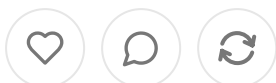


How a Split FDA Advisory Panel Voted Six of Seven Peptides Onto the 503A Compounding List Over Its Own Scientists, Rejecting Only Emideltide, and What That Actually Changes for the Market

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How a Split FDA Advisory Panel Voted Six of Seven Peptides Onto the 503A Compounding List Over Its Own Scientists, Rejecting Only Emideltide, and What That Actually Changes for the Market

FDA's career scientists recommended against all 7 peptides up for review at last week's advisory committee meeting. The committee voted yes on 6. Here is what that split actually tells you...

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Abstract

On July 23 and 24, 2026, FDA's Pharmacy Compounding Advisory Committee met in White Oak to evaluate seven peptide bulk drug substances for the Section 503A list. FDA career staff recommended against all seven. The committee voted yes on 10 of 11 items. Key points:

1. Day 1 votes: 8 yes, 6 no, 1 abstain for BPC-157, KPV and TB-500, with free base and acetate salt voted separately. MOTS-c came in at 7 yes, 5 no, 2 abstain.
2. Day 2 votes: Emideltide failed at 6 yes, 7 no, 1 abstain. Epitalon passed at 7 yes, 5 no, 1 abstain. Semax passed at 8 yes, 5 no, 1 abstain.
3. On Day 1, the eight yes votes were the eight temporary members added to the committee shortly before the meeting. The bloc held until one member broke ranks on Day 2.
4. The votes are non-binding. Nothing is legal today that was not legal a week ago.
5. All seven had already come off Category 2 on April 23, 2026, so this was an advisory vote, not a re-ban risk.
6. Every nomination in the packet had been withdrawn by its original nominator. FDA ran the review anyway.
7. Even a best-case final rule reaches only 503A pharmacies filling patient-specific prescriptions. 503B outsourcing facilities have a separate bulks list and are untouched.
8. FDA's 2019 proposed rule on 26 other substances is still unfinished seven years later, which makes the eight to twelve month timeline in the trade press look brave.
9. The binding constraint after rulemaking is API sourcing, not the list. Section 503A requires bulk substances from an FDA-registered establishment with certificate of analysis, and most peptide API in circulation today does not clear that bar.
10. A second PCAC meeting is due before the end of February 2027 for Cathelicidin LL-37, GHK-Cu, Dihexa acetate, Melanotan II and PEG-MGF. That slate is

materially riskier than this one.

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What actually happened at White Oak

Two days, seven substances, one advisory committee that had been reconstituted before it walked in the door. FDA's own scientists, working from briefing documents that ran the standard four factor analysis on each substance, came back with the

answer seven times: do not include. That is a clean sweep. Career staff at the Off Compounding Quality and Compliance and the clinical review team did not split difference on a single one.

The committee voted the other way on six.

Day 1 handled BPC-157, KPV, TB-500 and MOTS-c. BPC-157 free base got 8 yes, no, 1 abstain. Then the acetate salt was voted separately and produced the identical tally. KPV, same. TB-500, same. MOTS-c slipped a little at 7 yes, 5 no, 2 abstain, which means somebody who had been comfortable with wound healing decided obesity and osteoporosis indications were a bridge too far. The session ran hours ahead of schedule.

The detail that got buried in most of the coverage is who those eight yes votes belonged to. On the first three substances, the yes bloc consisted entirely of the temporary members added to the committee shortly before the meeting. All eight appointees voted yes. Six pre-existing members voted no. One abstained. On MC seven of the eight new appointees voted yes and one abstained, which is the who explanation for the shift in the tally. That is not a committee deliberating toward a split. That is two groups arriving with conclusions already packed, and one of them being slightly larger.

The tone in the room was not triumphant. One patient representative said out loud that he was voting on something without knowing what the something was, and called it a black box. That is an unusual thing to say into a live webcast right before pressing a button. Another member framed her yes vote around harm reduction, describing a patient who had brought her a research grade vial that turned out to be contaminated with recreational drugs. A physician from Keck pointed at the randomized data on BPC-157, said it suggests no separation from placebo, and warned that an endorsement could be actively harmful. Those three positions are the entire meeting in miniature. Nobody can say what the substance is, the gray market is genuinely dangerous, and the clinical evidence does not support a green light.





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