



October 14, 2026

Kyle A. Diamantas, J.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993
Submitted via email to: kyle.diamantas@fda.hhs.gov.

Re: Meeting of the Pharmacy Compounding Advisory Committee on Peptides

Dear Acting Commissioner Diamantas,

We are writing with concern about the recent meeting of the Pharmacy Compounding Advisory Committee (PCAC or Advisory Committee), held on July 23-24, 2026, at which the Advisory Committee, in a series of close votes, chose to recommend six of seven peptides under consideration for inclusion on the 503A bulk drug substance compounding list (503A Bulks List). Not only do those substances pose a risk to public health and safety, but the Advisory Committee's convening and vote, if followed by a corresponding rulemaking, violates established FDA criteria for listing new substances and is substantively and procedurally defective.

For years, the Agency has exercised appropriate caution with respect to these seven peptides. In September 2023, based on the available evidence (or lack thereof), the Agency issued an interim restriction placing these substances in Category 2, a designation for "Bulk Drug Substances that Raise Significant Safety Concerns."¹ This continues to be the view of expert Agency staff, who, in briefing materials made available to PCAC's members,² recommended against the listing of all seven peptides considered.

As a matter of law, prior to including a substance on the 503A Bulks List, FDA must assess each substance according to the following four criteria: 1) Ability to characterize the product physically and chemically, 2) Safety issues raised by use in compounded products, 3) Available evidence of effectiveness, and 4) Historical use in compounded products.³ In their briefing materials, FDA staff scientists carefully considered each of these factors and reached the inevitable conclusion: all seven peptides should "NOT be included on the 503A Bulks List."⁴ For most of these products – including the highly-discussed BPC-157, *no* regulatory factor favored inclusion on the 503A Bulks List.⁵

Regrettably, the recent convening and recommendations of the PCAC were an inversion of the sound and measured leadership that FDA staff has provided on this issue. While every permanent Advisory Committee member appointed prior to March 2026 voted in

accordance with the recommendations of FDA staff scientists, the newly appointed permanent PCAC members (appointed under pressure from HHS Secretary Robert F. Kennedy Jr.)⁶ voted in near lockstep to list the peptides, frequently relying on factors other than the permitted four (see analysis below). Every vote in favor of listing came from these new permanent members.

We reviewed the rationale provided by these new permanent members in justifying their votes to include the peptides on the 503A Bulks List using the meeting livestream. According to our analysis of the voting justifications, 7 of the 8 recently appointed permanent members raised at least one criterion beyond the four specified in FDA regulations for at least one peptide (Table 1). Members cited reasons such as “medical freedom,” the presence of these products on the “gray market,” or the “bioterrorism [which] may potentially exist for us” to justify their votes.⁷ All told, there were 18 instances related to 12 specific committee member votes in which a member cited a criterion not in regulation (Table 1). As a result, the Advisory Committee voted to list six new peptides, despite the failure to meet relevant criteria prescribed by regulation. No new evidence that would undermine the Agency’s careful finding that those same substances posed a safety risk was presented at the Advisory Committee meeting.

While the Advisory Committee’s vote to greenlight the listing of these six products was contrary to the regulatory criteria, the decision did not come as much of a surprise. According to public reporting,⁸ at least six of the eight newly-added permanent members of the PCAC have ties to peptide businesses or clinics and could stand to benefit financially if the Agency decides to allow the compounding of these substances. Predictably, these conflicted members of the Advisory Committee voted *en masse* to list the majority of the peptides; indeed, every vote in favor of these seven compounds came from one of the eight newly appointed permanent members.⁹ Despite the clear appearance of conflict—which has generated significant media attention¹⁰—the Advisory Committee Designated Federal Officer announced at the meeting that “no conflict of interest waivers under 18 U.S.C. § 208 have been issued in connection with this meeting.”¹¹ We urge the Agency to document in writing precisely why the service of these members did not fall afoul of 18 U.S.C. § 208 or 5 C.F.R. § 2635.502, the latter of which governs when a committee member’s apparent conflicts “would cause a reasonable person to question their impartiality” – a condition that plainly appears to have been met here.

The appointment of new members, many of whom have no relevant experience other than their work in the peptide industry and often little experience in the technical aspects of compounding more generally, shortly before the vote on these substances was conducted, is strongly suggestive that the members were selected not on their merits, but rather because their views on peptides align with those of the Secretary, who has publicly vowed to end what he perceives as the Agency’s “war on peptides.”¹² The vote of an Advisory Committee on unscientific and extra-legal bases, conducted by a group dominated by industry interests that, at a minimum raise questions about compliance with relevant conflict-of-interest statutes and regulations, threatens to confuse the public, drive demand for a currently illegal drug product, and divert patients away from FDA-approved drug products for these conditions, eroding public trust in our institutions at a critical moment.

Fortunately, the Advisory Committee's vote is just that – advisory. Though by statute the Agency must call a meeting of the PCAC before updating the 503A Bulks List, the Agency need not adhere to the Committee's recommendation before issuing a new rule.¹³ This means that the Agency has an opportunity to publicly correct course from the Advisory Committee's recommendations and instead properly follow the science and regulatory criteria.

Given these concerns, allowing the compounding of peptides based on PCAC's vote would be antithetical to FDA's mission of protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. These irregularities provide ample justification for the Agency to side with its own scientific staff over the conflict-ridden votes and frequent extra-regulatory justifications offered by certain members.

It also bears noting that any rulemaking that relies on an Advisory Committee vote that was both procedurally and substantively flawed would be highly susceptible to legal challenge under the Administrative Procedure Act.¹⁴ A successful legal challenge would render the improper listing of these peptides a waste of Agency resources and would serve to deepen public confusion on this issue.

It is not too late for FDA to follow the scientific advice of its own staff and reject the addition of these unproven compounds to the 503A Bulks List. FDA must take this opportunity to further its mission and stand up for good science and public health. CSPI would welcome the opportunity to discuss these matters with you in person.

Sincerely,

Peter Lurie, MD, MPH

Executive Director and President
Center for Science in the Public Interest

Isabella Xu, MPH

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Table 1. Rationales for votes of permanent committee members appointed since March 2026 at the July 23-24, 2026 Pharmacy Compounding Advisory Committee Meeting

Yellow highlights indicate elements of a committee member's justification that go beyond the four criteria for including a bulk drug substance in the 503A Bulks List established in FDA regulations.

Member Name	BPC-157 (Vote; Rationale)	KPV (Vote; Rationale)	TB-500 (Vote; Rationale)	MOTS-C (Vote; Rationale)	Emideltide (Vote; Rationale)	Epitalon (Vote; Rationale)	Semax (Vote; Rationale)
Gabriel Alizaidey, MD	Y; Disappointed in how FDA's data was incomplete, which swayed the vote towards "yes."	Y; Potential benefits outweigh the potential harms.	Y; No further explanation.	Y; No further explanation.	Y; Felt that the 4 relevant criteria were met.	Y; Felt that the 4 relevant criteria were met. There has been a mismatch in real world data and evidence displayed at the meeting.	Y; Felt that the 4 relevant criteria were met.
Asare Christian, MD	Y; Despite limited safety data, it wasn't a significant signal for risk. This provides an alternative treatment to support patient care.	Y; No significant risks raised with this peptide based on limited information received. There will be more	Y; No further explanation.	A; Due to limited data, "potential immunogenicity" based on his clinical experience, he does not have enough to make a decision.	Y; Patients and physicians should have the option to explore this peptide when current medications/compounds are not accessible or may not work for them, even in the context of	Y; We are using Phase 1 criteria (dosing, safety, efficacy) which is not what we are being asked to do. As a physician, I still have to do more to allow patient access beyond the tools currently available for	Y; So that patients who may benefit can have access to this compound. Same Phase 1 criteria explanation as prior. If there is potential to explore something, we should. No significant

		opportunities to study it and increase options for patients.			uncertainty.	treatment. All the presentations so far do not have strong evidence, risk is there and needs to be managed. Presentations have not stressed significant safety signals.	safety concerns and we have post-market analysis for collecting more data. Patients should have guidance from physicians while we are still collecting data in the future.
Senator Bobby Harshbarger, PharmD	Y; Echoed Dr. Pope's comment, 503A standards are not the same as new drug approval standards.	Y; Asked for restriction to topical and transmucosal use.	Y; No further explanation.	Y; No further explanation.	Y; "Our duty is to apply to 503A standards," not the investigational new drug application standard. This vote is permitting patient-specific compounding with a valid prescription, not mass production for unidentified consumers or	Y; Focused on 503A Bulk List criteria, looking through the lens of patient-specific prescription and not mass production.	Y; Felt that all 4 criteria were met, agreed with Dr. Mohammed's comments.

					copying of commercially available drugs.		
Melissa Loseke, DO	Y; Conditional “yes,” would like to see some tighter restrictions to protect patients from contaminated research grade products and to address concerns about bioterrorism caused by sourcing peptides from China.	Y; Felt that all 4 criteria were met, asked for restriction for topical only.	Y; Ongoing discrepancies in the information committee members are receiving.	Y; Responded to a public session speaker’s comment that that it would be asinine to approve heroin, that we have 12 FDA-approved drugs that are direct analogs of heroin.	Y; Based on evidence provided for a well-defined molecular substance, decades of human exposure, zero reports, a benign safety profile and a legitimate role in individualized patient care that current FDA-approved medications do not fully serve.	Y; Criteria for which the appointed position is asking of me were met. “I am not required and the ask is not burden of proof from an FDA perspective. So, my criteria were met.”	Y; “Yes” based on 503A criteria used for evaluating the peptides.
Haleem	Y; Patient	Y;	Y; Allowing	Y; No	Not present at	Not present at	Y; We took a

Mohammed, MD	safety, the greater good, and medical freedom.	American s are already using gray market vendors, and there needs to be more control to keep patients safe.	for prescriber- directed compoundin g in a licensed pharmacy against a lower documented harm rate.	further explanation.	vote.	vote.	decision that patients are already making and kept it in a system with rules and regulations. "The demand does not vanish when we vote no. Our patients want peptides." The FDA has zero control over the websites selling research use only products. Argued that gray market pipeline is the risk, and regulation is the safer choice. Claimed that FDA scientists were underprepared and used old data. Could not vote against patient safety and medical
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David Pope, PharmD	Y; Shift the decision to patients and providers, need to keep measuring safety issues, need to keep this in America.	Y; Asked for with restriction to topical use.	Y; No further explanation.	Y; Encouragement to support 503A pharmacies in reporting adverse event.	N; Complex regimen and potential dangerous downstream consequences.	Y; Agrees with Dr. Christian's comments. Getting this in front of patients, physicians, and pharmacists is important so they can judge the risk and determine if the peptide is right for them.	Y; No further explanation.
Joshua Starbuck, MD	Y; Echoed Dr. Loseke's comments.	Y; No further explanation.	Y; No further explanation.	Y; Echoed David Pope's comments, noted that there has been a lot of miscommunication and there are great opportunities for public education.	Y; It does not impact sleep architecture to the same extent that other current insomnia agents do. Packet provided by APBM addressed previous concerns.	Y; No further explanation.	Y; Felt that the 4 criteria were met.
Kris H. Wusterhausen, DO	Y; FDA's case about safety concern is	Y; FDA did not prove any significant	Y; No further explanation.	Y; No further explanation.	Y; Good safety data, and trying to return the	Y; Agreed with Dr. Christian's comments.	Y; Felt all 4 criteria were met. There is a plethora of

	not convincing.	t side effects, so he felt there was safety.			treatment between physician and patient.		safety data out there on Semax, but it is “harder to get a hold of.”
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¹ Food & Drug Admin., *Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act* (Sept. 29, 2023), <https://join.a4pc.org/hubfs/PDFs/503A-Categories-Update-for-September-2023-FINAL.docx.pdf>.

² See Food & Drug Admin., *FDA Briefing Document: Pharmacy Compounding Advisory Committee* (July 2026), <https://www.fda.gov/media/193343/download>.

³ 21 C.F.R § 216.23(c).

⁴ *FDA Briefing Document*, *supra* n. 2.

⁵ See Food & Drug Admin., *FDA Briefing Document: Pharmacy Compounding Advisory Committee* (July 2026), <https://www.fda.gov/media/193343/download>.

⁶ Rachel Roubein, *FDA Raised Conflict of Interest Concerns Ahead of New Peptide Panel*, Wash. Post (July 17, 2026), <https://www.washingtonpost.com/health/2026/07/17/fda-raised-conflict-interest-concerns-ahead-new-peptide-panel/>.

⁷ [Roubein](#), *supra* n.6; Berkeley Lovelace Jr., ‘Pandora’s box’: FDA peptide votes could open the door to more unproven drugs, NBC News (July 24, 2026), <https://www.nbcnews.com/health/health-news/fda-peptide-votes-open-door-unproven-drugs-pandoras-box-rcna589105> .

⁸ Roubein, *supra* n. 6; Lizzy Lawrence & Sarah Todd, Longevity, *Wellness Physicians Named to Panel Advising FDA on Peptides*, STAT (June 29, 2026), <https://www.statnews.com/2026/06/29/new-fda-peptide-advisers-compounding-committee-conflicts/>.

⁹ See Mengyuan Fu et al., *FDA Advisory Committee’s Vote May Open a Drug-Compounding Back Door for Unapproved Peptides*, Health Affairs (Aug. 6, 2026), <https://www.healthaffairs.org/content/forefront/fda-advisory-committee-s-vote-may-open-drug-compounding-back-door-unapproved-peptides>.

¹⁰ See, e.g., Roubein, *supra* n. 6; Lovelace, *supra* n. 7.

¹¹ See Food & Drug Admin., *July 23, 2026 Meeting of the Pharmacy Compounding Advisory Committee (PCAC)* (July 23, 2026), <https://www.youtube.com/watch?v=DhDC0DAYdBI>.

¹² Sabrina Siddiqui & Sara Ashley O’Brien, *Peptides Are Everywhere. RFK Jr. Wants to Make Them Even Easier to Buy*, Wall St. J. (Mar. 22, 2026), <https://www.wsj.com/health/rfk-jr-china-peptides-market-2ce249df>.

¹³ 21 U.S.C. § 353a(c)(1).

¹⁴ See, e.g., *Am. Acad. of Pediatrics v. Kennedy*, 823 F. Supp. 3d 141 (D. Mass. 2026); *Lorillard, Inc. v. Food & Drug Admin.*, 56 F. Supp. 3d 37 (D.C. 2014), *reversed on other grounds by R. J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 810 F.3d 827 (D.C. Cir. 2016).