

Dear Healthcare Professional,

At Novo Nordisk, our top priority is patient safety. As the only company in the United States with FDA-approved products containing semaglutide, identified under the trade names **Wegovy**<sup>®</sup> (semaglutide) injection 2.4 mg, **Ozempic**<sup>®</sup> (semaglutide) injection 0.5 mg, 1 mg, or 2 mg, and **Rybelsus**<sup>®</sup> (semaglutide) tablets 7 mg or 14 mg, available by prescription only, we have been concerned by reports of medical spas, weight loss clinics, pharmacies, and other companies selling or offering compounded “semaglutide” to patients. Novo Nordisk does not sell semaglutide to any entities for use in compounding and compounded “semaglutide” products do not have the same safety, quality, and effectiveness assurances as Novo Nordisk’s FDA-approved drugs.

As a follow up to a letter shared in September 2022 with interested Health Care Professionals, please see below for additional information regarding potential safety and efficacy risks with compounded drugs claiming to contain semaglutide.

### **Adverse Events and Administration Errors**

Based on data as of December 31, 2023, the FDA’s Adverse Event Reporting System (FAERS) database includes 352 cases of adverse events associated with compounded “semaglutide.” Of those cases, 268 were classified as “serious” adverse events, 84 reported hospitalization, and five involved deaths. A recent publication highlighted administration errors where patients accidentally self-administered doses of compounded “semaglutide” up to 10 times greater than the intended amount.

### **Other Ingredients and New Dosage Forms**

Some entities sell compounded “semaglutide” in combination with other ingredients, such as the peptide BPC-157, or in dosage forms, such as sublingual tablets or troches, which have not been studied in clinical trials. FDA has found that compounded drugs containing BPC-157 may pose significant safety risks (e.g., immunogenicity) and prohibited the use of BPC-157 in compounding.

### **Impurities and Inaccurate Strengths**

Analyses of samples of compounded “semaglutide” products have revealed that compounded “semaglutide” samples contain peptide-related impurities not found in the semaglutide in Novo Nordisk’s FDA-approved semaglutide medicines. In some cases, the level of unknown impurities is up to 33%. When these types of peptide-related impurities are present in compounded drugs administered to patients, they have the potential to stimulate an immune reaction upon repeated injections, which can lead to serious and life-threatening reactions such as anaphylaxis for patients. In addition, testing results have shown that certain compounded “semaglutide” samples have substantially lower strengths than labeled (e.g., 19% reduction in strength), rendering them potentially less effective than expected.

### **Regulatory and Advocacy Group Warnings**

FDA published a warning on its website about the potential safety risks posed by compounded “semaglutide” products, including that “illegally marketed semaglutide” could “contain too little, too much, or no active ingredient at all, or contain other harmful ingredients.” Seven state boards of pharmacy (AL, KY, LA, MS, NC, NJ, WV) also warned that compounded “semaglutide” may not contain the same active ingredient as Wegovy<sup>®</sup>, Ozempic<sup>®</sup>, and Rybelsus<sup>®</sup>. The Alabama Board of Medical Examiners cautioned that compounded “semaglutide” products “may be contaminated, improperly stored and transported, or adulterated.” The Mississippi State Board of Medical Licensure “strongly advise[d] medical licensees to refrain from prescribing, dispensing, or administering compounded semaglutide until further notice” because such drugs are “unproven and potentially unsafe.”

Advocacy groups for practitioners and patients, such as The Obesity Society, Obesity Medicine Association, and Obesity Action Coalition, issued a statement recommending patients avoid compounded GLP-1 drugs. The groups warn that compounded drugs “are not the same as the drug provided by the manufacturers,” and “may pose serious health risks because of impurities or other non-pharmaceutical additives.”

We hope our efforts here will help reduce the risk that patients will receive poor quality products claiming to contain semaglutide in the future. For additional information, please visit [semaglutide.com](https://www.semaglutide.com), our US hub for patients, retailers, and healthcare professionals like yourself for information on the responsible use of our semaglutide medications.

**Please see the accompanying Prescribing Information, including Boxed Warnings, for [Wegovy](#)<sup>®</sup>, [Ozempic](#)<sup>®</sup>, and [Rybelsus](#)<sup>®</sup>.**

Respectfully,

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