April 1, 2020

Gail Bormel
Associate Director, Compounding
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20903

Re: Request for 503A and 503B Compounding Enforcement Discretion

Dear Dr. Bormel,

As COVID-19 response has ramped up, hospital pharmacy departments are under intense strain. In addition to trying to ensure they have adequate stock of all medications, hospitals are struggling to purchase supplies of personal protective equipment for compounding and maintain staffing levels as colleagues fall ill. Established pharmacy care delivery models are being upended in the race to meet surging patient demand.

In order to meet patient needs and adapt hospitals to the increasing volume of COVID-19 cases, pharmacy departments need regulatory flexibility. Recognizing FDA's role in ensuring medication safety, we respectfully request that the FDA exercise enforcement discretion over certain elements of compounding oversight during the national emergency, except in cases of imminent threat to patient safety or gross negligence. Specifically, we request that FDA:

- Hospital and Health-System Guidance: Issue a public statement that FDA will not enforce the "one-mile radius" requirement its draft Hospital and Health-System guidance. The one-mile radius requirement hampers hospitals' ability to move compounding to a centralized facility that is better equipped to handle high volume and meet patient needs during a public health emergency. Although FDA has signaled that it does not intend to enforce the one-mile radius requirement, state Boards of Pharmacy have incorporated the guidance into their regulations. Absent a formal statement from FDA, Boards of Pharmacy are hesitant to provide any flexibility at the state level.

- 503B Segregation and CGMP Requirement for 503A products: Relax the requirement that 503Bs physically segregate 503A compounding from their 503B operations and allow 503A products to be prepared under CGMP conditions, but using <797> beyond-use dates instead of performing sterility testing normally required for 503B preparations. This flexibility will be critical for hospitals who have registered as 503Bs. Hospitals are managing much higher volumes of medication preparation and need to reallocate space and resources to cope with the demands during the COVID-19 outbreak.

  Specifically, for 503A compounding done within a hospital-owned 503B, FDA should waive requirements for stability and sterility testing for 503A products for the duration of the national emergency. The 503B would be required to assign a beyond-use date consistent with USP requirements and would only be allowed to compound from sterile products. No 503A products subject to the testing waiver would be compounded from bulk API. Additionally, any 503A products produced by the 530B would only be distributed to hospitals under common control with the 503B – no products would be sold commercially. This would remove any incentive to produce 503B products at lower standards.

- Expanded Shortage Designations for Compounding of Commercially-Available Product: For the duration of the national emergency, define "drugs in shortage" to include drugs on the ASHP drug shortage list for the purposes of 503B compounding of "commercially available" product. This time-limited flexibility would help ensure that 503Bs can provide product to hospitals as efficiently as possible during the national emergency.

We thank FDA for working with us to address the pressing needs of hospitals and their patients during the COVID-19 response. Additional flexibilities may be required as the situation on the ground shifts, so ASHP will ensure that we are sharing information with the agency as efficiently as possible. Please let us know if we can provide any additional information – including setting up calls with compounding pharmacists in frontline hospitals – that would assist you in granting the enforcement discretion requested above.

Sincerely,

Jillanne Schulte Wall, J.D.
Senior Director, Health & Regulatory Policy