The Partnership for SAFEMEDICINES®

ILLEGAL INGREDIENTS LINKED TO KNOCKOFF WEIGHT LOSS DRUGS POURING IN FROM FOREIGN SOURCES

GLP-1 injectable medications are highly effective for treating diabetes and obesity, with rigorous testing and U.S. Food and Drug Administration (FDA) approval.

Compounded versions have surged in popularity with medspas, telehealth companies, and compounding pharmacies promoting them despite the lack the safety and efficacy assurances. The FDA has warned that these knockoff versions sometimes contain illicit semaglutide or tirzepatide—the active pharmaceutical ingredients (APIs) in weight loss drugs.

Working with George Karavetsos, former director of FDA's Office of Criminal Investigations and a federal prosecutor, PSM analyzed the FDA's import records and related databases to investigate the origin, legality, and intended use behind the weight loss drug ingredients entering the U.S. and reaching American consumers.

Our research reveals a troubling influx of unauthorized weight loss drug ingredients, many intended for compounded versions, entering the U.S. from illegal foreign sources. Despite laws requiring U.S. Customs and Border Protection (CBP) and the FDA to block them, they continue to arrive at an alarming rate.

Knockoff Ingredients Flowing Past U.S. Checks

Between September 2023 and January 2025:

2,465 bulk shipments of semaglutide and tirzepatide for U.S. importation inspection

239 shipments of semaglutide or tirzepatide from unregistered entities

195 were allowed into the U.S. despite clear legal prohibitions

ILLEGAL INGREDIENTS FOR KNOCKOFF WEIGHT LOSS DRUGS FLOODING INTO THE U.S. FROM FOREIGN SOURCES

Many shipments' labels should've automatically disqualified them from crossing American borders:

- "Non-sterile"
- "Investigational"
- Unapproved forms, like ointments and suppositories

> *We call on drug compounders, including medspas and telehealth companies, to operate with transparency, integrity, and responsibility to their customers."*
>
> **— Shabbir Safdar, Executive Director, Partnership for Safe Medicines**

> *U.S. law enforcement and regulators must ensure Americans are not exposed to the dangers of illegal drug ingredients from foreign sources."*
>
> **— George Karavetsos, former director of FDA's Office of Criminal Investigations**

Urgent Action to Protect American Patients

1. **GLP-1 compounders should disclose the manufacturer of their API to customers.**
2. **FDA must refuse entry to any drugs that "appear" misbranded, adulterated, or otherwise unapproved.**
3. **FDA should add unregistered, rogue manufacturers to the Import Alert watch list.**
4. **FDA and state boards of pharmacy should prioritize inspections of compounders that attempt to important GLP-1 API from unregistered facilities.**
5. **FDA must refuse shipments if their information or labeling does not meet regulatory requirements.**

READ THE FULL REPORT AND LEARN MORE AT SAFEMEDICINES.ORG

The Partnership for SAFEMEDICINES®