SEMAGLUTIDE Source of Semaglutide as Active Ingredient

• Introduction

Numerous GLP-1 receptor agonist medications exist that are injectable, including OZEMPIC® and WEGOVY®. Both medications have Semaglutide as their active ingredient. Both drugs are FDA-approved, commercially available medications and can be prescribed by healthcare providers for patients. With an overwhelming demand for these medications creating shortages in the marketplace, numerous pharmacies have jumped into the arena of compounding injectable Semaglutide medications as well as nasally delivered Semaglutide medications.

• Background

As an overview, compounded medications are typically custom-made by pharmacies. Pharmacies that engage in compounding are required to meet both federal and state requirements when preparing compounded medications. The FDA issued a statement, available <u>here</u>, due to concerns it has about some of these compounded Semaglutide medications. The FDA expressed its concerns about compounded Semaglutide medications that are made with Semaglutide salts, chemicals for research use only, or ingredients from unregistered manufacturers that do not meet FDA safety requirements. Such medications should not be dispensed to patients (or prescribed).

Due to the shortage of OZEMPIC® and WEGOVY®, some pharmacies have promoted their compounded medications as "generic" versions of these drugs. Compounded medications are not FDA-approved and cannot, under any circumstance, be considered a generic version of a commercially available drug. Pharmaceutical manufacturer Novo Nordisk has instituted legal proceedings against some US medical spas, weight loss or wellness clinics and compounding pharmacies to cease and desist from false advertising, trademark infringement and/or unlawful sales of compounded Semaglutide medications.

• Conclusion

If you are made aware of, encounter, or are contacted by a person or company trying to market or sell you a compounded Semaglutide medication in an injectable format or a nasal format, you are strongly advised to ascertain whether Semaglutide salts, chemicals for research use only, or ingredients from unregistered manufacturers are the source of the Semaglutide in the medication. If you find this to be the case, you are encouraged to report such conduct to regulators that could include, but not be limited to, the state pharmacy board, the state attorney general, consumer complaint divisions, as well as the FDA through the following link – <u>https://www.fda.gov/safety/report-problem-fda</u>.