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U.S. Food & Drug Administration
Docket No. FDA-2025-N-6895
"Pharmacy Compounding Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments — Bulk Drug Substances Nominated for Inclusion on the Section 503A Bulk Drug Substances List."

July 1, 2026

To Whom it May Concern:

The Partnership for Safe Medicines (PSM) submits these comments in connection with the Pharmacy Compounding Advisory Committee (PCAC) meeting scheduled for July 23-24, 2026, at which the PCAC will evaluate seven bulk drug substances nominated for inclusion on the 503A Bulks List: BPC-157, KPV, TB-500, MOTs-C, Emideltide (also known as delta sleep-inducing peptide, or DSIP), Semax, and Epitalon.[1] These comments apply to all peptides under consideration, but can be applied to MOTs-C if you need a specific peptide.

PSM is a nonprofit coalition of patient safety advocates, healthcare professionals, pharmacists, and public health organizations committed to protecting patients from unsafe, ineffective, and counterfeit medicines. PSM has documented the public health consequences and patient harms resulting from contaminated, mislabeled, or substandard compounded medicines. PSM regularly engages with regulators and policymakers on issues related to illicit compounding, drug supply chain integrity, and the patient safety risks posed by unapproved active pharmaceutical ingredients (API) entering the United States from unverified foreign sources.

PSM urges the PCAC to oppose the addition of any of the seven substances under consideration to the 503A Bulks List because of:

1. The absence of adequate clinical evidence to support the safety or efficacy of these substances in human beings,
2. The public health concerns associated with widespread compounding of unapproved products, particularly when many members of the public may not understand that compounded products are not FDA-approved. and
3. Regulators' lack of capacity to oversee the companies marketing, making, shipping and selling these products.

Rather than sanctioning the distribution of these peptides without adequate evidence, we suggest that the FDA:

- Encourage companies in this space to invest in clinical trials to develop the evidence necessary to meet FDA's standards for approval and dedicate experienced FDA staff to ensure fast, accurate assessment,

[1] July 23-24, 2026: Meeting of the Pharmacy Compounding Advisory Committee (PCAC), https://www.fda.gov/advisory-committees/advisory-committee-calendar/july-23-24-2026-meeting-pharmacy-compounding-advisory-committee-07232026.

- Strengthen the agency's enforcement capacity to better control the black market for these products and limit illegal importation, and
- Secure the compounding supply chain by increasing regulation of 503A pharmacies by requiring them to report production volume and adverse events to federal authorities.

Legal Framework: The 503A Bulks List Standard

Section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes licensed pharmacists and physicians to compound medicines without FDA approval under specified conditions. One of these conditions relates to what bulk substances are appropriate to compound. Relevant here, the statute permits 503A compounders to compound from bulk drug substances that "appear on a list developed by the Secretary through regulations" (the 503A Bulks List). To appear on the 503A Bulks List, a nominated bulk drug substance must satisfy the criteria set forth in 21 U.S.C. §353a(b)(1)(A)(i), as interpreted through FDA guidance and prior PCAC deliberations.

Specifically, FDA evaluates whether the nominated substance:

- Presents a clinical need that cannot be met by an FDA-approved product;
- Has a sufficient base of evidence to support a reasonable expectation of safety and efficacy for the proposed use; and
- Can be compounded in a manner that does not present undue patient safety risks, including risks arising from the quality and purity of the API.

The seven substances before the PCAC fail to satisfy these criteria. In each case, the evidentiary record is dominated by animal studies, in vitro data, or foreign clinical trials conducted outside of FDA-recognized frameworks and with several methodological deficiences – none of which provides adequate assurance that these substances are safe and effective for use in human beings. FDA has previously declined[2] and continues to recommend against the addition of each of these substances to the 503A Bulks List on these grounds.[3]

The Clinical Evidence Does Not Support Inclusion of Any of the Seven Substances

FDA has reviewed all of the substances and has recommend to the PCAC that the evidence weighs against including these substances to the 503A Bulks List. PSM has reviewed the published scientific literature for each of the seven substances under consideration and agrees.

[2] FDA's prior declinations are documented at: FDA, Certain Bulk Drug Substances for Use in Compounding May Present Significant Safety Risks, https://www.fda.gov/drugs/human-drug-compounding/certain-bulk-drug-substances-use-compounding-may-present-significant-safety-risks.

[3] Per briefing documents at: July 23-24, 2026: Meeting of the PCAC, https://www.fda.gov/advisory-committees/advisory-committee-calendar/july-23-24-2026-meeting-pharmacy-compounding-advisory-committee-07232026#event-materials.

The table below summarizes the state of human evidence and key safety concerns for each substance.[4] See appendix A for a more detailed discussion about each substance.

Substance	Proposed Use	State of Human Evidence	Key Concerns
BPC-157	Ulcerative colitis	Fewer than 36 human subjects across 3 studies; all other evidence from animal models.	API purity concerns; FDA previously declined and continues to recommend exclusion.
KPV	Wound healing; inflammatory conditions	Anti-inflammatory properties demonstrated in animal and in vitro human cell studies only; no live human trials.	No human exposure data; FDA previously declined and continues to recommend exclusion.
TB-500	Wound healing	Parent compound thymosin beta-4 evaluated in small trials; TB-500 itself tested for tolerance/toxicity only in one human trial.	API purity concerns; FDA previously declined and continues to recommend exclusion.
MOTs-C	Obesity; osteoporosis	No effective clinical protocol developed; one ongoing prediabetes trial with no results reported.	No human data; risk of substitution for approved GLP-1 therapies; FDA previously declined and continues to recommend exclusion.
Emideltide (DSIP)	Opioid withdrawal; insomnia; narcolepsy	Small human trials in 1980s-90s; never approved anywhere.	API purity concerns; four-decade absence of follow-on development; FDA previously declined and continues to recommend exclusion.
Semax	Cerebral ischemia; migraine; trigeminal neuralgia	Human data limited to inadequate studies conducted abroad and not under IND	FDA previously declined and continues to recommend exclusion.
Epitalon	Insomnia	Human data limited to inadequate studies conducted abroad and not under IND	FDA previously declined and continues to recommend exclusion.

Public Health and Enforcement Challenges

Independent of whether these substances meet the formal criteria for inclusion on the 503A Bulks List, PSM believes that authorizing their compounding will exacerbate existing public health and enforcement concerns and undercut FDA's role protecting Americans.

[4] FDA's prior declinations, supra note 2; July 23-24, 2026: Meeting of the PCAC, supra note 3.

Approving these peptides for compounding will mislead the U.S. public about their efficacy and safety

U.S. consumers already struggle to distinguish between the likely efficacy and relative safety of FDA-approved medications, lawful compounding derived from FDA-approved drugs, legal compounding for which there is no FDA-approved product, and chemicals sourced from the gray market or labeled for research use only. They also struggle to identify safe sources for these medicines. In a 2025 survey of 1,500 U.S. adults, 65% of respondents falsely believed all websites offering online medicines and health services are reviewed or approved by FDA or state regulators and 57% of the GLP-1 users among the participants believed that compounded and generic medicines were the same thing.[5]

As Jimmie Wilson, a woman who suffered liver failure after being treated with a legal, compounded GLP-1, pointed out in a March 2026 editorial, misunderstandings like these lead patients to take medicines with no clear understanding of the relative risks involved: “What I didn’t know is that compounded drugs and name-brand drugs are not the same. I made the choice to use a compounded drug because I was told it would be cheaper. I was unaware of the trade-offs.”[6]

It isn’t just Ms. Wilson: Australian[7] and U.K. authorities are reporting that patients taking unapproved versions of the peptide-based drug retatrutide have developed liver failure, including one fatality.[8] People all over the world and in the U.S. are taking black market “reta” because they believe that it will inevitably be approved by the FDA. They are unaware of the risks they are facing and falsely believe that all retatrutide, no matter who makes it, is the same.

This misunderstanding of how medicine is made and the FDA’s role, shows there are significant public health risks in exposing American patients to mass compounding of unapproved **peptides**.

If the FDA allows 503A pharmacies to compound these peptides, American patients will interpret their availability as evidence that they are regulated and safe, even though the agency’s own staff cannot confirm their safety or effectiveness and, indeed, have concluded that the available evidence weighs against their inclusion on the 503A Bulks List. Such a decision will endanger Americans and contradict the agency's mission to safeguard and improve public health.

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[5] ASOP Global Foundation 2025 U.S. Consumer Behavior Survey, https://asopfoundation.pharmacy/wp-content/uploads/2025/11/ASOP-Foundation-2025-Consumer-Behavior-Survey.pdf
[6] WIlson, Jimmie, “How risky can the weight-loss drug boom be? I learned the hard way,” Washington Post, March 31, 2026, https://www.washingtonpost.com/opinions/2026/03/31/weight-loss-compounding-pharmacies/.
[7] “Warning issued over counterfeit weight-loss drugs labelled as retatrutide,” Australian Broadcasting Corporation, June 19, 2026, https://www.abc.net.au/news/2026-06-20/liver-failure-fake-retatrutide-health-risk/106814372.
[8] “Warning as man dies after taking unapproved weight-loss drug 'Reta' - and 76 others injured,” Daily Mail, June 30, 2026, https://www.msn.com/en-xl/news/other/warning-as-man-dies-after-taking-unapproved-weight-loss-drug-reta-and-76-others-injured/ar-AA26T1PL

Adding unapproved peptides to the bulks list will intensify regulatory challenges for the FDA and Customs and Border Protection.

The compounded GLP-1 market has exacerbated regulatory challenges associated with compounding pharmacies and the telehealth industry and offers insight into future problems with a compounded peptide market. Over the last five years, it has become clear that:

- **Not all compounding pharmacies are using legal API.**

  FDA warning letters to 503A compounders in Colorado[9] and Michigan[10] and inspections records in California[11] and Michigan[12] make it clear that compounders are not always using pharmaceutical-grade API from registered facilities. A company that supplies compounding facilities was also caught selling API from unregistered facilities, as well as as-yet-unapproved retatrutide.[13]

  Even when FDA catches these violations, it doesn't license these pharmacies, so it often relies on state boards of pharmacy for disciplinary action, which leads to uneven response, as pharmacy boards' resources and authority vary widely between states.

- **Not all compounding pharmacies are confining themselves to legal products.**

  Public announcements by telehealth companies about the source of their products[14] show that compounding pharmacies continued to make GLP-1 products despite the agency's declaration that semaglutide and tirzepatide were no longer in shortages in 2025.[15] **Others continue to supply the drugs[16] even after FDA's April 1 clarification, which should have ended almost all compounding of these products.[17]**

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[9] Warning letter, Belmar Pharma Solutions, Drug Depot, LLC., dba APS Pharmacy, March 31, 2023, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/belmar-pharma-solutions-drug-depot-llc-dba-aps-pharmacy-653740-03312023.
[10] Warning letter, Pharmaceutical Care Solutions dba Pharmacy Solutions, August 02, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/pharmaceutical-care-solutions-dba-pharmacy-solutions-610201-08022021.
[11] Form 483, Lynn Oaks Compounding Pharmacy, April 15, 2022, https://www.fda.gov/media/163497/download.
[12] Form 483, SNF Holdings, March 2, 2023, https://web.archive.org/web/20250226232131/https://www.fda.gov/media/172442/download.
[13] Warning letter, Darmerica, LLC, December 08, 2025, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/darmerica-llc-716152-12082025.
[14] Fifty410 email -- no longer selling ProRX, April 2026, https://www.reddit.com/r/compoundedtirzepatide/comments/1sg3vck/fifty410_email_no_longer_selling_prorx/; BPI stopping production of Compounded Tirzepatide, April 2026, https://www.reddit.com/r/gimmecare/comments/1sspll6/bpi_stopping_production_of_compounded_tirzepatide/.
[15] FDA clarifies policies for compounders as national GLP-1 supply begins to stabilize, last updated April 1, 2026: https://www.fda.gov/drugs/drug-alerts-and-statements/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.
[16]See, among many examples, https://greenwichrx.net/#weight-loss and https://hallandalerx.com/products/?_product_categories=weight-management.
[17] FDA clarifies policies, supra note 17.

- **Customs and FDA are unable to stop shipments of illegal compounding supplies at the border.**

  Between January 1 and March 31, 2026, FDA freight shipment data identified 127 shipments of peptides classified as "peptides n.e.c." (not elsewhere classified) entering U.S. ports. 50 of these shipments (approximately 39%) originated from manufacturers operating entirely outside of FDA oversight, lacking both facility inspections and explicit authorization to import drugs into the United States. The PCAC substances under review were represented in this problematic supply chain.

Peptide	Shipments (Q1 2026)	Countries of Origin	Border Refusal Rate
BPC-157	6	U.S., Canada, China	33%
Epitalon	2	Australia	100%
TB-500 (combined w/ BPC-157)	1	Canada	0%

The visible import data represents a floor, not a ceiling, as ITACS records only reflect declared legal imports and don't capture smuggled materials, misdeclared shipments, or domestically synthesized research chemicals. The independent confirmation organization ISMP/ECRI has also documented the absence of verifiable supply chain integrity for peptide compounds,[18] and FDA enforcement actions and Department of Justice (DOJ) prosecutions confirm that this pattern of unlawful importation has resulted in patient harm.[19]

503As and telehealth companies continue to engage in misleading and unlawful compounding despite FDA enforcement

Much of the illegal compounding activity is happening at the behest of telehealth companies exploiting the weight loss and wellness market. The FDA has posted over a hundred warning letters sent to telehealth companies since September 2025.[20] They typically involve the illegal sale of unapproved weight loss injectables[21] or false claims about compounded semaglutide or tirzepatide being clinically the same as FDA-

[18] ISMP/ECRI, Peptide Compounds – White Paper Based on CEA, https://assets.ecri.org/PDF/Peptide%20Compounds%20-%20White%20Paper%20Based%20on%20CEA.pdf.
[19] FDA Warning Letter, Darmerica LLC, supra note 15; U.S. Dep't of Justice, "Nicholasville Compounding Pharmacy and Its Owner Plead Guilty to Unlawful Distribution," https://www.justice.gov/usao-edky/pr/nicholasville-compounding-pharmacy-and-its-owner-plead-guilty-unlawful-distribution.
[20] FDA's posted warning letters to telehealth companies can be found by searching "telehealth' here: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.
[21] Warning letter, MedClub by Dr. Jenn, September 09, 2025 https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/medclub-dr-jenn-712126-09092025

approved medicines.[22]

Traditional enforcement tools FDA has used with manufacturers of FDA-approved drugs often have not worked with telehealth companies and 503A compounding pharmacies, neither of which see the FDA as their front line regulator. While 503As are accountable to state boards that can revoke their licenses, telehealth companies do not appear to see themselves as clearly accountable to any specific regulator.

The Available Evidence Weight Against Adding These Peptides to the 503A Bulks List

Supporters of adding these seven peptides to 503A bulks list have suggested that creating a legal path to acquire these substances would create a safe supply chain and discourage buyers from turning to the black market. PSM believes that the benefits of a regulated market don't outweigh the risks. We also underscore that compounded products are subject to significantly less regulation than FDA-approved drugs.

- **No standards for these peptides:** According to FDA's briefing documents, these substances are not well-enough characterized to define manufacturing standards, making it difficult to distinguish legitimate products from the black market.[23]

- **False clinical legitimacy conveyed by any addition to the 503A Bulk List:** Briefing documents also assert a paucity of clinical knowledge determining whether these substances are safe or effective. Consumers may see FDA's action as a sign of legitimacy, but adding these substances to the 503A Bulks List essentially makes the American public subjects of a large, uncontrolled human trial.

- **No mechanism for monitoring patient harm**: Because there is no federal requirement for 503A pharmacies to report adverse events, federal regulators will have no insight into whether these peptides are harming people.

- **Americans often can't differentiate legal from illegal dispensers:** Data about prescription drug purchasing practices casts doubt about whether U.S. consumers will distinguish between legitimate and black market sellers: a 2025 survey found that only 39% of consumers used an official source to verify the license of an online pharmacy before ordering. Although 73% of respondents felt it was important to buy medicines from a U.S. licensed pharmacy, 59% of them purchased medicines shipped from or intended for sale outside the U.S. anyway.[24]

[22] Warning letter, NativeMed LLC dba NativeMed, June 08, 2026, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/nativemed-llc-dba-nativemed-728287-06082026
[23] Per briefing documents at: July 23-24, 2026: Meeting of the PCAC, supra note 3.
[24] ASOP survey, supra note 7.

- **Existing illegal import stream already straining capacity:** As noted above, the FDA freight data shows that FDA and CBP are already struggling to stop illegitimate peptides from entering the country. The increased volume of peptide shipments that would result if these substances were added to the 503A Bulks List would further strain agency resources.

- **Legal operators will be dragged down by illegal operators**: The example of cannabis legalization in several states suggests that legalizing these peptides won't eliminate the black market without vigorous enforcement - enforcement the FDA is not currently resourced to execute. Although California legalized recreational marijuana in 2016, black market growers are estimated to produce eight times more of the drug than legal sellers.[25]

- **Allowing new substances to come to the market as compounded products first undermines the FDA approval system**: Legitimizing substances without clinical data undercuts the economic model that motivates companies to invest in drug trials as well as undercutting the public's faith in FDA-approval. Adding these peptides to the Bulks List will create a permanently less safe supply chain of compounded products with no clinical safety or efficacy data that will compete with potential future FDA-approved medicines and, more broadly, discourage investment in the research and development necessary to obtain FDA approval.

Conclusion

The seven bulk drug substances before the PCAC share a common profile: limited or no adequate human clinical trials, a history of FDA declinations, unresolved concerns about API purity and supply chain integrity, and ongoing import patterns that reflect significant regulatory noncompliance. Under these circumstances, there is no scientifically supportable basis for recommending their addition to the 503A Bulks List.

PSM respectfully urges the Committee to recommend against inclusion of BPC-157, KPV, TB-500, MOTs-C, Emideltide (DSIP), Semax, and Epitalon on the 503A Bulks List. As FDA itself has noted in briefing documents, the evidence weighs against inclusion of all of these substances on the 503A Bulks List.

In addition, adding these bulk drug substances to the 503A bulks list will add troubling weight on regulators already straining to oversee the telehealth and compounding industries, and threaten public health.

The purpose of the 503A Bulks List is not to serve a mechanism for legitimizing the distribution of substances with no clinical data and whose safety and efficacy in human beings remain

[25] Stringer, Grant, "Prop. 64 at 10: Why the illicit cannabis market still dominates in California," Mercury News, April 16, 2026, https://www.mercurynews.com/2026/04/16/prop-64-at-10-why-the-illicit-cannabis-market-still-dominates/.

unknown. PSM stands ready to work with FDA, the PCAC, and other stakeholders to ensure that compounding serves its intended, limited function: filling genuine clinical gaps when an FDA-approved medicine is not available.

Sincerely,

Shabbir Safdar
Executive Director
The Partnership for Safe Medicines

Appendix A

1. BPC-157

BPC-157 is proposed for compounding for the treatment of ulcerative colitis. Systematic reviews published in July and August 2025 indicate that BPC-157 shows some promise in animal models for musculoskeletal recovery and gastrointestinal healing.[26] However, the aggregate human evidence consists of fewer than 36 subjects across three studies: a 16-subject knee injection study, a 12-patient bladder injection study, and a 2-subject infusion study. This body of evidence is wholly insufficient to support a finding that BPC-157 is safe and effective for ulcerative colitis or any other human indication.

FDA declined to add BPC-157 to the 503A Bulks List in the past,[27] and maintains that stance in briefing materials for the July 2026 meeting, citing poor chemical characterization, a lack of information about safety profile and immunogenicity risks, and insufficient evidence of effectiveness.[28] BPC-157 is also classified as a prohibited substance by the World Anti-Doping Agency (WADA), a designation that reflects international scientific consensus regarding its uncharacterized risks.[29] PSM is aware of no new evidence that would justify a different outcome at this meeting.

2. KPV

KPV is proposed for wound healing and inflammatory conditions. The published literature establishes that KPV has anti-inflammatory properties in animal models and in vitro human cell studies.[30] However, no controlled trials in live human subjects have been conducted. As FDA previously noted in declining to add KPV to the 503A Bulks List[31] and continues to note in current guidance,[32] the absence of human exposure data is a disqualifying gap. Anti-inflammatory properties demonstrated in cell cultures do not establish that a compound is safe, appropriately dosed, or risk-free when administered to human patients.

3. TB-500

TB-500 is proposed for wound healing. TB-500 is a synthetic fragment of thymosin beta-4. The parent compound has been evaluated in small clinical trials for dry eye, venous ulcers, and

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[26] Systematic review, PubMed PMID 40756949 (July 2025), https://pubmed.ncbi.nlm.nih.gov/40756949/; Systematic review, PMC12446177 (August 2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12446177/.
[27] Operation Supplement Safety, "BPC-157: Prohibited Peptide and Unapproved Drug Found in Health and Wellness Products," https://www.opss.org/article/bpc-157-prohibited-peptide-and-unapproved-drug-found-health-and-wellness-products.
[28] FDA Briefing Document, PCAC Meeting July 23 - 24, 2026 BPC-157 – Related Bulk Drug Substances, https://www.fda.gov/media/193343/download.
[29] U.S. Anti-Doping Agency, supra note 5.
[30] Brzoska T. et al., PMC2431115, https://pmc.ncbi.nlm.nih.gov/articles/PMC2431115/; Bhatt D. et al., PMC5498804, https://pmc.ncbi.nlm.nih.gov/articles/PMC5498804/; ScienceDirect 2025, https://www.sciencedirect.com/science/article/abs/pii/S004081662500117X.
[31] FDA prior declination on KPV, supra note 2.
[32] FDA Briefing Document, PCAC Meeting, July 23 - 24, 2026, KPV–Related Bulk Drug Substances, https://www.fda.gov/media/193346/download.

cardiac injury.[33] However, TB-500 itself has been the subject of only a single human trial – a tolerance and toxicity study, not a study of clinical efficacy.[34] The existence of parent-compound trials does not establish that the fragment shares its therapeutic properties or safety profile.

Like BPC-157, TB-500 is banned in sports by WADA.[35] FDA previously declined to add it to the 503A Bulks List[36] and continues to recommend its exclusion.[37] PSM finds no basis in the current evidence to support reaching a different conclusion now.

4. MOTs-C

MOTs-C is proposed for obesity and osteoporosis. The published literature acknowledges that MOTs-c has demonstrated effects on glucose metabolism in skeletal muscle in preclinical models, but a 2023 review in *Frontiers in Endocrinology* concluded that no effective method of applying MOTs-c in clinical practice has been developed.[38] A clinical trial evaluating its use in prediabetes is underway but has not reported results.[39]

PSM notes with particular concern the proposed indication of obesity. Approved, FDA-regulated therapies for obesity, including semaglutide and tirzepatide, are the product of decades of rigorous clinical development. Adding MOTs-C to the 503A Bulks List would enable compounders to market an unapproved, untested alternative to patients who may forgo or delay access to proven therapies. This substitution risk presents a concrete and foreseeable patient harm that the PCAC must weigh heavily. FDA previously declined to add MOTs-C to the 503A Bulks List[40] and continues to recommend its exclusion.[41] PSM finds no supporting evidence to support reaching a different conclusion at this time.

5. Emideltide (DSIP)

Emideltide (delta sleep-inducing peptide, or DSIP) is proposed for opioid withdrawal, chronic insomnia, and narcolepsy. Small human trials were conducted in the 1980s and 1990s for insomnia and drug withdrawal.[42] However, no regulatory body anywhere in the world approved DSIP after these trials, which reflects an unfavorable assessment by the scientific and regulatory community. The absence of subsequent development over four decades is not an

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[33] Thymosin beta-4 dry eye trial, PubMed PMID 25826322, https://pubmed.ncbi.nlm.nih.gov/25826322/; venous ulcer trial, PMID 17495250, https://pubmed.ncbi.nlm.nih.gov/17495250/; cardiac trial, PMID 41490200, https://pubmed.ncbi.nlm.nih.gov/41490200/.
[34] TB-500 human tolerance and toxicity trial, PMC13095733, https://pmc.ncbi.nlm.nih.gov/articles/PMC13095733/.
[35] Banned Substances Control Group, supra note 6.
[36] FDA prior declination on TB-500, supra note 2.
[37] FDA Briefing Document, PCAC Meeting, July 23 - 24, 2026, TB-500-Related Bulk Drug Substances, https://www.fda.gov/media/193349/download.
[38] Ding Y. et al., "MOTS-c: A promising target for disease treatment and prevention," Front Endocrinol (Lausanne). 2023 Jan 25;14:1120533. doi: 10.3389/fendo.2023.1120533.
[39] ClinicalTrials.gov, NCT07505745, https://clinicaltrials.gov/study/NCT07505745.
[40] FDA prior declination on MOTs-C, supra note 2.
[41] FDA Briefing Document, PCAC Meeting, July 23 - 24, 2026, MOTS-c-Related Bulk Drug Substances, https://www.fda.gov/media/193347/download.
[42] DSIP insomnia trial (1984), PubMed PMID 6391926, https://pubmed.ncbi.nlm.nih.gov/6391926/; DSIP drug withdrawal trial (1984), PMID 6548969, https://pubmed.ncbi.nlm.nih.gov/6548969/.

oversight. It indicates that the evidence did not support continued pursuit of approval, supporting FDA's previous decision[43] and current recommendation[44] to decline adding DSIP to the 503A Bulks List.

6. Semax

Semax is proposed for cerebral ischemia, migraine, and trigeminal neuralgia. Semax is approved for stroke and neurological conditions in Russia.[45] PSM respectfully submits that a foreign regulatory approval – particularly one issued by a regulatory authority that does not operate under FDA's standards for clinical evidence, manufacturing oversight, or product quality – does not constitute adequate demonstration of safety and efficacy for purposes of the 503A Bulks List. The PCAC must evaluate Semax against the same evidentiary standards it applies to all other nominated substances. Under that standard, Semax fails because there are no FDA-recognized adequate and well-controlled clinical trials.FDA has previously declined to add it to the 503A Bulks List[46] and continues to recommend its exclusion.[47]

7. Epitalon

Epitalon is proposed for insomnia. Human trials examining the peptide's effects on longevity, sleep quality, and eye health have been conducted in Russia and Ukraine.[48] For the same reasons as for Semax, PSM does not consider these trials adequate evidence of safety and efficacy under the applicable standard. Clinical research conducted outside the framework of ICH-harmonized Good Clinical Practice guidelines, without FDA oversight, and in regulatory environments that differ materially from U.S. standards does not provide the assurance of reliability that FDA's framework requires. Rather, it supports FDA's previous decision[49] and current recommendation to decline adding Epitalon to the 503A Bulks List.[50]

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[43] FDA prior declination on Emideltide/DSIP, supra note 2.
[44] https://www.fda.gov/media/193344/download
[45] Semax approval and clinical research in Russia, PMC13164565, https://pmc.ncbi.nlm.nih.gov/articles/PMC13164565/.
[46] FDA prior declination on Semax, supra note 2.
[47] FDA Briefing Document, PCAC Meeting, July 23 - 24, 2026, Semax – Related Bulk Drug Substances https://www.fda.gov/media/193348/download.
[48] Epitalon human trials (longevity, sleep quality, eye health), PMC11943447, https://pmc.ncbi.nlm.nih.gov/articles/PMC11943447/.
[49] FDA prior declination on Epitalon, supra note 2.
[50] FDA Briefing Document, PCAC Meeting, July 23 - 24, 2026, Epitalon-Related Bulk Drug Substances https://www.fda.gov/media/193345/download