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Client Alert: Navigating the Peptide Compounding Wave and Upcoming FDA Vote

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Driven by the fast growth of the GLP-1 weight-loss market, there is currently a bright spotlight on peptides in the wellness industry. While several GLP-1 drugs that are approved by the Food & Drug Administration (FDA) contain peptides, many peptides are not themselves FDA-approved substances, nor are they included on the FDA's list of substances that may be used in pharmacy compounding (the FDA's 503A Bulks List).

By way of background, under Section 503A of the Food, Drug and Cosmetic Act, a licensed pharmacy can only compound a drug for an individual patient using a bulk substance if such substance (1) is FDA-approved, (2) has a recognized United States Pharmacopeia monograph, or (3) appears on the FDA's 503A Bulks List. If a peptide is not on the 503A Bulks List, pharmacies are generally prohibited from compounding it.

Soon, numerous peptides that are currently not on the 503A Bulks List will be up for consideration by the FDA's Pharmacy Compounding Advisory Committee (PCAC).

On July 23-24, 2026, the FDA's PCAC will consider including the following heavily demanded peptides on the 503A Bulks List:

Bulk drug substance	Uses evaluated
BPC-157 (free base) BPC-157 acetate	Ulcerative colitis

Bulk drug substance	Uses evaluated
KPV (free base) KPV acetate	Wound healing and inflammatory conditions
TB-500 (free base) TB-500 acetate	Wound healing
MOTs-C (free base) MOTs-acetate	Obesity and osteoporosis
Emideltide (free base) Emideltide (acetate)	Opioid withdrawal, chronic insomnia, and narcolepsy
Emideltide (free base) Emideltide (acetate)	Opioid withdrawal, chronic insomnia, and narcolepsy
Semax (free base) Semax acetate	Cerebral ischemia, migraine, and trigeminal neuralgia
Epitalon (free base) Epitalon acetate	Insomnia

Importantly, in 2023, the FDA banned the above-mentioned peptides from routine compounding by categorizing them as "Category 2" due to their potential significant safety risks. Consideration of the peptides for inclusion on the FDA's 503A Bulks List marks a strong departure from past FDA attitudes towards peptides and their use in drug compounding.

Even if the PCAC votes favorably, the vote is not binding, and the FDA may choose not to follow the committee's recommendations—though this would be rare. If the FDA were to accept PCAC's recommendation to add certain peptides to the 503A Bulks List, the agency would then initiate the formal rulemaking process. This process may take up to two years or more. Pharmacies and providers may not compound these substances until a final rule authorizing such compounding takes effect.

If additional peptides are ultimately added to the 503A Bulks List, providers should treat this development as

a regulatory pathway for patient-specific compounding, not as a blanket endorsement of routine prescribing. Providers should ensure that market demand and consumer interest are weighed against appropriate clinical evidence, patient-specific need, quality controls, and a documented risk-benefit analysis before clinical use.

The upcoming vote has the potential to change the landscape of legal compounding of peptides in a health care industry that has experienced much patient demand for GLP-1s. If you have questions about how PCAC's vote may impact your practice, please contact Daphne Kackloudis, Jordan Burdick, or Kate Crawford.

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