ENDOCRINE SOCIETY
Hormone Science to Health

November 13, 2026

The Honorable Robert F. Kennedy Jr.
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Submitted Electronically to http://regulations.gov

Re: Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances (HHS-OASH-2026-0496)

Dear Secretary Kennedy:

On behalf of the Endocrine Society, I am writing regarding the interim policy to allow the compounding of six unapproved injectable peptides: BPC-157, Epitalon, KPV, MOTS-c, Semax, and TB-500. Founded in 1916, the Endocrine Society represents approximately 18,000 physicians and scientists engaged in the management and research of endocrine disorders, including obesity. The Society is at the forefront of research and clinical practice using new hormone-based therapies to treat obesity and related medical problems. Many of our members have specific expertise in understanding injectable peptides and in obesity research, prevention, and treatment.

I would like to express the Endocrine Society's opposition to this proposal and urge you not to move forward with this interim policy. There is a lack of clinical evidence and research on all six of these injectable peptides. This lack of evidence raises the potential of patient harm and undermines the gold standard drug approval system in place at the Food and Drug Administration (FDA). Further, there is broad concern in the health professions community about the safety of compounded semaglutide. In addition, FDA scientists have raised concerns about the safety of this policy, indicating there is not enough human evidence on the safety and efficacy to allow for the compounding of these peptides.[1] According to the FDA's own scientists, all six of these substances lack the clinical evidence needed to ensure these peptides are safe and effective. Only one of these

[1] FDA Raised Conflict of Interest Concerns Ahead of New Peptide Panel, Washington Post, July 17, 2026, Retrieved from: https://www.washingtonpost.com/health/2026/07/17/fda-raised-conflict-interest-concerns-ahead-new-peptide-panel/; Meeting of the Pharmacy Compounding Advisory Committee, Food and Drug Administration, July 23-24, 2026, Retrieved from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/july-23-24-2026-meeting-pharmacy-compounding-advisory-committee-07232026#event-materials

2055 L Street NW
Suite 600
Washington, DC
20036

T. 202.971.3636
F. 202.736.9705

endocrine.org

six peptides, BPC-157, has undergone a human study, and that study included just 16 participants.[2] This lack of robust evidence could harm the health of the patients we treat.

We are also concerned about the potential confusion our patients may experience because of this policy. Recent survey results have shown that only 17% of consumers correctly understand that compounded GLP-1s are not FDA approved and roughly half of current GLP-1 users mistakenly believe that compounded versions have gone through the same approval and testing process as FDA approved mediations.[3] Unfortunately, misleading marketing tactics and social media influencers add further confusion for patients. This confusion regarding compounded GLP-1 medications would likely be similar for these six peptides.

Finally, we object to the process your department has taken to implement this interim policy. As you know, the FDA has a foundational standard that ensures appropriate consideration by the FDA's leading scientists. The FDA scientists staff found that none of these peptides met the criteria to be included on the 503A Bulks List. However, the FDA Pharmacy Compounding Advisory Committee (PCAC), which included a significant number of new members with ties to peptide related businesses and clinics, recommended the inclusion of six peptides on the Bulks List.[4] This undermines the evidence-based research the FDA has followed since the agency's founding and sets a dangerous precedent for allowing more unapproved compounding in the future.

Thank you for the opportunity to comment on this policy. On behalf of our members and the patients they treat, we urge you to not move forward with this proposal. If you have any questions, please reach out to Rob Goldsmith, Director, Advocacy and Policy, at rgoldsmith@endocrine.org.

Sincerely,

Nanette Santoro, MD
President

[2] Lee E, Padgett B. Intra-Articular Injection of BPC 157 for Multiple Types of Knee Pain. Altern Ther Health Med. 2021 Jul;27(4):8-13. PMID: 34324435. Retrieved from: https://pubmed.ncbi.nlm.nih.gov/34324435/
[3] The Shortage is Over. The Risks are Not: How Illegal Mass Compounding Is Undermining Patient Safety And What Must Happen Next, Americans for Safe & Effective Medicines, Retrieved from: https://safeandeffectivemeds.org/wp-content/uploads/2026/07/ASEM_PolicyBrief.pdf
[4] FDA raised conflict of interest concerns ahead of new peptide panel, The Washington Post, July 17, 2026, Retrieved from: https://www.washingtonpost.com/health/2026/07/17/fda-raised-conflict-interest-concerns-ahead-new-peptide-panel/

2055 L Street NW
Suite 600
Washington, DC
20036

T. 202.971.3636
F. 202.736.9705

endocrine.org