TEXAS Pharmacy Association
Together Pharmacy Advances

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Dockets Management Staff (HFA-305)
Food and Drug Administration
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Submitted electronically via Regulations.gov

RE: Docket No. FDA-2025-N-6895 for "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"

SUBJECT: The Texas Pharmacy Association supports inclusion of the seven nominated peptides on the Section 503A Bulk Drug Substances List, for the uses under review, conditioned on the quality and clinical standards described in this comment.

Dr. Stevenson and Docket Management Staff,

The Texas Pharmacy Association (TPA) appreciates the opportunity to provide comments to the FDA and its Pharmacy Compounding Advisory Committee (the Committee) on its docket: *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 [Docket No. FDA-2025-N-6895].*

TPA is a strong voice for all Texas pharmacy professionals, promoting advocacy, continuing education and practice innovation by empowering pharmacists to improve patient outcomes. Founded in 1879, TPA serves members practicing in all pharmacy settings and specialties. This includes pharmacists who oversee the preparation of compounded medications every day, under the oversight of the Texas State Board of Pharmacy and in conformance with United States Pharmacopeia standards. The pharmacists who do this work understand the chemistry, the quality systems, and the clinical judgment that responsible compounding requires.

We speak for a profession, not for a product. Texas pharmacists have a deep community of compounding expertise and a regulatory environment that takes both access and accountability seriously. That standing is the basis for this comment.

We note that the July 23 – 24, 2026 Pharmacy Compounding Advisory Committee meeting is open to the public, in person and through an online platform, and that the agency has invited written and oral comment. The Texas Pharmacy Association welcomes a process that is on the record and looks to the evidence.

Our Summary of Recommendations

The Texas Pharmacy Association (TPA)'s position is straightforward: **Licensed compounding pharmacists are the last checkpoint between the peptides of discussion and the patient. BPC-157, KPV, TB-500, MOTS-c, Emideltide, Semax, and Epitalon, each in their free base and acetate forms, should be added to the Section 503A Bulk Drug Substances List, for the uses the agency has evaluated, so that individual patients can obtain these substances in a regulated system that requires a valid prescription and preparation by a licensed pharmacist using pharmaceutical-grade ingredients, validated processes, and lot-level testing.**

Removing these substances from the Section 503A Bulk Drug Substances List does not kill the demand. Instead, it means that these substances currently exist in a gray market of research-grade vendors, foreign websites, and informal distribution—where there is no prescriber, no pharmacist, no quality control, and no accountability. This hurts patients.

Allowing qualified pharmacists to compound these substances does not create a new risk. It replaces an unregulated supply with a regulated one. That is the safer path for patients and the greater public, and it is the one the pharmacy compounding profession is built to support.

The evidence supporting the seven substances is uneven. Our comments state plainly where evidence is strong and where it is thin. We do not ask the Committee to overlook that unevenness. Instead, **we ask the Committee to weigh it against the documented reality of what happens when these substances are available only outside the regulated system.**

TPA does not seek patient access without rigor. We **strongly support** clinical protocols, informed consent, pharmaceutical-grade sourcing, validated sterile and nonsterile processes, stability and potency testing, and documented pharmacist review for every one of these substances. Access without those safeguards is not access. It is exposure. Our recommendations distinguish between the substances where the evidence supports compounding now and those where a more measured path is appropriate. **Our position is that regulated, monitored, consent-based compounding is the responsible way to serve existing demand while the evidence matures, and that it is far preferable to the unmonitored use that prohibition produces.**

Regulatory Background

Section 503A of the Federal Food, Drug, and Cosmetic Act, codified in 21 U.S.C. 353a, allows licensed pharmacists and physicians to compound medications for individuals when certain conditions are met. One of those conditions concerns the bulk drug substances used in compounding. A bulk substance qualifies if it complies with an applicable United States Pharmacopeia (USP) or National Formulary monograph, or, absent a monograph, is a component of an FDA-approved drug, or, absent both, appears on a list the agency establishes by regulation, known as the 503A Bulks List. While the agency continues the rulemaking process to populate that list, it has applied an interim policy that places nominated substances into three categories:

Category 1 (the agency does not intend to act during review), Category 2 (significant safety risks identified), or Category 3 (insufficient supporting information).

In recent years, the FDA placed several peptides—including those being discussed in the July 23-24, 2026 Committee meeting—into Category 2 based on concerns about immunogenicity with certain routes of administration, complexities in characterizing peptide-related impurities and the active pharmaceutical ingredient, and limited or absent human safety data for the proposed routes of use. In effect, the recategorization removed these substances from lawful compounding.

In April 2026, the agency revised its interim list and removed twelve peptides from Category 2, seven of which are the topic of these comments. TPA acknowledges that removal from Category 2 does not by itself authorize compounding; however, this removal has created a dangerous regulatory gap as these substances are no longer designated as posing a "significant safety risk" within the regulated supply chain.

The agency has identified the specific uses it evaluated for each substance,[1] and this comment addresses those uses directly:

Substance (free base and acetate)	Use(s) evaluated by FDA
BPC-157	Ulcerative colitis
KPV	Wound healing and inflammatory conditions
TB-500	Wound healing
MOTS-c	Obesity and osteoporosis
Emideltide (DSIP)	Opioid withdrawal, chronic insomnia, and narcolepsy
Semax	Cerebral ischemia, migraine, and trigeminal neuralgia
Epitalon	Insomnia

Our Concerns

TPA strongly supports the inclusion of the noted seven peptides to the interim Section 503A Bulk Drug Substances List, for the uses the agency has evaluated because regulated pharmacist compounding—with appropriate safeguards and further scientific rigor—is a far safer alternative than the unregulated gray-market access that currently exists. Our concerns are as follows:

1. Patient safety is strengthened through regulatory oversight, not prohibition.

The central fact of the last three years is that prohibition did not remove these substances from use. Instead, it removed them from the part of the system that has safeguards via licensed

[1] 91 FR 20465

prescribers and pharmacists. Patients who want these peptides today commonly obtain them from vendors that label their products "for research use only," from overseas sellers, or from informal sources, with no prescription, no clinical oversight, and no assurance of identity, purity, or sterility.[2] The compounded alternative places the same substance inside a system that has a prescriber, a pharmacist, validated preparation, and lot-level testing.[3] The question before the Committee is not whether these substances will be used. It is whether their use will be supervised.

2. Compounding is foundational to pharmacy. The judgment of a licensed pharmacist, exercised under accountability, is a safeguard that the gray market cannot offer.

Compounding predates modern pharmaceutical manufacturing and is widely recognized as an important and necessary practice that provides specialized formulations for patients when commercially available medicines may not be appropriate or available.[4] Pharmacists and pharmacies are trusted sources for compounded medications. Nearly two-thirds of Americans (62%) trust pharmacists when it comes to information about compounded medications.[5] The people who prepare these medications under state board oversight understand the practical questions the Committee is weighing, from endotoxin limits to route-specific risk. That expertise should inform the agency's decision, and it should be part of the system that serves patients once these substances are listed.

To emphasize, prescriber-directed, patient-specific compounding critically serves people whom mass manufacturing does not reach, including patients who need an alternative route, a different dose, the removal of an excipient they cannot tolerate, or a formulation for a condition the commercial market has not prioritized. The peptides under review fit that pattern. The Committee's decision should reflect the enduring role of compounding in individualized care.

3. The burden of proof should track the actual risk.

The 2023 reclassification of these substances rested on categories of theoretical concern about immunogenicity with certain routes of administration, complexities in characterizing peptide-related impurities and the active pharmaceutical ingredient, and limited or absent human safety data for the proposed routes of use. Those concerns are legitimate as questions. They are not, by themselves, evidence of harm.

The appropriate response to a characterization or purity concern is a characterization or purity standard—not an indefinite prohibition that pushes patients toward suppliers who meet

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[2] Mendias CL, Awan TM. Safety and Efficacy of Approved and Unapproved Peptide Therapies for Musculoskeletal Injuries and Athletic Performance. Sports Med. Published online April 12, 2026. doi:10.1007/s40279-026-02437-0

[3] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on the Clinical Utility of Treating Patients with Compounded Bioidentical Hormone Replacement Therapy; Jackson LM, Parker RM, Mattison DR, editors. The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use. Washington (DC): National Academies Press (US); 2020 Jul 1. 2, An Overview of Compounding. Available from: https://www.ncbi.nlm.nih.gov/books/NBK562881/

[4] Kochanowska-Karamyan AJ. Pharmaceutical Compounding: The Oldest, Most Symbolic, and Still Vital Part of Pharmacy. *Int J Pharm Compd*. 2016;20(5):367-374.

[5] Carpenter L, App B. Public Opinion on Compounding Pharmacies. Embold Research. February 25, 2025. https://a4pc.org/hubfs/Pharmacy-Compounding-Foundation_US_FOR-PUBLIC-RELEASE_Feb-2025-1.pdf?hsLang=en

no standard at all. Where the agency identifies a specific risk, the pharmacy profession can and should be held to a specific control.

4. Rigor is the price of access, and the pharmacy profession accepts it.

TPA does not ask for unconditional access. We strongly support, for each substance the agency lists, a defined set of obligations: pharmaceutical-grade bulk substances with a certificate of analysis, validated sterile or nonsterile processes consistent with United States Pharmacopeia (USP) standards,[6] stability-based beyond-use dating, potency and purity testing, clinical protocols, informed consent that is honest about the state of the evidence, and documented pharmacist review. This framing allows the profession to support lawful access and to support enforcement against bad actors at the same time, without contradiction. Those who meet the standard should be allowed to serve patients. Those who do not should face the consequences.

The Patient-Safety Case in Detail

The gray market in peptides is not hypothetical.[7,8] Products sold as "research chemicals" are exempt, by their labeling, from the quality expectations that apply to medicines.[9] This can mean, if administered, the patient who injects them has no way to confirm what the vial contains. The contrast with regulated compounding is precise and worth stating in full.

In a compounding pharmacy operating under Section 503A, a peptide preparation begins with a bulk substance accompanied by a certificate of analysis from a qualified supplier. The pharmacist confirms identity and purity, prepares the medication under validated sterile or nonsterile conditions consistent with USP General Chapters 795 and 797, assigns a beyond-use date supported by stability data, and tests for potency, sterility, and bacterial endotoxins as applicable under USP General Chapters 71 and 85.[10] The medication is dispensed against a prescription within a bona fide prescriber-patient relationship, supported by a clinical protocol, informed consent that states honestly what is and is not known, and a monitoring plan where the clinical situation warrants one. The pharmacy retains records sufficient for board inspection and traceability. Each step is required and overseen by state board of pharmacies.

None of the steps outlined above exist in the gray market.

Additionally, this existing regulated framework also gives pharmacies a critical capability the gray market cannot match: the ability to identify, trace, and recall a specific lot when a quality

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[6] USP Compounding Standards: https://www.usp.org/compounding/legal-considerations. Accessed June 23, 2026.

[7] O'Mary L. Gray Market Peptides: So much hype, so little data. Medscape. May 1, 2026. https://www.medscape.com/viewarticle/gray-market-peptides-so-much-hype-so-little-data-2026a1000dzg?form=fpf

[8] Clegg R. Walker A. Wellness peptide craze: Why people are injecting drugs 'not for human consumption.' BBC News. Feb 28, 2026. https://www.bbc.com/news/articles/cdr268m5pxro

[9] 21 CFR 312.2

[10] USP. General Chapter <795> Pharmaceutical Compounding: Nonsterile Preparations; General Chapter <797> Pharmaceutical Compounding: Sterile Preparations; General Chapter <71> Sterility Tests; General Chapter <85> Bacterial Endotoxins Test.

concern arises. Because pharmacists maintain direct relationships with patients and prescribers, they can respond to complaints, investigate potential defects, and remove affected preparations from circulation. Research-grade and informal suppliers have no comparable mechanism. A defective product in those channels reaches patients, with no system for retrieval, no accountability, and no responsible party to receive or act on a complaint.

The capacity to monitor quality, respond to concerns, and execute recalls is a core reason why patients are better protected when these substances are prepared and dispensed by licensed pharmacists. These important standards are the dividing line between a medicine and a research chemical. They are also the basis on which the profession can support enforcement against those who operate outside the regulated system.

The agency's own concern about immunogenicity illustrates this point. Immunogenicity risk is driven in part by chemical aggregates and impurities, which are precisely the attributes that pharmaceutical-grade sourcing, validated processes, and lot testing are designed to control. In a regulated pharmacy, those safeguards are paired with a pharmacovigilance pathway grounded in state board oversight and internal procedures for documenting and responding to adverse reactions. While formal reporting of adverse reactions through MedWatch is not required of 503A pharmacies, the outlet exists. Pharmacists are equipped to report adverse reactions and follow up with the prescriber and the patient to take appropriate action.

A patient who obtains an uncharacterized research-grade peptide faces the risk of an adverse reaction with no mitigation. Yet, a patient who receives a compounded preparation does so within a system designed to minimize and address risk. Listing these substances, with appropriate standards, does not increase immunogenicity risk at the population level — it increases the likelihood of reducing it.

Addressing the Agency's Stated Concerns

TPA takes the agency's 2023 concerns seriously and responds to each individually:

Peptide-related impurities. Synthetic peptides can carry process-related impurities, including truncated and deletion sequences and residual reagents, resulting in variants that may behave differently in the body.[11] These are measurable. The appropriate control is a specification supported by validated analytical methods, with impurity limits and a certificate of analysis for each lot. Compounding pharmacies that prepare peptides should be expected to source from suppliers that provide this documentation and to verify it, as required by USP standards[9] and strongly encouraged by the Alliance for Pharmacy Compounding.[12] The validated methods that go into qualifying a material as pharmaceutical grade are what reduce risk.

[11] D'Hondt M, Bracke N, Taevernier L, et al. Related impurities in peptide medicines. J Pharm Biomed Anal. 2014;101:2–30. doi:10.1016/j.jpba.2014.06.012.

[12] APC. How Compounding Pharmacies Validate Active Pharmaceutical Ingredients. https://a4pc.org/hubfs/PDFs/API-Vendor-Validation.pdf?hsLang=en. Accessed June 24, 2026.

Active pharmaceutical ingredient (API) characterization. A bulk peptide should be identified and characterized by appropriate methods, including assessment of identity, content, and counterion where an acetate salt is used.[10] The agency's decision to review each substance in both its free base and acetate forms is consistent with this expectation, and the listing can specify the validated characterization required.

Aggregation. Some peptides can aggregate, which bears on both stability and immunogenicity. Aggregation is addressable through formulation, controlled storage, validated handling, and stability-based beyond-use dating, supported by testing. This is standard practice for sterile injectable compounding under USP General Chapter 797.[9]

Immunogenicity by route of administration. The agency specifically flagged immunogenicity risk for certain routes, including for MOTS-c and BPC-157. The profession can address this by aligning route and formulation with the available evidence, by controlling the aggregate and impurity profile that drives immunogenicity, and by informed consent that discloses the uncertainty. Where the risk for a given route is not adequately characterized, the listing and the clinical protocol can be limited accordingly.

Limited human data. For several of these substances, human evidence is limited, and for some it is preliminary. We do not dispute this, and we address it directly in future sections of this letter. Our position is that regulated, monitored, consent-based compounding is the responsible way to serve existing demand while the evidence matures, and that it is far preferable to the unmonitored use that prohibition produces.

8. Conclusion

The Texas Pharmacy Association supports adding the seven nominated peptides to the Section 503A Bulk Drug Substances List, for the uses the agency has evaluated, under the quality and clinical standards set out in this comment. We hold two ideas at once — Patients deserve access to safe therapies with genuine promise, and regulated, monitored, consent-based compounding is far more responsible than the current unmonitored use of these peptides. The Pharmacy Compounding Advisory Committee process is where those two ideas can be reconciled. Licensed pharmacists want it to work, and we are prepared to meet its standards.

Respectfully submitted,

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