PEPPIES

Peptides for Life

peppies.com

July 9, 2026

Pharmacy Compounding Advisory Committee
c/o Takyiah Stevenson, PharmD — Designated Federal Officer
Center for Drug Evaluation and Research, U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993

Re: Docket No. FDA-2025-N-6895 — Bulk Drug Substances Nominated for Inclusion on the Section 503A Bulk Drug Substances List (Pharmacy Compounding Advisory Committee, July 23–24, 2026)

Dear Members of the Committee:

Peppies is an independent consumer-education resource devoted to explaining therapeutic peptides and the regulatory process in plain English. We are not affiliated with the FDA. We do not sell, promote, or facilitate the sale of any peptide, and we will not do so unless and until it is legal. We take no position in this comment on whether any individual substance before you meets the scientific standard for the 503A list — that is the province of the Committee and the agency's scientists, whose safety concerns we take seriously. We write about one thing: the documented consumer-safety consequences of the *status quo*.

1. The demand for these peptides is large, growing, and — since 2023 — almost entirely unregulated.

When the FDA placed this group of peptides in "Category 2" in 2023, public appetite for them did not fall; by every available measure it has climbed. U.S. imports of peptide and hormone compounds from China reached roughly $328 million in the first three quarters of 2025 — about double the same period a year earlier.[1] Analysts tracking on-chain peptide sales estimate the grey market has crossed a $100-million-plus annual run rate, with first-quarter 2026 inflows up more than 150% — and note that some overseas suppliers recently pivoted from selling fentanyl and amphetamine precursors.[2] As even the compounding-industry bar has observed, restricting supply without extinguishing demand "likely just redirected it" outside the regulated system.[3] That product now reaches ordinary adults through encrypted messaging apps and "research use only — not for human consumption" storefronts.

2. By the FDA's own account, no one can presently vouch for the safety of these substances.

[1]U.S. customs data on peptide/hormone imports from China, reported in The Week, 2026.

[2]Chainalysis, on-chain analysis of the grey-market peptide trade, June 2026.

[3]FDA Law Blog (Hyman, Phelps & McNamara), "FDA's Pep(tide) Rally! What Compounders and Industry Need to Know," 2026.

In its briefing documents for this meeting, the FDA states plainly that it "lacks sufficient information to know whether the drug would cause harm when administered to humans," and repeatedly flags risks of immunogenicity, peptide-related impurities, and an absence of human safety data.[4] For KPV it identified no human exposure data of any kind, and for several of the seven, no dedicated toxicology at all. We do not dispute this — it is exactly why the unregulated market is so dangerous. These are not well-characterized substances even in principle, and the grey market strips away every remaining safeguard.

3. The product sold on that market is frequently not what its label says.

Independent testing bears this out. Peer-reviewed analysis of falsified peptide products found purity ranging from 5% to 75%, with arsenic and lead above the limits set for injectable drugs — the arsenic in its more toxic inorganic form.[5] A 2026 white paper by ECRI and the Institute for Safe Medication Practices, naming BPC-157, TB-500 and epitalon among others, reached similar conclusions.[6] Independent lab testing of BPC-157 vials bought online found purity as low as 71%, alongside measurable endotoxin and heavy metals.[7] As one endocrinologist commenting on grey-market injectables put it: "My issue is safety. I can't assess risk if I don't know the exact composition of a product."[8] Consumers are reconstituting and injecting these powders themselves, by the subcutaneous route the FDA identifies as highest-risk for immunogenic reactions.

4. Documented harm — and documented crime — are already on the record.

The FDA's own adverse-event data include a consumer who developed shortness of breath and went to the emergency room after injecting compounded BPC-157, and a Semax buyer hospitalized with eye pain that remained unresolved a year later.[9] For epitalon, the FDA notes that the very telomerase-activating, "anti-aging" mechanism it is marketed on is itself a potential cancer liability.[10] And this is not only a safety story: in 2020 a Kentucky compounding pharmacy pleaded guilty to distributing unapproved drugs including BPC-157, DSIP, epitalon and Semax, forfeiting more than $1.7 million.[11]

5. Responsible compounders agree the black market is the danger — and that is the point.

The danger we are describing is not the licensed pharmacist working under a prescription and subject to inspection. It is the anonymous seller on an encrypted app shipping unidentified powder from overseas. The Alliance for Pharmacy Compounding has drawn that same line, and we stand with it: the grey market is the hazard, and it exists today precisely because a legal, accountable channel for these substances does not.[12]

---

[4] FDA briefing documents, July 23–24, 2026 PCAC meeting (fda.gov); FDA, "Certain Bulk Drug Substances… That May Present Significant Safety Risks."

[5] Janvier et al., Talanta, 2018 (analysis of falsified polypeptide products).

[6] ECRI and the Institute for Safe Medication Practices (ISMP), white paper on compounded peptide products, 2026.

[7] Independent laboratory testing of online-purchased peptide vials, 2026 (illustrative; single-lab, non–peer-reviewed).

[8] Anne Peters, MD, USC Keck School of Medicine, quoted in Medscape Medical News, 2026.

[9] FDA briefing documents for BPC-157 and Semax, July 2026 PCAC meeting (FDA Adverse Event Reporting System cases).

[10] FDA briefing document for Epitalon, July 2026 PCAC meeting.

[11] U.S. Department of Justice, Eastern District of Kentucky, guilty-plea announcement, Tailor Made Compounding LLC, 2020.

[12] Alliance for Pharmacy Compounding (Scott Brunner, CEO), "It Ain't Legal, Folks."

6. Our request.

A regulated channel can be inspected, tested for identity, potency and sterility, dispensed against a prescription, and monitored after the fact. An anonymous online seller can do none of these things. We ask the Committee to weigh, alongside the evidence on each substance, the safety consequences of leaving demand to an unregulated market that the record shows is neither empty nor being effectively policed — and, for any substance the Committee does advance, to pair access with rigorous identity, potency and sterility standards and meaningful post-market surveillance. The goal we share with the FDA is the same: fewer people harmed.

Thank you for your service, and for considering this comment.

Respectfully submitted,

Ken Underwood
Founder, Peppies
peppies.com · ken@peppies.com