SpencerFane®

FDA and Novo Nordisk Warn of GLP-1 Telehealth Compounding Take Down – What's Next?

As we reported here, on September 16, 2025, FDA published over 55 warning letters to online sellers of compounded versions of GLP-1, the popular weight-loss injections marketed as Wegovy (semaglutide injection, manufactured by Novo Nordisk) and Zepbound (tirzepatide injection, manufactured by Eli Lilly). The FDA letters cited misleading direct-to-consumer advertising and marketing in a variety of forms. At the time, the effort felt like "compliance theater," not expected to change much behavior among GLP-1 compounders or marketers. For the most part, telehealth providers and compounding pharmacies have continued both advertising and compounding products as patient-specific variants or copies of GLP-1 products.

On February 6, however, FDA's approach appeared to shift with an announcement that it would be taking steps both to restrict GLP-1 active pharmaceutical ingredients (APIs) that continue to be used in non-FDA-approved compounded products to combat "misleading direct-to-consumer advertising and marketing." Unequivocally, FDA warned: "Entities engaged in the manufacture, distribution, or marketing of unapproved compounded GLP-1 products should be aware that failure to adequately address any violations may result in legal action without further notice, including, without limitation, seizure and injunction." FDA specifically named Hims & Hers – a popular and outspoken telehealth provider that advertises compounded GLP-1 products – in the announcement.

On February 9, Novo Nordisk also escalated its enforcement actions by suing Hims & Hers "for infringing U.S. Patent No. 8,129,343 with its compounded semaglutide products for the U.S. market." Novo alleged that Hims & Hers has continued to "mass compound injectable versions [of Novo's Wegovy (semaglutide)] made with inauthentic API" and further engaged in promotional campaigns suggesting its

compounded semaglutide products compare to the safety and efficacy of Novo's Wegovy products "putting patient health and wellbeing at risk." Novo further cited FDA's February 6 statement.

Why the sudden ramp up against GLP-1 compounders and marketers? One factor is that Novo launched its newly FDA-approved once-daily tablet for Wegovy (semaglutide) in January. Some compounders had been mass compounding semaglutide tablets in the absence of an FDA-approved alternative but were generally expected to discontinue the practice once an FDA-approved version was available on the market. Instead of stopping, Hims & Hers advertised a commercial launch of a compounded semaglutide tablet on February 5.

It is also hard to imagine that it is a coincidence that these enforcement escalations follow TrumpRx launching on February 5, advertising access to lower-cost, FDA-approved GLP-1 options, directly to patients. According to the TrumpRx website, for example, monthly costs for Wegovy tablets are now available at $149-$299 (versus $1349),[1] Wegovy injections at $199-$349 (versus $1349), and Zepbound injections at $299-$449 (versus $1087).

How will the GLP-1 telehealth and compounding pharmacies respond? Some compounders will likely continue to assert that they are properly engaging as 503A pharmacies in patient-specific compounding pursuant to physician orders (503B outsourcing facility mass compounding was generally only permitted during shortages of the FDA-approved GLP-1 products). In 2018, FDA published guidance to 503A pharmacies on what will be considered unauthorized compounding of a product that is "essentially a copy" of an FDA-approved product, with an exception available when the "prescriber documents on the prescription that the compounded drug product produces a significant difference for the identified individual patient." Under the 2018 guidance, "FDA generally does not intend to question prescriber determinations that are documented in a prescription or notation." To date, patient-specific GLP-1 compounding activities have often included adding supplemental ingredients to combat side effects of the GLP-1 products or customizing doses, with a significant percentage of prescriptions for customization written by telehealth prescribers.

While not directly addressing the legitimacy of patient-specific compounding of GLP-1 products, FDA has sent a cautionary sign to 503A pharmacies operating in this space. 503A pharmacies are state-licensed pharmacies, which has led many in the industry to believe that FDA does not have any oversight over 503A pharmacies. But, the reality is that 503A pharmacies are also under FDA jurisdiction for compliance with requirements under the Federal Food, Drug and Cosmetic Act (FD&C Act) for the compounded products they produce, noting that they are exempt from certain labeling requirements and current good manufacturing practices (cGMPs) applicable to FDA-approved drugs and 503B compounded drugs.

FDA's Warning Letter to 503A pharmacy Boothwyn Pharmacy, LLC, issued on January 16, but not published until February 10, identifies violations for the pharmacy's GLP-1 and other compounded products concerning insanitary conditions and strength, quality, or purity noncompliance with the compounded products' stated contents – all fair game under the FD&C Act. If such items are not addressed in a satisfactory or timely manner, FDA has the authority to engage additional advisory action, or, without further warning, initiate product recalls, product seizure, injunctions, and criminal actions, which could include civil monetary penalties, along with referral to states for additional action, including action related to the licenses of the pharmacy and pharmacists.

Reading the writing on the wall and what it may signify, telemarketing companies, pharmacies, and other stakeholders selling GLP-1 products that are not FDA approved should consider this change in tone and action from both FDA and manufacturers in planning for the future, including in preparing to defend ongoing GLP-1 compounding or potentially realigning their compounding capacity for future markets. We will continue to monitor these developments and are available to answer any questions about these shifting tides.

This blog was drafted by Spencer Fane attorneys Brian Malkin and Beth Siemer, attorneys in the Washington, D.C., and St. Louis, Missouri, offices of Spencer Fane, respectively. For more information, visit spencerfane.com.

—

1 Comparison prices are as listed on TrumpRx.gov, not independently verified as market prices, last visited 2/23/2026.

Click **here** to subscribe to Spencer Fane communications to ensure you receive timely updates like this directly in your inbox.