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Publications

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Tiny Chains, Big Changes? What FDA's Latest Actions Mean for Peptide Compounding

Key Takeaways:

- FDA will convene the Pharmacy Compounding Advisory Committee (PCAC) on July 23-24, 2026, to discuss seven peptides for potential inclusion on the 503A bulks list. An additional five peptides will be considered at a PCAC meeting to be held before the end of Feb. 2027.
- FDA separately announced on April 15, 2026, that these same substances will be removed from 503A Category 2 after seven calendar days because the nominations were withdrawn, although the agency confirmed it was still planning to bring them to PCAC.
- That procedural removal should not be read as a go-ahead to compound these peptides. Under FDA's current policy, removal of a bulk drug substance from Category 2 does not, on its own, authorize use of that substance in compounding or bring it within FDA's interim enforcement discretion policy for substances in Category 1.

On April 16, 2026, FDA published a Federal Register notice announcing a forthcoming public meeting to consider whether seven peptides—BPC-157, KPV, TB-500, MOTs-C, Emideltide (DSIP), Semax and Epitalon—should be included on the 503A bulks list.[1] Inclusion on the 503A bulks list means FDA has formally determined through rulemaking that a bulk drug substance may be used in compounding under Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The notice followed FDA's April 15, 2026, announcement that the same substances would be removed from 503A Category 2 after seven calendar days because the underlying nominations for inclusion on the bulks list had been withdrawn.[2]

How Category 2 Removal Fits Into the 503A Framework

FDA's 503A categories are an interim framework the agency uses to classify nominated bulk drug substances while it evaluates whether they should be added to the 503A bulks list. Category 1 includes substances for which FDA has received sufficient supporting information and may be eligible for the bulks list, with FDA generally applying interim enforcement discretion; Category 2 includes substances supported by sufficient

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information but FDA has identified significant safety risks, making them ineligible for the Category 1 enforcement-discretion policy; and Category 3 includes substances for which the nomination lacked sufficient information for FDA review.[3]

Political Signals vs. Regulatory Reality

These announcements follow statements from HHS Secretary Robert F. Kennedy, Jr. supporting broader access to peptides. On April 15, he publicly characterized FDA's category update as an action that "begins to restore regulated access and will immediately begin shifting demand away from the black market." Secretary Kennedy's comments and support for broader access to peptides no doubt precipitated FDA's action and his comments may be why some observers have concluded that the peptides in question can be compounded without much regulatory risk even before FDA completes the regulatory process. Until this process is complete, we believe caution is still appropriate.

Why Removal Does Not Authorize Compounding

Importantly, FDA's recent actions should not be understood as authorizing compounding with these peptides under Section 503A, and FDA has not moved these peptides into Category 1 or otherwise indicated that it will exercise enforcement discretion regarding their use in human compounding. However, compounding pharmacies and other stakeholders should monitor for updates on FDA's enforcement discretion policies in this area given the recent announcements and Secretary Kennedy's statements.

Background on Section 503A and the Bulks List

503A Compounding

Section 503A is the principal federal pathway under which certain drug products compounded by traditional pharmacies may qualify for exemptions from three otherwise applicable requirements of the FD&C Act: premarket approval, labeling with adequate directions for use and current good manufacturing practice requirements. These exemptions are available only if all of section 503A's conditions are satisfied.

Drug products may only be compounded using bulk drug substances that either (i) comply with an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, (ii) are components of an FDA-approved drug product, or (iii) appear on the 503A bulks list established by FDA regulation. The bulk substance must also be manufactured by a registered establishment and accompanied by a valid certificate of analysis.

The 503A bulks list is established through notice-and-comment rulemaking, a time-intensive process that requires the FDA to review nominations, develop proposed rules and issue final determinations. Because that regulatory process is lengthy, FDA created an interim policy to address nominated substances while the bulks list remained under development. Under that interim framework, FDA classified substances nominated prior to January 7, 2025, into Categories 1, 2 and 3. Only Category 1 substances fall within FDA's interim enforcement policy, under which the agency generally does not intend to take action against a pharmacy that compounds drugs from those substances if the other conditions in the guidance are met. Category 2 and Category 3 substances do not receive that interim enforcement discretion.

FDA's Prior Safety Concerns With Peptides

2023 Peptides Placed on Category 2 List

Peptides are short chains of amino acids, and peptide-based drugs can be attractive therapeutic candidates due to their biological specificity. More recently, public interest in peptides has soared as social media influencers and others have praised various peptides, including many that have never been FDA-approved, for benefits such as muscle gain and anti-aging.

In 2023, during the Biden administration, FDA placed 19 peptide or peptide-related bulk drug substances into Category 2. FDA's rationale was based on the agency's concerns that these substances presented potential safety risks, citing concerns including immunogenicity, peptide-related impurities, complexities in active ingredient characterization and the lack of sufficient safety information or human exposure data.

Implications for Compounding Pharmacies

The immediate practical question for pharmacies is whether removal from Category 2 makes these peptides newly eligible for compounding under Section 503A. In our view, the removal alone should not be understood as a new FDA determination of eligibility. These substances have not been formally added to the 503A bulks list, and the FDA has not yet indicated that it intends to exercise enforcement discretion. In that sense, removal from Category 2 appears to leave the peptides in a state of continued regulatory uncertainty rather than creating a clear new pathway for compounding under Section 503A. Whether FDA adopts a peptide-specific approach remains to be seen.

Practical Steps While Uncertainty Persists

Pharmacies interested in compounding drugs from the peptides at issue in FDA's recent actions should monitor for further announcements from the agency in this area. While Secretary Kennedy's statements suggest that the current administration favors greater access to compounded peptide-based drugs, the regulatory uncertainty surrounding these peptides remains unresolved. Some immediate steps and considerations include:

- **Peptides remain in a regulatory grey area**. Because these peptides have not been added to the 503A bulks list and FDA has not stated that it will exercise enforcement discretion with respect to them, pharmacies should treat compounding involving these substances as an area of ongoing legal and regulatory uncertainty.
- **Evaluating potential bulk drug substance sources.** For any future compounding of these peptides, keep in mind FDA's emphasis on compounders' knowledge of bulk suppliers, testing and quality. Bulk drug substances marketed as "research grade" or "research use only" may present heightened regulatory and quality risk.
- **Consider submitting comments ahead of the July PCAC meeting.** Stakeholders with relevant scientific, clinical, or operational data may wish to address the factors FDA uses to evaluate bulk drug substances for inclusion on the 503A bulks list. Comments submitted by **July 9, 2026,** will be provided to the Committee, while comments submitted by **July 22, 2026,** will still be considered by FDA.

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

[1] 91 Fed. Reg. 20465 (April 16, 2026).

[2] Food & Drug Admin., 503A Categories Update (April 15, 2026).

[3] *See* Food & Drug Admin., Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act (January 2025).