

NEXTGEN Rx

COMPOUNDING PHARMACY

2.24.2025

Attention: Compounded Tirzepatide Prescribers,

Update: FDA's *Declaratory Order* ON 12/19/2024 Re: resolution of drug shortage relating to: Mounjaro® and Zepbound®

On 02/11/2025 the FDA updated their messaging on compounded Tirzepatide to announce they will be utilizing "enforcement discretion" for compounded prescriptions containing Tirzaptide to allow for a pending date of the district court's decision on the plaintiffs' preliminary injunction motion in *Outsourcing Facilities Association (OFA) v. FDA (N.D. Tex.)*. See below:

"FDA has not changed its intentions regarding enforcement discretion as described below. To clarify, the timeframes during which the agency does not intend to take action against compounders for violations of the FD&C Act arising from conditions that depend on tirzepatide injection products' inclusion on FDA's drug shortage list are:

For a state-licensed pharmacy or physician compounding under section 503A of the FD&C Act until February 18, 2025, **or** until the date of the district court's decision on the plaintiffs' preliminary injunction motion in *Outsourcing Facilities Association (OFA) v. FDA (N.D.Tex.)*, whichever is longer.

For outsourcing facilities under section 503B until March 19, 2025, **or** until the date of the district court's decision on the plaintiffs' preliminary injunction motion in *OFA v. FDA*, whichever is longer.

FDA may still take action regarding violations of any other statutory or regulatory requirements, such as to address findings that a product may be of substandard quality or otherwise unsafe."

NextGenRx acquires compounded Tirzepatide from a registered 503B compounding facility, as such our supplier that we have partnered with in order to supply our mutual patients has until 3/19/2025 **(or later)** to comply with the FDA's order. We currently believe that we will be able to dispense compounded Tirzepatide beyond 03/19/2024, however, we do not have a firm date as to when/if the supply will be shut down.

What's next? We have been communicating with our patients to attempt to "stock up" on the number of vials they order for refills prior to **March 11th, 2025**. Additionally, we have requested that they continue to follow up with us beyond 03/19/2025 to check the availability.

It is a pleasure to be able to serve you and your patients through the art of compounding. We look forward to assisting you and your practice's needs for years to come. Please stay tuned for alternative dosage forms using Semaglutide for patients who are unable to tolerate the price of the brand name medications.

Sincerely,

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