Alliance for Pharmacy Compounding

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TO: State Boards of Pharmacy

FROM: Scott Brunner, CAE, Chief Executive Officer
scott@a4pc.org

Tenille Davis, PharmD, RPh, BCSCP, FAPC, Chief Advocacy Officer
tenille@a4pc.org

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SUBJECT: *Clarification on Tirzepatide Injection Shortage and FDA Enforcement Discretion*

In reviewing certain Board of Pharmacy meeting agendas, we note there may be some confusion regarding the FDA's current stance toward the compounding of copies of tirzepatide injection in light of current litigation. This memo provides some clarity.

As you may know, the Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 600 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers. Many of our members have prepared compounded copies of tirzepatide injection both during the prolonged shortage of the commercial products and in the current period of "enforcement discretion" by the FDA.

Following the FDA's removal of tirzepatide from the shortage list in October, the Outsourcing Facility Association and others filed a lawsuit against the FDA. As a result, FDA's Office of Compounding Quality and Compliance Director Gail Bormel indicated in an October 17 letter to APC that the agency intended to take enforcement discretion – meaning the agency does not intend to take action against compounders for continuing to produce copies of tirzepatide injection, as long as all other conditions of Section 503A of the FDCA are met – during the preliminary injunction phase of that lawsuit.

That lawsuit was paused last autumn during a period in which the FDA asked the court to allow it a period of time to reconsider its decision to mark the tirzepatide injection shortage as

resolved. On December 19, the FDA reiterated that the shortage was indeed over and spelled out the 60- and 90-day transition period for 503As and 503Bs, respectively. Immediately following the reiteration, OFA indicated the lawsuit would continue. The court held a briefing on January 14 that determined a schedule for the preliminary injunction phase. OFA filed that motion January 28; plaintiffs have not yet filed their responses, though they are expected any day. So, we are in the enforcement discretion period Gail Bormel indicated in her October 17 letter.

On February 11, 2025 – last week – the FDA reaffirmed that enforcement discretion related to compounding tirzepatide from bulk drug substances based on the drug's inclusion on the FDA drug shortage list. In light of the litigation, *OFA v. FDA*, that agency communication clarifies the following timeframes:

- For 503A state-licensed pharmacies and physicians, enforcement discretion applies until February 18, 2025, ***or*** *until the district court rules on the plaintiffs' preliminary injunction motion in OFA v. FDA (N.D. Tex.), whichever is later.*
- For 503B outsourcing facilities, enforcement discretion applies until March 19, 2025, ***or*** *until the district court rules on the preliminary injunction motion, whichever is later.*

The FDA also stated that it may still take enforcement action against compounded tirzepatide for other violations of statutory or regulatory requirements, including concerns related to product quality or safety.

State boards should monitor these evolving legal and regulatory changes and communicate updates to licensees as needed. Bottom line: As FDA indicated in its communication last week, the February 18 and March 19 transition deadlines are not firm at this time.

If we can be helpful to your agency, please let us know.