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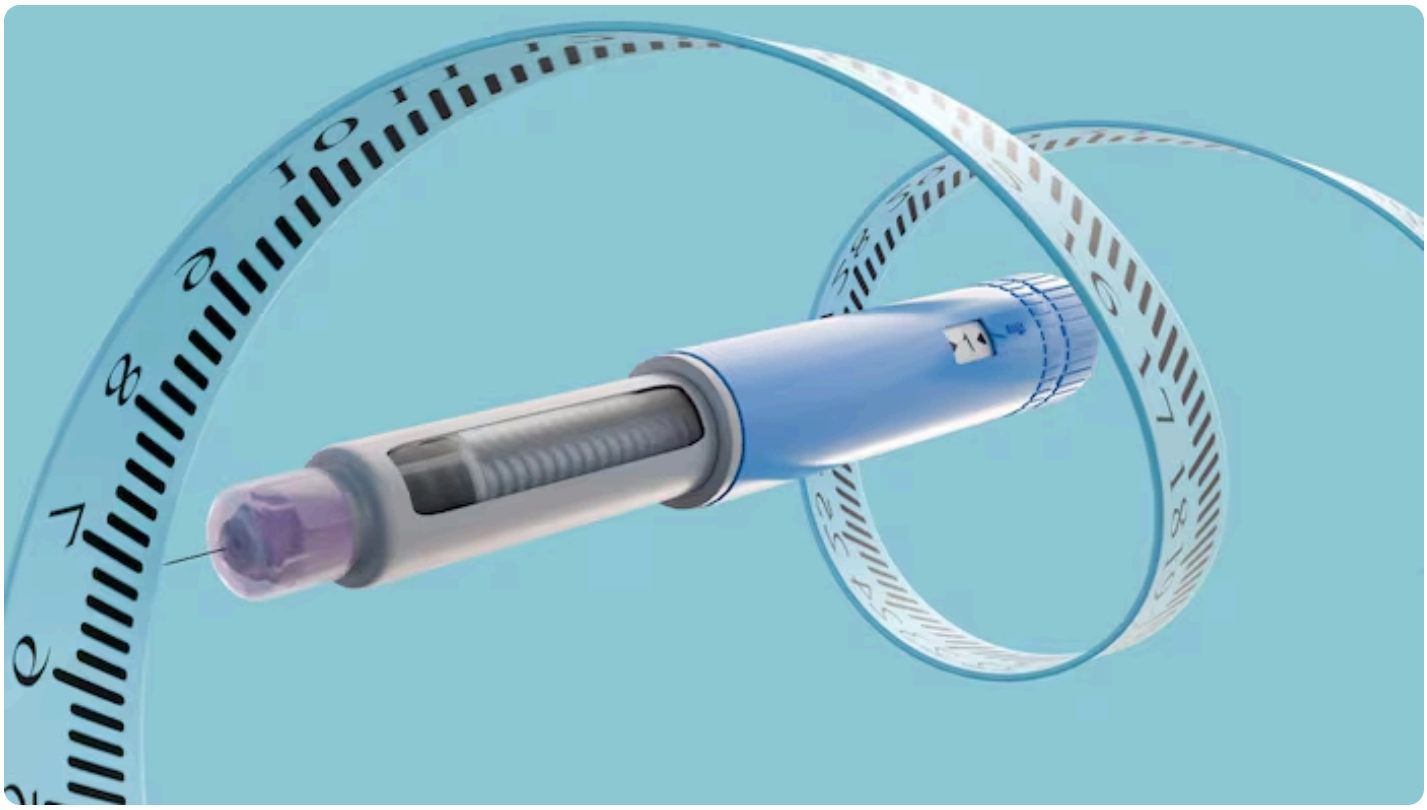
Compounders Argue US FDA's GLP-1 Green List Validates Legit Practices

Oct 13 2025 • By Aakash Babu

The compounding industry said the FDA's "green list" of GLP-1 API imports for compounded drugs validates legitimate compounding pharmacies' role in the US health system.



The green list would not restrict compounding by state-licensed pharmacies. (Shutterstock)

Key Takeaways

- The “green list” intends to prevent US entry of potentially dangerous GLP-1 active pharmaceutical ingredients from unverified foreign sources.
- Compounding pharmacies cheered because they believe the move validates the legitimate practice.
- The green list could help reduce counterfeit and illicit products in the US, but would not restrict compounding by state-licensed pharmacies.

Compounding pharmacies are cheering the US Food and Drug Administration’s “green list” import alert intended to stop unverified sources of GLP-1 (glucagon-like peptide-1) active pharmaceutical ingredients from sending products to the US market as a validation of the legitimate practice and its role in the health care system.

“I read the announcements and the placement of the GLP-1 ‘green list’, as the FDA acknowledging that compounding of GLP-1s can occur as long as the standards are met,” Lee Rosebush, Chairman of the Outsourcing Facilities Association (OFA) told the *Pink Sheet*.

The list would include GLP-1 APIs from facilities inspected and in compliance with the FDA's standards. The effort is intended to tackle "serious concerns" with compounded versions of semaglutide and tirzepatide, such as dosing errors, the use of unapproved salt forms and serious adverse events.

"By strengthening oversight of imported APIs and cracking down on illegal drugs entering the US, we are taking aggressive action to protect consumers from poor-quality or dangerous GLP-1 drugs," FDA Commissioner Martin Makary said in a statement.

The agency said it would continue to work with state regulators, monitor the market, and take enforcement actions as necessary to prevent unsafe or fraudulent GLP-1 drugs from reaching US consumers.

"Our priority is protecting public health by ensuring all active ingredients used in GLP-1 drugs are obtained from compliant manufacturers," said George Tidmarsh, director of the FDA's Center for Drug Evaluation and Research.

Scott Brunner, CEO of the Alliance for Pharmacy Compounding, believes the move ended the argument that drugmaker APIs are different from state-licensed compounding pharmacy APIs.

"At no point in the shortage of GLP-1s, and in the aftermath of the GLP-1 shortage, has FDA raised any concerns about the quality of the active pharmaceutical ingredient [that legitimate compounding pharmacies were using]," Brunner told the *Pink Sheet* in an interview.

Big Pharma Woes

Big Pharma companies and compounders have fought for decades over competition concerns and pricing. The GLP-1 shortage and the subsequent increase in compounded versions cut into big pharma profits.

Novo Nordisk, in its latest quarterly results, cut its sales forecast for the year, citing "persistent use of compounded GLP-1s, slower-than-expected market expansion and competition" relating to its blockbuster GLP-1 drug Wegovy (semaglutide).

Compounders only can operate when the FDA deems a drug in shortage. Now that Novo's output is meeting demand, the regulator mandated the end of compounding on May 22, [illegible]ough compounders are looking for workarounds.

The green list would not restrict compounding by state licensed pharmacies, but could help reduce counterfeit and illicit products in the US. Novo has said an estimated 1 million patients took “knock-off” semaglutide, much of it manufactured in China.

Since Mike Doustdar took charge, the Novo has resolved to regain market share, while mounting aggressive legal action against illegal GLP-1 compounders still operating in the US. The company has filed more than 130 lawsuits across 40 states, resulting in 44 permanent injunctions to stop “unsafe, illegal marketing” of counterfeit Wegovy and Ozempic.

“It is important that FDA crack down on imports of illicit ‘semaglutide’ API and take action to protect patients from the safety risks posed by taking knockoff drugs made with inauthentic, substandard API, including API that has already been imported into the US,” Novo told the *Pink Sheet* in an emailed statement.

The company also said it had shared patient safety information with the FDA and other regulators for more than two years, and would continue “to work across stakeholders with a focus on patient safety and transparency.”

“Should a counterfeit product that is illegally made be stopped?” Rosebush said. “Yes, it should be stopped, but compounded product that is done properly is not counterfeit or illicit.”

“It (compounding) is essential for patients who need a customized dose or formulation or who need a medication that is not commercially available,” he added.

Concerns Remain

The FDA said the “green list” does not prevent the legal import of GLP-1 APIs from compliant manufacturers or create new limits on the legal compounding of GLP-1 drugs. However, the agency remains concerned about dosing errors, counterfeit versions of compounded drugs, illegal online sales and underreporting of adverse events.

The FDA also has been cracking down on firms advertising or marketing compounded GLP-1s as part of its direct-to-consumer ad reform efforts. The agency posted a raft of warning letters on Sept. 16 along with several untitled letters, that cited TV advertising and other [illegible]tions.

More than 100 violation letters were sent in all, in addition to letters to sponsors alerting them of the new compliance expectations.

And even though the FDA is taking enforcement action against compounding pharmacies, the same action is being taken across the GLP-1 space, Rosebush argued.

As of July 31, the FDA said it had received more than 1,100 adverse event reports associated with compounded versions of semaglutide and tirzepatide. However, compounders maintain that AEs for branded GLP-1 drugs in the same period dwarf the reports for compounded products.

“Any serious adverse event should be reported and investigated,” Brunner said. “Unfortunately, we don’t always have that investigatory piece, both for compounding drugs and on the FDA approved drug side of things.”

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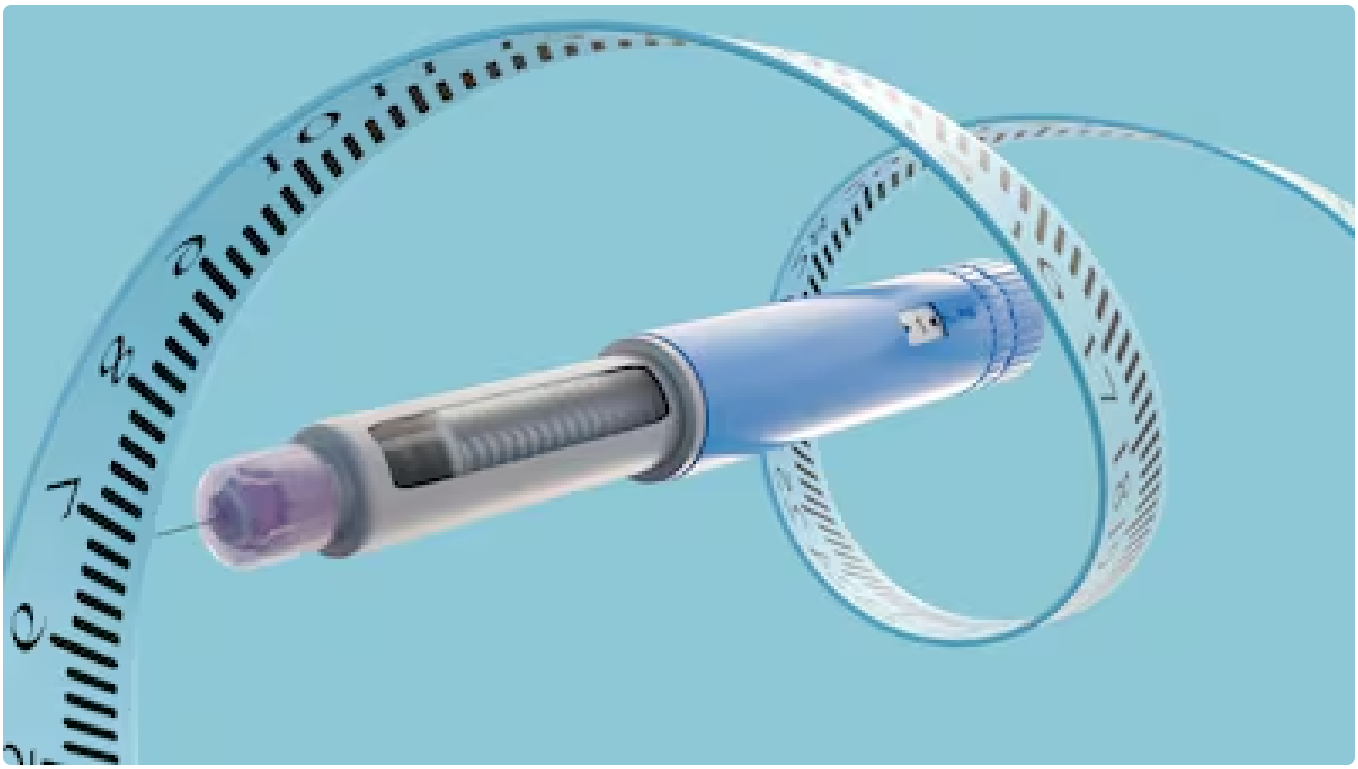

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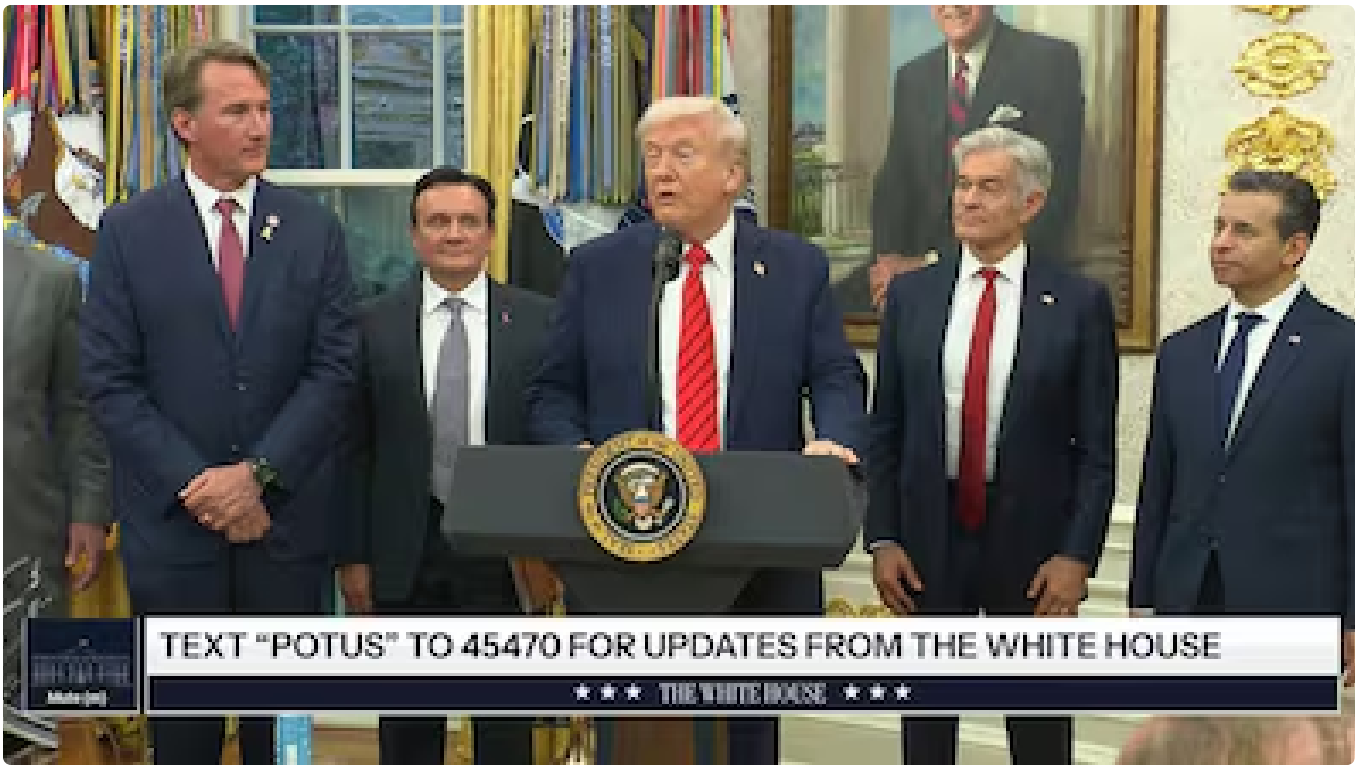

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