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FDA Sends Warning Letters to More Than 50 GLP-1 Compounders and Manufacturers

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ALERTS

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Key Takeaways

- The U.S. Food and Drug Administration (FDA) sent over 50 warning letters to GLP-1 drug compounders and manufacturers in September 2025. The agency warned the companies that their statements that compounded products are "generic" versions of the FDA-approved drugs with the "same active ingredient" and equivalent safety and efficacy are false and misleading and in violation of the Federal Food, Drug, and Cosmetic Act.
- In light of the warnings, companies marketing GLP-1 drug products should reassess their labeling, promotional statements, and social media content for potential enforcement risks.

In September 2025, the U.S. Food and Drug Administration (FDA) issued more than 50 warning letters to U.S. and international companies that compound or manufacture glucagon-like peptides (GLP-1) semaglutide and tirzepatide.[1] Most were issued on September 9, 2025, but the FDA continues to publish new letters.

The warnings target statements on websites and in promotional materials that the FDA considers to be false or misleading. Specifically, the FDA considered claims that compounded products are "generic versions" or contain the "same active ingredient" as FDA-approved GLP-1 drugs are false or misleading.[2] The FDA emphasizes that it does not evaluate compounded drugs for safety, effectiveness, or quality, and that they are not the same as the FDA-approved versions.[3]

The FDA also warned companies of claims that indicate their products are safe and effective for weight loss, including claims that they offer "real results" or "proven effectiveness."[4] Although most of the letters were addressed to compounders, brand name manufacturers that hold FDA approvals also received warnings concerning a prime-time TV special that the FDA says created "a misleading impression regarding the safety" of their products.[5]

Companies receiving warning letters have 15 working days to respond with a corrective action plan or a justification. Failure to address the violations may result in additional enforcement action, such as product seizures or an injunction.

The FDA's warnings occur during skyrocketing demand for GLP-1 therapies to treat obesity and Type 2 diabetes. With compounders stepping in to meet that demand, the FDA is reasserting its requirements over a fiercely competitive market.

For companies engaged in compounding of GLP-1 drug products, the warnings signal a need to reassess labeling, advertising, and promotional strategies. The FDA's letters suggest that claims

suggesting equivalence to approved drugs—whether direct or implied—may face enforcement action. Companies should examine their promotional statements, social media content, and particularly their websites for potential risks.

For additional information concerning how compounders can reduce the risk of enforcement action and navigate the FDA's requirements, please contact Wilson Sonsini attorneys Wendy L. Devine or Eva F. Yin.

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[1] FDA, Warning Letters, available at: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters (last visited: Sep. 23, 2025).

[2] *See, e.g.*, FDA, Warning Letter to Expert Aesthetics (Sep. 9, 2025); Warning Letter to The HCG Institute (Sept. 9, 2025); Warning Letter to Bioverse, Inc. (Sept. 9, 2025), available at: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.

[3] FDA, *FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss*, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concems-unapproved-glp-1-drugs-used-weight-loss (last visited: Sep. 23, 2025).

[4] *See, e.g.*, FDA, Warning Letter to Elevate Your Wellness LLC (Sept. 9, 2025), Warning Letter to GLP-1 Solution, Warning Letter to Tuyo Health, Inc. (Sept. 9, 2025), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters (last visited: Sep. 23, 2025).

[5] FDA, Warning Letter to Novo Nordisk, Inc. (Sep. 9, 2025), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/novo-nordisk-inc-716495-09092025; Warning Letter to Eli Lilly and Company (Sep. 9, 2025), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/eli-lilly-and-company-716485-09092025.