Statement of Compounding Semaglutide

WASHINGTON Medical Commission
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The compounding of semaglutide by pharmacies and FDA-registered outsourcing facilities has risen due to the FDA shortage status of Ozempic and Wegovy.

The federal Food Drug & Cosmetic Act (FD&C Act), prohibits compounding regularly, or in inordinate amounts, "any drug products that are essentially copies of a commercially available drug product." 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.[1]
3. There is a specific change for an identified patient whose medical needs cannot be met by the commercially available product.

Compounding pharmacies are responsible for checking the FDA's website on a regular basis to determine whether Ozempic and Wegovy are on the FDA's drug shortage list. If a drug is listed on the FDA's drug shortage list as "currently in shortage" (and not in "resolved" status), then the drug is not considered by the FDA as a commercially available drug product, which means compounding pharmacies may be able to prepare a compounded version of that drug if they meet requirements of the FD&C Act. This includes, among other things, requirements of the FD&C Act related to bulk drug substances.

More specifically, the FD&C Act requires that bulk drug substances used to compound must:

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 FDA; or[2]
3. if such a monograph does not exist and the drug substance is not a component of a drug approved by the FDA, appear on the final or interim 503A or 503B bulk drug substances list published by the FDA.

With respect to semaglutide:

1. There is no USP or NF monograph for semaglutide.
2. Ozempic and Wegovy contain semaglutide base – not a salt form. Therefore, only the base is a component of an FDA-approved human drug product. The salt forms are different active ingredients than used in FDA-approved drugs, and do not meet FD&C Act requirements for compounding.
3. Semaglutide does not – in any form – appear on the FDA's "bulks list" for compounding. Therefore, no salt form of semaglutide may be used in a compounded drug product.

Even if a compounding pharmacy or FDA-registered outsourcing facility obtained semaglutide base for potential compounding use, the compounding pharmacy or FDA-registered outsourcing facility must also ensure that the active pharmaceutical ingredient (API) received is a pharmaceutical grade product (not "research use only"), accompanied by a valid certificate of analysis, and is sourced from an establishment registered with the FDA and licensed in Washington state and its resident state.

The commission has determined that a failure of licensees to comply with the requirements of the FD&C Act when compounding a semaglutide drug product may result in disciplinary or enforcement action by the commission and/or the FDA (e.g. RCW 18.64.026(1) and RCW 18.130.180(7)). In addition, pharmacies and pharmacists that dispense semaglutide drug products that have been compounded in a manner that is not compliant with the FD&C Act's requirements may also be subject to disciplinary or enforcement action by the commission and/or the FDA (e.g. WAC 246-945-305(2) and WAC 246-945-415(1)).

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Notice to Consumers/Patients
Consumers should be reminded that these medications are legitimately available by prescription only, and should only be prescribed in direct consultation with, and under the supervision of, a licensed healthcare professional.[3]

From the FDA's webpage, Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss | FDA:

FDA has received adverse event reports after patients used compounded semaglutide. Patients should not use a compounded drug if an approved drug is available to treat a patient. Patients and health care professionals should understand that the [FDA] does not review compounded versions of these drugs for safety, effectiveness, or quality.

Patients should be aware that some products sold as 'semaglutide' may not contain the same active ingredient as FDA-approved semaglutide products and may be the salt formulations. Products containing these salts, such as semaglutide sodium and semaglutide acetate, have not been shown to be safe and effective.

Patients should only obtain drugs containing semaglutide with a prescription from a licensed health care provider, and only obtain medicines from Washington state-licensed pharmacies or outsourcing facilities registered with FDA.

References (not an exhaustive list):

- Chapter 18.64 RCW
- RCW 18.130.180
- Chapter 246-945 WAC
- FD&C Act § 503A(b)(1)(A)(i)-(iii), (b)(1)(D), (b)(2)
- Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov)
- Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov)
- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov)
- Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov)

[1]Please note that, at the time of publication, the FDA has stated it "does not intend to take action against an outsourcing facility for filling orders that it received for a compounded drug that is identical, or nearly identical, to an approved drug that was on FDA's drug shortage list at the time that the outsourcing facility received the order, provided the drug also appeared on the FDA drug shortage list within 60 days of the outsourcing facility distributing or dispensing the drug" (Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov)). FDA-registered outsourcing facilities should consult with the FDA to confirm the future status of this enforcement policy.

[2] The Food, Drug, and Cosmetic Act (FD&C Act) references the Secretary of the U.S. Department of Health and Human Services (HHS). The FDA is an agency within the U.S. Department of Health and Human Services (HHS Organizational Charts Office of Secretary and Divisions | HHS.gov).

[3] FDA alerts health care providers, compounders and patients of dosing errors associated with compounded injectable semaglutide products | FDA