

The FDA peptide compounding review, in brief

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WHAT IS HAPPENING

On **July 23–24, 2026**, the FDA's Pharmacy Compounding Advisory Committee (PCAC) reviewed seven peptides for a possible legal compounding pathway under section 503A. The seven:

BPC-157 KPV TB-500 MOTS-c DSIP / Emideltide Semax Epitalon

The committee's vote is **advisory and non-binding**. Any real change to access would require separate formal FDA rulemaking, with its own public comment period. Public docket: **FDA-2025-N-6895**.

WHY IT MATTERS — THE NUMBERS

~**\$328M** U.S. imports of peptide/hormone compounds from China, first 3 quarters of 2025 — roughly double the year before.
U.S. customs data, via The Week, 2026

\$100M+ Estimated annual run-rate of the on-chain grey-market peptide trade; Q1 2026 inflows up 150%+.
Chainalysis, 2026

5%–75% Purity range found in testing of falsified peptide products — with arsenic and lead above injectable-drug limits.
Janvier et al., Talanta, 2018

8 of 14 Grey-market vendors with FDA warning letters still actively selling months later.
Public Citizen / ProPublica, 2026

In the FDA's own words: the agency "lacks sufficient information to know whether the drug would cause harm when administered to humans." That uncertainty is exactly why the *unregulated* market — where no one verifies identity, potency, or sterility — is the danger.

FOLLOW THE INCENTIVES

Only two groups benefit from keeping peptides in an unregulated limbo: **brand drugmakers** (whose exclusivity is protected when lower-cost compounding is kept narrow) and **the black market** (which needs there to be no legal competition). Everyone else — consumers, licensed pharmacies, doctors, and public health — bears the cost.

LICENSED COMPOUNDING ≠ THE GREY MARKET

A licensed compounding pharmacy is state-board regulated, follows USP sterile-compounding standards, and dispenses against a prescription. An anonymous "research use only" seller is none of those. Conflating the two tars the accountable channel with the sins of the black market.

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