Our Course Warned Steered Our Users Away... ...Then the FDA Took Action.

On September 18, 2026, the Food and Drug Administration issued a warning letter to a large Houston compounding pharmacy over its compounded semaglutide and tirzepatide. The products FDA named were **tirzepatide with niacinamide** and **semaglutide with cyanocobalamin**. Our course had already identified that exact pattern, and told learners what it was even before the FDA took action against one of the major compounding suppliers..

WHAT THE COURSE TAUGHT

> *"First B12, now niacinamide at a flat 2 mg/mL across every strength."*

> *"Compounded semaglutide on a monthly subscription, justified by the 'personalized reason' misrepresentation. Illegal post-shortage."*

> *"Routine compounding of these molecules is no longer legal."*

Beyond Injectables, GLP-1 module. Released August 2026.

WHAT FDA WROTE

> *"The volume of products you are producing suggests that differences between products you are compounding and the FDA-approved products are pretextual."*

> *"...purported prescriber determinations of 'significant difference' that appear to be repeated verbatim."*

> *Products "appear to be essentially copies of FDA-approved semaglutide and tirzepatide products," compounded "regularly and in inordinate amounts."*

FDA Warning Letter 738238, September 18, 2026.

Read who FDA is describing.

Not the marketing. Not the label. **The determination of significant difference is written by the prescriber**, and FDA's finding is that those determinations were repeated verbatim across patients. The document that was supposed to justify the compound became the evidence that it was pretextual. If you signed one, you wrote it.

WHAT OUR LEARNERS WERE TOLD TO DO INSTEAD

1 **Prescribe the approved product.** Four injectables and two orals are approved for weight management. None of them require a pretext.

2 **Treat the additive as cosmetic.** A fixed-dose vitamin across every strength is not clinical individualization, and it never was.

3 **Never write a boilerplate justification.** If the same sentence fits every patient, it documents nothing except that you knew.

4 **Know the dates.** Enforcement discretion ended March 5, 2025 for tirzepatide and April 24, 2025 for semaglutide.

Source. FDA Warning Letter 738238, issued September 18, 2026, to a Houston compounding pharmacy following an inspection conducted November 3 to 14, 2025. Published at fda.gov. Quotations are verbatim. The recipient is not named here because the point is not the pharmacy.

About warning letters. A warning letter sets out the agency's allegations and requests a response. It is not a final agency determination, a finding of liability, or an adjudication, and the recipient has an opportunity to respond.