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Medications

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What the FDA’s Guidance on Compounded GLP-1 Medications Means for You

If you're using compounded GLP-1 medications like semaglutide or tirzepatide for weight management, recent FDA updates may have raised questions about your treatment's future. Let's break down what these changes mean and how Mochi is here to support you.



Sydney Wexler, RDN

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Table of Contents

- What Did the FDA Announce?
- Is Compounding Still Legal?
- Is Compounding Going Away?
- Will Mochi Continue Offering Compounded Medications?
- Our Commitment to Personalized Obesity Care

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What Did the FDA Announce?

The FDA has determined that the national shortages of GLP-1 medications, specifically semaglutide and tirzepatide, have been resolved. As a result, the agency is ending its temporary allowance for compounding pharmacies to produce versions of these drugs that are essential copies of the FDA-approved products (1).

- To facilitate a smooth transition, the FDA provided a grace period:
- For state-licensed pharmacies (Section 503A): The enforcement discretion ended on April 22, 2025.
 - For FDA-registered outsourcing facilities (Section 503B): The enforcement discretion ended on May 22, 2025.

After these dates, compounding pharmacies are expected to stop producing compounded versions that are essential copies of the approved medications.

Is Compounding Still Legal?

Yes, compounding remains a legal and vital part of personalized medicine (2). Compounded medications are custom-prepared to meet an individual patient's specific needs (3). For example, they may include a specific dosage strength not available commercially or additional active ingredients clinically indicated for the patient.

These medications are created by licensed pharmacies, based on a valid prescription from a licensed provider. While they are not FDA-approved (meaning they haven't gone through the FDA drug approval process), they are still regulated at the state and/or federal level, and must meet important safety and quality standards.

Interested in a personalized treatment plan that meets your unique needs? [Start your care journey with Mochi today.](#)

Is Compounding Going Away?

No, compounding is not going away. The FDA's recent guidance specifically targets compounded medications that are copies of FDA-approved drugs now readily available on the market. Personalized compounded medications that differ from commercial products and are prescribed based on individual patient needs can still be legally prepared and dispensed (2).

