks and stands in stark contrast to the robust pharmacovigilance and product quality complaint handling by manufacturers of FDA-approved drugs. We strongly encourage FDA to complete the rulemaking related to the MOU and 5% limit provisions and revise the burden estimates accordingly.

FDA must enforce the statutory 5% limitation on out-of-state distribution for 503A compounders to protect patient safety. FDA's current enforcement discretion policy allows compounders to flood the nationwide market with compounded drugs, including unproven compounded GLP-1 drugs made with unverified, foreign-sourced active pharmaceutical ingredient and that are not made in compliance with current good manufacturing practices (CGMP). Enforcement of the 5% limit is particularly important given the prevalence of compounders collaborating with telehealth companies to advertise and sell compounded drugs nationwide in large amounts, often in violation of the 5% interstate distribution limit.[9]

II. The Comment Request Does Not Accurately Reflect the Total Number of 503B Outsourcing Facilities or Their Adverse Event Reporting and Recordkeeping Burdens

FDA inaccurately characterizes the number of outsourcing facilities required to submit adverse event reports ("AERs") under section 503B and underestimates their reporting and recordkeeping burdens. For "503B AERs" and "503B Recordkeeping AERs," the comment request estimates 55 total respondents with an total estimated annual burden of 61 hours (for 503B AERs) and 880 hours (for 503B recordkeeping AERs). These estimates do not reflect the number of currently registered outsourcing facilities or their adverse event reporting and recordkeeping burdens.

Under section 503B of the FDCA, outsourcing facilities must "submit adverse event reports to [FDA] in accordance with the content and format requirements established through guidance or regulation under [21 CFR 310.305]." FDA has published guidance detailing the adverse event reporting requirements applicable to 503B outsourcing facilities.[10] As the Agency explains in the guidance:

> Adverse event reporting for drug products compounded by outsourcing facilities is a critical mechanism by which FDA identifies signals of potential quality problems that may be associated with a particular drug or drug component and which may have been caused by

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[9] The recent explosion in irresponsible and misleading advertising by telehealth companies, including about compounded GLP-1 drugs like the Hims & Hers Super Bowl commercial, puts patients' safety at risk. *See, e.g.,* FDA, Warning Letter to Hims & Hers Health, Inc. dba Hers (Sept. 9, 2025); BBB National Programs. National Advertising Division Will Refer Willow Health to State and Federal Regulatory Authorities for its Compounded Semaglutide Product Claims, Dec. 4, 2025, https://bbbprograms.org/media/newsroom/decisions/willow-health; Letter from Attorneys General Tong et al, to Meta Platforms, Inc. (Dec. 2025), https://www.attorneygeneral.gov/wp-content/uploads/2025/12/Ltr-to-Meta-re-GLP-w-AG-office-seals_compressed.pdf.

[10] *See* FDA, Guidance for Industry, Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the FDCA (Oct. 2015).

substandard conditions or processes at a facility where the drug or its components were made or handled.[11]

Despite the detailed requirements set forth in the FDCA and implementing regulations, and detailed further in FDA guidance, the Agency estimates an unusually low burden associated with these requirements—an average burden per response of 1.1 hours for annual adverse event report submissions and 16 hours for annual recordkeeping. These low reporting estimates are not realistic for outsourcing facilities that are fully complying with federal law.[12] We strongly encourage FDA to reconsider these estimates.

In addition to the low burden estimates, the Agency also undercounts the estimated number of respondents. The comment request estimates only 55 respondents even though there are 95 registered outsourcing facilities, all of which are required to comply with federal adverse event reporting requirements.[13] We thus also encourage FDA to revise the estimated number of respondents.

Given that adverse event reporting is a "critical mechanism" for identifying safety concerns, especially for compounded drugs which are *not* FDA-approved, PhRMA strongly encourages FDA to better enforce outsourcing facilities' obligations to report adverse events and to adjust its estimated reporting and recordkeeping burdens accordingly.

III. Conclusion

PhRMA strongly agrees with FDA that "[u]nnecessary use of compounded drugs may expose patients to potentially serious health risks."[14] Accordingly, strong enforcement against illegal compounding is critical to patient safety. We strongly encourage FDA to enforce all the requirements set forth in sections 503A and 503B, including those relating to adverse event reporting and handling of product quality complaints, to advance its mission of protecting the public health. The burden estimates from information collection activities on compounding should be revised to reflect that reality.

Respectfully submitted,

/s/
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[11] *Id.* at 3.
[12] Adverse event reports by outsourcing facilities are likely currently underreported. For example, based on FDA's Adverse Event Reporting System database, only two outsourcing facilities have been identified as the sender of an adverse event associated with compounded semaglutide despite there being 920 cases of adverse events associated with compounded semaglutide. We urge FDA to evaluate outsourcing facilities' written and implemented procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to ensure outsourcing facilities have the systems in place to comply with federal adverse event reporting requirements.
[13] *See* FDA, Registered Outsourcing Facilities (accessed Jan. 5, 2026), https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities.
[14] FDA, Compounding and the FDA: Questions and Answers (accessed Jan. 5, 2026), https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.