NABP
National Association of Boards of Pharmacy

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July 9, 2026

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: *Docket No. FDA-2025-N-6895; Pharmacy Compounding Advisory Committee Meeting — Consideration of Seven Peptide Substances for the Section 503A Bulk Drug Substances List*

Dear Sir or Madam:

The National Association of Boards of Pharmacy ("NABP") is an independent, international, and impartial association that, since 1904, has worked with its member boards of pharmacy to protect public health. Its members are the boards of pharmacy in all 50 states, the District of Columbia, and the U.S. territories, along with pharmacy regulatory authorities in several Canadian provinces NABP supports those boards through licensure, accreditation, inspection, and supply-chain integrity programs.

These comments concern the Pharmacy Compounding Advisory Committee ("PCAC") meeting set for July 23 and 24, 2026, on seven peptide substances proposed for the Section 503A Bulk Drug Substances List ("503A Bulks List"): BPC-157, KPV, TB-500, MOTs-C, Emideltide (DSIP), Semax, and Epitalon. Five more peptides are expected to be reviewed by the PCAC by the end of February 2027. These comments apply to both groups of peptides.

NABP does not support or oppose the inclusion of any peptide on the 503A Bulks List. That decision rests with FDA. Our purpose is the same regardless of how the Agency decides: (1) to identify the regulatory infrastructure that does not currently exist to oversee these substances safely at scale; and (2) the harm its absence would pose. Our member boards can inspect the pharmacies, investigate the complaints, and discipline the licensees under whatever framework results, and we write from that vantage point.

One observation runs through all five gaps identified below. Congress built the 503A framework, and the exemptions that come with it, around low-volume, patient-specific compounding. The compounded GLP-1 period has pushed compounding well past that scale, and the framework strained, regardless of whether a given operator was compliant. A compliant compounding pharmacy is not subject to finished product traceability requirements, still has no federal obligation to report adverse events, and still depends on active ingredients that FDA cannot inspect at scale.

The peptides under review would magnify that problem. Demand is large and growing, and the potential volume is likely to dwarf the volumes seen with GLP-1s. The current peptide activity already occurs in an unregulated market, but that is not a reason to treat authorization as low-risk. Authorization would move existing demand into a system that is not equipped to handle it; it would make an under-equipped system the official one. And these peptides are not in the FDA drug approval process: there is no application, no

approved finished product, and no manufacturer subject to the oversight an approved drug carries. To our knowledge, there is also no reference standard for these products.

Gap 1: Sharing Information Between Federal and State Regulators

Federal and state regulators operate under statutory limits on what they can share. Section 503A directs FDA, in consultation with NABP, to develop a standard Memorandum of Understanding on interstate distribution of compounded drugs. FDA published a first draft in 1999, issued revised drafts in 2015 and 2018, and made a final MOU available for signature in 2020. However, after litigation, FDA suspended that MOU and has said it will pursue rulemaking. The single coordination instrument the statute calls for remains unsettled nearly thirty years after Section 503A was enacted.

Approved drugs generate a continuous stream of regulatory information through a manufacturer of record and registered establishments. The peptides under review produce none of that. The same statutory limits on sharing therefore operate against a thinner baseline of information, across twelve substances at once.

Gap 2: The Traceability Tools Do Not Reach Compounded Preparations

The Drug Supply Chain Security Act of 2013 gives the approved-drug supply chain three tools that compounded preparations do not have: (1) serialization, which puts a unique identifier on every package at the individual saleable unit level; (2) product verification, which lets trading partners and regulators confirm a product is what it claims to be; and (3) product tracing, which documents each change of hands so that a product's ownership history can be reconstructed. Together, they let a specific package be identified, authenticated, and traced back through the supply chain. Congress built these tools after real failures, including contaminated heparin from foreign suppliers, and a scheme in which counterfeiters refilled genuine HIV-medication bottles and moved them through unauthorized distributors using falsified records, caught only by checking the transaction documentation federal law requires.

Section 582 excludes drugs compounded under Sections 503A and 503B from these requirements. The exclusion applied to compounding as Congress understood it: short supply chain, low-volume, and patient-specific. When compounding instead operates at commercial-scale volumes, the products move through the supply chain without serialization, verification, or tracing. The 2012 New England Compounding Center outbreak, in which a pharmacy operating at industrial scale distributed contaminated product across twenty states and killed sixty-four people, is the reminder of what large-scale compounding can do when it outgrows the framework built for it. Authorizing twelve peptides by adding them to the 503A Bulks List would extend this exclusion across a larger and more diffuse body of compounded product, with no unit-level identifier available to investigate or contain a problem when one arises.

Gap 3: Verifying the Bulk Substance

A compounded preparation is only as sound as the bulk substance it is made from. Under Section 503A, a pharmacy confirms a substance's compliance mainly through the Certificate of Analysis from its manufacturer. That framework, set up in 1997, assumed the Certificate would come from a manufacturer reasonably within reach of FDA inspection. Two features of the current environment strain that assumption. By FDA's own accounting, roughly three-quarters of establishments manufacturing active ingredients for the U.S. market are overseas. And FDA's ability to inspect them is constrained: GAO has

reported that as of 2024, roughly 2,000 manufacturing establishments had not been inspected since before the pandemic, including hundreds of plants in the countries that supply the most active ingredient.

A Certificate of Analysis derives its authority from comparison against an established reference standard, typically a USP or other compendial standard that defines what the substance is and how to test it. For the peptides under review, no such official reference standard exists. A manufacturer's Certificate therefore attests to identity and purity using its own methods and its own reference material, with no independent standard to measure it against, and the analytical methods these peptides require are ones that pharmacies are not equipped to perform or confirm on their own. None of the peptides has an approved finished product to supply that missing reference. Their bulk substance is largely foreign and, in many cases, comes from establishments not registered with FDA at all. So, the verification gate fails twice over: the document cannot be checked against an authoritative standard, and the manufacturer that issued it often sits beyond the reach of inspection.

Gap 4: 503A Compounding Sits Outside Federal Adverse Event Reporting

Mandatory adverse event reporting under 21 CFR Part 314 applies to manufacturers and applicants of approved drugs. Section 503B outsourcing facilities have their own reporting obligation under FDA's 2021 rule. Section 503A pharmacies have no comparable federal requirement. A patient harmed by a peptide compounded in a 503A pharmacy does not enter any federal database as a matter of obligation. Voluntary MedWatch reports capture only a small share of events, and because compounded preparations lack the codes and manufacturer-linked lot numbers the system uses to detect signals, even those are hard to attribute. One reported case illustrates the result: a patient suffered acute liver failure after a compounded tirzepatide injection, and the event reached regulators and prompted proposed state legislation through injury and a state-level response, not through any federal channel. Whether similar events occurred elsewhere is the question the current system cannot answer.

The concerns that placed these peptides in Category 2 in 2023, including immunogenicity, impurities, and limited human data, are the kind that emerge over time and across many patients. They are exactly the signals a functioning monitoring system is built to catch, and exactly what the current system is least able to catch for compounded preparations.

Gap 5: Authority Spread Across Agencies and Jurisdictions

Compounded-product activity crosses lines among pharmacy practice, medical practice, telehealth, aesthetic services, and consumer protection. The traditional model assumes a separate prescriber, dispensing pharmacy, and administering clinician, each regulated by a different body; medical spa, wellness clinic, and telehealth-pharmacy models often combine those roles in one business, leaving unsettled which regulator has authority and against which standards. State boards of pharmacy, state medical boards, state attorneys general, and FDA each hold a piece, and coordination is usually case-by-case. Where it happens, it works, as Mississippi's multi-board guidance and Ohio's medical spa sweep showed, but not every state has that capacity, and federal-to-state coordination is the least developed.

The peptide market runs heavily through direct-to-consumer telehealth, wellness, and aesthetic channels, where the prescriber, pharmacy, and administrator roles frequently combine in one business. Closing this gap is not solely FDA's responsibility; much of the coordination sits with the state boards and among state authorities. We raise it because the federal-to-state portion, and FDA's enforcement reach over marketing and intended use, are pieces only the Agency can contribute.

Recommendations

We respectfully recommend that FDA take the following steps before or alongside any final rule placing these peptides on the 503A Bulks List.

First, within existing authority, build the most structured federal-state information-sharing arrangement the law allows, working with NABP and the boards: establish volume reporting for compounded products shipping into and out of states, real-time inspector access to registered establishment status, routine sharing of unredacted Warning Letter and import alert information, and a clear channel for boards to refer findings to the Agency. Where the law constrains the coordination both sides want, identify the limit so Congress and the public can judge whether the current toolset is adequate.

Second, recognize in any decision to authorize compounded substances at scale that those preparations move through the supply chain without serialization, verification, or tracing, and consider what compensating measures are available within FDA's authority to identify and contain a contaminated or substandard product.

Third, issue guidance on what a Certificate of Analysis for a peptide bulk substance should contain, including how identity and purity are to be established where no official reference standard exists, make registered establishment information available to state inspectors in real time, and address how the bulk substance for these peptides will be subject to manufacturer-level oversight given the documented constraints on inspecting foreign establishments.

Fourth, work with NABP and the boards to develop an adverse event reporting mechanism for 503A pharmacies dispensing, including any newly added peptide bulk drug substances, structured so reports reach both FDA and the licensing board in a timely manner.

Fifth, join NABP, the boards, medical boards, and attorneys general in a coordinated referral path for cross-jurisdictional cases, and extend FDA's GLP-1 telehealth marketing enforcement to compounded peptides. NABP is ready to coordinate the state-to-state portion; the federal-to-state connection and FDA's marketing enforcement are the Agency's to contribute.

Conclusion

The volume of compounded peptides traversing the US will be large. The compounded GLP-1 period already showed that demand of this kind blows past the small-scale, patient-specific compounding Congress had in mind when it built the 503A framework, and peptide demand is likely to be larger still. Compounded preparations cannot be traced, so a contaminated or substandard product cannot be found and pulled off the shelf. No federal system captures the harm these products cause, or even measures how much product is in use. And the bulk substances they are made from come largely from foreign, potentially unregistered sources, certified against no official reference standard. Each of these is a real threat to patients, and together they describe a system being asked to carry far more than it was built to hold.

These were reasonable choices for the scale of compounding Congress had in mind, and the safety concerns that placed these peptides in Category 2 in 2023 are real. That much of this activity already occurs in an unregulated market is not a reason to treat authorization as low-risk, because authorization would simply make an under-equipped system the official one without building what the system lacks. Filling the gaps identified above would support NABP’s member boards’ patient safety and public health protection missions, which also complements and amplifies FDA’s similar mission. We ask only that, if

these substances are authorized, authorization not outrun the infrastructure needed to oversee them, and we urge FDA to use the time before any final rule to build that infrastructure with NABP and the state boards of pharmacy.

Respectfully submitted,

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Executive Director/Secretary
National Association of Boards of Pharmacy