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Re: Information Collection Request, Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

Docket No. FDA-2025-N-4348 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."

The Massachusetts Pharmacists Association (MPhA) respectfully submits these comments in response to the U.S. Food and Drug Administration's proposed information collection concerning human drug compounding under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.

MPhA represents pharmacists practicing across community, hospital, and institutional settings throughout Massachusetts, including pharmacies engaged in sterile and nonsterile compounding to meet patient-specific clinical needs.

MPhA supports the FDA's commitment to patient safety and the appropriate oversight of compounding activities. Pharmacists share the Agency's goal of ensuring the quality, safety, and integrity of compounded medications. However, we urge the FDA to ensure that any information collection requirements are proportionate, risk-based, and narrowly tailored to avoid unnecessary administrative burden, particularly for community and independent pharmacies operating under Section 503A authority.

Massachusetts already maintains a comprehensive regulatory framework governing pharmacy compounding through the Massachusetts Board of Registration in Pharmacy, including licensure, inspection, recordkeeping, and enforcement requirements. MPhA respectfully encourages the FDA to consider existing state oversight structures when evaluating the scope and necessity of federal data collection, and to avoid duplicative reporting obligations that may divert limited pharmacy resources away from direct patient care without a corresponding patient safety benefit.

Compounded medications play a critical role in patient care when commercially available products are unavailable, inappropriate, or insufficient to meet individualized treatment needs. Excessive or duplicative administrative requirements risk discouraging pharmacies from

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providing compounding services, potentially reducing patient access to essential therapies, particularly for vulnerable and medically complex populations.

Accordingly, MPhA respectfully recommends that the FDA:

1. Ensure that any information collection requirements are risk-based and scaled appropriately to pharmacy size, scope of practice, and compounding complexity.
2. Coordinate with state boards of pharmacy to minimize duplicative or conflicting oversight.
3. Carefully consider the potential impact of additional administrative requirements on patient access to compounded medications.

MPhA appreciates the opportunity to comment and welcomes continued engagement with the FDA to advance patient safety while preserving access to essential pharmacy services.

If there are any questions or any information is needed from us, please contact our Director of Government Affairs, Maria Sosa, via msosa@lantonlaw.com or (216) 860-2756.

Respectfully submitted,

Massachusetts Pharmacists Association

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