Kentucky Board of Pharmacy

Important Update- Compounding Semaglutide and Tirzepatide

The Kentucky Board of Pharmacy (Board) staff has received inquiries concerning the compounding of GLP-1 medications such as semaglutide and tirzepatide. Semaglutide is available as a commercially available drug product marketed as Ozempic™ and Rybelsus™ for treating diabetes and as Wegovy™ for weight loss. Tirzepatide is available as a commercially available drug product marketed as Mounjaro™ for treating diabetes and as Zepbound™ for weight loss.

The federal Food Drug & Cosmetic Act prohibits pharmacies from compounding "drug products that are essentially copies of a commercially available drug product."1 In general, compounding pharmacies may not compound semaglutide or tirzepatide, a commercially available drug product.

Further, 201 KAR 2:076 also prohibits the compounding of essential copies of a commercially available drug product unless authorized by 21 U.S.C. 353(a). This is enforceable by the Kentucky Board of Pharmacy for individuals or entities licensed or permitted by the Commonwealth.

On March 10, the FDA provided the following timeline updates for compounders:

Tirzepatide: On March 5, 2025, the district court denied the plaintiffs' preliminary injunction motion in Outsourcing Facilities Association v. FDA, 4:24-cv-00953 (N.D. Tex.). Therefore, consistent with FDA's February 11, 2025 update:

- For a state-licensed pharmacy or physician compounding under section 503A of the FD&C Act, the period of enforcement discretion described below has ended.
- For outsourcing facilities under section 503B, FDA 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 until March 19, 2025.

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Semaglutide: On April 24, 2025, the district court denied the plaintiffs' preliminary injunction motion in Outsourcing Facilities Association v. FDA, 4:25-cv-00174 (N.D. Tex.) regarding compounded semaglutide. Therefore, consistent with FDA's March 10, 2025, update:

- For a state-licensed pharmacy or physician compounding, dispensing or distributing semaglutide injection products under section 503A of the FD&C Act, the period of enforcement discretion (described below) has ended.
- For outsourcing facilities compounding, distributing or dispensing semaglutide injection products under section 503B, FDA does not intend to take action for violations of the FD&C Act arising from conditions that depend on semaglutide injection products' inclusion on FDA's drug shortage list until May 22, 2025.

https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize

When Is Compounding of Semaglutide or Tirzepatide Permissible?

FDA does not consider a drug to be "commercially available" if it appears on the FDA's shortage list.2 As is true of all drug products, pharmacists and pharmacies should regularly monitor FDA's shortage list at the link provided below.2

Also, the federal FD&C Act states that a compounded drug product is not "essentially a copy" of a commercially available drug product if a change is made for an identified individual patient and the prescribing practitioner has determined that the change will produce a significant difference for that patient.3 FDA has explained:

However, if a prescription identifies only a patient name and drug product formulation, this would not be sufficient to establish that the prescriber made the determination described by section 503A(b)(2). Note also that the significant benefit that the prescriber identifies must be produced by the change the

compounder will make to a commercially available drug product (i.e., a change in drug product formulation). Other factors, such as a lower price, are not sufficient to establish that the compounded drug product is not essentially a copy of the commercially available drug product.4

Is adding another commercially available drug, such as B12, still considered compounding a commercially available drug product?

The FDA has explained:

FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if the compounded drug product contains the same APIs as two or more commercially available drug products in the same, similar, or easily substitutable strength and if the commercially available drug products can be used (regardless of how they are labeled) by the same route of administration prescribed for the compounded drug, unless there is documentation as described in section III.B.2 (see above reference to compounding for an individualized patient*).*

The Bottom Line

Compounding a commercially available product is allowable only in certain narrow circumstances, as described above.

The Board is charged with protecting the public. Therefore, compounding semaglutide or tirzepatide drug products in a way that fails to conform with governing law may lead to enforcement action by the Food and Drug Administration and the Kentucky Board of Pharmacy.

Pharmacies should also be aware that pharmaceutical manufacturers may initiate legal proceedings against prescribers and compounders to combat illegal semaglutide or tirzepatide drug product compounding.

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1. FD&C Act § 503A(b)(1)(D).

2. The FDA's shortage list may be found at https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

3. FD&C Act § 503A(b)(2).

4. Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act at pp. 8-9.

5. FD&C Act § 503A(b)(1)(A)(i).