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FDA Tightens the Belt on GLP-1 Compounding, Escalating Threat of Enforcement

Key Takeaways

- On Feb. 6, 2026, FDA announced that it would take action to restrict access to GLP-1 ingredients for non-FDA approved compounded drugs.
- On the same day, the HHS General Counsel announced on social media that his office had referred Hims & Hers to the DOJ for investigation of potential federal law violations.
- These announcements signal possible future enforcement actions and scrutiny for compounding pharmacies as weight loss drugs remain in the news.
- Companies engaged in or considering compounding should carefully evaluate their overall operations, prescribing models and commercialization strategies, including advertising and other public-facing communications related to compounded GLP-1 products.
- The intense reaction from FDA to the Hims & Hers compounded semaglutide pill likely arises from the fact that Novo Nordisk received a Commissioner's National Priority Voucher (a prominent initiative of FDA Commissioner Marty Makary) for the Wegovy pill, and the Wegovy pill's availability through the recently-activated TrumpRx website.

Fresh off the Seahawks' win against the Patriots, the week's most consequential showdown was not confined to the Super Bowl, as the fight over compounded GLP-1 weight-loss drugs moved into prime time. After a year of lawsuits, cease-and-desist letters and public sparring between branded manufacturers and compounding companies, Hims & Hers and Novo Nordisk went head-to-head (this also follows a short-lived collaboration between the companies last year, where Novo Nordisk had provided Hims & Hers direct access to Wegovy). FDA signaled it was ready to throw some flags – and possibly even move the goalposts – by suggesting a more categorical enforcement posture to restrict GLP-1 active pharmaceutical ingredients (APIs) from being used to compound the popular weight-loss drugs that are mass-marketed by pharmacies and digital health platforms.

On Feb. 5, 2026, Hims & Hers announced the launch of a compounded oral semaglutide product marketed as an alternative to Novo Nordisk's FDA-approved Wegovy pill. The compounded product was advertised as containing "the same active ingredient as

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Wegovy" while acknowledging it is "not approved or evaluated for safety, effectiveness, or quality by the FDA." Novo Nordisk, which has been aggressively protecting its market position through hundreds of lawsuits, immediately responded by characterizing Hims's product as an "unapproved, inauthentic and untested knockoff" and pledged to pursue legal and regulatory action. Less than 24 hours later, FDA publicly announced its intent to take decisive steps to restrict companies from mass-marketing non-FDA approved GLP-1 products. On February 7, 2026, amid regulatory and industry pressure, Hims & Hers announced it would no longer offer the compounded semaglutide pill.

FDA's Announcement

On February 6, FDA issued a public announcement, stating that it intends to take “decisive steps,” including the use of all available compliance and enforcement tools, to restrict the manufacturing, distribution and marketing of certain non-FDA approved compounded GLP-1 products. In a post on social media, FDA Commissioner Marty Makary also emphasized that "FDA will take swift action against companies mass-marketing illegal copycat drugs, claiming they are similar to FDA-approved products,” underscoring FDA’s position that it cannot verify the quality, safety, or effectiveness of non-approved drugs.

FDA's planned actions include:

1. Restricting access to GLP-1 APIs used in non-approved compounded drugs;
2. Deploying "all available compliance and enforcement tools," which could include warning letters, court injunctions, or administrative product seizures; and
3. Taking steps to address what it characterizes as “misleading direct-to-consumer advertising and marketing” where companies have stated that compounded drugs use the same active ingredient as FDA-approved drugs or “generic” versions of the same drugs approved by FDA.

Notably, FDA’s announcement does not distinguish between compounded products that are direct copies of approved drugs and those that incorporate formulation changes, alternative dosage forms, or other modifications. It also does not differentiate between traditional pharmacy compounding under Section 503A and bulk compounding by outsourcing facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), raising questions about how the agency intends to apply the existing statutory and regulatory framework for compounding to GLP-1 products.

Legal Framework

FDA’s announcement renews focus on the boundaries between traditional pharmacy compounding under Section 503A, bulk compounding under 503B and drug manufacturing requiring FDA approval.

Sections 503A and 503B of the FD&C Act establish frameworks for lawful drug compounding, that together play a critical role in the U.S. drug supply chain. Section 503A allows traditional pharmacies that meet applicable conditions to compound medications for individual patients based on patient-specific prescriptions. In contrast, Section 503B permits FDA-registered outsourcing facilities to compound certain drugs in bulk, without patient-specific prescriptions, subject to compliance with current good manufacturing practice and other limitations. Hospitals and health systems routinely rely on both 503A pharmacies and 503B outsourcing facilities to provide essential therapies that are not otherwise available in appropriate formulations, strengths, or dosage forms, including compounded products used in acute and specialized care settings.

Both pathways generally prohibit compounding drugs that are “essentially a copy” of

commercially available FDA-approved products. At the same time, the statute expressly permits pharmacies and outsourcing facilities that meet the other conditions of section 503A or 503B to compound copies of approved drugs that appear on FDA's drug shortage list. This mechanism has long enabled compounders to help address shortages and ensure continuity of patient care. GLP-1 products were included on FDA's drug shortage list through most of 2023 and 2024, during which time compounders relied on this statutory mechanism. Beginning in late 2024, FDA removed certain GLP-1 products from the shortage list, narrowing the scope of permissible compounding for these products and placing an increased emphasis on the statutory "essentially a copy" limitations and FDA's interpretation of those limitations.

Under Section 503A, a compounded drug is not "essentially a copy" where a change from the commercially available drug, made for an individual identified patient, produces a "significant difference" for that patient, as determined by the prescribing practitioner. Under Section 503B, a compounded drug is deemed "essentially a copy" if it is "identical or nearly identical" to a commercially available approved drug, or if it contains a bulk drug substance that is a component of an approved drug, unless there is a change that produces a "clinical difference" for an individual patient, as determined by the prescribing practitioner.

Hims appeared to be positioning its compounded semaglutide as a "personalized medication" tailored to individual patient needs. However, FDA's announcement emphasizes concerns over "mass marketing" of compounded GLP-1 products, and the scale of Hims's telehealth platform and its broad marketing approach may make it more challenging to convince the agency that such products are individualized compounded products rather than standard offerings.

Novo Opens New Front Against Hims

In this fast-moving dispute, Novo filed a patent infringement lawsuit against Hims on February 9th based on Novo's patent covering the semaglutide compound. In the suit, Novo seeks not only an order barring Hims from marketing its product but also potentially "hundreds of millions" of dollars of damages. To date, Novo has stayed away from enforcing its patents against drug compounding companies, instead asserting the Lanham Act and a variety of unfair competition and other state law claims in an effort to remove compounders from the market. The assertion of one of its core patents against a compounder may be the start of a new, aggressive strategy that the compounding industry will need to account for. Hims' statement after the lawsuit was filed suggests it will try to position the lawsuit as "Big Pharma" versus consumer choice.

Implications for Compounding Pharmacies and Telehealth Providers

The recent FDA and HHS actions signal an intent to take a more aggressive approach to policing certain compounding, particularly for GLP-1 medications. These actions follow a slew of September warning letters addressing allegedly false or misleading promotion of compounded GLP-1 products.

Companies engaged in or considering compounding operations should carefully evaluate:

- Whether modifications from the approved drug are sufficiently supported by documentation demonstrating a patient-specific "significant difference" (under Section 503A) or "clinical difference" (under Section 503B), as determined by the prescribing practitioner;
- Whether operations employ production or distribution models that FDA may view as "mass marketing"; and
- Marketing claims that could imply compounded products are equivalent to FDA-

approved drugs.

The outcome of HHS' referral of Hims to DOJ, and any resulting enforcement action or litigation, may provide additional insight into FDA's enforcement priorities, including how the agency addresses compounded GLP-1 products. And FDA's more aggressive approach to compounding GLP-1s is almost certain to draw legal challenges and be subject to court review.