

company statement

Novo Nordisk takes additional legal actions to help protect US patients from potentially unsafe and ineffective compounded drugs claiming to contain semaglutide that are not FDA approved

- *Novo Nordisk is pursuing legal proceedings against two compounding pharmacies for selling adulterated and misbranded compounded drugs claiming to contain semaglutide*
- *Testing of compounded drugs from these pharmacies revealed unknown impurities up to 33%, a peptide FDA determined cannot be used in compounding due to safety risks, and/or inaccurate strengths with at least 19% less "semaglutide" than labeled*
- *Novo Nordisk secured preliminary injunction against six medical spas, medical clinics, and/or weight-loss clinics for false and misleading advertising of compounded "semaglutide" products*
- *Patient safety is a top priority for Novo Nordisk, and we continue to take action to protect patients and encourage responsible use of our FDA-approved semaglutide medicines*

PLAINSBORO, N.J., November 30, 2023 – Novo Nordisk announced today, that as part of its ongoing commitment to patient safety, it is taking several additional legal actions to protect US patients and consumers from adulterated and misbranded injectable compounded drugs that claim to contain semaglutide that are being sold by two compounding pharmacies, Wells Pharmacy and Brooksville Pharmaceuticals.

"Compounded products do not have the same safety, quality and effectiveness assurances as FDA-approved drugs, and adulterated and misbranded injectable compounded drugs may expose patients to significant health risks," said Jason Brett, Executive Director, Medical Affairs at Novo Nordisk Inc. "Following several analyses of compounded drugs claiming to contain semaglutide, we have seen concerning levels of unknown impurities as high as 33% and lower levels of strength than labeled in the compounded products, which could potentially put patient's health at risk. Our priority is to protect patient safety and to ensure that patients have a safe and positive experience with our FDA-approved semaglutide medicines."

The company is strongly committed to continue reinforcing the responsible use of Novo Nordisk's FDA-approved medicines – including on [semaglutide.com](https://www.novonordisk.com/semaglutide).

The compounded drugs claiming to contain semaglutide from these two compounding pharmacies were tested and the results revealed several concerning findings:

- The presence of unknown impurities— one sample with a concerning level of 33%— which may pose potential safety risks to patients;
- Products from one of the compounding pharmacies containing a second peptide called BPC-157, which FDA announced in September 2023 cannot be used in compounding due to significant safety risks;
- Peptide-related impurities in the compounded products, including amino acid additions and deletions and dimers, not found in the pharmaceutical-grade semaglutide used in Novo Nordisk’s FDA-approved products, Ozempic®, Wegovy®, and Rybelsus®. These peptide-related impurities in the compounded products have the potential to stimulate an immunological reaction with the possibility to lead to serious and life-threatening reactions; and/or
- Inaccurate strength on the label of the compounded products claiming to contain semaglutide, including a sample with at least 19% less than the labeled strength, putting patients at risk of taking drug products that are less effective than expected based on their labeling.

Novo Nordisk aims to secure court orders to prevent these two compounding pharmacies from continuing their unlawful sales of adulterated and misbranded drugs claiming to contain semaglutide. In addition, the company is also seeking to prevent one of these compounding pharmacies, Wells Pharmacy, from using false and misleading statements claiming or implying that its compounded drug claiming to contain semaglutide has been approved by FDA, that its product has been subjected to the same clinical studies and trials as Novo Nordisk’s FDA-approved semaglutide medicines, and that BPC-157 is beneficial for the human body without disclosing its significant safety risks. FDA has warned that it has received an increasing number of adverse event reports and complaints after patients used compounded products claiming to contain semaglutide. The agency has cautioned that it does not review compounded versions of these drugs for safety, effectiveness or quality. Patients should not use a compounded drug if an approved drug is available.

As of November 29, 2023, Novo Nordisk has filed a total of 12 legal actions against medical spas, weight loss or medical clinics, and compounding pharmacies to cease and desist from false advertising, trademark infringement and unlawful sales of non-FDA approved compounded products claiming to contain semaglutide, including:

- Seven complaints filed against medical spas, weight-loss, and medical clinics that are engaging in trademark infringement and false advertising in connection with their sales of non-FDA approved, compounded products that claim to contain semaglutide— in a manner that deceives patients into believing they are actually receiving Novo Nordisk’s FDA-approved semaglutide medicines; and
- Five legal actions filed against compounding pharmacies that are engaging in the unlawful sales of compounded products claiming to contain semaglutide, including drug products that are adulterated and misbranded with respect to strength, thereby posing potential safety and effectiveness risks to patients.

To date, Novo Nordisk has successfully obtained preliminary injunctions against six medical spas, medical clinics, and/or weight-loss clinics that engaged in false advertising and trademark infringement in connection with their sales of compounded drugs claiming to contain semaglutide, sourced from compounding pharmacies. These injunctions prevent these medical spas and other entities from deceiving patients into believing that their compounded drugs claiming to contain semaglutide are:

- Genuine, authentic, and brand-name, FDA-approved semaglutide medicines Wegovy® or Ozempic®;
- Sponsored by or associated in any way with Novo Nordisk or Novo Nordisk's products;
- Approved by FDA, reviewed by FDA for safety, effectiveness, or quality, or demonstrated to FDA to be safe and effective for their intended use;
- Proven to achieve certain therapeutic results or effects, including by relying on the clinical trial results for Novo Nordisk's products; and
- Contain any ingredient (including but not limited to semaglutide) that is supplied by Novo Nordisk, is approved by FDA, or is the same as any ingredient in any Novo Nordisk product.

The preliminary injunctions also require these medical spas and other entities to include clear and prominent corrective advertising in future marketing or promotional materials, alerting patients that their compounded drugs have not been reviewed or approved by FDA for safety, effectiveness, or quality and that FDA-approved medicines containing semaglutide are available. Novo Nordisk intends to also seek permanent injunctions against these same medical spas and other entities in the near future.

About Ozempic®

Ozempic® (semaglutide) injection 0.5 mg, 1 mg or 2 mg is a once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist indicated along with diet and exercise to improve blood sugar (glucose) in adults with type 2 diabetes and to reduce the risk of major cardiovascular events such as heart attack, stroke or death in adults with type 2 diabetes with known heart disease.

About Rybelsus®

Rybelsus® (semaglutide) tablets 7 mg or 14 mg is an analog of the naturally occurring hormone glucagon-like peptide-1 (GLP-1). Rybelsus® is the first and only GLP-1 receptor agonist (RA) in a pill. It is taken once daily and is approved for use in two therapeutic doses: 7 mg and 14 mg.

About Wegovy®

WEGOVY® (semaglutide) injection 2.4 mg is a once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist indicated for chronic weight management in adults and adolescents aged ≥12 years with obesity (BMI ≥30 for adults, BMI ≥ 95th percentile for age and sex for adolescents), or some adults with excess weight (BMI ≥27) (overweight) who also have weight-related medical problems. Wegovy® should be used with a reduced calorie meal plan and increased physical activity.

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