



July 9, 2026

Takyiah Stevenson, PharmD
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Electronically Submitted via
[regulations.gov](https://www.regulations.gov)

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

Members of the Pharmacy Compounding Advisory Committee:

The Chronic Care Policy Alliance (CCPA) appreciates the opportunity to comment on the committee's consideration of several peptide substances for inclusion on the Section 503A Bulks List. We respectfully urge the FDA not to add the nominated peptide substances to the Section 503A Bulks List at this time.

CCPA is a national coalition of patient advocacy organizations committed to advancing policies that protect patients living with chronic illnesses and improve access to safe, effective, and high-quality care. We recognize that pharmacy compounding serves an important role when a patient's individual medical needs cannot be met by an FDA-approved medicine. However, compounding should remain a carefully limited exception. It should not become a routine pathway for broader patient access to substances that have not undergone FDA's premarket review for safety, effectiveness, manufacturing quality, and consistency.

Interest in peptide therapies has grown rapidly in recent years, with patients increasingly encountering these substances through online advertising, telehealth platforms, social media, and other digital channels. As public awareness continues to grow, it becomes increasingly important that decisions regarding routine compounding remain grounded in scientific evidence and patient safety.

Unlike FDA-approved medicines, the nominated peptide substances have not undergone FDA's premarket review. FDA has established criteria for evaluating whether bulk drug substances are appropriate for routine compounding, including consideration of safety, effectiveness, and historical use. CCPA believes those criteria serve an important patient protection function and should continue to guide FDA's evaluation of these nominations.

CCPA supports continued research into peptide therapies and recognizes that some of these substances may ultimately demonstrate important clinical benefits for patients living with chronic



Chronic Care
Policy Alliance

State Advocates
Working Together
to Bridge the Gaps
in Chronic Care

diseases. However, promising therapies should complete the appropriate scientific evaluation before they become broadly available. This helps ensure that patients receive treatments that are supported by evidence, manufactured under appropriate quality standards, and accompanied by clear information regarding their risks and benefits.

For these reasons, CCPA respectfully urges FDA not to add the nominated peptide substances to the Section 503A Bulks List at this time.

Thank you for the opportunity to provide these comments.

Sincerely,

Elizabeth Helms
CEO
Chronic Care Policy Alliance (CCPA)
liz@chroniccarealliance.org