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

Report issues to FDA

Compounding and the FDA: Questions and Answers (/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers)

Understanding unapproved versions of these drugs

FDA is aware that some patients and health care professionals may look to unapproved versions of GLP-1 (glucagon-like peptide-1 (GLP-1) receptor agonists) drugs, including semaglutide and tirzepatide, as an option for weight loss. This can be risky for patients, as unapproved versions do not undergo FDA's review for safety, effectiveness and quality before they are marketed.

FDA recommendations for health care professionals and patients

- Compounded drugs should only be used in patients whose medical needs cannot be met by an FDA-approved drug.
- Patients should obtain a prescription from their doctor and fill the prescription at a state-licensed pharmacy.
- Visit FDA's BeSafeRx (/drugs/buying-using-medicine-safely/besaferx-your-source-online-pharmacy-information) campaign for resources to safely buy prescription medicines online.
- Talk to your doctor if you have questions about your medicines.

Concerns with compounded versions of these drugs

A compounded drug (/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers) might be appropriate if a patient's medical need cannot be met by an FDA-approved drug, or the FDA-approved drug is not commercially available. However, compounded drugs are not FDA approved. This means the agency does not review compounded drugs for safety, effectiveness or quality before they are marketed.

The agency has identified some areas of concern for compounded GLP-1 drugs. FDA is working with its state regulatory partners and will continue to communicate with compounders regarding these concerns.

FDA actions at the border

The agency has established a green list import alert (66-80) (https://www.accessdata.fda.gov/CMS_IA/importalert_1186.html) to help stop GLP-1 active pharmaceutical ingredients (APIs) that have potential quality concerns from entering the U.S. supply chain. This import alert does not apply to GLP-1 API from manufacturers that, based on an FDA inspection or other FDA evaluation, appear to be in compliance with FDA's rigorous standards for manufacturing practices.

This action will help protect consumers from receiving poor-quality compounded drugs containing foreign-made APIs (which are also called bulk drug substances) that may be manufactured without appropriate controls to assure quality. This action does not stop the legal importation into the U.S. market of GLP-1 APIs from compliant API manufacturers, nor does it create any new limits on the legal compounding of GLP-1 drugs.

Fraudulent compounded GLP-1 drugs

FDA is aware of fraudulent compounded semaglutide and tirzepatide marketed in the U.S. that contain false information on the product label. In some cases, the compounding pharmacies identified on the labels of the products do not exist. In other cases, the labels of the fraudulent compounded medicine contain the name of a licensed pharmacy that, based on information FDA has gathered, did not compound these products.

FDA is aware of one reported adverse event associated with a product labeled as compounded tirzepatide from a pharmacy that did not actually compound the product. The adverse event report included symptoms such as redness, site swelling, pain, and a red lump at the injection site.

Recommendations for consumers

The agency encourages patients to be vigilant and know the source of their medicine.

- Carefully check labels of compounded GLP-1 drugs for warning signs such as spelling errors or incorrect addresses and ensure your medicine is provided by a licensed pharmacy and prescribed by a licensed health care provider.
- If you receive a product with a licensed pharmacy name on the label that you think might be fraudulent, contact the pharmacy to ask if it is their product.
- Talk to your doctor if you have questions about your medicines.

Dosing concerns with compounded semaglutide and tirzepatide

FDA received multiple reports of adverse events, some requiring hospitalization, that may be related to dosing errors (/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded) associated with compounded injectable semaglutide products. These dosing errors resulted from patients measuring and self-administering incorrect doses of the drug, and in some cases, health care professionals miscalculating doses of the drug.

Additionally, the agency has received adverse event reports that may be related to patients prescribed compounded semaglutide or tirzepatide products in doses beyond what is in the FDA-approved drug label. This could mean using more product in a single dose, taking doses more frequently or increasing the amount more quickly (titration schedule). Some of the adverse events are serious and some patients reported seeking medical attention for their symptoms, including nausea, vomiting, diarrhea, abdominal pain and constipation.

Health care providers should be vigilant when prescribing compounded semaglutide or tirzepatide products and determining appropriate doses and titration and dosing schedules for patients. The agency also encourages patients to talk with their health care provider or compounder about how to measure and administer the intended dose of compounded semaglutide or tirzepatide.

Retatrutide and cagrilintide cannot be used in compounding

Retatrutide and cagrilintide cannot be used in compounding under federal law. Additionally, these are not components of FDA-approved drugs and have not been found safe and effective for any condition.

The agency has issued warning letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters) to companies distributing active pharmaceutical ingredients, such as retatrutide and certain other GLP-1 drugs.

Salt forms should not be used to compound semaglutide

The agency is aware that some semaglutide products sold by compounders may be the salt forms. These salt forms, including semaglutide sodium and semaglutide acetate, are different active ingredients than are used in the approved drugs. The agency does not have information on whether these salts have the same chemical and pharmacologic properties as the active ingredient in the approved drug, and we are not aware of any lawful basis for their use in compounding.

Adverse events related to compounded versions of semaglutide and tirzepatide

FDA has received reports of adverse events related to compounded versions of semaglutide and tirzepatide. However, federal law does not require state-licensed pharmacies that are not outsourcing facilities to submit adverse events to FDA so it is likely that adverse events from compounded versions of these drugs are underreported. Many of the adverse events reported for compounded products appear to be consistent with adverse events related to the FDA-approved versions of these products.

As of July 31, 2025, the FDA has received:

- 605 reports of adverse events associated with compounded semaglutide.
- 545 reports of adverse events associated with compounded tirzepatide.

It is not always possible to determine if the adverse event directly resulted from use of the drug or if other factors may have contributed to these adverse events.

Illegally marketed versions of these drugs

Counterfeit Ozempic

FDA is aware of counterfeit Ozempic (/drugs/drug-safety-and-availability/fda-warns-consumers-not-use-counterfeit-ozempic-semaglutide-found-us-drug-supply-chain) marketed in the U.S. Counterfeit (/drugs/buying-using-medicine-safely/counterfeit-medicine) drugs claim to be authentic, but could contain the wrong ingredients, contain too little, too much or no active ingredient at all or other harmful ingredients, and are illegal.

The agency investigates reports of suspected counterfeit drugs to determine the public health risks and the appropriate regulatory response. FDA remains vigilant in protecting the U.S. drug supply from these threats.

Illegal online sales of these drugs

FDA monitors the internet for fraudulent or unapproved drugs and has issued warning letters (/drugs/drug-supply-chain-integrity/internet-pharmacy-warning-letters)to stop the distribution of illegally marketed semaglutide and tirzepatide. These illegally marketed drugs:

- may be counterfeit
- could contain the wrong ingredients or harmful ingredients
- could contain too little, too much or no active ingredient at all

The agency urges consumers to be vigilant when purchasing drugs online and only purchase from state-licensed pharmacies (/drugs/besaferx-your-source-online-pharmacy-information/locate-state-licensed-online-pharmacy).

Versions sold falsely for research purposes or not for human consumption

FDA has warned (/news-events/press-announcements/fda-roundup-february-13-2024) companies that have illegally sold unapproved drugs containing semaglutide, tirzepatide or retatrutide (/news-events/press-announcements/fda-roundup-december-17-2024) that are falsely labeled “for research purposes” or “not for human consumption.” These products have been sold directly to consumers for human use with dosing instructions. The agency urges consumers not to purchase these products which are of unknown quality and may be harmful to their health.

Reporting issues to FDA

FDA encourages health care professionals, patients and compounders to report adverse events or quality problems with these or any medications to FDA’s MedWatch Adverse Event Reporting (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program) program:

- Complete and submit the report online (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm), or
- Download and complete the form (/media/85598/download?attachment), then submit it via fax at 1-800-FDA-0178.

You also may contact the CDER Division of Drug Information at druginfo@fda.hhs.gov (mailto:druginfo@fda.hhs.gov) or 855-543-3784.