APhA
American Pharmacists Association

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Gail Bormel, J.D., R.Ph.
Director, Office of Compounding Quality and Compliance

c/o Director, Division of Prescription Drugs
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2016-D-0271 for "Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act"

Dear Gail:

The American Pharmacists Association (APhA) is pleased to submit comments on FDA's recent revised draft guidance for industry entitled "Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act" ("revised draft guidance").

APhA is the only organization advancing the entire pharmacy profession. Our expert staff, and strong volunteer leadership, including many experienced pharmacists, allow us to deliver vital leadership to help pharmacists, pharmaceutical scientists, student pharmacists and pharmacy technicians find success and satisfaction in their work, while advocating for changes that benefit them, their patients and their communities. Many of our members are affected by the policies laid out in this revised draft guidance and we sought their input in developing these comments.

APhA appreciates the increased flexibility FDA provided by removing the 1-mile restriction on hospital and health-system compounded products without first receiving a valid prescription order (including a chart order) for an identified individual patient. As FDA found, that policy did not take into consideration the structure of health systems, many of which operate under a centralized compounding model and may service patients at facilities at other sites located outside a 1-mile radius that do not have compounding capabilities.

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To ensure that that hospital and health-system compounding can continue to meet patient needs, APhA offers the following recommendations to improve the revised draft guidance to make it workable:

- **Remove the restriction that compounded drug products must be used or discarded within 24-hours of transfer out of the pharmacy.** While well intended, this restriction conflicts with existing USP standards on beyond use dates (BUDs), fand will limit patient access to vital compounded medications, particularly those in shortage, at a hospital or health-system. As you know, 503A compounders follow USP standards. It is unrealistic for compounders to economically or logistically compound enough products to meet patient needs that will be used in such a short-period of time. It would also limit the ability of any compounder to simply compound a drug and hold the residual drug for a single patient for any doses needed beyond this 24-hour window. Furthermore, FDA should clarify and affirm in this guidance that products prepared in accordance with FDA-approved labeling instructions falls outside of FDA's compounding policies and BUDs identified in that labeling should be followed. It also limits access to compounded medications at rural hospitals and health-systems that cannot receive products from 503B outsourcing facilities in a timely manner, which could have serious patient care implications. At a minimum, FDA should allow for use of USP and manufacturer guidance for beyond use dating for emergency use when a patient could come to harm should there be a delay in therapy.
- **Adopt the USP BUD requirements.** Rather than introduce an arbitrary 24-hour limit, FDA should defer to the USP BUD requirements, a standard time-based metric that hospitals and health-systems already observe.
- **Clarify the revised draft guidance only applies to sterile compounding.** As currently written, the revised draft guidance seems to apply to both sterile and non-sterile compounding. Non-sterile compounding is the most common type of drug compounding and is performed widely by both hospital and non-hospital compounding pharmacies. Without clarification, FDA's revised draft guidance will unnecessarily limit patients' access to necessary non-sterile compounded medications at hospitals and health-systems.
- **Refrain from urging a "503B-first" approach:** FDA should remove statements urging hospitals and health-systems to first obtain compounded medications from 503B outsourcing facilities. 503Bs simply cannot meet hospitals and health-systems patient needs. FDA even acknowledged this during the pandemic by issuing flexibility and permitting 503A compounding to fill the gap for manufactured drugs in shortage. The

fact remains that 503B facilities cannot supply all hospital and health-system compounded products because compliance with CGMP requirements makes it cost and/or time prohibitive and many 503B facilities have defined formulary lists. If patients require a compounded product that is not within 503B offerings, the 503B pharmacy has no obligation to compound the product often leaving hospitals and health-systems and their patients without access to the medication. Hospital pharmacies consistently inform us they are at the mercy of outsourcing facilities who chose to compound specific products that bring in business and revenue. Hospitals and health-systems have been compounding drug products for centuries and currently comply with USP 797 and USP 800 standards, which is often required by state boards of pharmacy and the Joint Commission. As such, confidence and reliance on compounding within a hospital or health-system under 503A requirements should be recognized as acceptable by FDA, not as a second choice.

Thank you for considering our recommendations. We look forward to FDA improving the revised draft guidance to ensure patients in hospitals and health-systems have access to the safe and effective compounded medications they need. If you have any questions or require additional information, please contact Michael Baxter, Senior Director of Regulatory Policy, at mbaxter@aphanet.org.

Sincerely,

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Senior Vice President, Pharmacy Practice and Government Affairs