PEPHORMIA

FREE BRIEFING · THE JULY 2026 FDA PEPTIDE HEARING

The 7 peptides the FDA is weighing.

On 23–24 July 2026, an FDA committee votes on BPC-157, TB-500, KPV, MOTS-c, DSIP, Semax and Epitalon. Here is what the peer-reviewed evidence actually says about each — and what a "yes" would, and wouldn't, mean.

What's on the table — and what isn't

FDA PCAC · DOCKET FDA-2025-N-6895

DAY 1 · 23 July
healing & metabolic

- **BPC-157** · ulcerative colitis
- **KPV** · wound healing / inflammation
- **TB-500** · wound healing
- **MOTS-c** · obesity / osteoporosis

DAY 2 · 24 July
brain & longevity

- **DSIP** · "emideltide" · sleep
- **Semax** · cognition / neuroprotection
- **Epitalon** · longevity / telomeres

Advisory vote only — not drug approval, not consumer legalisation.

Read this first: the vote is about the **503A compounding list** — whether pharmacies may compound these under prescription. It is not FDA approval, and it does not make them consumer products.

14MIN READ EDUCATION ONLY NO DOSING · NO SOURCING UPDATED JUL 2026

// BEFORE THE HYPE

What this vote actually decides.

The peptide internet is treating 23 July as a finish line. It isn't. The Pharmacy Compounding Advisory Committee (PCAC) is weighing whether these seven belong on the **503A Bulk Drug Substances List** — the list that lets a licensed compounding pharmacy prepare a substance for an individual patient **with a valid prescription**. Four steps sit between this vote and anything you could legally buy.

From committee vote to a legal prescription

THE REAL PATH

The detail almost no headline mentions

◆ PRIMARY · FDA

FACT	In its briefing materials, **FDA staff proposed that none of the seven be added** to the 503A list. PCAC can agree or diverge; the vote is non-binding either way.
SOURCE	FDA, PCAC meeting notice & briefing, 23–24 Jul 2026; Federal Register docket FDA-2025-N-6895.
DOESN'T SHOW	The outcome is genuinely uncertain — treat any prediction (either way) as speculation, not news.

WHY IT MATTERS ANYWAY

Whatever the vote, it's the clearest signal yet of where US peptide regulation is heading — and it's driving a global wave of curiosity. That's exactly why knowing the real evidence, per compound, is worth more now than ever.

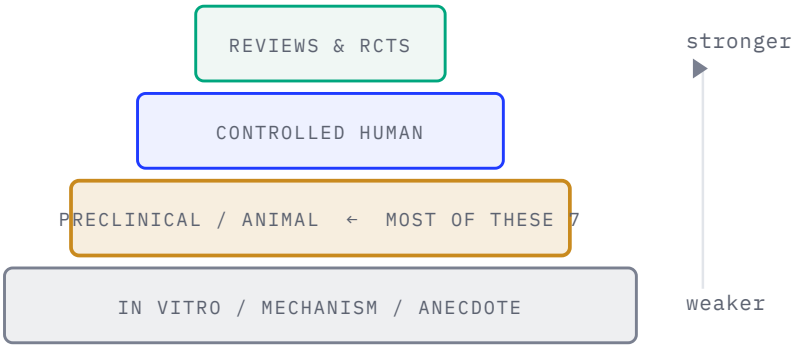
// THE ONE HABIT THAT PROTECTS YOU

Grade the evidence before you believe the claim.

Every peptide below gets a tier — the honest strength of its *human* evidence. Here's the scale we use, and the uncomfortable truth: for this group of seven, almost everything sits in the bottom two rungs.

The evidence ladder

WHERE THESE 7 MOSTLY SIT



Set your expectation now: "promising in animals" is real science — but it is not "proven in people." Most of these peptides have strong preclinical stories and thin (or no) controlled human trials.

OUR RULE

We never present animal or lab findings as human outcomes, and we never give dosing or sourcing for any compound here. This is a map of the evidence — not a how-to. These are prescription/scheduled substances in Australia and most markets.

// 01 · BPC-157 — THE HEADLINE ACT

Enormous animal literature. Almost no human trials.

BPC-157 is a synthetic 15-amino-acid peptide based on a sequence found in gastric juice. One group at the University of Zagreb (Sikirić) has published **150+ preclinical studies** since the 1990s across gut, tendon, and vascular models. The mechanism story is genuinely rich — and the human evidence is genuinely thin.

35 : 1

A 2025 systematic review (HSS Journal) found 35 preclinical animal studies to a single uncontrolled 16-patient human chart review — and **no completed controlled human trials**.

BPC-157 · tissue repair & gut protection

◆ PRECLINICAL-DOMINANT · SINGLE GROUP

WHAT'S STUDIED	Cytoprotection, tendon/ligament and GI mucosal healing, angiogenesis — overwhelmingly in rodents. The nomination under review is for **ulcerative colitis** (early human GI work exists under the code PL-14736).
SOURCE	Vasireddi N, et al. Systematic review, HSS Journal 2025 (36 studies) · Sikirić et al. preclinical body of work.
DOESN'T SHOW	No controlled human efficacy trials; half-life <30 min with no published human PK; WADA-prohibited for athletes.

HONEST READ

The strongest case in the whole docket — yet still resting on one lab's animal work plus a tiny uncontrolled human series. Compelling hypothesis; unfinished human science.

// 02 · KPV & 03 · TB-500

A promising anti-inflammatory, and a fragment with a human-data gap.

KPV · α-MSH-derived tripeptide

◆ PRECLINICAL

WHAT'S STUDIED	KPV is the C-terminal tripeptide of α-MSH; it shows anti-inflammatory activity in cell and rodent models of colitis and inflammatory conditions. FDA is reviewing it for **wound healing & inflammatory conditions**.
SOURCE	α-MSH / KPV anti-inflammatory preclinical literature (IBD models).
DOESN'T SHOW	Human efficacy is not established; the evidence is preclinical.

TB-500 · thymosin β4 fragment (Ac-LKKTETQ)

◆ ANIMAL-DOMINANT

KEY NUANCE	TB-500 is a 7-amino-acid **fragment** (residues 17–23) of thymosin β4 — not the full protein. Most human clinical work is on *full-length* Tβ4 (e.g. RGN-259), not the fragment, so the two should not be treated as interchangeable.
SOURCE	Thymosin β4 / TB-500 reviews, 2025; FDA nomination use: wound healing.
DOESN'T SHOW	Essentially no controlled human trials on the fragment itself; WADA-prohibited (Section S0), prescription-only in AU/NZ.

HONEST READ

Both have real mechanistic and animal support and almost no human trial data. "Used for years in horses" is not the same as "proven in people."

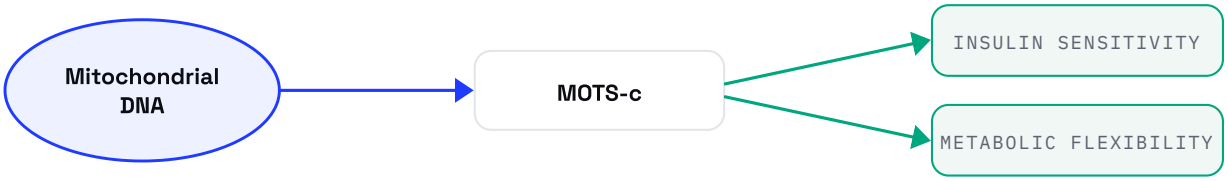
// 04 · MOTS-C — THE MITOCHONDRIAL ONE

Exciting biology, earliest-stage human evidence.

MOTS-c is a **mitochondrial-derived peptide** — encoded in mitochondrial DNA — that acts as a metabolic regulator, improving insulin sensitivity and metabolic flexibility in animal models and responding to exercise. It's one of the more scientifically novel entries. FDA is reviewing it for **obesity and osteoporosis**.

Why MOTS-c is different

MITOCHONDRIAL SIGNAL



The appeal: unlike most peptides, MOTS-c is a natural mitochondrial signal — which is also why its human dosing, safety and long-term effects are so under-studied.

MOTS-c · metabolic regulator

◆ PRECLINICAL / EARLY

WHAT'S STUDIED	Insulin sensitivity, metabolic flexibility and exercise response — largely in cell and animal models since its 2015 discovery.
SOURCE	MOTS-c mitochondrial-derived-peptide literature (discovery Lee et al., Cell Metab 2015).
DOESN'T SHOW	Human clinical efficacy and long-term safety are not established.

// 05 · DSIP 06 · SEMAX 07 · EPITALON

The brain-and-longevity trio — mostly older, mostly elsewhere.

DSIP · delta sleep-inducing peptide (”emideltide”)

◆ OLD & INCONSISTENT

WHAT'S STUDIED	Isolated in the 1970s and studied for sleep regulation and stress; findings across decades have been **inconsistent**, and its very mechanism as a sleep agent remains debated.
DOESN'T SHOW	No robust modern controlled evidence establishing a reliable sleep benefit in humans.

Semax · Russian neuropeptide

◆ SMALL REGIONAL TRIALS

WHAT'S STUDIED	An ACTH(4–10) analogue developed in Russia; used there for stroke/cognition, supported mainly by **small Eastern-European trials** not widely replicated to Western standards.
DOESN'T SHOW	Little independent, large-scale controlled data outside its region of origin.

Epitalon · telomere tetrapeptide

◆ ANIMAL + OLDER RUSSIAN WORK

WHAT'S STUDIED	A synthetic tetrapeptide (Khavinson) claimed to affect telomerase/telomeres and lifespan — chiefly in animal studies and older Russian-language human reports.
DOESN'T SHOW	Longevity and telomere claims are not established by modern independent controlled human trials.

// THE BOTTOM LINE

Whatever the vote — here's what actually changes.

IF YES (ADDED)

A slow path opens for **prescription compounding** in the US. Months of rulemaking follow. Not OTC, not a consumer product, not automatic in Australia.

IF NO (DECLINED)

Status quo: they stay outside legal compounding. The grey market doesn't vanish — which is exactly why honest education matters.

IN AUSTRALIA, TODAY

These remain **prescription / scheduled**. A US compounding vote does not change AU law. We don't sell or source them — full stop.

THE HONEST VERDICT

Seven peptides, one shared story: real, interesting biology; mostly preclinical or small/regional human data; and a regulatory decision that's about **compounding access under prescription**, not proof that they work or permission to buy them. If you take one thing from this briefing: judge each compound by the **tier** of its human evidence, not the volume of its hype.

A note on scope

EDUCATION ONLY

These are prescription / scheduled peptides — not cosmetics.
PEPHORMIA covers them as an education topic only. We do not sell, supply, dose or source them

Listen — 12 min
THE 7 FDA-HEARING PEPTIDES · NARRATED EDITION

Sources & references

1 **U.S. Food & Drug Administration.** Meeting of the Pharmacy Compounding Advisory Committee, 23–24 July 2026, White Oak, MD — meeting notice, agenda & bulk-substance review charts. fda.gov advisory-committee calendar

2 **Federal Register.** PCAC meeting & nominated 503A bulk drug substances (BPC-157, KPV, TB-500, MOTS-c, Emideltide/DSIP, Semax, Epitalon). Docket FDA-2025-N-6895 (notice published 16 Apr 2026).

3 **Vasireddi N, Hahamyan H, Salata M, et al.** Emerging use of BPC-157 — a systematic review. **HSS Journal** 2025 (36 studies: 35 preclinical, 1 uncontrolled human chart review).

4 **Sikirić P, et al.** Body-protection-compound BPC-157: preclinical body of work (gastrointestinal, musculoskeletal, vascular models), University of Zagreb, 1990s–present.

5 **Goldstein AL, Kleinman HK, et al.** Thymosin β4 in tissue repair and regeneration — mechanism & preclinical reviews (context for the TB-500 fragment).

6 **Lee C, Zeng J, Drew BG, et al.** The mitochondrial-derived peptide MOTS-c promotes metabolic homeostasis. **Cell Metabolism** 2015;21(3):443–454.

7 **α-MSH / KPV anti-inflammatory literature** — preclinical models of colitis and inflammatory disease (KPV as the C-terminal tripeptide of α-MSH).

8 **Khavinson VK, et al.** Epitalon (Ala-Glu-Asp-Gly) — telomerase/telomere and geroprotective studies (animal & older human reports).

9 **Semax (ACTH 4–10 analogue)** — Russian clinical & preclinical literature on cognition, stroke and neuroprotection (small regional trials).

10 **DSIP (delta sleep-inducing peptide)** — sleep-regulation research since the 1970s; mixed/inconsistent findings across studies.

IMPORTANT — PLEASE READ

PEPHORMIA is an education platform. This briefing is general information only — **not medical advice, diagnosis or treatment**, and not an endorsement of any peptide. The compounds discussed are **prescription and/or scheduled substances** in Australia and most markets; several are prohibited in sport (WADA). We do **not** sell, supply, dose, formulate, source or facilitate access to any of them — they appear here solely as an educational and regulatory topic. Evidence is graded honestly: most of these peptides rest on preclinical, animal, or small/regional human data, and outcomes of the FDA vote are uncertain. Always consult a qualified healthcare professional. Verify primary citations before relying on any claim.