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HHS Draws New Lines for Peptide Compounding: What Changes for 503A Pharmacies

Key Updates

- On Oct. 30, 2026, HHS announced an interim enforcement discretion policy that provides for Section 503A compounders to use six specified peptides — BPC-157, Epitalon, KPV, MOTS-c, Semax and TB-500 — under certain circumstances.
- The policy imposes detailed conditions regarding peptide identity, administration routes, ingredient sourcing and testing, labeling, delivery devices and reporting. It does not extend to Section 503B outsourcing facilities or change the regulatory status of “research-use-only” peptides.

Why It Matters

- The policy creates a potential pathway for expanded access to compounded peptides, but its conditions exceed those associated with FDA's interim enforcement discretion policy for compounding with “Category 1” bulk drug substances and may go beyond some pharmacies’ existing sourcing verification and reporting capabilities.
- Several platforms have already begun advertising peptide offerings starting at $109 per month, with higher prices for bundled services.

Next Steps

- Pharmacies considering compounding under the policy should assess their products, suppliers, testing protocols, reporting capabilities and other operating procedures against the conditions of the new HHS policy and applicable state laws. Telehealth platforms, med spas and other providers interested in compounded peptide offerings should also evaluate the policy’s implications.

On Oct. 30, 2026, HHS published an Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances that provides an interim pathway for compounding drugs using six peptide bulk drug substances — BPC-157, Epitalon, KPV, MOTS-c, Semax and TB-500 — when specified conditions are met.

The policy follows the July meeting of FDA’s Pharmacy Compounding Advisory

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Committee (PCAC), which voted in favor of adding these six peptides to FDA's 503A Bulks List. As discussed in our previous alert, that recommendation did not itself authorize compounding with these substances but opened the door to potential interim enforcement discretion while FDA considers whether to add them to the list through formal rulemaking.

Notably, the new policy was issued by HHS rather than FDA, which is a highly unusual approach for policies addressing requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The AP has reported that this approach was tied to significant concerns raised by FDA scientific staff.

What Has Changed for 503A Compounders?

Under the new policy, HHS does not intend to take enforcement action against state-licensed pharmacies, federal facilities or licensed physicians compounding with BPC-157, Epitalon, KPV, MOTS-c, Semax or TB-500 if (1) all the HHS-specified conditions are satisfied and (2) the compounders meet all other applicable requirements under Section 503A of the FD&C Act. This offers compounders that meet the specified conditions greater certainty about the risk of federal enforcement of FDA requirements for these peptides. However, the conditions require careful review and could have significant operational implications:

- **Peptide identity and routes of administration.** The policy applies only to the specific peptide forms and permitted routes of administration identified in its appendices. For example, the policy provides that BPC-157 acetate may be compounded for subcutaneous, intramuscular, oral or topical administration, while compounding of Semax free base is limited to intranasal administration. Each of the other covered peptides has its own limitations.
- **API sourcing and testing.** Compounders must obtain peptide bulk drug substances (also referred to as active pharmaceutical ingredients, or APIs) from FDA-registered manufacturers operating in compliance with current good manufacturing practice requirements, and the APIs must be accompanied by valid certificates of analysis (COAs).[1] HHS expects those COAs to list the physical location of the manufacturing facility. In addition, the policy establishes detailed expectations for ingredient characterization and testing, including identity, purity, potency and impurities, as outlined in Appendix B. It further imposes expectations for identifying the original manufacturer and validating suppliers and COAs when intermediaries are involved.
- **API and delivery device restrictions.** Peptides compounded under the policy are expected to contain ***only a single API***. The policy also limits the types of drug delivery devices that may be co-packaged with or contain compounded products to FDA-cleared syringes.
- **Oral dosage forms.** HHS expects compounders to maintain documentation supporting adequate human bioavailability for the specific oral formulations dispensed to patients.
- **Labeling.** HHS expects product labeling to include the statement, "This is a compounded drug product. Not for resale." It further expects product labeling provided to patients to include the process for reporting adverse events and product quality issues.
- **Product, adverse event and quality reporting.** Importantly, the policy calls for compounders to report information about compounded peptide products, serious adverse events and product quality issues to FDA and to the states where the products are compounded and distributed.
    - The policy states that "product reporting" includes the active ingredient and strength, original API manufacturer and facility identifier, dosage form and route of administration. However, the mechanism for reporting this information to FDA and relevant states is not clear.

- HHS expects serious adverse events associated with use of compounded products in humans to be reported to FDA's MedWatch program, regardless of whether the events are considered drug-related. Product quality issues are also expected to be reported to MedWatch.

These conditions go beyond those ordinarily associated with FDA's interim enforcement discretion for "Category 1" bulk drug substances and beyond the sourcing verification and reporting infrastructures that many pharmacies may currently have in place.

Important Limits on the Policy

Although the policy represents a meaningful change in HHS's enforcement position, it does not technically change the legal status of these peptides for use in compounding under Section 503A — which requires completion of a formal rulemaking process. It is important to keep in mind that state boards of pharmacy and other state regulators may not adopt the same approach as HHS policy. This makes it critical for compounding pharmacies to understand the requirements and policies of the states in which they are licensed, as risk of enforcement activity may vary by state.

The policy also does not change the regulatory status of "research grade" or RUO peptides frequently sold directly to consumers online. HHS specifically states that the policy is intended to "discourage the continued, widespread use of certain research-use-only peptides supplied by foreign manufacturers," and FDA has previously issued warning letters to online peptide retailers asserting that certain peptides marketed with "research" disclaimers are unapproved new drugs.

Looking Ahead

HHS's Federal Register notice described the new policy as a draft, open for an unusually brief comment period through Nov. 13, 2026. HHS also indicates that it may revisit the policy in the future if, for example, safety signals or product quality concerns emerge.

The new policy provides an avenue for expanded access to certain compounded peptides, but its limitations are significant, and it remains to be seen how actively FDA may pursue compounders who do not adhere to those limits. For pharmacies planning to compound peptides under the new policy, a gap analysis to determine whether their products, suppliers and operating procedures meet the policy's conditions is a key next step. Telehealth platforms, med spas and others interested in compounded peptide offerings should also evaluate the policy's implications for supplier quality diligence when establishing or continuing pharmacy relationships.

For questions about the new HHS policy, FDA and state pharmacy board requirements or provider considerations, please contact Stuart Pape, Mark Armstrong, Claire Davies or your regular Polsinelli attorney.

[1] 21 U.S.C. § 353a(b)(1)(A)(ii)-(iii).