Alliance for Pharmacy Compounding

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NCPA®
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

January 21, 2026

Submitted electronically via regulations.gov

Documents Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA–2025–N–20773

To Whom It May Concern:

The Alliance for Pharmacy Compounding and the National Community Pharmacists Association submit these comments in response to the Food and Drug Administration's notice entitled "Agency Information Collection Activities; Proposed Collection; Comment Request; Human Drug Compounding."

These comments are limited to the statement in the notice indicating that the proposed information collection is intended to account for the burden attributable to activities associated with States entering into memoranda of understanding (MOUs) with the Secretary under section 503A(b)(3) of the FD&C Act.

No information collection burden exists where the FDA correctly distinguishes dispensing from distribution

We respectfully submit that there is no information collection burden associated with section 503A MOUs if the FDA correctly defines and applies the statutory distinction between dispensing and distribution.

Section 503A authorizes state-licensed pharmacies to compound and dispense patient-specific prescriptions pursuant to the practitioner–patient–pharmacist relationship. It does not authorize 503A pharmacies to engage in wholesale distribution of compounded human drug products. Compounded human drugs produced by 503A pharmacies are dispensed pursuant to prescriptions and are not distributed in interstate commerce as manufactured drugs.

The FDA has acknowledged this distinction that 503A pharmacies are not permitted to distribute compounded human drug products but rather dispense patient-specific prescriptions. As a result, the statutory condition that would trigger MOU-related reporting under section 503A(b)(3) — interstate *distribution* of compounded drugs by pharmacies — does not occur when pharmacies are operating lawfully under section 503A.

Because lawful 503A pharmacy practice does not involve distribution, there is no ongoing state activity requiring entry into MOUs, no reporting obligations triggered by such MOUs, and therefore no associated recordkeeping, reporting, or information collection burden for states or pharmacies.

Including information collection burden estimates associated with section 503A MOUs, without acknowledging that the MOU framework is effectively inapplicable to lawful human drug compounding by 503A pharmacies, risks overstating regulatory burden and perpetuating confusion regarding the scope of permissible pharmacy activity.

We respectfully urge the FDA to clarify in the final information collection analysis that no burden exists related to section 503A MOUs where the FDA correctly distinguishes dispensing from distribution and applies section 503A consistent with the statute and the FDA's stated position.

Thank you for your consideration of these comments.

Sincerely,

Alliance for Pharmacy Compounding
National Community Pharmacists Association

The Alliance for Pharmacy Compounding is the industry trade association and the voice for pharmacy compounding, representing more than 600 compounding small businesses — including 8,000+ compounding pharmacists and technicians in both 503A and 503B settings — as well as prescribers, educators, researchers, and suppliers.

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members employ 205,000 individuals and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.