100 Daingerfield Road, Suite 100
Alexandria, VA 22314

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Alliance for Pharmacy Compounding

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October 3, 2024

Gail Bormel, JD, RPh
Director, Office of Compounding Quality and Compliance
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Off Ramp for Compounding Shortage Drugs

Dear Dr. Bormel:

As the tirzepatide injection shortage is now indicated as resolved and we look ahead to a time when other FDA-approved GLP-1 drugs are no longer listed as "currently in shortage," I write to enunciate our serious concerns about continuation of drug therapy for patients taking compounded GLP-1 drugs dispensed by 503A pharmacies.

As you know, APC is the voice for pharmacy compounding, representing more than 600 compounding small businesses across America – including 5,000 compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers.

We urge that FDA immediately implement an "off-ramp" period of *at least* 60 days after a GLP-1 drug come off shortage. During this time, the agency would exercise enforcement discretion — and would strongly urge state boards of pharmacy to do the same — as pharmacists work with prescribers to assure transition of those patients to the appropriate FDA-approved GLP-1 drug. Without such an off-ramp, an extraordinary number of patients risk being left temporarily, maybe permanently, without a therapy they have been relying on and that is indicated for them to take for the rest of their lives.

Current FDA guidance allows 503A compounding pharmacies to dispense patient specific compounded versions of FDA-approved drugs when those drugs are listed as "currently in shortage" on the FDA Drug Shortage List. When an FDA-approved drug is removed from the shortage list, 503A pharmacies must immediately cease compounding and dispensing them. 503B outsourcing facilities are afforded a 60-day period during which they may continue distributing a compounded copy of an FDA-approved drug after it comes off shortage, but 503As are not afforded such a transition period. We believe they should be — to ensure patient care continuity.

We note that, in practice, even the 60-day window afforded 503Bs often proves inadequate for both patients and healthcare providers. It often takes much longer for FDA-approved versions of the drug to become widely available to wholesalers, hospitals, and clinics. FDA notes as much in its unusual notes associated with the various dosage strengths of Mounjaro and Zepbound on it Drug Shortage List. The slowness with which Eli Lilly's Zepbound has been attainable from wholesalers by pharmacies for dispensing, even after the company's recent and much-heralded announcement of its newfound

"availability" and its subsequent removal from the FDA Drug Shortage List, is but one indicator of this phenomenon. A drug that is not accessible to the patient is *not* available.

For these particular blockbuster drugs, an extended but brief off-ramp period for 503A pharmacies would better ensure continuity of patient care, providing more time for compounded medications to bridge the gap until the FDA-approved drugs are *in fact* available. Such discretion would allow for a smoother transition, giving pharmacies time to contact prescribers for updated prescriptions and to navigate insurance prior authorization processes. Moreover, such a policy would prevent abrupt discontinuations in patient care that will undoubtedly result from the sudden unavailability of compounded copies.

In addition, a statement from FDA encouraging state boards of pharmacy to exercise similar enforcement discretion would go a long way toward ensuring continued patient access to necessary medications.

Ensuring continuity of care must remain a priority, especially when it comes to addressing drug shortages. The requested adjustments would allow compounding pharmacies to continue to play a vital role in maintaining patient access to essential treatments.

Thank you for your time and consideration. If you have questions, please contact me at scott@a4pc.org or 404.844.8607.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer