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## Not Joking Around: FDA Offers Additional Clarification on Compounded GLP-1 Policy in April Fool's Day Announcement

### Key Takeaways

- On April 1, 2026, FDA issued a statement reminding 503A pharmacies and 503B outsourcing facilities that compounded drugs qualify for the statutory exemptions under the Federal Food, Drug, and Cosmetic Act (FD&C Act), only when applicable conditions are satisfied, with specific focus on the "essentially a copy" standard.
- Neither semaglutide nor tirzepatide currently appears on FDA's 503B bulks List or FDA's drug shortage list, largely foreclosing bulk compounding of "essentially a copy" of these agents by outsourcing facilities under Section 503B.
- For 503A pharmacies, FDA reiterated a limited enforcement policy from its 2018 guidance, Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act: the agency does not intend to take action where a compounder fills four or fewer prescriptions per calendar month of a drug that is "essentially a copy" of a commercially available drug.
- FDA used a semaglutide + vitamin B12 (cyanocobalamin) combination as an example of a compounded product (potentially "the same APIs of two or more commercially marketed drugs") that it may consider "essentially a copy," depending on route of administration and strength.
- Compounding pharmacies, outsourcing facilities and telehealth prescribers should carefully review their GLP-1 compounding operations, documentation practices and prescriber "significant difference" determinations in light of this restated guidance.

### Background and FDA's Announcement

FDA's April 1, 2026, update to its compounding policy page follows more than 18 months of regulatory activity surrounding the compounding of GLP-1 medications, primarily semaglutide (Ozempic®/Wegovy®) and tirzepatide (Mounjaro®/Zepbound®). Both drugs were added to FDA's drug shortage list in 2022 due to surging demand, which triggered statutory provisions permitting 503A pharmacies and 503B outsourcing facilities to compound those products. As supply began to normalize, FDA resolved the tirzepatide shortage in December 2024 and the semaglutide shortage in February 2025, and provided phased enforcement grace periods for compounders to wind down operations. On

### Related People

- Chad A. Landmon
- Stuart M. Pape
- Suzanne E. Bassett
- Joshua D. McCann, Pharm.D.

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February 6, FDA announced its intention to take decisive enforcement action against non-FDA-approved compounded GLP-1 drugs, specifically identifying restrictions on GLP-1 active pharmaceutical ingredients (APIs) used in mass-marketed compounded products. Together with the April 1 clarification, FDA is signaling that it was not joking when it expressed its intention to actively police GLP-1 compounded products that fall outside the FD&C Acts exemptions.

In this latest announcement, FDA reiterated its 2018 guidance while also clarifying its position on compounded GLP-1s combined with an additional API. This reminder matters because FDA's guidance has long taken a broad view of when a product is "essentially a copy" and when they can be compounded.

- **Section 503A — Traditional Pharmacy Compounding.** Under Section 503A, a drug may be compounded for an identified individual patient based on a valid prescription. The compounding pharmacy may not regularly or in inordinate amounts compound drugs that are essentially copies of commercially available drug products. A compounded product is considered "essentially a copy" if it has the same API as a commercially available drug in the same, similar, or easily substitutable strength, and can be used by the same route of administration, unless the prescriber documents a patient-specific change that produces a significant difference.
- **Section 503B — Outsourcing Facilities.** Under Section 503B, outsourcing facilities may not compound drugs that are essentially copies of one or more approved drug products, and they are prohibited from compounding using bulk drug substances unless the substance appears on FDA's 503B bulks list or the drug appears on FDA's drug shortagel at the time of compounding, distribution and dispensing. FDA's April 1 update explicitly confirms that neither semaglutide nor tirzepatide currently appears on either list. Accordingly, outsourcing facilities should examine current operations for compliance and enforcement risk.

In the GLP-1 space, those principles became especially important after semaglutide and tirzepatide came off the shortage list. During the shortage period, compounders had stronger arguments for compounding formulations that otherwise mirrored approved GLP-1 products. After the shortages were resolved, many compounders sought to differentiate compounded GLP-1 offerings by adding a second ingredient – most frequently vitamin B12/cyanocobalamin – to argue the compounded formulation was not the same as the FDA approved product. FDA's April 1 example appears directed at that post-shortage playbook and signals that the agency may view many semaglutide-plus-additive products as remaining essentially copies, absent robust, individualized clinical justification.

Despite this new focus, FDA reminded pharmacies of a limited enforcement safe harbor for 503A compounders: the agency does not currently intend to take action against a pharmacy that compounds an essentially a copy product, provided it fills no more than four prescriptions of that preparation per calendar month.

## Implications for Compounding Pharmacies and Prescribers (and Outsourcing Facilities)

The April 1 clarification, read alongside FDA's escalating enforcement posture since early 2026, may signal a maturing and increasingly restrictive regulatory environment for GLP-1 compounding. Pharmacies, outsourcing facilities and associated prescribers and telehealth platforms should consider the following actions:

- **Audit current GLP-1 compounding volume**. 503A compounding pharmacies should examine current production trends and formulation trends, including

semaglutide or tirzepatide combinations with added APIs, and assess whether monthly volumes remain within any enforcement safe harbor or instead suggest routine commercial substitution.

- **Review and strengthen prescriber documentation**. The “significant difference” determination under 503A is patient-specific and must be made and documented by the prescribing practitioner. Generalized or formulaic significant-difference language may not satisfy FDA's requirements. Pharmacies should work with prescribers to ensure individualized, clinically supported documentation is in place for each patient.
- **Evaluate combination product formulations**. FDA's singling out of semaglutide and vitamin B12 as a potential essentially a copy example suggests the agency is skeptical of add-on ingredients that may not produce a genuine, documented significant difference for the patient. Pharmacies offering semaglutide-plus or tirzepatide-plus formulations should reassess route-of-administration and strength comparisons and whether the added ingredient changes the clinical analysis in a meaningful, patient-specific way.
- **Review 503B sourcing and copy-risk analyses**. Outsourcing facilities should confirm whether any GLP-1 compounding relies on bulk substances, reassess whether any product is identical or nearly identical to an approved drug and document the basis for continuing any formulation in light of FDA's express statement that semaglutide and tirzepatide are not on the 503B bulks list or drug shortage list.
- **Expect future court challenges.** FDA’s evolving policy changes may be subject to court challenges by compounding pharmacies or outsourcing facilities that find themselves the target of FDA’s enforcement activities, particularly in the post *Loper Bright* world.

Should you have questions regarding the information discussed, please reach out to Chad Landmon, Stuart Pape, Suzanne Bassett, Joshua McCann, or your preferred Polsinelli attorney.