FDA Advisory Committee Recommends Several Peptides for Compounding for Various Uses Despite Staff Opposition: What Stakeholders Need to Know

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July 30, 2026

The explosive growth of the GLP-1 market has fueled demand not only for weight-loss therapies, but also for peptides marketed for wellness, fitness, and longevity purposes. As demand has increased, so too has the gray market for peptide products. FDA has already demonstrated its intent to exercise enforcement efforts against GLP-1 dupes and products seeking to capitalize on GLP-1 demand in novel ways. (See our prior post on FDA's enforcement efforts here.)

Although several FDA-approved GLP-1 therapies are peptide-based, many popular peptides are neither FDA-approved nor included on FDA's list of bulk drug substances that can be used in compounding (the "503A Bulks List"). As a result, these peptides cannot be lawfully compounded under Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Against this background, the FDA's Pharmacy Compounding Advisory Committee (PCAC) met last week to evaluate whether seven highly sought after peptides should be recommended for inclusion on the 503A Bulks List. The uses evaluated varied significantly and include obesity, wound healing, and insomnia. The Committee recommended adding six out of seven of the peptides under review for inclusion on the 503A Bulks List, with votes as follows:

Peptide	Uses Evaluated	Votes in Favor and Against Adding to the 503A Bulks List
BPC-157	Ulcerative colitis (UC)	8 in favor, 6 opposed, 1 abstention
MOTs-C	Obesity and osteoporosis	7 in favor, 5 opposed, 2 abstentions
TB-500	Wound healing	8 in favor, 6 opposed, 1 abstention
KPV	Wound healing and inflammatory conditions	8 in favor, 6 opposed, 1 abstention

Emideltide (also known as Delta Sleep Inducing Peptide, or DSIP)	Opioid withdrawal, chronic insomnia, and narcolepsy	6 in favor, 7 opposed, 1 abstention
Epitalon	Insomnia	7 in favor, 4 opposed, 1 abstention
Semax	Cerebral ischemia, migraine, and trigeminal neuralgia	8 in favor, 5 opposed, 1 abstention

Importantly, a favorable PCAC recommendation does not immediately authorize compounding. Before any peptide is added to the 503A Bulks List, FDA must initiate a formal notice-and-comment rulemaking—a process that may take over a year to complete. And while these outcomes could significantly affect compounding pharmacies, wellness providers, manufacturers, telehealth platforms, and investors operating in the peptide space, companies who consider this development a green light to compound or market the above (and other) peptide substances face enforcement risk until FDA formally places them on the 503A Bulks list.

Further—and notwithstanding the Committee's votes—FDA staff recommended against adding any of the peptides under review to the 503A Bulks List, repeatedly citing:

- Insufficient evidence of safety and effectiveness;
- Insufficient or nonexistent human clinical trial data;
- Inadequate characterization and quality information;
- Uncertainty regarding substance identity and composition; and
- Potential safety concerns, including immunogenicity risks.

Given that FDA staff remain skeptical of the available evidence underlying many of these peptides, and the agency is under no obligation to follow the Committee's recommendations, it is unclear whether these substances will end up on the 503A Bulks List. For now, companies operating in the peptide space should continue to approach peptide compounding and marketing with caution, as enforcement risk persists until the evaluated substances are formally added to the 503A Bulks List.

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