NATURAL PRODUCTS ASSOCIATION

444 North Capitol Street NW Suite 638,
Washington, D.C. 20001
(202) 223-0101, Fax (202) 223-0250
www.npanational.org

July 22, 2026

Dear Committee Members;

The Natural Products Association (NPA) appreciates the opportunity to provide comments regarding the advisory committee's consideration of the inclusion of the following bulk drug substances on the 503A Bulks List: BPC-157-related bulk drug substances (BPC-157 free base/BPC-157 acetate), KPV-related bulk drug substances (KPV free base/KPV acetate), TB-500-related bulk drug substances (TB-500 free base/TB-500 acetate), MOTs-C-related bulk drug substances (MOTs-C free base/MOTs-C acetate), Emideltide (also referred to as Delta Sleep-Inducing Peptide (DSIP)) and related bulk drug substances, Semax-related bulk drug substances, and Epitalon-related bulk drug substances.

While we recognize that the purpose of this meeting is to evaluate these substances for potential inclusion on the 503A Bulks List, we respectfully urge the Committee to recognize that such consideration should NOT be interpreted as foreclosing the possibility that certain naturally occurring peptides may also be appropriate for other FDA-regulated categories, including foods and dietary supplements, where permitted under applicable law.

As scientific understanding of bioactive peptides continues to evolve, so too does our knowledge of where these compounds naturally occur. Some peptides under consideration are known to occur naturally, while others remain the subject of ongoing scientific investigation regarding their presence in foods or the broader food supply. The existence of a compound within a drug development pathway should not, in itself, preclude scientific evaluation of its potential status as a lawful food or dietary ingredient. Rather, regulatory classification should continue to be determined by statutory requirements, intended use, and the totality of the available scientific evidence.

This issue is not limited to peptides. Throughout the history of food, nutrition, and medicine, naturally occurring constituents—including botanical compounds, amino acids, fatty acids, and other bioactive substances—have been studied both for therapeutic uses and for their role in supporting health and wellness. Congress via the Federal Food, Drug, and Cosmetic Act (FDCA) established distinct regulatory pathways for these categories, and preserving those pathways is essential to continued innovation and consumer access.

Peptides or bioactive peptides are short chains of amino acids generated through the breakdown of larger proteins. Numerous studies have demonstrated that these peptides may influence normal physiological processes through structure/function mechanisms while also providing nutritional value. Their biological activity is influenced by amino acid composition, sequence, molecular structure, charge, stability, and bioavailability. When marketed as foods or dietary supplements and used consistently with the requirements of the Federal Food, Drug, and Cosmetic Act, their intended purpose is not to diagnose, cure, mitigate, treat, or prevent disease, but rather to support the normal structure or function of the body and overall health.

Research in this field is advancing rapidly. Enzymatic hydrolysis remains the primary method for generating bioactive peptides from food proteins, while microbial fermentation and other food processing technologies continue to expand opportunities for identifying novel peptides. FDA's Human Foods Program acknowledged this emerging area during its March public meeting, highlighting the growing scientific interest in food-derived bioactive peptides.

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At the same time, extensive scientific resources including databases such as BIOPEP, PepBank, EROP-Moscow, and the Antimicrobial Peptide Database (APD) continue to catalog naturally occurring peptides while researchers identify additional compounds from animal, marine, plant, and fermented food sources. These discoveries underscore that our understanding of naturally occurring dietary peptides remains incomplete. As analytical technologies improve, additional naturally occurring peptides are likely to be identified within the food supply.

Equally important, innovation in food formulation and delivery technologies is improving the bioavailability of naturally occurring food components, including peptides. Advances that enhance absorption or stability should not alter the fundamental regulatory framework governing naturally occurring substances or limit their future evaluation as foods or dietary ingredients were supported by science and consistent with applicable law.

NPA supports continued scientific research into peptide therapeutics and recognizes the important role these compounds may play in advancing healthcare. At the same time, we encourage FDA to ensure that actions taken within one regulatory framework do not inadvertently restrict legitimate scientific inquiry or future regulatory consideration under other statutory pathways. Specifically, we ask that as there has been no authorization as a new drug; that listing for compounding is not a determination of drug status; and should NOT preclude ingredients from other pathways, so long as other aspects are in compliance with the FDCA.

As our understanding of naturally occurring bioactive peptides continues to evolve, it is important that the regulatory system remain sufficiently flexible to accommodate new scientific evidence while preserving the distinct legal frameworks established by Congress.

Thank you,

Daniel Fabricant, Ph.D.
President and CEO
Natural Products Association

cc: FDA office of the Commissioner