FDA NEWS RELEASE

FDA Launches Green List to Protect Americans from Illegal Imported GLP-1 Drug Ingredients

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For Immediate Release:

September 05, 2025

The U.S. Food and Drug Administration today established a “green list” import alert to help stop potentially dangerous GLP-1 (glucagon-like peptide-1) active pharmaceutical ingredients (APIs) from unverified foreign sources from entering the U.S. market. This is part of the agency’s decisive steps to safeguard consumers from illegal GLP-1 active ingredients imported from overseas to ensure patient safety and a secure drug supply chain.

Certain GLP-1 drugs, including semaglutide and tirzepatide, are FDA-approved for specific uses such as treating type 2 diabetes and, in certain cases, chronic weight management. However, the agency is aware that some patients are turning to compounded versions of these drugs, which are not approved by the FDA. To protect patients who use these compounded drugs, the green list will include GLP-1 APIs from facilities the agency has inspected or evaluated that appear to be in compliance with the FDA’s rigorous standards – standards applicable to all APIs manufactured in the U.S. APIs from other sources are subject to detention without physical examination.

“Americans should be confident that the prescription drugs they take are safe,” said **FDA Commissioner Marty Makary, M.D., M.P.H.** “By strengthening oversight of imported APIs and cracking down on illegal drugs entering the U.S., we are taking aggressive action to protect consumers from poor-quality or dangerous GLP-1 drugs.”

“Our priority is protecting public health by ensuring all active ingredients used in GLP-1 drugs are obtained from compliant manufacturers,” **said George Tidmarsh, M.D., Ph.D., Director of the FDA’s Center for Drug Evaluation and Research.** “Targeting illegal foreign GLP-1 active ingredients at the border is a critical part of this work.”

The FDA previously identified serious concerns with compounded versions of semaglutide and tirzepatide, including dosing errors, use of unapproved salt forms and adverse events—some requiring hospitalization.

The agency will 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 U.S. consumers.

Visit FDA’s Concerns with Unapproved GLP-1 Drugs Used for Weight Loss (/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss) for more information.

Media:
FDA Request for Comment (https://www.hhs.gov/request-for-comment-form/index.html?Agency=FDA)
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