August 4, 2025 – Public Service Alert

The Federal Food & Drug Administration (FDA) has made Boards of Pharmacy aware of information related to fraudulent activity associated with compounded GLP-1 (glucagon-like peptide-1 (GLP-1) receptor agonist) drugs, including semaglutide and tirzepatide.

FDA is aware that health care providers and patients are turning to compounded GLP-1 drugs, including semaglutide and tirzepatide, as an option for weight loss. FDA is also aware of an increased interest in, and interaction with, third parties (e.g., telehealth platforms, marketing firms, or operators of websites that are not state-licensed pharmacies or outsourcing facilities) to easily obtain such drugs.

Please be advised FDA has received multiple reports alleging the sale and distribution of unapproved GLP-1 drugs falsely claiming to be compounded by a state-licensed pharmacy. These reports describe patients receiving GLP-1 drugs, often through third-parties, with labels that bear the name of either (1) a state-licensed pharmacy that had no role in the drug's production, sale or distribution; or (2) what appears to be a fictitious state-licensed pharmacy. Reports also indicate that some drugs were dispensed without a valid patient-specific prescription. On February 28, 2025, the Federal Bureau of Investigation also highlighted fraudulent compounding practices in Alert Number: I-022825-PSA.

Health care providers and patients need to be aware of how they could be exposed to fake or otherwise unsafe prescription drugs. The legitimacy of a prescriber and the source of a prescription drug should be carefully verified. For additional resources on how to safely obtain prescription drugs, please consult FDA's BeSafeRx and Know Your Source campaigns. Health care providers and patients should also report adverse events or quality problems associated with compounded drug products to FDA's MedWatch Adverse Event Reporting program.

If you have questions or wish to submit any relevant information, please contact the Office of Compounding Quality and Compliance at compounding@fda.hhs.gov

Related Link

https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss