

Are Compounded Peptides Legal?



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Key Takeaways

- HHS does not intend to take enforcement action against State-licensed pharmacies, Federal facilities, or licensed physicians that compound six former Category 2 peptides, including BPC-157, if every condition is met.
- The peptides remain off the 503A Bulks List, and compounders must meet strict sourcing, certificate of analysis, labeling, and MedWatch reporting conditions.
- The non-binding Policy does not override State pharmacy and medical boards, and the HHS comment period runs for two weeks after the notice is published on October 30, 2026.

On October 28, 2026, the U.S. Department of Health and Human Services (“HHS”) filed a [notice with the Federal Register](#) announcing an [“Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances”](#) (the “Policy”). The notice is signed by Secretary Robert F. Kennedy, Jr., and is scheduled for publication on October 30, 2026. Under the Policy, HHS does not intend to take enforcement action against a State-licensed pharmacy, Federal facility, or licensed physician that compounds a drug product with one of six former Category 2 peptides, provided every condition of the Policy is met.

What is the 503A Bulks List, and why weren't these peptides on it?

"Compounding" is the practice of combining or altering ingredients to create a medication tailored to an individual patient. Compounded drugs are not FDA-approved, meaning FDA does not review their safety, effectiveness, or quality before they reach patients. Section 503A of the Federal Food, Drug, and Cosmetic Act allows pharmacies and physicians to compound without going through the FDA approval process, but only with ingredients that meet certain standards. An ingredient (known as a "bulk drug substance") qualifies if it meets an applicable United States Pharmacopeia or National Formulary monograph, is a component of an FDA-approved drug, or appears on a list of eligible bulk drug substances established through formal rulemaking (the "503A Bulks List"). None of the six peptides listed in the Policy qualify under those standards, so compounding with them has not been permitted. The Policy does not change that list. Instead, it announces that HHS does not intend to enforce the rules against compounders who meet its conditions until each peptide is formally addressed in a final rule. Written comments may be submitted through [regulations.gov](https://www.regulations.gov) (Docket No. HHS-OASH-2026-0496) during a two-week HHS comment period that begins when the notice is published on October 30, 2026.

Why is HHS pausing enforcement on former Category 2 peptides?

HHS states that, based on Pharmacy Compounding Advisory Committee ("PCAC") meetings and data on peptide utilization, there is significant interest in compounding with these peptides given the lack of approved products. It describes the Policy as a way to expand patient access while the U.S. Food and Drug Administration ("FDA") reviews the substances. HHS also states that the Policy is intended to discourage the widespread use of research-use-only peptides supplied by foreign manufacturers, by giving patients a more controlled alternative. Each peptide had been in FDA's "[Category 2](#)" (a group of substances for which FDA had published safety risk information and which FDA said compounders could not use without risk of enforcement) from September 2023 until April 22, 2026. According to the Policy, neither the placement in nor the removal from Category 2 changed the peptides' status under Section 503A. FDA's Center for Drug Evaluation and Research recommended against adding any of them to the 503A Bulks List, but the PCAC voted in favor.

The Policy covers only the following six peptides, each limited to specific forms and routes of administration:

- BPC-157 acetate (subcutaneous, intramuscular, oral, and topical);
- TB-500 acetate (subcutaneous or intramuscular injection);
- Epitalon acetate (subcutaneous or intramuscular injection, dispensed in intermittent courses);
- Semax free base (intranasal);
- KPV acetate (topical and oral); and
- MOTS-c acetate (subcutaneous or intramuscular injection).

Peptide compounding conditions.

The Policy sets ten conditions and all of them must be met. The conditions are demanding and focus on making sure the ingredients are what they claim to be, that products are made safely, and that problems are reported. HHS intends to refrain from enforcement only if all of the following are met:

- I. The peptide is one of the six listed in Appendix A to the Policy;

- i. The raw ingredient matches the precise chemical identity described in Appendix B to the Policy and is used only in the forms described therein;
- ii. The raw ingredient comes from a facility registered with FDA and arrives with a valid certificate of analysis that meets the testing standard in Appendix B;
- iii. The company that actually made the ingredient (not just a company that repackaged, relabeled, or distributed it) is registered with FDA and follows FDA's current good manufacturing practice ("CGMP") quality standards, and its facility location is listed on the certificate of analysis;
- iv. The compounder reports the products it makes, any serious adverse events, and any product quality problems to FDA's MedWatch safety and adverse event reporting program and to the States where the products are made and sent, and the patient labeling describes how to report adverse events and quality issues;
- v. The label states, "This is a compounded drug product. Not for resale.";
- vi. Each product contains only one of the listed peptides as its active ingredient (no combination products);
- vii. For pills and other oral forms, the compounder keeps documentation showing the product is actually absorbed by the body in meaningful amounts;
- viii. The only delivery device packaged with the product is an FDA 510(k)-cleared syringe; and
- ix. The product otherwise complies with federal drug law, including the requirement that it be made in sanitary conditions and prepared only in response to a valid prescription for an individual patient.

Notably, the Policy does not make these peptides FDA-approved, and it does not mean FDA has found them safe or effective. It also does not add any peptide to the 503A Bulks List, although FDA may propose adding some or all of them in future rulemaking. The notice describes the Policy as a draft that does not create any legal rights and is not binding on HHS or the public. HHS may also change or withdraw the Policy, in whole or in part, if safety or quality issues arise.

State pharmacy and medical board rules still apply.

The Policy also reflects only how HHS intends to use its own federal enforcement resources. It does not override State law. State pharmacy, medical practice, and controlled substance laws still apply, and State boards of pharmacy and medicine keep their authority to license, inspect, and discipline. State rules on compounding, licensing of out-of-state pharmacies, telehealth prescribing, and scope of practice also continue to apply.

How does the Policy impact physicians, pharmacies, telehealth platforms, and suppliers?

In short, the Policy creates a limited, conditional path to compounding these six peptides. A product that fails any condition is not protected. Pharmacies, prescribing physicians, [telehealth platforms](#), and [companies that make or distribute the raw ingredients](#) should review their sourcing, certificates of analysis, labeling, and adverse event reporting before relying on the Policy. They should also consider whether to submit comments during the two-week HHS comment period. Physicians and pharmacies should also remain mindful that [State medical and pharmacy boards](#) may scrutinize the prescribing and dispensing of these products regardless of the federal Policy.

For more information about the Policy or if you need assistance evaluating compliance, contact Lippes Mathias health law partner [Gregory Measer](#), a former FDA regulatory counsel, at gmeaser@lippes.com or another member of our [Health Care Practice Team](#).

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