CLOSER LOOK

MEMORANDUM

Hims & Hers withdraws plan to offer $49 compounded oral Wegovy following backlash from the FDA and threatened legal action from Novo Nordisk – February 8, 2026

Follows FDA warning letter to Hims & Hers, threat of legal action by Novo Nordisk, and a stricter enforcement plan for non-FDA-approved GLP-1 RAs

Two days after announcing plans to offer $49 compounded oral Wegovy, last Thursday, February 5, the San Francisco, California-based company Hims & Hers has reversed the offer, posting on its X account that it will no longer move forward with the product. This announcement follows the threat of legal action from Novo Nordisk, which identified the compounded pill as an "unapproved, inauthentic, and untested knockoff semaglutide," as well as the FDA's announcement on Friday of its intent to take action against non-FDA-approved GLP-1 RAs. We're impressed by Novo Nordisk's hard line and imagine its lawyers have been busy.

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FDA's enforcement plan against non-approved GLP-1 RAs

The FDA announced on Friday its plan to take stronger action against compounded GLP-1 RAs, explicitly calling out Hims & Hers. The agency said it intends to limit access to GLP-1 RA active pharmaceutical ingredients (APIs) when they are being used in compounded products that are marketed in ways that resemble FDA-approved medications, like they have been doing. According to the FDA, these steps aim to protect consumers from products whose quality, safety, and effectiveness have not been confirmed by the agency.

The FDA also signaled that it is intensifying its oversight of direct-to-consumer (DTC) advertising[1], following up on the warning letters it issued Hims & Hers last September (2025). The FDA stressed that companies may not portray compounded GLP-1 RA products as generics, may not assert they are the "same as" approved drugs, or suggest they rely on the same active ingredients or have clinically-proven efficacy. The agency further stated that companies involved in producing, distributing, or promoting unapproved compounded GLP-1 receptor agonists (RAs), without failing to correct violations, could face legal action, including product seizures or injunctions, without further notice. We imagine the tone of the letter sounded extremely "cease and desist"-like.

Broader regulatory momentum: SAFE Drugs Act

The reversal also comes amid legislative efforts to tighten oversight of compounding. The bipartisan SAFE Drugs Act of 2025 seeks to restrict mass production of "essentially copies" of FDA-approved drugs, increase transparency in interstate distribution, and strengthen FDA authority over outsourcing facilities. The ADA, Obesity Action Coalition, and Partnership for Safe Medicines have endorsed the bill, citing safety concerns around compounded GLP-1 RAs. This is unsurprising given previous statements by the three organizations, starting back in early 2024 and reinforced as recently as last week:

- **Leading Obesity Expert Organizations Release Statement to Patients on Compounded GLP-1 Alternatives** – January 8, 2024

- **Obesity Care Organizations Issue Joint Statement**: Do Not Use Compounded Alternatives to GLP-1 Medicines – January 9, 2024 (*issued by The Obesity Society, The Obesity Action Coalition, and The Obesity Medicine Association*)
- **The American Diabetes Association Announces Statement on Compounded Incretin Products** - December 2, 2024
- **OAC Statement About Grey Matter GLP-1 Products and Safe Obesity Care** – December 12, 2025
- **Partnership for Safe Medicines statement on "deeply concerning" compounding of GLP-1 weight loss pills** – February 5, 2026

Pricing dynamics for weight loss drugs continue to shift, with new MFN pricing in effect

Hims & Hers's withdrawn compounded oral semaglutide offer had been positioned far below the new Most Favored Nation (MFN)-aligned prices now available through TrumpRx, which launched last Friday. Under the program, Novo Nordisk agreed to substantially lower cash-pay prices for its GLP-1 RAs, including oral Wegovy, which now can start as low as $149 per month. Against this backdrop, Hims & Hers's proposed $49 first-month price stood out as an unusually steep discount when compared with newly reduced manufacturer pricing. As MFN pricing expands, we hope that patients may face fewer (to no!) incentives to seek unsafe compounded alternatives.

Close Concerns' Questions

1. How might Hims & Hers adjust its obesity-care strategy for its remaining portfolio as compounded GLP-1 RAs face tighter regulatory constraints?
2. What impact might the SAFE Drugs Act have on the long-term viability of compounding?
3. What operational or compliance changes will compounders need to make in response to the FDA's warning that failure to correct violations may result in seizure or injunction?

--by Kayla Mathieu, Jeremy Alkire, and Kelly Close

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[1] For reference, the US and New Zealand are the only two countries that allow direct-to-consumer advertisements for prescription drugs.