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## FDA issues 30 warning letters to telehealth companies about false or misleading claims on compounded GLP-1 RAs – March 3, 2026

*The FDA has issued thousands of warning letters regarding compounding since [September 2025](#)*

The FDA [announced](#) that it has issued additional [warning letters](#) to dozens of telehealth companies for making false or misleading claims about compounded GLP-1 RAs. The letters cite a variety of violations, including obscuring the source of products and implying that compounded drugs are FDA-approved or clinically proven. In the press release, FDA Commissioner Dr. Marty Makary said that compounding should be used to overcome shortages or address unique needs but not to “circumvent” federal regulatory pathways. This follows [thousands of letters](#) issued by the FDA since [September 2025](#), which similarly warned telehealth companies about misleading marketing of compounded products. The wave of enforcement actions reflects the [extraordinary commercial demand](#) for GLP-1 RAs, fueled by rapid uptake for weight loss and diabetes, early supply constraints, and high out-of-pocket costs that have created incentives for telehealth platforms and compounding pharmacies to enter the market aggressively, making this therapeutic class especially vulnerable to misleading promotion.

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## Online weight loss clinics and telehealth companies received an FDA warning letter for being misleading

According to the [FDA database](#) of warning letters, dozens of telehealth companies<sup>[1]</sup> have received warning letters about compounded products. The FDA claims that these companies mislead or misbrand compounded semaglutide, tirzepatide, and liraglutide as compounded by their own organizations and that they are FDA-approved or proven for their clinical efficacy. The pharmaceutical and telehealth firms involved are required to remove these misleading advertisements or risk further warnings or FDA action.

One FDA-registered 503B outsourcing facility, [GenoGenix](#), also received a letter from the FDA for unsafe drug manufacturing practices, nonsterile facilities, incorrect labeling of active pharmaceutical ingredients (APIs), and distribution of unapproved drugs like semaglutide, tirzepatide, and retatrutide.

## Recently, Hims & Hers withdrew its plan to offer compounded oral Wegovy at \$49 per month

Just [last month](#), telehealth company Hims & Hers retracted its plan to offer \$49 compounded oral Wegovy after [regulatory scrutiny](#) and [legal action](#) from Novo Nordisk. The FDA had announced that it would take stronger action against non-FDA-approved GLP-1 RAs by: (i) limiting access to APIs for compounding drugs that resemble FDA-approved medications; and (ii) intensifying its oversight of direct-to-consumer advertising. Indeed, the FDA issued letters two weeks after the initial [announcement](#).

Hims & Hers received a warning letter from the FDA in [September 2025](#), which cited illegal sale of unapproved and misbranded drugs.

## The FDA has increased oversight, including a “green list” to regulate imports of GLP-1 RA active pharmaceutical ingredients

In [September 2025](#), the FDA issued a “green list” [import alert](#) to regulate APIs for GLP-1 RAs manufactured from facilities overseas. The green list includes APIs from facilities the FDA has inspected or evaluated to have met the US manufacturing standards. Facilities not on the list will be required to prove that manufacturing and distribution follow the Current Good Manufacturing Practice requirements.

### Close Concerns’ Questions

1. How does the FDA distinguish compounding for personalization from the resemblance of branded products? Would mass personalization and adding vitamin B, for example, be considered legal?
2. What additional enforcement tools, such as product seizure and injunctions, might the FDA use if similar violations continue to occur?
3. Will future legislation aim to require telehealth companies and outsourcing facilities conduct efficacy testing and provide scientific evidence?

-- by *Kat Moon, Jeremy Alkire, and Kelly Close*

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[1] Companies include [Zappy](#), [SkinnyRx](#), [Strut Health](#), [Refills Health](#), [Zeuss](#), Weightless Medical’s [WeightCare](#), [Viv Health](#), [Ivim Services](#), [Join Josie](#), [Peaks Curative](#), [Good Girl](#), [Kin Meds](#), [PharmaZee](#), [BluefitMD](#), [Drippgym Mobile Parent’s Amp Health](#), [Newman Clinic](#), [NewSelf](#), [24HrDoc](#), [Alan Health Technologies](#), [Belle Health](#), [Bliv Wellness](#), [Deluxe Aesthetics](#), [Aspen Aesthetics](#), [FitRx](#), [MaxLife](#), [Genesis Health](#), [Better Health Labs](#), [Levity](#), and [MEDVi](#).