APhA
American Pharmacists Association

January 8, 2024

The Honorable Robert Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

**Re: Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry [Docket No. FDA–2015–D–3517]**

Dear Commissioner Califf:

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments on the "Interim Policy on Compounding Using Bulk Drug Substances Under section 503A of the Federal Food, Drug, and Cosmetic Act," Guidance for Industry.

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. We offer the following comments developed with input from our members, including feedback from APhA's Compounding Core Group, consisting of over 3,400 members.

FDA proposes in the draft guidance to retain the policy related to nominated substances currently appearing in 503A Category 1 until the substances are addressed in a final rule or removed based on additional information (e.g., safety risks). In addition, FDA proposed that any substances nominated from now on cannot be used until a determination is made following rulemaking. Upon reviewing the draft guidance, we have identified several areas that would benefit from increased transparency, data retention, and data sharing.

**General Recommendations**

- Retain the existing lists of nominated substances in Categories 2 and 3 on the FDA website.

- Provide the criteria or the evaluation process for substances nominated for the bulks list that raise significant safety risks.
- Publish a list of all substances nominated on or after the date of publication of this guidance on the FDA website.

**Substances Not Nominated, Nominated Without Adequate Support, or Nominated On or After the Date of Publication of This Guidance**

APhA encourages FDA to retain the existing list of substances nominated without adequate support (previous Category 3 list) for reference by stakeholders wishing to nominate substances in the future. Without this list continuing to be available, assumptions could be made that these previously nominated substances were found to be lacking evidence for FDA to evaluate them. Having continued access to this list is helpful and shows that a more robust nomination was needed, providing direction to potentially interested individuals or organizations.

APhA encourages FDA to publicly publish a list of all substances nominated on or after the date of publication of this guidance. The knowledge that a substance has been nominated prevents duplicative efforts by individuals or organizations that would also support that substance. If a nomination is known to exist, then interested parties could work to support that nomination rather than a variety of groups submitting nominations on their own.

**Substances Appearing in 503A Category 1**

APhA supports FDA continuing its enforcement discretion for the substances in Category 1, as outlined in the interim policy.

**Substances Nominated for the Bulks List That Raise Significant Safety Risks**

APhA encourages FDA to provide detailed information about the safety risks perceived to exist with each of these substances. Providing this information informs health care providers about the potential risks of these substances and the data on the potential existence of these risks. In addition, stakeholders who want to provide future nominations can better understand how FDA evaluates potential safety risks. Understanding FDA's perspective helps shape the data that should be provided to FDA in any future nomination or can prevent nominations of substances that have similar safety risks in the available data.

APhA encourages FDA to retain a public list of substances that were nominated and raise significant safety risks (previous Category 2 list) so that it may be referenced by interested

parties in the future. Maintaining this information informs providers of patient care that these substances may have concerning risks and may prevent future nominations of these substances unless new data emerges.

Thank you for the opportunity to provide our perspective and recommendations to the FDA. We look forward to working with FDA to ensure patients have access to the safe and effective compounded medications they need. If you have any questions or require additional information, please contact APhA at mbaxter@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Vice President, Federal Government Affairs