

INTELLIGENCE ALERT:

Distribution of unregulated, uninspected, unsanitary and potentially unsafe diabetes and weight loss injectables through unlicensed med spas poses immediate threat to public safety

Based on recent investigative reporting by the Partnership for Safe Medicines (PSM), patients in your state may be receiving weight loss injectables from unlicensed sources that do not meet FDA requirements for safety and sterility. The Partnership for Safe Medicines has been tracking and documenting illegal imports of pharmaceutical ingredients and is particularly concerned about dangerous products being dispensed through unlicensed med spas. **PSM has established a dedicated contact from CBP/HSI to support investigations by state law enforcement on this issue.**



ISSUE:

Unregulated, uninspected, unsanitary and potentially unsafe diabetes and weight loss injectable products and ingredients are illegally imported into the U.S. through various illicit means, including import document falsification, transshipment and exploitation of regulatory loopholes. As a result, significant amounts of potentially unsafe medicines are being distributed in the U.S. through unlicensed med spas and, in some cases, directly from medical professionals.



LATEST INCIDENT:

A shipment of 10kg of tirzepatide, the active ingredient in Lilly's Mounjaro and Zepbound products, arrived at a port of entry in the FDA Southeast division on May 25, 2025.

- ▶ It was made in a facility not registered with the FDA.
- ▶ The manifest showed it contained three dosages of tirzepatide marked as "for compounding."
- ▶ 10kg is equivalent to four million 2.5mg starting doses of the medicine.
- ▶ The shipment was initially detained but ultimately released into the U.S. to its destination on June 9, 2025.
- ▶ The Chinese manufacturer, Chengdu Miao Ding Xin Pharmaceutical Technology Co., Ltd., was later added to an import alert list to flag future shipments for detention, refusal, or seizure.



THREAT:

Diabetes and weight loss medicines are sterile injectables and require the highest level of supply chain diligence. Pharmaceutical sterility is incredibly important, as contamination of any kind can result in severe side effects or death. If a producer is not registered with the FDA, their production facility is not inspected or scrutinized by FDA inspectors to ensure safety and regulatory compliance. Only licensed and registered manufacturers should be trusted to uphold sterility standards.



ACTIONS ENCOURAGED:

- ▶ PSM is available to provide detailed briefings to law enforcement on the scope and current investigative data on this issue. To schedule a briefing, contact PSM at editors@safemedicines.org
- ▶ Law enforcement is encouraged to alert the public about the danger of unlicensed med spas. PSM has provided sample PSAs enclosed with this alert.
- ▶ Share this alert with other regulatory and enforcement officials. An illegally operating med spa can violate a broad variety of federal and state statutes including false advertising, consumer fraud, violations of the state-incorporated Food, Drug, and Cosmetic Act, and health department statutes.
- ▶ **Reach out to PSM for CBP/HSI support of law enforcement investigations on this issue.**



ADDITIONAL RESOURCES: PSM has regular reports of illegal imports of medicines at www.safemedicines.org/2025/05/pharma-borders.html