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## FDA Signals it Has No Appetite to Add Popular GLP-1 Drug Substances to the 503B Bulks List

### Key Takeaways

- FDA has proposed excluding semaglutide, tirzepatide and liraglutide from the 503B bulks list.
- The proposal would materially limit 503B bulk compounding of these GLP-1 products.
- Comments on the proposal are due June 29, 2026. Bulk compounders should consider submitting comments that directly address FDA's clinical-need framework, including patient safety considerations and any specific medical necessity for compounding these products from bulk drug substances.

On April 30, 2026, FDA proposed to exclude semaglutide, tirzepatide and liraglutide from the 503B bulks list via a Federal Register notice published on May 1, a move that, if finalized, would limit mass compounding of these substances by outsourcing facilities.

FDA explained that, after reviewing nominations for semaglutide, tirzepatide and liraglutide, it found no demonstrated clinical need for outsourcing facilities to compound these drugs from bulk substances. In FDA's view, the nominations did not show that FDA-approved products are medically unsuitable for certain patients or that compounded versions are necessary to address a specific medical need. FDA is accepting comments through June 29, 2026, before issuing a final determination.

### 503B Background

Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) describes the conditions that must be satisfied for drug products compounded by an outsourcing facility to be exempt from otherwise applicable requirements of the FD&C Act: premarket approval, labeling with adequate directions for use and supply chain security requirements. These exemptions are available only if all of Section 503B's conditions are satisfied. Among them, the outsourcing facility generally may not compound a drug using a bulk drug substance unless the substance is on FDA's 503B bulks list—i.e., the list of bulk drug substances for which there is a clinical need—or the drug compounded from that substance appears on FDA's drug shortage list at the time of compounding, distribution and dispensing.

### Related People

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### Related Capabilities

- Health Care
- Food, Drug & Device

## Summary of the Notice

FDA's proposed determination applies to three high-profile GLP-1-related drug substances: semaglutide, tirzepatide and liraglutide. FDA evaluated nominations seeking to add these substances to the 503B bulks list and tentatively concluded that the submissions did not show a clinical need for outsourcing facilities to compound drug products from bulk active pharmaceutical ingredients (APIs). FDA's analysis focused on whether an attribute of the relevant FDA-approved products makes those products medically unsuitable for certain patients, and whether the proposed compounded product would address that medical unsuitability. FDA also reiterated that supply issues, convenience and cost are not part of FDA's clinical-need analysis for the 503B bulks list because Section 503B separately addresses compounding from bulk substances when the compounded drug is on FDA's drug shortage list at the time of compounding, distribution and dispensing.

FDA's notice discusses—and generally rejects—arguments based on alternative strengths, titration schedules, "microdosing," oral/sublingual/buccal dosage forms, excipient concerns, alternative container-closure systems and combinations with other substances. In FDA's view, the nominations did not identify sufficient evidence that the FDA-approved products are medically unsuitable for identified patient populations or that the proposed compounded products are needed to address a product-specific attribute.

## Implications for Bulk Compounders

For 503B outsourcing facilities, the proposal is a significant signal that FDA does not view bulk compounding of these substances as supported by the 503B clinical-need pathway.

The immediate impact will vary by drug. FDA has stated that semaglutide and tirzepatide do not currently appear on the 503B bulks list or FDA's drug shortage list, which substantially limits any 503B basis for compounding those products from bulk API. By contrast, FDA's current shortage database includes liraglutide. Therefore, the shortage-list pathway may remain relevant for liraglutide while that status continues; however, a final decision excluding liraglutide from the 503B bulks list would foreclose the separate clinical-need route once any shortage-based basis is unavailable.

Bulk compounders should review current and planned GLP-1 compounding programs and consider submitting comments supporting inclusion on the 503B bulks list that specifically address FDA's clinical-need framework. Given what's at stake, we anticipate that FDA's final decision will be subject to a legal challenge in court, and any comments submitted will be part of the administrative record and could have an impact on the final outcome in court.

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