Semaglutide Position Statement – Oregon Board of Pharmacy v. 2/2025

Background

The Oregon Board of Pharmacy (Board) is committed to protecting the health, safety and welfare of all Oregonians. Board staff has received inquiries regarding the compounding of semaglutide and other glucagon-like peptide-1 (GLP-1) receptor agonists. Semaglutide, sold under the brand names Mounjaro, Ozempic, Rybelsus, and Wegovy, is an antidiabetic and anti-obesity medication used for the treatment of type 2 diabetes and for long-term weight management, respectively.

Demand for GLP-1 drugs has surged, and some are in short supply. This has resulted in some patients and health care professionals turning to compounded versions of these medications, often marketed and sold from online pharmacies, that are not approved by the FDA. This can be risky, as non-FDA approved versions do not undergo FDA's review for safety, effectiveness and quality before they are marketed. The FDA has issued warnings about using non-FDA approved compounded versions of these GLP-1 medications.[1] These non-FDA approved drugs may:

- be counterfeit, contaminated, or adulterated.
- contain the wrong ingredients or harmful ingredients.
- contain too much, too little, or no active ingredient at all.

FDA Recommendations for patients: [1]

- Patients should obtain a prescription from their doctor and fill the prescription at a state-licensed pharmacy.
- Visit FDA's BeSafeRx campaign for resources to safely buy prescription medicines online.

How can I determine if the medication is commercially available?

The FDA does not consider a drug to be commercially available if it appears on the FDA's drug shortage list [2] with a status of "currently in shortage" (not "resolved").

Can semaglutide and other GLP-1 medications be compounded if the medication is commercially available?

The federal Food Drug & Cosmetic Act (FD&C Act) prohibits pharmacies from compounding *"drug products that are essentially copies of a commercially available drug product."* [3] The FD&C Act and the FDA have recognized that a compounded drug will not be considered a copy of a commercially available drug product in the following three situations:

(1) The drug has been discontinued and is no longer marketed.

(2) The drug is not readily available and is listed on the FDA's drug shortage list.

(3) There is a specific change for an identified patient whose medical needs cannot be met by the commercially available product.*****

***** 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).

Additional considerations include:[4]

- 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).
- 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.
- Adding additional substances to a compounded product that is otherwise an essential copy of a commercially available drug product is not included in FDA's list of circumstances meeting Section 503A(b)(2)'s requirements.

If the compounding of semaglutide and other GLP-1 medications is permitted, how must it be performed?

When compounding of a GLP-1 drug product is allowed under the FD&C Act, substances used to compound must:[5]

(1) Comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding;

(2) If such a monograph does not exist, be components of drugs approved by the Secretary of HHS; or

(3) If such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary of HHS, appear on a list developed by the Secretary through regulation.

With respect to semaglutide:

(1) There is no USP or NF monograph for semaglutide.

(2) Ozempic™ and Wegovy™ contain semaglutide base. Hence, only the base is a component of an FDA-approved human drug product. No salt form of semaglutide is contained in an FDA-approved drug.

(3) Semaglutide does not – in any form – appear on the FDA's "bulks list" for compounding.[6] So, for this separate and independent reason, no salt form of semaglutide may be used in a compounded drug product.

If a pharmacy obtains semaglutide base for potential compounding use, the pharmacy must ensure that the API received is a pharmaceutical-grade product, accompanied by a valid certificate of analysis, and is sourced from an establishment registered with the FDA under Section 510 of the FD&C Act. Therefore, "research use only" products, or products produced by establishments which are not registered with the FDA, may not be used for compounding in any circumstance.

Conclusion:

The Board is charged with protecting the public. Therefore, the compounding of semaglutide and other GLP-1 drug products in a way that fails to conform with governing law, or the dispensing of such products, may lead to enforcement action by the Board.

References:

[1] FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss

[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)(1)(D)

[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)

[6] Section 503A Bulks List Final Rule Questions and Answers