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November 13, 2026

Comments on the Department of Health and Human Services' Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances (HHS-OASH-2026-0496)

Public Citizen, a national nonprofit consumer advocacy organization with over one million members and supporters nationwide, submits the below comments to the U.S. Department of Health and Human Services (HHS) concerning the enforcement discretion policy regarding 503A compounding using certain peptide bulk drug substances.

On October 30, 2026, the HHS announced a draft "enforcement discretion policy" that would allow six unapproved and potentially unsafe peptides — BPC-157, Epitalon, KPV, MOTS-c, Semax, and TB-500 — to be manufactured, marketed, and prescribed without potential federal enforcement actions.[1] Public Citizen urges HHS to reconsider and not implement the enforcement discretion policy.

In July 2026 the Food and Drug Administration's (FDA's) Pharmacy Compounding Advisory Committee (PCAC) discussed the six peptides. FDA scientists recommended against adding each of the peptides to the 503A bulks list (that would allow the substances to be compounded), due to a lack of adequate data on the efficacy and safety of these substances.[2]

Just prior the meeting, HHS appointed new PCAC members who were predisposed to add the six peptides to the 503A bulks list. By appointing the new members, HHS cleared the way for the committee to make the recommendations the department desired. Without the votes of the newly appointed members, none of the six peptides would have been recommended.

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[1] HHS enforcement discretion policy regarding 503A compounding using certain peptide bulk drug substances. October 30, 2026. https://www.hhs.gov/sites/default/files/hhs-503a-peptide-enforcement-discretion-policy-appendix-b.pdf. Accessed November 13, 2026.

[2] Public Citizen. Stacked FDA peptide advisory committee delivers for RFK Jr. July 23, 2026. https://www.citizen.org/news/stacked-fda-peptide-advisory-committee-delivers-for-rfk-jr/. Accessed November 13, 2026.

To date, the FDA has not announced its decision about whether to add any of the peptides to the 503A bulks list. However, with its announcement of the enforcement discretion policy, the HHS effectively bypassed the FDA and its decision-making process. HHS has thus not only undermined the FDA's authority to halt the marketing and sale of unapproved drugs but also set a dangerous regulatory precedent that threatens public health and puts patients at risk.

Peptides, like any other investigational drug, should go through the standard FDA approval process for new drugs and not be made available to the public because "HHS believes that there is significant interest in the use of these peptides in compounding" or because it "advances patient choice and freedom."[3]

Since there are no adequate data yet on the safety and efficacy for these six peptides, Public Citizen also strongly disagrees that the enforcement discretion policy is "appropriately protecting patient safety."[4]

Instead of this flawed enforcement discretion policy, which may put patients at risk, HHS should support vigorous FDA enforcement of regulations to prohibit the manufacture, distribution, and marketing of both research-use-only peptides and other unapproved peptides.

Thank you for your consideration of our comments regarding this important issue.

Sincerely,

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[3] HHS enforcement discretion policy regarding 503A compounding using certain peptide bulk drug substances. October 30, 2026. https://www.hhs.gov/sites/default/files/hhs-503a-peptide-enforcement-discretion-policy-appendix-b.pdf. Accessed November 13, 2026.
[4] *Ibid.*