July 2026

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2025-N-6895, 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

Dear Dockets Management Staff:

The Partnership for Innovation and Empowerment (PIE) submits this comment ahead of the July 23 to 24, 2026 meeting of the Pharmacy Compounding Advisory Committee (PCAC), which will consider adding fourteen bulk drug substances, seven peptides in both free base and acetate form, to the Section 503A Bulk Drug Substances List. (source)

PIE asks FDA and the Committee to:

- Decline, for now, to add BPC-157, KPV, TB-500, MOTs-C, Emideltide, Semax, and Epitalon to the 503A Bulks List, since none of the fourteen substances currently satisfies FDA's own three part statutory test on characterization, safety, and effectiveness;
- Direct FDA resources toward public, plain language guidance that helps patients in underserved communities, who are disproportionately likely to be self-directing peptide use without a primary care physician to consult, recognize mislabeled or "research use only" products before this Committee revisits the question; and
- Publicly disclose the financial and professional relationships of any PCAC participant who prescribes, produces, or promotes these substances commercially, so that the public can weigh the Committee's eventual recommendation with full knowledge of who is at the table.

The underlying evidence has not changed

These substances remain unapproved by FDA and, until recently, sat in Category 2, meaning FDA had already identified significant safety risks and had prohibited their use in compounding pending further evaluation. (source) Most lack the large scale, controlled human clinical trials that FDA ordinarily requires before a drug reaches patients. As the Associated Press has reported, there is little research behind the muscle building, weight loss, and anti-aging claims driving current demand, and most of these peptides have never been reviewed for safety by FDA. (source) Physicians are raising the same concerns. In a recent installment of its *What Doctors Wish Patients Knew* series, the American Medical Association featured a sports medicine physician who put it plainly: there is not yet enough statistically significant evidence to recommend these newer injectable peptides safely, in contrast to well studied peptide drugs like insulin and GLP-1 medications. (source) Some, like TB-500, have shown effects in animal studies, including accelerated tumor growth and immune interference, that warrant caution rather than expanded access.

Why this matters to the communities we serve

PIE works alongside underserved communities on access to affordable, reliable healthcare, including our ongoing advocacy on 340B hospital reform and pharmacy benefit manager practices that leave low income and rural patients facing pharmacy deserts and unpredictable access to medication. That work has taught us a hard lesson: when oversight is thin, the people who pay for it first are the ones with the least room to absorb a bad outcome, whether that is a wrong dose, a contaminated product, or a medication that simply is not what the label says it is. We are concerned that expanding legal access to these fourteen substances, before FDA's own scientific review is resolved, risks repeating that pattern in a new form.

A note on process

We recognize the argument that adding these substances to the 503A list would move patients out of the unregulated gray market and into licensed compounding pharmacies under physician supervision. That is a legitimate goal, and we do not dismiss it. But moving a substance onto a legal compounding pathway does not, on its own, generate the missing safety and effectiveness data, it primarily expands the pool of patients who can be legally exposed to that missing data. We would also note recent reporting that this Committee's roster leans more heavily than prior panels toward professionals with a commercial stake in peptide prescribing and sales. That composition may be entirely appropriate, but the public record should reflect it plainly so that the Committee's eventual recommendation carries the confidence it needs.

Thank you for the opportunity to comment. We would welcome the opportunity to provide additional information or testimony to the Committee.

Respectfully submitted,

Brady J. Buckner
President, Partnership for Innovation and Empowerment