
Novo Nordisk to pursue legal action against Hims & Hers over introductory offer for \$49 for first month of compounded oral Wegovy – February 5, 2026

Follows [September 2025 FDA warning letter issued to Hims & Hers over GLP-1 RA marketing and safety concerns](#)

Novo Nordisk [announced](#) today that it will pursue legal and regulatory action against Hims & Hers following the company's [announcement](#) that it will introduce a compounded oral semaglutide pill, which would be promoted at \$49 for the first month. Novo Nordisk called the product an “unapproved, inauthentic, and untested knockoff semaglutide pill” and described Hims & Hers’ actions as illegal mass compounding that puts patient safety at risk.

In today's [press release](#) from Hims & Hers, the company emphasized that the compounded semaglutide pill is personalized to: (i) lower side effects; (ii) offer smaller doses; and (iii) protect active pharmaceutical ingredient (API) through digestion and support absorption. It also said that APIs are sourced directly from FDA-registered facilities. It states that the FDA does not approve or evaluate compounded products for safety, efficacy, or quality.

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Pricing dynamics: Compounded oral semaglutide remains cheaper than cash price of oral Wegovy

While Novo Nordisk has significantly reduced Wegovy prices across channels, compounded oral semaglutide from Hims & Hers remains cheaper. [Currently](#), Novo Nordisk offers oral Wegovy at \$149-\$299 per month via self-pay. Under the [Most Favored Nation deal](#)^[1], Novo Nordisk also agreed to offer Wegovy pill at \$150 per month on [TrumpRx](#). Despite these reductions, Hims & Hers’ new compounded oral semaglutide pill is priced at \$49 for the first month of its five-month plan, followed by a monthly cost ranging between \$99-\$145.

Hims & Hers reported strong 3Q25 financial results, driven by GLP-1 RA demand

Despite controversy over the company's compounded therapies, Hims & Hers delivered [continued](#) growth in [3Q25](#), reporting \$599 million in revenue, up 49% from 3Q24. In 3Q25, the company's subscriber base grew to 2.5 million, up 21% from 3Q24. Management reaffirmed a full-year 2025 revenue guidance between \$2.3 billion and \$2.4 billion.

We look forward to hearing the company's 4Q25 and full-year financial results on [February 23, 2026](#), when the company may comment on its compounded oral semaglutide launch and Novo Nordisk's legal action.

Previously, Novo Nordisk terminated its partnership with Hims & Hers following the end of the semaglutide shortage

As background, in [June 2025](#), Novo Nordisk terminated a short-lived partnership with Hims & Hers, which had allowed the telehealth platform to dispense cash-pay Wegovy. Novo Nordisk ended the agreement after just 55 days, alleging Hims & Hers’ violations of federal compounding rules and misleading marketing. The termination came shortly after FDA formally declared the semaglutide injectable shortage resolved in [February 2025](#) and state-licensed pharmacies and

503B outsourcing facilities were no longer allowed to produce compounded copies of semaglutide. Upon the termination of the partnership, Novo Nordisk alleged that Hims & Hers was sourcing semaglutide APIs from unverified foreign manufacturers and presenting compounded products as equivalent to branded GLP-1 RAs. Hims & Hers rejected the claims and accused Novo Nordisk of anticompetitive pressure to increase Wegovy prescription uptake.

FDA issued a warning letter to Hims & Hers over marketing and safety concerns

In [September 2025](#), the FDA issued a formal warning letter to Hims & Hers, citing multiple violations related to the company's promotion of compounded GLP-1 RA products. The FDA found that Hims & Hers' marketing materials were "false or misleading" because they implied that compounded semaglutide products were equivalent to FDA-approved GLP-1 RA therapies and failed to adequately disclose the risks associated with unapproved compounded drugs. FDA also noted that several of the company's promotional claims minimized or omitted safety information, including the lack of FDA review for compounded semaglutide. The FDA instructed Hims & Hers to correct the violations and provide a detailed plan for compliance within 15 days of receiving the letter.

SAFE Drugs Act aims to restrict mass compounding and strengthen FDA regulation

Amid controversy around compounded drugs, bipartisan lawmakers introduced the [SAFE Drugs Act of 2025](#) in [December 2025](#) to curb large-scale compounding of "essentially copies" of FDA-approved drugs and expand the FDA's authority over outsourcing facilities. The legislation would codify and tighten existing 503A/503B rules by restricting mass production of compounded versions of drugs like semaglutide, increasing transparency for interstate distribution, and requiring more frequent FDA inspections. The bill also proposes new user fees for outsourcing facilities to bolster the FDA's enforcement capacity. The ADA, Obesity Action Coalition, and Partnership for Safe Medicines endorsed the bill, citing persistent safety and quality concerns around compounded GLP-1 RAs.

Close Concerns' Questions

1. How might consumers weigh safety concerns against the substantial price difference between FDA-approved and compounded oral GLP-1 RAs?
2. What mechanisms will regulators use to monitor the quality and sourcing of APIs used in compounded oral semaglutide?
3. How might the [SAFE Drugs Act](#), if passed, reshape the legal landscape for telehealth platforms offering compounded GLP-1s, and would Hims & Hers' new oral semaglutide pill be permissible?

-- by Kayla Mathieu, Kat Moon, Monica Oxenreiter, and Kelly Close

[1] The Most Favored Nation deal also allows [Medicare](#) beneficiaries to access to Ozempic and Wegovy at \$245 per month with a \$50 co-pay starting in mid-2026. Under the [Medicare Drug Price Negotiation Program](#) (MDPNP), starting in 2027, Ozempic and Rybelsus are set to cost ~\$277 per month and Wegovy at \$385 per month, down nearly 71% from the original list price. It is unclear whether the pricing of oral Wegovy will be further negotiated in these programs.