ASOP GLOBAL | ALLIANCE FOR SAFE ONLINE PHARMACIES

July 22, 2026

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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

To Whom It May Concern:

The Alliance for Safe Online Pharmacies Global (ASOP Global) respectfully submits these comments in response to the Food and Drug Administration's ("FDA") notice regarding whether certain peptide bulk drug substances should be included on the section 503A Bulk Drug Substances List ("503A Bulks List"), including the seven substances scheduled for review at the Pharmacy Compounding Advisory Committee ("PCAC") meeting on July 23–24, 2026: BPC-157, KPV, TB-500, MOTS-c, emideltide (DSIP), Semax, and Epitalon.

Founded in 2009, ASOP Global is a 501(c)(4) nonprofit organization dedicated to protecting patients from illegal online drug sellers and ensuring access to safe, legitimate online pharmacies. ASOP Global works to make the internet safer for patients through research, education, advocacy, and collaboration. With chapters in the US, Europe, and Canada, ASOP Global's members span the patient safety, pharmacy, provider, academic, technology, manufacturing, payment, and internet-security communities, all sharing a common commitment to patient safety online.

Given our mission – to protect patients from illegal and unsafe medicines sold online – ASOP Global uniquely appreciates the harm reduction arguments made by stakeholder, in sum: it'd be better to allow patient access to unproven products through regulation than to risk patients continuing to buy them from gray markets sellers and the unregulated internet. But this presents a false dichotomy.

The question is not whether it's safer for patients to buy unproven, unsafe products from a supply chain that FDA and states will try to regulate, instead of the current gray market. The question is instead what must FDA, states, law enforcement, and the private sector do to enforce existing laws and standards of safety and science, so that patients can trust the medicines they buy online are safe and effective?

Said another way, FDA's decision on these peptides must be driven by legal and ethical standards of science and safety, not influenced by the failure of the existing enforcement and private sector ecosystem to stop the gray market sales of unauthorized and unsafe peptides on the internet. These are different questions. The issue before the FDA in this docket is only about the science and safety of each product up for consideration. Accordingly, ASOP will focus our comments on the issue at hand, though we have many ideas for how to curb the rampant online sale of unapproved and unsafe medicine.

Based on the scientific record (or lack thereof) for these seven peptides, **ASOP Global urges FDA and the PCAC to recommend against adding the nominated peptide substances to the 503A Bulks List.** The

evidence available for these substances remains insufficient to establish human safety, effectiveness, product quality, appropriate dosing, supply chain integrity, or workable post-market oversight at the scale that listing would predictably entail. The agency should not treat consumer demand, black-market activity, or the commercial readiness of telehealth platforms and other businesses as a substitute for the rigorous scientific and regulatory standards that ordinarily govern prescription drug access. Specific recommendations follow in Section IV below.

I. The Online Peptide Market Presents Serious Safety and Enforcement Risks

While we understand one of the arguments for adding these peptides to the 503A Bulks List is to create a regulated environment for patient access, reducing the demand from gray market sellers. This is wishful thinking, akin to presuming that the creation of iTunes drove demand away from Napster (an early 2000's illegal music streaming service). True, some patients (just like some consumers in the 2000's), will be drawn to the highly regulated market, but the mere fact that a regulated market exists does not mean that patients will automatically only buy there. In Napster's case, it took strong enforcement actions and legal repercussions to move everyday consumers away from the gray market into the lawful (iTunes, then others) market. [1] [2] Here too, if FDA creates a lawful pathway for these peptides to be compounded, such action must be paired with strong, meaningful enforcement of the illegal market.

As ASOP Global Foundation's data shows, patients are lured by price and convenience.[3] Where a regulated market exists but is more expensive and harder to access (a foreseeable consequence of regulation, which increases compliance costs and adds friction to an otherwise frictionless internet marketplace), patients will still be lured into buying from illegal, unsafe sources.[4] Absent any meaningful enforcement over the gray and black market online sellers, merely creating an authorized market without new guardrails will not improve patient safety. Worse, it will give bad actors the guise of legitimacy - the easy ability to claim to be compliant to attract patients interested in the new "FDA authorized unapproved peptide market."

Online pharmacies, telemedicine platforms, direct-to-consumer health services, social media channels, marketplaces, and standalone websites are now common ways for patients to acquire prescription medicines, but illegal sellers exploit those same channels to sell counterfeit, misbranded, unapproved, and otherwise unsafe drugs. Numerous websites market peptides under labels such as "research use only" or "not for human consumption" while simultaneously targeting consumers with claims about weight loss, muscle recovery, anti-aging, wound healing, and cognitive enhancement. These disclaimers do not insulate sellers from FDA enforcement: FDA has repeatedly determined that the totality of a seller's marketing, labeling, and promotional claims can establish intended human drug use regardless of pro forma research-only language. [5]

Our concerns are further exacerbated by the existing market, foreign, anonymous, and unknown sellers. Consumers have no way to know where the products came from, whether they were tested, how they

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[1] Raine, L. et al. (2004), Pew Research Center. *14 of Internet users say they no longer download music files*. Available at: https://www.pewresearch.org/internet/2004/04/25/14-of-internet-users-say-they-no-longer-download-music-files/

[2] Forde, E. (2019), The Guardian. *Oversharing: how Napster nearly killed the music industry*. Available at: https://www.theguardian.com/music/2019/may/31/napster-twenty-years-music-revolution

[3] ASOP Global Foundation. *2025 Consumer Behavior and Perception Survey*. Available at: ASOP-Foundation-2025-Consumer-Behavior-Survey.pdf

[4] National Association of Boards of Pharmacy (2024). *RogueRx Activity Report: Injectable Weight Loss Drugs: How Illegal Online Drug Sellers are Taking Advantage of Patients.* Available at: https://nabp.pharmacy/wp-content/uploads/2024/04/RogueRx-Activity-Report-Injectable-Weight-Loss-Drugs-2024.pdf

[5] *Id.*

were handled, or whether there is any meaningful recourse if harmed. Of particular concern, bad actors historically involved in the illegal sale of fentanyl and fentanyl precursors have now expanded into the peptide market, and US consumers are buying them. [6]

According to the ASOP Global Foundation's 2025 U.S. Consumer Behavior Survey, 38% of U.S. adults report purchasing prescription medicines online, 73% of those purchasers began doing so within the past three years, and 55% now buy all or most of their prescriptions online.[7] Notably, 19% of online prescription purchasers report having purchased peptides, and 11% report purchasing products labeled "for research purposes only".[8] Notably, 27% of online purchasers report receiving counterfeit or substandard medicine, or being harmed by medicine purchased online, and 65% of U.S. adults falsely believe that all websites offering online prescription or health services have been reviewed or approved by FDA or state regulators.[9]

The peptide and GLP-1 markets illustrate how these misunderstandings converge. Among consumers who purchased GLP-1 medications online, the same survey found that 68% reported purchasing peptide GLP-1 drugs and 56% reported purchasing GLP-1 drugs marketed "for research purposes only".[10] These purchasers also reported using higher-risk sources at meaningful rates, including online international pharmacies, online compounding pharmacies, wellness clinics and med-spas, and social media and messaging apps.[11]

The National Association of Boards of Pharmacy's (NABP) 2024 RogueRx Activity Report found illegal sellers advertise drug products as "peptides," claim they are "for research purposes only" or "not for human consumption," and deliver lyophilized powder that patients must reconstitute themselves with bacteriostatic water.[12] NABP further reports that these sellers historically offered investigational new drugs, unapproved drugs to bodybuilders, but have expanded with the advancement and popularity of GLP-1 agonists such as semaglutide and tirzepatide being added to their catalogs, using altered names, misspellings, marketplaces, and social media to evade detection.[13]

FDA's own enforcement record documents the scope of the problem. In February 2024, FDA warned US Chem Labs that its "Semaglutide," "Tirzepatide," and "Thymalin" products were unapproved and misbranded drugs, notwithstanding "research chemicals only" labeling.[14] The same month, FDA issued a warning letter to Synthetix Inc. d/b/a Helix Chemical Supply for selling "Semaglutide" and "Tirzepatide" products online as unapproved new drugs.[15] In December 2024, FDA warned Summit Research Peptides after observing online offers of "Semaglutide," "Retatrutide," "Cagrilintide," "Tirzepatide," and

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[6] Reed, T. (2026), Axios. *Chinese fentanyl makers find new U.S. market in peptides*. Available at: https://www.axios.com/2026/07/07/chinese-fentanyl-makers-pivot-peptides

[7] ASOP Global Foundation. *2025 Consumer Behavior and Perception Survey*. Available at: ASOP-Foundation-2025-Consumer-Behavior-Survey.pdf

[8] *Id*

[9] *Id*

[10] *Id*

[11] *Id*

[12] National Association of Attorneys General (2025) *State and Territory Attorneys General Urge FDA to Take Action Against Counterfeit and Illegally Sold GLP-1 Drugs*, NAAG. Washington, D.C., 19 February. Available at: https://www.naag.org/policy-letter/state-and-territory-attorneys-general-urge-fda-to-take-action-against-counterfeit-and-illegally-sold-glp-1-drugs/

[13] *Id*

[14] U.S. Food & Drug Administration, Warning Letter to US Chem Labs, MARCS-CMS 669074 (Feb. 7, 2024). Available at: fda.gov

[15] U.S. Food & Drug Administration, Warning Letter to Helix Chemical Supply, MARCS-CMS 668918(Feb. 7, 2024). Available at: fda.gov

"Mazdutide" products for sale in the United States.[16] In February 2025, FDA warned USApeptide.com for introducing unapproved and misbranded semaglutide and tirzepatide drug products into interstate commerce.[17] In March 2026, FDA issued a warning letter to Gram Peptides for online offers of "Retatrutide,", "Tirzepatide,", and bacteriostatic water for injection.[18] FDA itself has cautioned that unapproved versions of these drugs do not undergo the agency's review for safety, effectiveness, and quality, and has warned that patients who obtain them face risks including contamination, incorrect dosing, and variable or absent active ingredients. Despite these enforcement actions, the problem continues to grow.

These practices are not isolated marketing problems; they are patient-safety problems. Patients who obtain peptides through illegal online channels may receive products of unknown identity, purity, potency, sterility, or source, and they may self-administer injectable products without reliable medical supervision, dosing instructions, or adverse-event monitoring. FDA should evaluate the nominated substances against this foreseeable real-world market — not solely against narrow nominated uses or idealized assumptions about lawful, individualized compounding.

Recent criminal and civil enforcement actions confirm that this is not merely a labeling or marketing problem; a Southern District of New York conviction for a fake online pharmacy enterprise that shipped over one million fentanyl-laced pills and caused the death of a U.S. Army veteran, a $600 million resolution with Alibaba for failing to prevent illegal pharmaceutical sales on its platform, and a Massachusetts sentencing for a years-long scheme importing misbranded drugs from China—demonstrate that illegal online pharmaceutical distribution poses lethal public health risks at enormous scale. [19] [20] [21] The FDA's Office of Criminal Investigations played a central role in all three matters, yet the relatively modest penalties available under the FDCA in non-fatal cases remain insufficient to deter gray market schemes.

Strengthened criminal enforcement authority and enhanced FDCA penalties are needed to address the full spectrum of illegal pharmaceutical activity, including the growing misuse of peptides sold through unregulated online channels without adequate labeling, safety testing, or prescriber oversight. Consumers cannot reliably distinguish regulated compounding pharmacies from illicit online sources, and that burden should not fall on them. FDA must deploy its full enforcement authority—including criminal investigation and prosecution—rather than rely to supply-chain regulation and set a dangerous precedent for all regulated products.

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[16] U.S. Food & Drug Administration, Warning Letter to Summit Research Peptides, MARCS-CMS 695607 (Dec. 10, 2024). Available at: fda.gov

[17] U.S. Food & Drug Administration, Warning Letter to USApeptide.com, MARCS-CMS 696885 (Feb. 26, 2025). Available at: fda.gov

[18] U.S. Food & Drug Administration, Warning Letter to Gram Peptides, MARCS-CMS 721806 (Mar. 31, 2026). Available at:fda.gov

[19] U.S. Department of Justice, (2026). *Massachusetts Couple Sentenced to Prison for Importing Misbranded Drugs From China and Selling Them to Customers in U.S. for Performance Enhancing Purposes.* Available at: https://www.justice.gov/usao-ma/pr/massachusetts-couple-sentenced-prison-importing-misbranded-drugs-china-and-selling-them

[20] U.S. Department of Justice, (2026). *Alibaba Group and AUS Merchant Services Agree to Pay $600 Million to Resolve Allegations that they Failed to Prevent Illegal Sales of Pharmaceuticals, Pharmaceutical Equipment, and Other Illegal Products.* Available at: https://www.justice.gov/opa/pr/alibaba-group-and-aus-merchant-services-agree-pay-600-million-resolve-allegations-they

[21] U.S. Department of Justice, (2026). *Two Defendants Convicted Of Engaging In A Massive Enterprise To Distribute Fake Pharmaceuticals Online That Resulted In Death.* Available at: https://www.justice.gov/usao-sdny/pr/two-defendants-convicted-engaging-massive-enterprise-distribute-fake-pharmaceuticals

In short, illegal online drug sellers are already pervasive today, e.g. selling unlawful versions of otherwise FDA-approved, commercially available semaglutide and tirzepatide products and offering drugs in the pipeline for FDA approval like retatrutide. [22] [23] [24] Adding new compounded peptides to this mix would add fuel to the already-existing inferno of patient risk online, especially if not paired with new enforcement authorities and resources to take meaningful action against illegal actors.

II. FDA Should Apply the Section 503A(c)(2) Criteria Rigorously, Substance by Substance, and Should Not Act Without Peptide-Specific Evidence

Under section 503A(c)(2) of the FD&C Act and FDA's 2019 final rule on the 503A Bulks List (84 Fed. Reg. 4696), FDA evaluates each nominated bulk drug substance against four criteria: (1) the substance's physical and chemical characterization; (2) any safety issues raised by its use in compounded drug products; (3) the available evidence of effectiveness, if any; and (4) the substance's historical use in compounded drug products, including references in peer-reviewed medical literature. ASOP Global urges FDA and the PCAC to apply these criteria rigorously to each of the seven peptides on the July 2026 agenda — individually, not as an undifferentiated category — and not to treat the demand or commercial momentum of the broader "peptide" market as a substitute for substance-specific evidence.

Evaluation of these peptides requires resolution of key safety issues: the source of the active ingredient, whether adequate testing has been performed, whether identity, purity, and potency have been independently verified rather than accepted solely on the basis of the supplier's certificate of analysis, and whether sterility and stability are adequately supported.

Recent reporting reinforces ASOP's concerns regarding the broad misuse and public consumption of untested and unsafe products. Bloomberg Businessweek reports that many popular peptides, as substances that are not approved by the FDA, are absent from the historical list of ingredients permitted for compounding, and in some cases have "hardly been tested in humans," with unknown long-term safety and side-effect profiles, but are being sold online. [25] That report confirms there are no large-scale human clinical trials proving the safety or effectiveness of most of the compounds expected to come before PCAC, and that PCAC has historically required such evidence before making an affirmative recommendation.[26]

Adding these substances to the 503A Bulks List would also magnify oversight gaps across the online drug ecosystem. Section 503A pharmacies are not subject to the same federal registration, current good manufacturing practice, drug reporting, adverse-event reporting, and inspection framework that applies to 503B outsourcing facilities, and have no comparable federal adverse-event reporting obligation. Without reliable reporting, tracing, and volume information, regulators will be poorly positioned to identify contaminated, substandard, ineffective, or harmful peptide products once they reach patients.

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[22] U.S. Food & Drug Administration (2026). *FDA Intends to Take Action Against Non-FDA Approved GLP-1 Drugs.* Available at: https://www.fda.gov/news-events/press-announcements/fda-intends-take-action-against-non-fda-approved-glp-1-drugs

[23] U.S. Food & Drug Administration (2026). *FDA Warns 30 Telehealth Companies Against Illegal Marketing of Compounded GLP-1s.* Available at: https://www.fda.gov/news-events/press-announcements/fda-warns-30-telehealth-companies-against-illegal-marketing-compounded-glp-1s

[24] Gilbert, D. et al.(2026), CBS News. *This weight-loss drug hasn't been approved by the FDA. Doctors are prescribing it anyway*. Available at: https://www.cbsnews.com/projects/2026/experimental-weight-loss-drug/

[25] Mull, A. et al, (2026). Bloomberg Business. *The Billion Dollar Peptide Gold Rush*. Available at: https://www.bloomberg.com/features/2026-peptide-legalization-gold-rush/

[26] *Id*

The suggestion that 503A listing would reduce black-market use is not sufficient to overcome these evidentiary and oversight gaps: the reporting cited above warns that adding these substances to the 503A Bulks List could make products lacking rigorous scientific backing "much more palatable to the buying public," even though potential side effects may include severe allergic reactions, liver or kidney damage, and accelerated tumor growth.[27] The appropriate response to illegal online peptide sales is targeted enforcement against unlawful sellers, stronger supply-chain controls, and rigorous clinical research — not the premature conversion of inadequately studied substances into broadly available compounded products.

ASOP Global's conclusion is not an outlier view. Other patient-safety and pharmacy-regulatory organizations that have separately reviewed the record before the PCAC — including the National Association of Boards of Pharmacy, the Collaborative for Evidence-Based Medicines, and the Partnership for Safe Medicines., amongst others — have likewise raised substantial concerns regarding the sufficiency of the evidence supporting these nominations.[28,29,30]That convergence of independent assessments, from organizations representing regulators, providers, and patient-safety advocates, should weigh heavily in the Committee's deliberations.

III. Any Listing Would Require Robust, Peptide-Specific Safeguards

For the reasons above, ASOP Global respectfully urges the PCAC to recommend against inclusion of the nominated peptides. If FDA nevertheless proceeds with listing any nominated substance, it should do so only with robust, peptide-specific guardrails addressing product quality, sourcing, prescribing, dispensing, advertising, and postmarket monitoring. These guardrails would not cure present gaps and should not be treated as a substitute for the scientific record required for a 503A listing decision — they are, however, the minimum checks necessary if FDA were to expand access to products that may otherwise be marketed aggressively to consumers who already struggle to distinguish FDA-approved medicines, lawful compounding, unapproved compounded products, and research-use chemicals sold online.

At a minimum, FDA should require: enhanced oversight of 503A pharmacies compounding listed peptides and increased coordination with state boards of pharmacy; specific quality benchmarks for sterile peptide compounding, including testing for identity, purity, potency, sterility, endotoxin, degradation products, aggregation, and peptide-related impurities; and robust API-quality and sourcing controls, including certificates of analysis, supplier qualification, quality testing, and information sufficient to identify the original manufacturer of each peptide bulk substance.

FDA should also work with NABP, state boards of pharmacy, medical boards, state attorneys general, Customs and Border Protection, and other enforcement partners to build a coordinated referral pathway for cross-jurisdictional cases involving compounded peptides, telehealth platforms, online pharmacies, med-spas, marketplaces, and social-media sellers, and should extend its existing enforcement focus on misleading GLP-1 telehealth marketing to compounded peptide products and direct-to-consumer claims that imply FDA approval, generic equivalence, proven efficacy, or clinical safety without adequate evidence.

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[27] *Id*

[28] National Association for Boards of Pharmacy, Comment on Bulk Substances Nominated for Inclusion on the Section 503A Bulk Drug Substances List, *Docket No. FDA-2025-N-6895*

[29] Collaborative for Evidence-Based Medicines (2026). *Comment on Bulk Drug Substances Nominated for Inclusion on the Section 503A Bulk Drug Substances List, Docket No. FDA-2025-N-6895*

[30] Partnership for Safe Medicines (2026). *Comment on Bulk Drug Substances Nominated for Inclusion on the Section 503A Bulk Drug Substances List, Docket No. FDA-2025-N-6895*

Conclusion

ASOP Global appreciates the opportunity to submit comments on Docket No. FDA-2025-N-6895 and to contribute to FDA's and the PCAC's deliberations on peptide bulk drug substances nominated for the section 503A Bulk Drug Substances List. The record before the Committee does not support listing BPC-157, KPV, TB-500, MOTS-c, emideltide (DSIP), Semax, or Epitalon: the evidence remains insufficient to establish safety and effectiveness for human use, the substances present unresolved quality and immunogenicity concerns, and the online peptide market creates foreseeable risks of consumer confusion, diversion, and patient harm.

ASOP Global urges FDA to continue advancing a strong public health framework that combines evidence-based drug review, enforcement against illegal online sellers, supply-chain integrity, international cooperation, intermediary accountability, and patient and provider education— while protecting patients from unlawful actors who exploit the online ecosystem to sell unsafe and unregulated prescription products.

Respectfully submitted,

S. Leigh Verbois, PhD on behalf of the ASOP Global Board of Directors