



What Happened at PCAC – An Update

July 28, 2026



Sarah Taylor, PharmD

On July 23rd and 24th, the Pharmacy Compounding Advisory Committee (PCAC) met to discuss the potential inclusion of various peptides, specifically BPC-157, Emideltide (DSIP), Epitalon, KPV, MOTs-C, Semax, and Thymosin Beta-4 fragment (TB-500), on the 503A bulks list. Below summarizes the voting results by the FDA and PCAC:

Nominated Substance	FDA Proposal to Include or Omit	PCAC Vote (Include or Omit)
BPC- 157 (Free base and Acetate)	Omit	Include (8 to 6 in favor, 1 abstention in both cases)
Emideltide (DSIP) (Free base and Acetate)	Omit	Omit (6 to 7 against, 1 abstention in both cases)
Epitalon (Free base and Acetate)	Omit	Include (7 to 4 in favor, 1 abstention in both bases)
KPV (Free base and Acetate)	Omit	Include (8 to 6 in favor, 1 abstention in both cases)
MOTs-C (Free base and Acetate)	Omit	Include (7 to 5 in favor, 2 abstentions in both cases)
Semax (Free base and Acetate)	Omit	Include (8 to 5 in favor, 1 abstention in both cases)
Thymosin Beta-4 (TB-500) (Free acid and Acetate)	Omit	Include (8 to 6 in favor, 1 abstention in both cases)

Some key points:

Several PCAC and FDA members voiced concerns regarding the lack of evidence on the safety and efficacy of the peptides in question, the lack of robust evidence in humans generally, and the lack of clarity on exact characteristics (e.g. salt form, amino acid sequence) of substances submitted for evaluation.

Several PCAC and FDA members expressed concern that addition to the 503A list may be interpreted by the general public as endorsement by the agency.

During the open public hearing, concern regarding the fact that peptides are being used by patients regardless of addition to the list was a common theme. Some speakers during the open public hearing suggested that adding these materials to the list could create safer access and more oversight for materials that will likely continue to be used.

Some speakers proposed that compounders offer a safer and more regulated way for patients and providers to access these therapies compared to what many referenced as the current 'gray market'.

What comes next?

The FDA has the final say on what gets added to the 503A bulks list. A positive vote from the committee does not guarantee that a substance will be added to the 503A bulks list. At this time, we await final FDA decisions. The substances in question are not yet permitted for compounding

Where can I watch the meetings?

Recordings of the meetings are available at the below links:

Day 1 (July 23rd 2026): July 23, 2026 Meeting of the Pharmacy Compounding Advisory Committee (PCAC) - YouTube

Day 2 (July 24th 2026): July 24, 2026 Meeting of the Pharmacy Compounding Advisory Committee (PCAC)

For further information or questions, please feel free to reach out to us by heading to www.fagronacademy.us!