November 13, 2026

Department of Health and Human Services
Office of the Assistant Secretary for Health
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Docket No. HHS-OASH-2026-0496 | Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances

To Whom It May Concern:

The Alliance for Safe Online Pharmacies Global (ASOP Global) respectfully submits these comments regarding the Department of Health and Human Services' (HHS) Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances.

ASOP Global recognizes the importance of patient access to medically necessary compounded drugs. However, ASOP has substantial concerns regarding the evidentiary record supporting compounding of certain peptide products under consideration by the Food and Drug Administration (FDA) (BPC-157, KPV, TB-500, MOTS-c, emideltide, Semax, and Epitalon) and in particular to expanding access to those compounded peptide products through enforcement discretion. Moving ahead with the enforcement discretion policy without evidence establishing safety or adequate protections to ensure safe use, while doing little to address the unlawful online market that is already exposing consumers to unapproved and potentially unsafe peptide products, puts patients and consumers at risk.

ASOP Global therefore urges HHS to pair any exercise of enforcement discretion with evidentiary support for the use of each covered peptide, meaningful patient safety protections, active surveillance, stronger enforcement against illegal online sellers (including websites, domain registrars, social media platforms, online marketplaces, telehealth operations), and clear public communications distinguishing enforcement discretion from FDA approval or a determination of safety and effectiveness.

I. Enforcement Discretion Is Not a Determination of Safety or Effectiveness

In ASOP Global's July 2026 comments to FDA's Pharmacy Compounding Advisory Committee (PCAC), we raised substantial concerns regarding BPC-157, KPV, TB-500, MOTS-c, emideltide, Semax, and Epitalon, including whether the record sufficiently established human safety, effectiveness, product quality, appropriate dosing, supply-chain integrity, and workable post-market oversight.[1] ASOP Global also urged FDA to apply the four statutory criteria under Section 503A(c)(2) rigorously and individually to each substance, rather than allow consumer demand or commercial momentum surrounding peptides generally to substitute for peptide-specific evidence.

ASOP Global is concerned that an interim enforcement policy could be perceived by patients, providers, telehealth companies, wellness clinics, med-spas, marketers, and online sellers as an affirmative federal determination regarding the covered peptides. That perception would be incorrect, but it is foreseeable.

[1] ASOP Global, Docket No. FDA-2025-N-6895 (2026), Available at: https://buysaferx.pharmacy//wp-content/uploads/2026/07/ASOP-Global-PCAC-Comments-July-2026.pdf

HHS should therefore ensure that communications regarding this policy make unmistakably clear that enforcement discretion does not constitute FDA approval; does not establish that a peptide is safe or effective for any particular use; and does not predetermine whether a substance ultimately qualifies for inclusion on the 503A Bulks List.

II. Expanding Access to Peptides Will Grow the Illegal Online Market

The availability of a limited compounding pathway does nothing to steer patients away from cheaper, readily accessible products already being sold illegally online. When patients and consumers go online, they are likely to encounter illegal online pharmacies selling fake prescription drugs, research-grade peptides, and other substandard, counterfeit, or falsified products. The National Association of Boards of Pharmacy (NABP) found that 95–97% of online drug-selling websites reviewed between 2011 and 2017 violated state or federal laws or pharmacy practice standards.[2] Today, NABP's Not Recommended List includes more than 40,000 website domains associated with unsafe or illegal online drug sales. None of the 40,000 illegal websites is operated by a pharmacy licensed in any U.S. state.[3] Independent 2024 research found that 42 percent of online-pharmacy search results for semaglutide led to illegal sellers and that every product test-purchased from those sellers was a probable substandard or falsified medicine. [4]

Adding to this problem, consumers often lack the knowledge needed to distinguish legitimate online pharmacies from illegal ones. ASOP Global Foundation research shows significant gaps in consumer understanding of online drug sales, including how online pharmacies are regulated, the differences between compounded drugs and generics, and the legality of research use only products. This confusion creates a foreseeable risk that consumers will mistake the enforcement-discretion policy as a federal endorsement of the safety, efficacy, and quality of these chemicals, including those sold through the unregulated online marketplace.[5]

Before the federal enforcement-discretion policy was issued, the ASOP Global Foundation launched Rx Watchdog on September 15, 2026, in partnership with S-3 Research. Unlike traditional point-in-time snapshots, Rx Watchdog is a public health monitoring platform that continuously monitors how prescription medicines, investigational new drugs, and emerging unapproved molecules are offered for sale by seemingly noncompliant sources across websites and social media. During its initial monitoring period, covering July and August 2026, the platform identified 20,983 peptide product listings across 330 domains. Importantly, many of these domains were not exclusively selling peptides but also marketed drugs across multiple therapeutic categories, including oncology products. As certain peptide products become eligible for enforcement discretion, these same websites, many already engaged in illegal sales, can be expected to continue operating and expand their offerings. This overlap will make it increasingly difficult to distinguish legitimate peptide sales from these sellers' broader unlawful activities, further complicating enforcement.

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[2] NABP, Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators, July 2016 (95.79% of 11,299 sites reviewed); *see also id.* (Aug. 2017) (95.8% of 11,688). Available at: https://nabp.pharmacy/wp-content/uploads/2016/07/NABP-Internet-Drug-Outlet-Report_Oct2012.pdf

[3] National Association of Boards of Pharmacy, Rogue Rx Activity Report: Disrupting Illegal Online Pharmacies: Lock-and-Suspend as a Tool to Protect Patients, 2022. Available at: https://nabp.pharmacy/wp-content/uploads/2022/10/Rogue-Rx-Activity-Report-Disrupting-Illegal-Online-Pharmacies-2022.pdf

[4] Ashraf et al., Multifactor Quality and Safety Analysis of Semaglutide Products Sold by Online Sellers Without a Prescription: Market Surveillance, Content Analysis, and Product Purchase Evaluation Study, 26 J. Med. Internet Res. e65440 (2024),, Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC11582493/

[5] ASOP Global Foundation, 2025 U.S. Consumer Behavior Survey 11 (2025), https://asopfoundation.pharmacy/wp-content/uploads/2025/11/ASOP-Foundation-2025-Consumer-Behavior-Survey.pdf ("2025 Consumer Survey") (online survey of 1,501 U.S. adults conducted by Abacus Data, Aug. 22–26, 2025).

Beyond the challenge of distinguishing legitimate from unlawful sellers, HHS faces another longstanding problem: online sellers routinely use 'research use only' (RUO) disclaimers to market products not intended for human consumption. RUO labeling designates products for laboratory research, not human use, but that does not prevent sellers from promoting unapproved substances to consumers seeking treatments. FDA warning letters demonstrate this practice. FDA has issued warning letters to US Chem Labs, Synthetix Inc. d/b/a Helix Chemical Supply, Summit Research Peptides, USApeptide.com, and Gram Peptides for selling unapproved semaglutide, tirzepatide, or similar products online, often under "research use chemicals only" labeling. These cases demonstrate that RUO disclaimers do not prevent products from being marketed or sold for human consumption. [6,7,8,9,10,11]

The online ecosystem also limits the effectiveness of conventional, case-by-case enforcement. ASOP Global members reported that domain-name registrars are often reluctant to act on complaints involving investigational or "research use only" products, while sellers increasingly migrate to disappearing social-media stories and invite-only groups on WhatsApp and Telegram. Members also reported persistent takedown backlogs on X, Telegram, and WhatsApp, and repeated reappearance of listings on online marketplaces. As a result, illegal sellers change domains, move platforms, or repackage claims faster than regulators and intermediaries can respond.

Treating regulated compounding as the solution to gray-market sales presents a false choice. The appropriate public-health question is not simply whether a regulated source is preferable to an unlawful source, but how FDA, States, law enforcement, internet intermediaries, and other stakeholders can enforce existing laws and safety standards so that patients can trust the medicines they obtain online.

Permitting broader availability without simultaneously strengthening enforcement creates an additional risk: unlawful sellers may cite the new federal policy as evidence that peptide products have been legitimized.

III. The Policy Should Be Accompanied by Enhanced Oversight and Surveillance

HHS states that it may revisit the interim policy, in whole or in part, if a safety signal or product-quality issue arises. That safeguard is important, but it depends on regulators having adequate mechanisms to detect such signals in the first place.

As ASOP Global explained in its July comments, traditional Section 503A pharmacies do not operate under the same federal registration, current good manufacturing practice, drug-reporting, adverse-event reporting, and inspection framework applicable to Section 503B outsourcing facilities. Those differences make reliable surveillance particularly important when expanding access to inadequately studied peptide products.

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[6] U.S. Food & Drug Administration, Warning Letter to Empower Clinic Services, LLC dba Empower Pharmacy, MARCS-CMS 738238 (Sept. 18, 2026). Available at: fda.gov

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

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

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

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

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

Accordingly, ASOP Global urges HHS to establish an implementation plan that includes:

1. **Active safety monitoring.** FDA should establish a mechanism for rapidly identifying adverse events, contamination, sterility failures, potency deviations, and other quality signals involving peptides compounded under the policy.
2. **Peptide-specific quality expectations.** FDA should articulate expectations concerning identity, purity, potency, sterility, endotoxins, degradation products, aggregation, peptide-related impurities, stability, and other quality characteristics relevant to sterile peptide products.
3. **API and supply-chain controls.** Compounders should maintain sufficient documentation to establish supplier qualification, testing and certificates of analysis, and the identity of the original manufacturer of peptide bulk substances.
4. **Federal-State coordination.** FDA should work closely with State boards of pharmacy and medical boards so that information regarding inspections, adverse events, product-quality concerns, disciplinary actions, and problematic suppliers can be shared rapidly.
5. **Periodic reassessment.** HHS should establish transparent criteria for reviewing whether continued enforcement discretion remains appropriate for each peptide and should not wait for formal rulemaking if significant safety or quality concerns emerge.

These safeguards reflect recommendations ASOP Global previously advanced to FDA if the agency elected to expand lawful access despite the unresolved scientific concerns surrounding these substances.

IV. HHS Should Couple the Policy with a Coordinated Enforcement Strategy

The enforcement discretion policy should not be treated as a substitute for enforcement against illegal online sellers.

ASOP Global's prior comments documented websites marketing purported peptides as “research use only” or “not for human consumption" while simultaneously making claims associated with weight loss, muscle recovery, anti-aging, wound healing, cognitive enhancement, and other human uses. They also identified risks associated with patients obtaining injectable products of unknown identity, purity, potency, sterility, and source without reliable medical supervision. Those risks are unlikely to diminish without targeted enforcement.

FDA should therefore coordinate with the NABP, state boards of pharmacy, state medical boards, state attorneys general, and enhance efforts with FDA’s Office of Criminal Investigations (FDA-OCI), U.S. Customs and Border Protection, the Department of Justice, and other appropriate enforcement partners to develop a coordinated strategy addressing unlawful peptide sales through online pharmacies, standalone websites, telehealth platforms, med-spas, online marketplaces, and social-media channels.

FDA should also prioritize enforcement where sellers are misleadingly suggesting that the October 2026 policy makes their products “FDA authorized” “FDA approved,” equivalent to approved medicines, or otherwise federally endorsed.

V. FDA's Final 503A Decisions Should Remain Grounded in Statutory Evidentiary Standards

Finally, interim enforcement discretion should not lower or otherwise affect the evidentiary standard FDA applies when determining whether an individual substance belongs on the 503A Bulks List.

Section 503A(c)(2) requires FDA to consider, among other factors, physical and chemical characterization, safety issues raised by use in compounded products, evidence of effectiveness, and historical use in compounding. ASOP Global previously urged FDA to evaluate those factors substance by

substance and not to treat widespread demand, unlawful online availability, or commercial readiness as substitutes for scientific evidence.[12]

If FDA moves toward rulemaking, it should maintain a clear analytical separation between whether the government will temporarily exercise enforcement discretion and whether the scientific record supports placing a particular peptide on the 503A Bulks List.

Conclusion

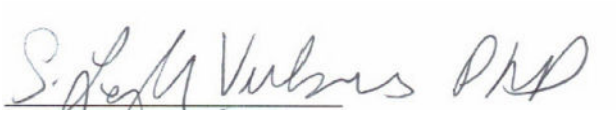
ASOP Global supports policies that provide patients with safe access to necessary medicines, but access and evidence are not interchangeable, and enforcement discretion should not be allowed to serve as a proxy for regulatory approval.

HHS's October 2026 policy creates a significant responsibility for FDA and HHS to ensure that expanded compounding does not unintentionally increase consumer confusion, facilitate unlawful marketing, or make it easier for illegal online sellers to operate alongside legitimate pharmacies.

The solution to the illegal peptide market cannot be to lower the evidentiary bar for lawful access while leaving unlawful sellers largely untouched. Patient safety requires both rigorous science and effective enforcement.

ASOP Global appreciates the opportunity to comment and looks forward to continuing to work with HHS, FDA, State regulators, law-enforcement agencies, and other stakeholders to protect patients from unsafe and illegally marketed medicines.

Respectfully submitted,



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[12] Federal Food, Drug, and Cosmetic Act § 503A(c)(2); 84 Fed. Reg. 4696 (2019). Available at: https://www.federalregister.gov/documents/2019/02/19/2019-02367/list-of-bulk-drug-substances-that-can-be-used-to-compound-drug-products-in-accordance-with-section