FDA Signals Potentially Evolving Stance Toward Compounding of Certain Peptides

 On April 15, 2026, the U.S. Food and Drug Administration ("FDA") announced that it will convene a public meeting of the Pharmacy Compounding Advisory Committee ("PCAC") on July 23-24, 2026, to consider whether to recommend seven (7) peptide bulk drug substances for inclusion on the list of substances that may be used in compounding under Section 503A of the Federal Food, Drug, and Cosmetic Act. Five (5) additional peptide and peptide-derived substances are also slated for separate PCAC evaluation through early 2027. On the same date, FDA also republished its interim 503A Bulks List, indicating its intent to remove 12 peptides from its Category 2 list ("Bulk Drug Substances that Raise Significant Safety Concerns"). This removal took effect following a seven calendar-day notice period.

These FDA actions follow comments in February by HHS Secretary Robert F. Kennedy Jr. on a show hosted by Joe Rogan, during which he expressed concerns about the gray-market nature of the current supply of certain peptide products and that he hoped there would be a pathway for consumers to obtain these products from "ethical suppliers".

The seven (7) peptide bulk drug substances expected to be considered by the PCAC in July, together with the uses identified for evaluation, are:

July 23, 2026:

- **BPC-157** (free base and acetate): ulcerative colitis
- **KPV** (free base and acetate): wound healing and inflammatory conditions
- **Thymosin Beta-4, Fragment (LKKTETQ)("TB-500")** (free base and acetate): wound healing
- **MOTs-C** (free base and acetate): obesity and osteoporosis

July 24, 2026:

- **Emideltide (DSIP)** (free base and acetate): opioid withdrawal, chronic insomnia, and narcolepsy
- **Semax** (free base and acetate): cerebral ischemia, migraine, and trigeminal neuralgia
- **Epitalon** (free base and acetate): insomnia

The peptide substances scheduled for consideration at the July 23-24, 2026, PCAC meeting are among those identified for removal from Category 2. FDA has also identified five (5) additional peptide and peptide-derived substances, including Cathelicidin LL-37, Dihexa acetate, GHK-Cu (injectable), Mechano Growth Factor (PEG-MGF), and Melanotan II, for removal from Category 2 and for later consultation with the PCAC at an advisory committee meeting expected before February 2027.

For those substances removed from the Category 2 list, such removal does not, in itself, establish eligibility for compounding under Section 503A. The regulatory status of these substances remains subject to further evaluation by FDA. FDA had previously identified a range of potential safety considerations associated with these substances, including risks related to immunogenicity, peptide-related impurities, and, in some cases, limited human exposure data. Against that backdrop, FDA's removal of these substances from the Category 2 list and its decision to seek PCAC input regarding their potential inclusion on the 503A bulks list suggests that the Agency is continuing to evaluate how such considerations should be weighed in light of other available data.

Inclusion of any substance on the 503A bulks list historically has been implemented through rulemaking, with advisory committee input forming part of that process. Although PCAC's recommendations are not binding, they generally have informed FDA's ultimate determinations. Accordingly, the upcoming PCAC deliberations may provide an important indicator of how FDA intends to approach these substances going forward.

FDA has also opened a **public docket** (FDA-2025-N-6895) in connection with the upcoming PCAC meeting. Comments submitted by July 9, 2026 will be provided to the Committee for consideration, and the docket will remain open for submissions through July 22, 2026.

If you have any questions or would like to submit a comment to the public docket, please contact the authors or the Goodwin attorney with whom you typically work.