

July 9, 2026

Pharmacy Compounding Advisory Committee  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

## **Re: Pharmacy Compounding Advisory Committee Consideration of Certain Peptides**

Dear Members of the Pharmacy Compounding Advisory Committee:

On behalf of the Alliance for Pharmacy Compounding, thank you for the opportunity to provide comments as the Pharmacy Compounding Advisory Committee evaluates certain peptide substances.

APC urges the Committee to approach its deliberations by recognizing that the safety of patients is best served when they have access to medications through a transparent, highly regulated healthcare system. In evaluating these peptides, the Committee has a critical opportunity to consider which regulatory path most effectively protects the public: one that encourages patients to work within the established prescriber-patient-pharmacist relationship, or one that, by default, leaves them to navigate an unregulated and increasingly active illicit marketplace. More pointedly, we believe a failure by FDA to equip the former will likely further fuel the latter.

### **The Committee's Broad Advisory Authority**

The PCAC's charter provides the Committee with a mandate that extends beyond binary "yes" or "no" recommendations. Under its charter, the Committee is tasked with reviewing "scientific, technical, and medical issues concerning drug compounding" to make "appropriate recommendations to the Commissioner."

The charter expressly clarifies that while the Committee provides expert recommendations, **"FDA retains full regulatory decision-making authority."** [1] This distinction is vital: the Committee is uniquely situated to advise FDA on the clinical utility and scientific profile of these peptides, while acknowledging that FDA possesses the regulatory tools to determine what specific safeguards or conditions of use should accompany their inclusion on a compounding list.

### **The Public Health Reality of the Peptide Marketplace**

This discussion does not take place in a vacuum. A robust and sophisticated illicit marketplace for peptides already exists outside the regulated drug distribution system. FDA has documented this threat extensively, issuing numerous warning letters to firms marketing unapproved and

misbranded peptides—such as thymosin beta-4, BPC-157, and others—that are often labeled "For Research Use Only" (RUO) to evade regulatory oversight while being promoted for human use. [2]

Despite these enforcement efforts and FDA's public health alerts regarding the risks of unapproved peptides, the consumer demand for these substances remains high. [3] When patients are unable to access these therapies through legitimate channels – state-licensed pharmacies, which operate under rigorous USP standards and professional oversight, for instance – they do not necessarily stop seeking the substances. Instead, they often look to unregulated channels that offer no guarantees of identity, purity, potency, or sterility.

APC strongly supports FDA's continued enforcement against these unlawful actors. However, it is a matter of public health realism to recognize that a policy of total prohibition within the regulated channel may inadvertently increase overall risk by driving patients into the least transparent corners of the marketplace.

### **A Regulated Pathway as a Risk-Mitigation Strategy**

APC is not suggesting that the existence of an illicit market overrides the statutory criteria for listing bulk drug substances. Rather, we submit that where the Committee finds a compelling need for these peptides, the most protective public health strategy is to provide a regulated, accountable pathway for their preparation.

Compassionate and effective public health policy should prioritize bringing patients into a system characterized by:

- **Professional Oversight:** Compounding under Section 503A requires a valid patient-specific prescription and the clinical judgment of both a licensed prescriber and a licensed pharmacist. [4]
- **Quality Standards:** State-licensed pharmacies must comply with stringent USP compounding standards and state board of pharmacy regulations.
- **Verified Sourcing:** Lawful compounders must use ingredients from FDA-registered facilities, ensuring a level of API (Active Pharmaceutical Ingredient) integrity that is absent in the RUO market.
- **Accountability:** Regulated pharmacies are subject to inspections, professional licensure, and adverse event reporting mechanisms.

### **Conclusion: Recommending Measured Access with Guardrails**

The Committee need not choose between unrestricted access and a blanket prohibition. Consistent with its charter, the Committee may recommend that FDA permit the compounding

of these peptides while also recommending that FDA consider targeted guardrails to address identified safety or quality concerns.

By recommending a disciplined, regulated pathway, the PCAC can help transition patients from the risks of the illicit market into the safety of the pharmacy-based healthcare system. This approach aligns with FDA's mission to promote the public health by ensuring that when patients use these substances, they do so under the care of health professionals and within a framework of rigorous quality and accountability.

Respectfully,



Scott Brunner, CAE  
Chief Executive Officer

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## References

[1] *Pharmacy Compounding Advisory Committee Charter*. U.S. Food and Drug Administration. [Link](#).

[2] See, e.g., FDA Warning Letter to Gorilla Mind LLC (re: marketing BPC-157 and other peptides as RUO while targeting human use), Sept. 2023; FDA Warning Letter to Peptides Warehouse (re: unapproved and misbranded peptide products), 2018.

[3] *FDA Warning on Unapproved Peptides*. FDA News and Alerts. [Link](#).

[4] *Federal Food, Drug, and Cosmetic Act, Section 503A (21 U.S.C. 353a)*. Human Drug Compounding Laws. [Link](#).