

## Statement on Compounding and Dispensing of Compounded GLP-1 and GIP Receptor Agonists

Approved by Kansas State Board of Pharmacy: April 25, 2024; April 17, 2025; April 23, 2026  
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The compounding of glucagon-like peptide-1 (GLP-1) and glucose-dependent insulintropic polypeptide (GIP) receptor agonists by pharmacies and outsourcers has risen due to the previous FDA shortage status of medications like semaglutide and tirzepatide. Communication from the FDA on March 9, 2026 confirms that tirzepatide and semaglutide injection products are no longer in shortage and enforcement discretion periods are no longer in effect.<sup>1</sup> Additionally, the FDA issued an updated [Drug Alert and Statement](#) on April 1, 2026, which should be referenced by any pharmacy, outsourcing facility, **or other compounding healthcare provider**.

The FDA has also issued warnings about compounded, contaminated, adulterated, and counterfeit versions of semaglutide and tirzepatide: [FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss | FDA](#).

### When is Compounding Permissible?

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. The compounded drug includes a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the commercially available product.

The FDA emphasizes that one condition for pharmacy compounding is that drug products may only be compounded based on the receipt of valid prescriptions for individually-identified patients. Furthermore, once a drug shortage is “resolved” FDA considers the drug product to be commercially available, and compounders operating under section 503A may not compound regularly or in inordinate amounts a drug that is essentially a copy of a commercially available drug. Kansas regulations similarly state that “[a] pharmacist shall not compound a sterile preparation that is essentially a copy,” which is defined to include “any sterile preparation ... that is comparable in active ingredients to a commercially available drug product,” unless:

1. The sterile preparation includes a change made for an identified individual patient that produces a clinically significant difference for the patient, as determined by the

prescribing practitioner, between the comparable commercially available drug product and the sterile preparation; or

2. The drug appears on the drug shortage list in section 506E of the federal food, drug, and cosmetic act, 21 U.S.C. 356e, at the time of compounding, distribution, and dispensing.

Furthermore, a pharmacist may compound pursuant to the above only if there is sufficient documentation of a specific medical need for the prescription or the product is temporarily unavailable due to problems other than safety or effectiveness. For the specific medical need, FDA requires the compounded product be “necessary” and not merely preference. Pharmacist documentation must include any unavailability in the patient’s prescription record, including the date the product was unavailable, and shall maintain documentation from the manufacturer or distributor demonstrating the product’s unavailability. The pharmacist shall cease compounding the sterile preparation as soon as the product becomes commercially available.

### **If/When Compounding is Permissible, How Must It Be Performed?**

If and when compounding of a 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 and tirzepatide:

1. There is no USP or NF monograph for either product.
2. Ozempic®, Wegovy®, and Rybelsus® contain semaglutide base – not a salt form. Mounjaro® and Zepbound® contain tirzepatide 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. Tirzepatide and semaglutide do not appear on the 503B Bulks List, nor do they appear on FDA’s drug shortage list. Therefore, no salt form of semaglutide or tirzepatide may be used in a compounded drug product. Human drug products compounded with tirzepatide or semaglutide do not currently qualify for the exemptions and human drug products compounded with tirzepatide or semaglutide would not be exempt from the requirements of FDA premarket approval and labeling with adequate directions for use and DSCSA requirements.

Even if a pharmacy or outsourcing facility obtained a semaglutide or tirzepatide base for potential compounding use, the pharmacy or outsourcing facility must ensure that the API received is a pharmaceutical-grade product (not “research use,” “investigational,” “food,” or “supplement” grade), accompanied by a valid certificate of analysis that identifies the original manufacturer, and is sourced from an establishment registered with the FDA as a manufacturer of the bulk drug substance.

**The Board has determined that even when compounding is allowable under the FD&C Act, the use of semaglutide or tirzepatide salts, the use of any non-pharmaceutical grade bulk substance, or a bulk substance not manufactured in an FDA-registered establishment, is prohibited.** Likewise, pharmacist dispensing of medications that have 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. For example, FDA may consider a compounded drug product that combines semaglutide API and another API, such as vitamin B12 (cyanocobalamin), to be essentially a copy of a commercially available drug product when the:

- drug products are used by the same route of administration – the compounded drug product is given the same way as the commercially available drug products, such as an injectable
- drug products are the same, similar or easily substitutable strength – the amounts of semaglutide and vitamin B12 in the compounded drug product are within 10% of the strengths of the respective commercially available drug products.

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.”

Pre-printed, pre-populated, check-box, or boilerplate prescriptions may not meet the requirements for pharmacist and pharmacy compounding. Furthermore, pharmacist or pharmacy-initiated requests for compounded formulations do not meet the requirement of a prescriber’s clinical determination. These do not provide sufficient documentation of a specific medical need for an individual patient, and do not adequately explain how a change in a compounded product results in a clinically significant therapeutic response from the commercially available product.

Article 13 of the Board’s regulations requires documentation by the pharmacy or outsourcing facility to ensure the need and significant difference requirement is met for **each** patient.

Furthermore, the FDA “consider[s] 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” of “significant difference.”<sup>ii</sup>

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

### **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. As noted above, FDA has [published](#) information regarding its concerns with unapproved GLP-1 drugs used for weight loss.

“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, 68-13-4
- FD&C Act § 503A(b)(1)(A)(i)-(iii), (b)(1)(D), (b)(2)
- [FDA Intends to Take Action Against Non-FDA-Approved GLP-1 Drugs | FDA](#)
- [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 \(fda.gov\)](#)

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<sup>i</sup> Tirzepatide injection products were placed on the shortage list in December 2022 and were removed from the list on December 19, 2024. Semaglutide injection products were placed on the shortage list in March and August 2022 and were removed from the list on February 21, 2025. Per FDA’s website, the Agency’s enforcement discretion period for outsourcing facilities making tirzepatide injection products ended on March 19, 2025, and for outsourcing facilities making semaglutide injection products, the enforcement discretion period ended on May 22, 2025. The enforcement discretion period for state-licensed pharmacies or physicians compounding tirzepatide injection products ended on March 5, 2025, and for state-licensed pharmacies or physicians compounding semaglutide injection products, the enforcement discretion period ended on April 28, 2025. See “FDA clarifies policies for compounders as national GLP-1 supply begins to stabilize” available at: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize>.

<sup>ii</sup> For example, if drug X and drug Y are commercially available oral drug products, FDA generally intends to consider a compounded oral drug product that combines drug X and drug Y in strengths that are within 10% of the strengths of the respective commercially available products to be essentially a copy of the commercially available drug product, unless a prescriber determination of a significant difference has been documented. For more information see Guidance for Industry: Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act (January 2018). (available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compounded-drug-products-are-essentially-copies-commercially-available-drug-product-under-section>).