# Legal and Compliance Framework for GLP-1 Peptide Therapies

Presented by **Daniel R. Eliav, Esq.**

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# Overview

- GLP-1 Gold Rush
- FDA Approved vs. Compounded GLP-1s
- Prescribing Compounded GLP-1s

# GLP-1 Gold Rush

## Drugs Like Ozempic Created a Gold Rush. These Drugmakers Want In.

Companies developing weight-loss drugs have raised or made deals valued at more than $1.4 billion in past year, analysts say

## The Day Pharma's Weight-Loss Gold Rush Intensified

Lilly's quarterly results Thursday, combined with Novo Nordisk's unsolicited offer for a startup, confirm the $72 billion anti-obesity market is among pharma's hottest

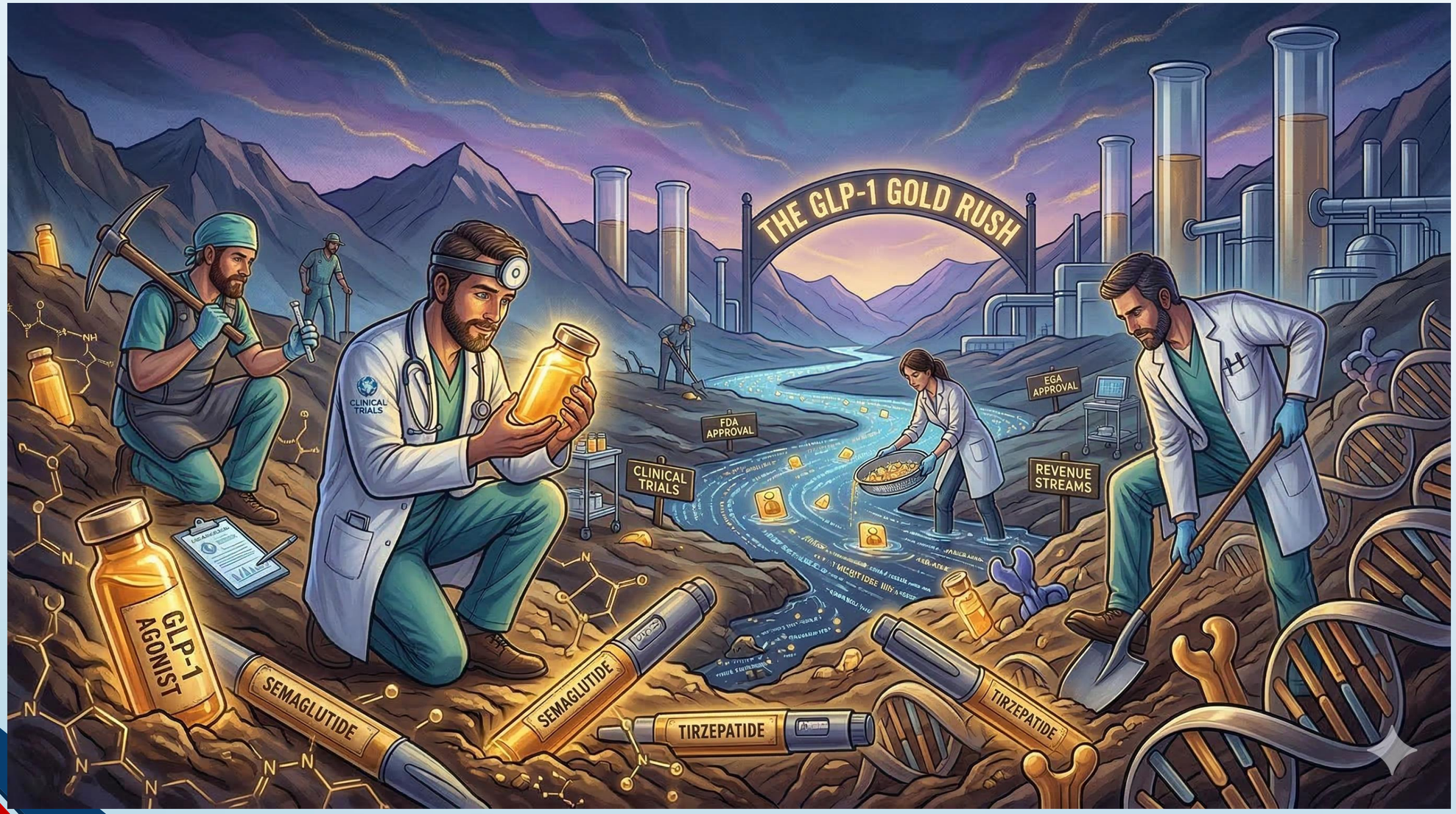
# GLP-1 Gold Rush

Demand for GLP-1 weight-loss treatment grew rapidly as public attention and consumer interest surged.

# GLP-1 Gold Rush

Telehealth and medical-aesthetics channels accelerated market entry and expanded consumer access at scale.

# GLP-1 Gold Rush



# GLP-1 Gold Rush

STAT+ | SPECIAL REPORT

## The Virtual Rx Boom

# The FDA is targeting telehealth marketing of GLP-1 drugs. Who's prescribing them?

Medical groups face 'tricky' questions when partners make misleading claims

By Katie Palmer March 12, 2026

Katie Palmer is investigating how telehealth is driving the consumerization of drugs

# GLP-1 Gold Rush

Among more than 70 telehealth companies warned by the FDA in the last six months, at least 30% have publicly stated affiliations with just four nationwide medical groups: Beluga Health, OpenLoop, MD Integrations, and Telegra.

These "white label" telehealth practices, which allow brands to quickly plug into a stable of clinicians often licensed to practice medicine across the country, have helped telemedicine companies grow rapidly. But in doing so, they are now closely tied to an industry attracting government regulators' scrutiny.

# GLP-1 Gold Rush

As the market expanded, compounded GLP-1 products became a major focus of both commercial opportunity and regulatory scrutiny.

# FDA Approved vs. Compounded Drugs

## FDA-approved

- Reviewed by FDA for safety and effectiveness for approved uses
- Manufactured and distributed under the approved product framework
- Promoted subject to FDA/FTC rules requiring truthful, non-misleading, substantiated claims


## Compounded

- Not FDA-approved
- Not reviewed by FDA for safety, effectiveness, or quality before marketing
- May be compounded only within applicable federal compounding limits
- Should not be presented as equivalent or interchangeable with an FDA-approved product

# How Compounding Became a Major Part of the GLP-1 Gold Rush

- High out-of-pocket costs for branded products made lower-cost alternatives commercially attractive.
- Much of the surrounding market developed on a cash-pay basis, which increased price sensitivity and intensified direct-to-consumer marketing pressure.
- Telehealth and medical-aesthetics channels accelerated availability of compounded drugs.

# Is Compounding of GLP-1s Allowed?

- For traditional 503A compounding, the key issue is often whether the compounded product is “essentially a copy” of a commercially available drug.
  - If the compounded product has the same active ingredient, the same or easily substitutable strength, and the same usable route of administration as a commercially available FDA-approved drug, FDA may view it as “essentially a copy.”
  - Shortage-based compounding is no longer the primary path.
    - Tirzepatide injection shortage was resolved in October 2024.
    - Semaglutide injection shortage was resolved in February 2025.
  - One potential basis for compounding under 503A is a prescriber’s documented determination that, for an identified individual patient, the compounded version will produce a significant difference.

# What qualifies as a clinical difference?

Possible examples:

- Change in dosage strength (e.g., > 10%)
- Omission of allergens or certain excipients
- Addition of another ingredient where supported by a genuine patient-specific clinical rationale.
- Different route of administration
- Differences in formulation to improve stability or adherence

NOT ALLOWED

- Increased access by lowering costs is NOT a sufficient reason.

# Documented on the Prescription

The patient-specific clinical basis should be documented on the prescription.

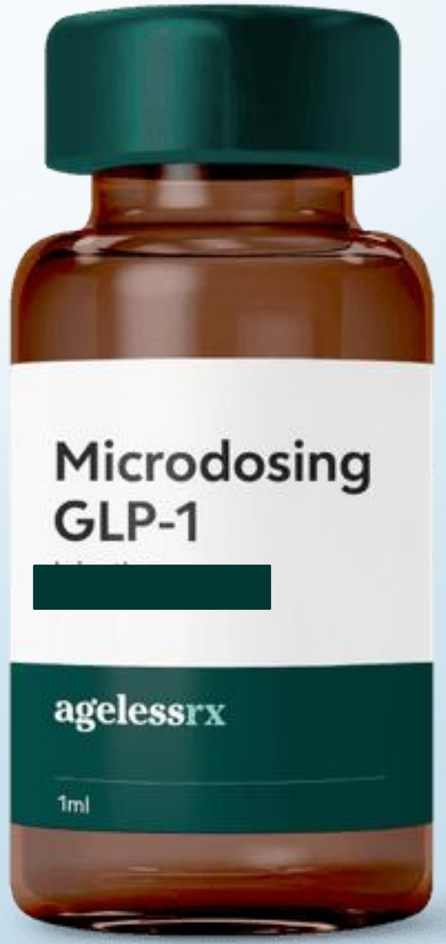
# What qualifies as a clinical difference?

All sample clinical difference statements provided in this presentation are hypothetical illustrations requiring independent clinical support and patient-specific documentation.

# What qualifies as a clinical difference?

## 10% or More Change in Dosage Strength

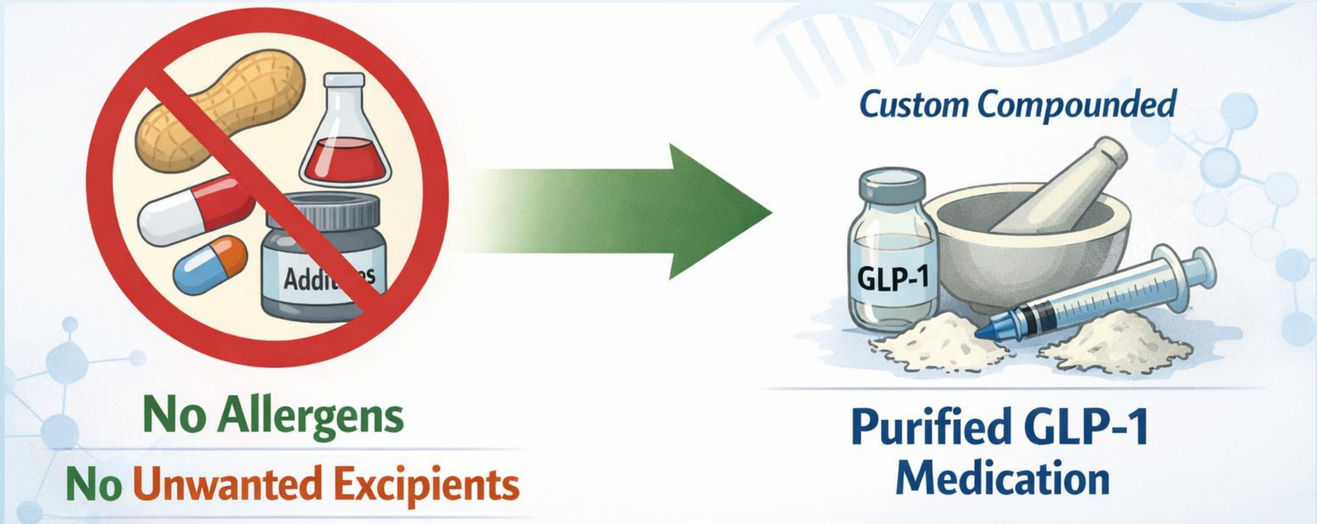
- Sample clinical difference statements
  - Patient requires a 3x weekly microdosing schedule due to gastrointestinal intolerance with standard weekly dosing.
  - Multi-dose vial needed for gradual 0.5mg increment titration; patient experienced hypoglycemia with standard titration protocol.
  - Patient requires precise dose adjustments; commercial strengths do not align with the patient's metabolic profile.



# What qualifies as a clinical difference?

## Omission of Allergens or Certain Excipients

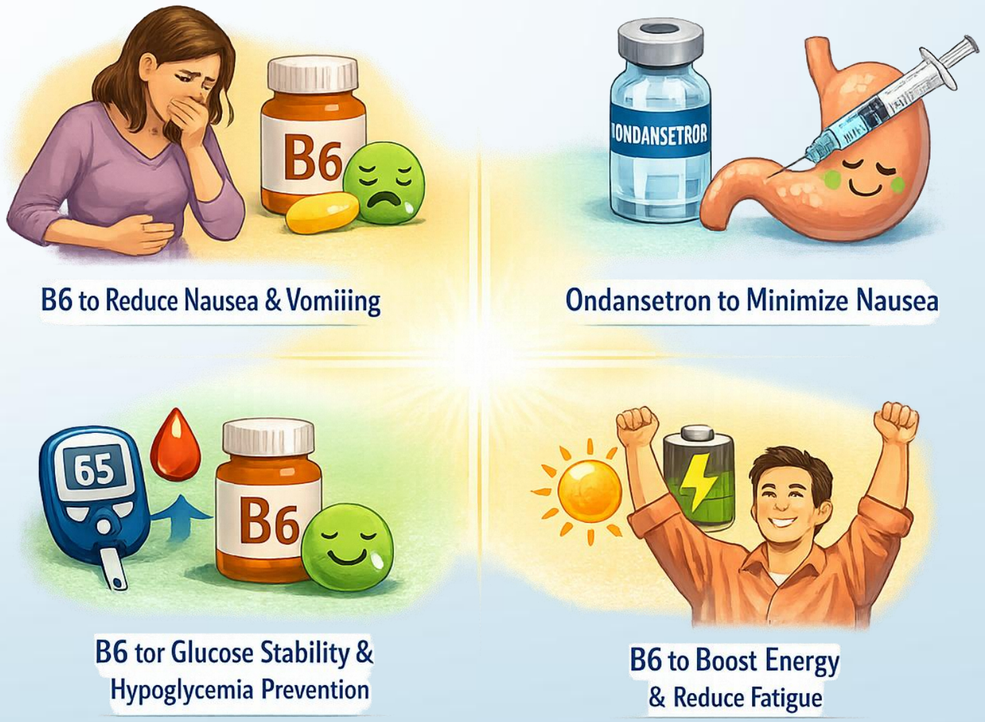
- Sample clinical difference statements
  - Patient cannot tolerate the preservative system in the commercial product; requires an alternative formulation.
  - Patient experiences allergic reactions or injection site issues due to polysorbate 80 in the commercial product; requires a modified formulation.
  - Patient develops injection site reactions to excipients in the commercial product; requires a tailored formulation.



# What qualifies as a clinical difference?

## Added Active Ingredients

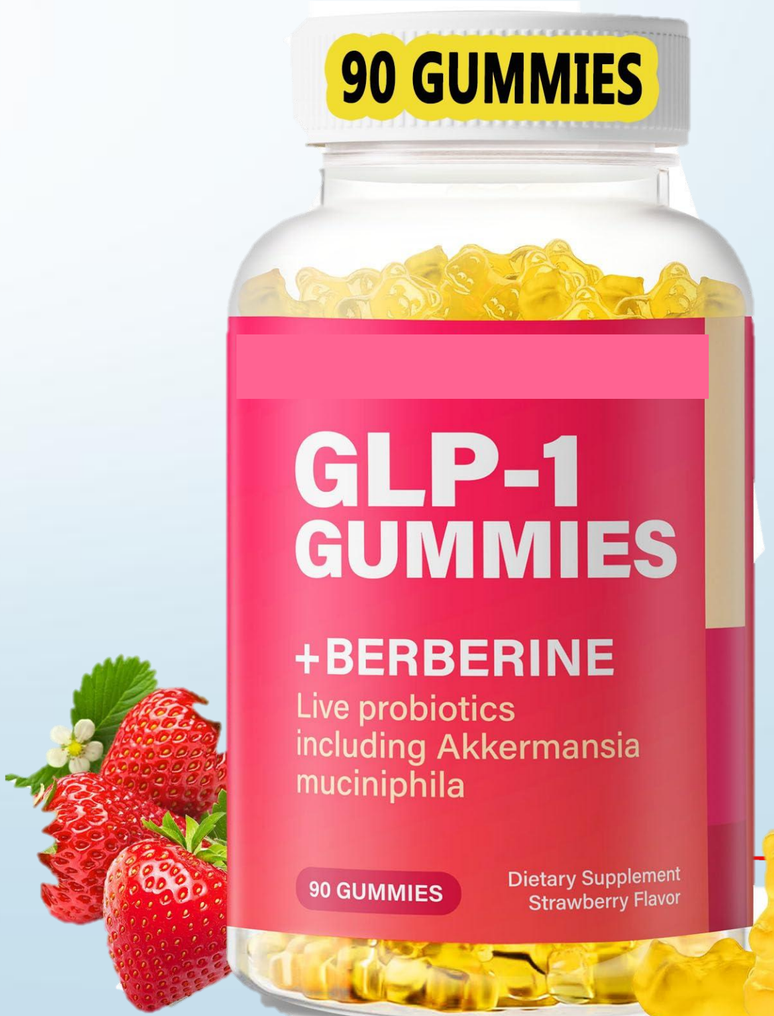
- In some cases, adding another ingredient may support a patient-specific significant-difference rationale, depending on the facts and clinical support.”
- Sample clinical difference statements
  - Patient discontinued commercial product due to nausea and vomiting; Addition of B6 required to reduce nausea and vomiting.
  - Addition of ondansetron required to minimize nausea.
  - B6 addition necessary to stabilize glucose fluctuations and reduce hypoglycemia risk.
  - B6 needed to boost energy and reduce fatigue, enhancing patient well-being.



# What qualifies as a clinical difference?

## Different Route of Administration

- Commercially Available Products
  - Semaglutide is available in an oral form (tablets).
  - Semaglutide is NOT commercially available in a sublingual form.
  - Tirzepatide is not commercially available in oral form tablets or sublingual.
    - Criticized as “snake oil” in Open Loop lawsuit
- Sample clinical difference statements
  - Patient unable to tolerate injections due to adverse reactions; requires oral formulation.
  - For sublingual form: patient struggles with swallowing tablets or managing injections.



# Recent FDA Warning Letters and Enforcement

- Sept. 9, 2025
- Feb. 4, 2026
- Feb. 6, 2026
- Mar. 3, 2026

# Recent FDA Warning Letters and Enforcement

- Sept. 9, 2025
  - FDA issued 58 warning letters to telehealth firms challenging claims that compounded GLP-1 products were “the same as,” “generic,” or used the same active ingredient as FDA-approved drugs and also challenged “clinically proven” claims.
  - 1000’s of letter to pharmaceutical companies

# Sept 9, 2025 – FDA Warning Letter

- The following claims concerning compounded semaglutide and tirzepatide products appear on your website:
- “Clinically proven success”
- “Clinically proven weight loss treatments”
- “The same active ingredients as Ozempic or Mounjaro”
- “Prescription weight loss with the same active ingredients as Mounjaro & Zepbound.”
- “While we don’t prescribe Ozempic, Wegovy, Zepbound, or Mounjaro directly, we may prescribe treatments containing the same active ingredients.”

# Recent FDA Warning Letters and Enforcement

GLOBAL LIFE SCIENCES UPDATE

## New U.S. FDA Letter Contradicts Decades-Old Precedent on Prescription Drug Promotion

MARCH 10, 2026

As noted in a **prior Update**, U.S. Food and Drug Administration (FDA) officials began a "crackdown" on direct-to-consumer (DTC) advertising of prescription drugs in September 2025, including by issuing a number of warning and untitled letters to the manufacturers of approved medicines. FDA has articulated positions in many of these letters that raise significant constitutional, legal, and regulatory concerns. A recent untitled letter is a particularly striking example because it directly conflicts with the position FDA took in a warning letter issued more than 20 years ago, which recognized that factual statements about a medical product's approved indications are truthful, nonmisleading, and not objectionable.

# Sept 9, 2025 – FDA Warning Letter


September 9, 2025

Dear Pharmaceutical Company,

For far too long, FDA has permitted misleading direct-to-consumer (DTC) prescription drug advertising. Today, FDA is taking action to rein in violative ads. Going forward, FDA intends to take aggressive action and ensure conformity with the law.

**You are hereby directed to remove any noncompliant advertising and bring all promotional communications into compliance.**

DTC advertising can distort the patient-clinician relationship and create increased demand for medications regardless of clinical appropriateness. Violative ads can also fundamentally alter patients' risk-benefit perception.

FDA is concerned patients are not seeing a fair balance of the information regarding a drug product. This concern is magnified when serious risks are not clearly presented, or the information is too difficult for seniors to read or hear.

# Recent FDA Warning Letters and Enforcement

- Feb. 4, 2026
  - FDA published warning about unapproved semaglutide, tirzepatide, and retatrutide products falsely labeled “for research purposes” or “not for human consumption” but sold directly to consumers for human use.

# Is Compounding of GLP-1s Allowed?

## FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss

Report issues to FDA

Compounding and the FDA: Questions and Answers

**Content current as of:**
02/04/2026

**Regulated Product(s)**
Drugs

### Understanding unapproved versions of these drugs

FDA is aware that some patients and health care professionals may look to unapproved versions of GLP-1 (glucagon-like peptide-1 (GLP-1) receptor agonists) drugs, including semaglutide and tirzepatide, as an option for weight loss. This can be risky for patients, as unapproved versions do not undergo FDA's review for safety, effectiveness and quality before they are marketed.

### FDA recommendations for health care professionals and patients

- Compounded drugs should only be used in patients whose medical needs cannot be met by an FDA-approved drug.
- Patients should obtain a prescription from their doctor and fill the prescription at a state-licensed pharmacy.
- Visit FDA's BeSafeRx campaign for resources to safely buy prescription medicines online

# Feb. 4, 2026 – FDA Warning Letter

- Compounded drugs do not undergo FDA review for safety, effectiveness, and quality.
- Improper storage during shipping may affect quality
- Foreign-sourced GLP-1 may be adulterated
  - Foreign-sourced APIs considered for detention without physical examination (DWPE), except for the products and firms identified on the Green List of Import Alert 66-80
- False information on the product label associated with adverse events.
- Dosing errors leading to adverse events.
- Retatrutide, cagrilintide, and salt forms prohibited.
- Versions sold falsely for research purposes or not for human consumption

# Recent FDA Warning Letters and Enforcement

- Feb. 6, 2026
  - FDA publicly announced a broader enforcement push against non-FDA-approved GLP-1 drugs and misleading direct-to-consumer marketing. This was an enforcement announcement, not a new batch of warning letters.

# Feb. 6, 2026 – FDA Warning Letter

**FDA STATEMENT**

## FDA Intends to Take Action Against Non-FDA-Approved GLP-1 Drugs

**For Immediate Release:** February 06, 2026

**Statement From:** Martin A Makary, M.D., M.P.H.
Commissioner of Food and Drugs - Food and Drug Administration

Today, the U.S. Food and Drug Administration is announcing its intent to take decisive steps to restrict GLP-1 active pharmaceutical ingredients (APIs) intended for use in non-FDA-approved compounded drugs that are being mass-marketed by companies — including Hims & Hers and other compounding pharmacies — as similar alternatives to FDA-approved drugs. These actions are aimed to safeguard consumers from drugs for which the FDA cannot verify quality, safety, or efficacy.  We take seriously any potential

# Recent FDA Warning Letters and Enforcement

- Mar. 3, 2026
  - FDA announced 30 additional warning letters to telehealth companies, focusing on both sameness/equivalency claims and branding or labeling that obscured the actual compounder or product source.

# Mar. 3, 2026 - FDA Warning Letters

FDA NEWS RELEASE

## FDA Warns 30 Telehealth Companies Against Illegal Marketing of Compounded GLP-1s

**For Immediate Release:** March 03, 2026

The U.S. Food and Drug Administration today announced the issuance of 30 warning letters to telehealth companies for making false or misleading claims regarding compounded GLP-1 products offered on their websites.

“It’s a new era. We are paying close attention to misleading claims being made by telehealth and pharma companies across all media platforms—and taking swift action,” **said FDA Commissioner Marty Makary, M.D., M.P.H.** “Compounded drugs can be important for overcoming shortages or meeting unique patient needs—but compounders should not try to compound drugs in a way that circumvents FDA’s approval process."

This is the second group of warning letters sent to telehealth firms since the agency launched in September a crackdown on misleading direct-to-consumer pharmaceutical advertisements. Over the past six months, the agency has sent thousands of letters warning pharmaceutical and telehealth firms to remove misleading ads, more than had been sent over the entire preceding decade.

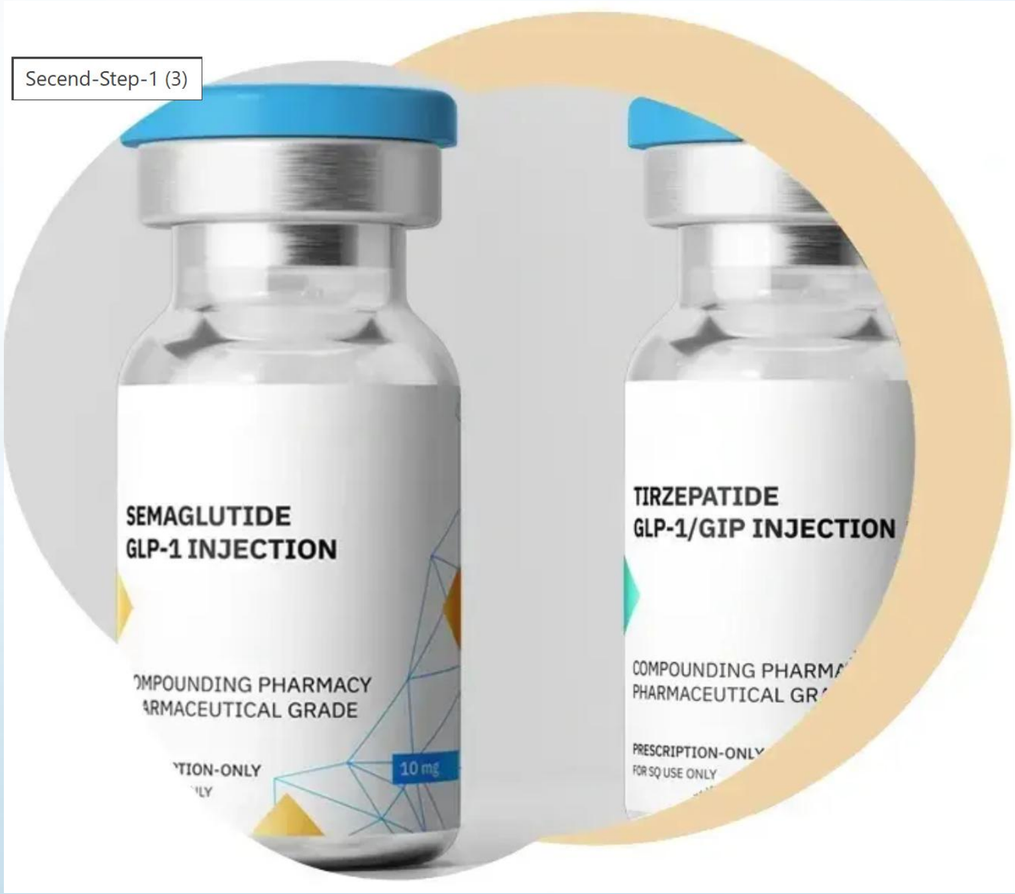
# Mar. 3, 2026 - FDA Warning Letters

“The compounded semaglutide and tirzepatide products displayed on your website identify **“Premium Health” on the pictured label**, suggesting Premium Health is the compounder of those drugs when in fact it is not.[2] Accordingly, the representations on your website that Premium Health is the compounder of these drug products are false or misleading, and the products are therefore misbranded under sections 502(a) and 502(bb) of the FDCA [21 U.S.C. §§ 352(a) and (bb)].”

# Mar. 3, 2026 - FDA Warning Letters

## December 9, 2025


## Today



# Day vs. OpenLoop Health Inc.

4. The claims here concern Defendants' so-called "oral tirzepatide" weight loss pill, a product that has never been approved by the FDA, has no demonstrated mechanism of absorption or efficacy, and functions as modern-day ***snake oil***—a mass-produced, pharmacologically inert compound when delivered via a pill, and misrepresented to consumers as a legitimate GLP-1 weight loss therapy.

# Day vs. OpenLoop Health Inc.

The OpenLoop oral tirzepatide lawsuit highlighted class action litigation risk around how compounded GLP-1 products are positioned and described in the market.

The complaint focused on alleged performance, safety, and equivalence-related marketing claims.

Particular attention was drawn to alleged statements presenting oral tirzepatide pills as a “safe and effective equivalent and alternative” to FDA-approved GLP-1 products.

High-risk positioning includes describing compounded products as safe or effective without adequate support and suggesting equivalence, interchangeability, or comparability to FDA-approved injectable tirzepatide.

# Patent and Trademark Issues

- Earlier litigation often focused on trademark and unfair-competition theories rather than patent claims.
- More recent litigation has included patent theories, which materially increases the risk profile for companies marketing compounded or copycat GLP-1 products.
- In February 2026, Novo sued Hims after Hims announced a compounded oral semaglutide product, and Reuters reported that this was Novo's first U.S. patent case against a compounder.
- Novo publicly stated that it was taking legal and regulatory action to protect patients, its intellectual property, and the integrity of the FDA drug-approval framework.
- The practical takeaway is that GLP-1 litigation risk is no longer limited to marketing and labeling theories; patent exposure is now part of the landscape.

# Summary and Conclusion

- Compounding remains lawful only within narrow statutory limits.
- Shortage status was temporary and has ended
- The ‘essentially a copy’ rule and patient-specific significant-difference standard are central.
- Any claim that implies equivalence or approved-drug sameness increases enforcement and litigation risk.
- Documentation is a key risk-control tool, not a cure-all.

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