

## **Statement on Compounding and Dispensing of Compounded Semaglutide and Other GLP-1 Receptor Agonists**

Approved by Kansas State Board of Pharmacy: April 25, 2024  
Last Updated: April 25, 2024

The compounding of semaglutide and other glucagon-like peptide-1 (GLP-1) receptor agonists by pharmacies and outsourcers has risen due to the FDA shortage status of Wegovy® and Ozempic®. Under the federal Food Drug & Cosmetic Act (FD&C Act) and Board regulations, compounding “drug products that are essentially copies of a commercially available drug product” is prohibited unless either of the following exceptions occurs:

1. The drug is not readily available and is listed on the [FDA drug shortage list](#), or
2. There is a specific change for an identified patient whose medical needs cannot be met by the commercially available product.

While correctly applying either of the above exceptions prevents FDA action on compounding drugs that are essentially copies of a commercially available drug product, compounders must ensure that compounded bulk drug substance complies with FDA Bulk Drug Substance Requirements. When a drug is in shortage, compounders may be able to prepare a [compounded](#) version of that drug if they meet certain requirements in the Federal Food, Drug, and Cosmetic (FD&C) Act.

When compounding of a semaglutide drug product is allowed under the FD&C Act, 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 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 – 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. So, for this separate and independent reason, no salt form of semaglutide may be used in a compounded drug product.

Even if a pharmacy or outsourcing facility obtained semaglutide base for potential compounding use, the pharmacy or outsourcing facility must ensure that the 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.

**The Board has determined that even when compounding of a semaglutide drug product is allowable under the FD&C Act, the use of semaglutide salts, the use of any non-pharmaceutical grade API, or one not produced by an FDA-registered establishment, is prohibited.** Likewise, pharmacist dispensing of semaglutide that has been compounded in a non-compliant manner (even if lawfully purchased) is prohibited because the compound does not qualify as a “drug” as defined by Kansas law. Any violation of the FD&C Act, the Kansas Pharmacy Act, or any rule or regulation thereunder may result in disciplinary or enforcement action by the Board and/or the FDA.

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 a change is made to the commercially available product for an identified individual patient and the prescribing practitioner has determined that the change will produce a significant difference for that patient, there is still a minimum threshold. The FDA has stated that “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.”

Drug manufacturers have become aware of the practice of using semaglutide salts for compounding and may choose to initiate legal proceedings to combat illegal compounding.

### **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.

“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 state-licensed pharmacies or outsourcing facilities registered with FDA.”

[Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss | FDA](#)

#### **References:**

- K.S.A. 65-1626(r) and (w), 65-1627(a) and (e), 65-1626a, 65-1657(f)
- K.A.R. 68-13-2, 68-13-3,
- 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 \(fda.gov\)](#)