

Congress of the United States

Washington, DC 20515

July 25, 2025

Commissioner Marty Makary
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Makary:

We are looking forward to working with you on many things, including FDA's critical mission to protect the American public from unsafe, unapproved and dangerous pharmaceutical products. For decades, the United States has been regarded as having the world's safest drug supply due to FDA's broad enforcement authority. However, we are concerned about recent reports revealing a surge in illegal and counterfeit anti-obesity medications (AOMs), which include semaglutide and tirzepatide, entering the U.S. from unregistered foreign entities.¹ Undoubtedly, illegal counterfeit medications pose an increased risk to patient safety with sometimes fatal consequences.

Counterfeit products and illegally manufactured AOMs are often made from illegally imported ingredients from unregistered foreign entities. Recently, the Federal Bureau of Investigations (FBI) issued a warning about counterfeit weight loss products containing semaglutide, the active ingredient in Ozempic and Wegovy.² The FBI warned that in one instance, fraudulent drugs purporting to contain semaglutide had been found instead to contain "mixtures of unknown drugs that do not contain semaglutide, drugs with high levels of impurities, and unsafe or unapproved drugs." This follows a February 19, 2025, letter from the National Association of Attorneys General to the FDA on behalf of a bipartisan coalition of 38 state and territory attorney generals expressing alarm that counterfeit drugs which can contain contaminants, or other unknown drugs, have entered the U.S. supply chain from China, Turkey, and India.³ FDA and U.S. Customs and Border Patrol's (CBP) own import database shows record of 239 shipments of GLP-1 active ingredients from unregistered foreign entities.⁴ The vast majority of these shipments are from Chinese suppliers that have never been inspected by FDA

¹ [New report reveals illegal ingredients for knockoff weight loss drugs flooding into U.S. from foreign sources, endangering patient safety – Partnership for Safe Medicines](#)

² [Internet Crime Complaint Center \(IC3\) | Safety Concerns Related to Fraudulent Compounding Practices Associated with Weight Loss Drugs](#)

³ [State and Territory Attorneys General Urge FDA to Take Action Against Counterfeit and Illegally Sold GLP-1 Drugs - National Association of Attorneys General](#)

⁴ [New report reveals illegal ingredients for knockoff weight loss drugs flooding into U.S. from foreign sources, endangering patient safety – Partnership for Safe Medicines](#)

and are not allowed to sell their unapproved AOMs for human use in China, which begs the question as to why they were cleared for U.S. distribution. There are also reports of widespread smuggling of unapproved AOMs into the U.S., including in packages marked as dog food, tea, facial masks, or t-shirts.

We understand the distinction between legitimate compounded drugs prepared in state-licensed pharmacies and counterfeit or compounded drugs made from illicit ingredients obtained from illegitimate sources. However, unapproved AOMs continue to be widely marketed online, in print, and on television.

These counterfeit GLP-1 drugs may contain dangerously high concentrations of active ingredients, unknown compounds, or contaminants. In many cases, these substances pose a significant threat to consumer health, including the potential for adverse reactions, toxic exposure, or overdose. We are particularly concerned that some consumers are reportedly mixing and injecting these substances themselves, potentially using non-sterile equipment or improper techniques. The health consequences of such unregulated use could be severe—including infection, organ damage, or fatal overdose.

We understand the critical role of the FDA to ensuring a safe and secure drug supply for the benefit of all American consumers. We also appreciate the recent warning from the FDA to Ozempic users and sellers to check their products' lot and serial numbers⁵. We further urge the agency to use its existing statutory authority to ramp up enforcement over illegally imported prescription drugs including AOMs, including by issuing warning letters, initiating civil enforcement actions, and monitoring noncompliant online retailers and compounders selling unapproved AOMs. FDA has a mandatory duty to refuse entry of drugs, including active ingredients used in counterfeit drugs, imported from unregistered entities under 21 U.S.C. § 381(a). Thus, FDA should immediately work with CBP to issue an import alert and step up enforcement at the border to prevent Chinese entities from undermining America's supply of safe medicines by shipping unsafe and illicit weight loss drugs into the United States in violation of federal law.

Given the urgency of this matter, we respectfully request a response and update on FDA's efforts by July 30, 2025. We look forward to working with the Administration to ensure the safety of the U.S. drug supply for American consumers.

Sincerely,



Richard Hudson
Member of Congress



Herbert C. Conaway, Jr.
Member of Congress

⁵ [FDA warns consumers not to use counterfeit Ozempic \(semaglutide\) found in U.S. drug supply chain](#)