APhA
American Pharmacists Association

November 13, 2026

[Submitted electronically to http://www.regulations.gov]

The Honorable Robert F. Kennedy, Jr.
Secretary
Department of Health and Human Services (HHS)
200 Independence Ave SW
Washington, DC 20201

RE: [Docket No. HHS-OASH-2026-0496] Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances

Dear Secretary Kennedy,

Trust. It is the foundation of every relationship between a patient and their pharmacist. Whether a patient picks up a prescription at a local community pharmacy or has it delivered to their home, they rely on several assumptions about the medication they receive: that it is safe, that it has undergone Food and Drug Administration (FDA) review and approval, and that, if compounded, it has been prepared to the highest standards. FDA's longstanding record of rigorous oversight is what has made those assumptions reasonable.

The American Pharmacists Association (APhA) has serious concerns about HHS's draft "Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances." By signaling that HHS will not take enforcement action against compounding these substances before the rulemaking process for the 503A Bulks List is complete, the agency is bypassing the established FDA process for evaluating bulk drug substances.

APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA provided comments to FDA and the Pharmacy Compounding Advisory Committee (PCAC) in July regarding the inclusion of the six bulk drug substances in this draft policy on the 503A Bulks List, as part of the PCAC meeting. APhA's position remains that, barring new

evidence that is presented to PCAC or FDA, APhA supports FDA's recommendation not to add the nominated substances to the 503A Bulks List at this time.[1] Compounding pharmacies are the most appropriate place for patients to access compounded preparations; however, such products should not circumvent established legislative, regulatory, policy, and distribution frameworks designed to promote patient safety.

As acknowledged in our comments to FDA and the PCAC earlier this year, demand for both non-FDA-approved and FDA-approved peptides continues to rise.[2] For many FDA-approved peptides, especially the glucagon-like peptide-1 (GLP-1) agonists used in obesity and diabetes care, this demand for compounded peptides was driven by significant drug shortages in recent years, which have mostly resolved.[3] For the peptides addressed in this draft policy that have not received FDA approval, a gray market has emerged due to heightened demand stemming from limited avenues for legitimate access and their rising popularity on social media and in the wellness community. Greater use of unapproved products raises significant patient safety concerns, especially when purchased on unregulated gray markets.[4] APhA acknowledges that regulating the gray market will be challenging; however, enforcement discretion is not a substitute for the scientific and regulatory safeguards in place to protect patients. The presence of a dangerous gray market alone should not establish that a substance is appropriate for human use in compounding.

APhA and FDA both recognize the important role of patient-specific compounding when a patient has a clinical need that cannot be met by an FDA-approved product or when there is a drug shortage. However, enforcement discretion should not be used as a substitute for the established processes for determining whether a bulk drug substance is appropriate for use in

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[1] FDA Briefing Document, Pharmacy Compounding Advisory Committee (PCAC) Meeting, July 23-24, 2026, Food and Drug Administration (June 2026). Available at: https://www.fda.gov/media/193342/download.

[2] *See* Bruce Y. Lee, *RFK Jr.'s HHS is Allowing These 6 Unapproved Peptides to be Sold*, Forbes (Nov. 7, 2026). Available at: https://www.forbes.com/sites/brucelee/2026/11/07/rfk-jrs-hhs-allows-compounding-pharmacies-to-sell-these-6-peptides/. *See* Amanda Mull, Madison Muller, and Ashleigh Furlong, *The Billion-Dollar Peptides Gold Rush*, Bloomberg (June 17, 2026). Available at: https://www.bloomberg.com/features/2026-peptide-legalization-gold-rush/.

[3] *FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize*, FDA (April 1, 2026). Available at: https://www.fda.gov/drugs/drug-alerts-and-statements/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.

[4] *See* Sara Ashley O'Brien, *Teen Boys and Young Men Are Injecting Peptides in Search of Perfection*, The Wall Street Journal (May 11, 2026). Available at: https://www.wsj.com/health/wellness/boys-peptides-stacks-looksmaxxing-trevor-larcom-835e58cd. *See also* Kyra Breslin, *Inside the Alarming Rise of Teens Injecting Black Market Peptides as an 'Easy' Way to Lose Weight and Get Tan*, New York Post (May 6, 2026). Available at: https://nypost.com/2026/05/06/lifestyle/why-teens-are-injecting-black-market-peptides-they-find-on-social-media/. *See also* Amy Maxmen, *People Say These Peptides Hurt Them. Their Stories Are Muffled in MAHA's Push for Medical Freedom.*, KFF Health News (Oct. 13, 2026). Available at: https://kffhealthnews.org/public-health/peptides-experimental-drugs-patient-harms-maha-medical-freedom/.

compounding under section 503A of the Federal Food, Drug, and Cosmetic Act. Additionally, because FDA has not completed its evaluation of all the information presented at the PCAC meeting and submitted to the public docket, the interim policy risks rendering portions of the 503A process functionally premature and diminishing the significance of FDA's review and rulemaking.

While the enforcement discretion policy document outlines ten circumstances that must be met before compounding, those criteria alone do not constitute the evidence needed to adequately satisfy the scientific and regulatory considerations relevant to determining whether the substance is appropriate for inclusion on the 503A Bulks List. In addition to the lack of available peer-reviewed scientific evidence, there are still concerns, including from the United States Pharmacopeia, about the quality and safety of these peptides because they lack USP-NF Monographs, USP Reference Standards, and established bulk drug substance names, although characterization is listed among the ten criteria to be met.[5] Another concern is that patients may not understand the difference between an FDA-approved drug and a substance permitted to be compounded under the draft guidance, as they may associate access to it at their local pharmacy with FDA review and approval, even though this interim policy does not constitute approval or inclusion on the 503A Bulks List. **Accordingly, until FDA has had sufficient time to review the PCAC's recommendations, evaluate the literature submitted by the public as part of the July 2026 meetings, and start the formal rulemaking process, APhA urges HHS to rescind this draft policy.**

In addition, increased adverse event reporting and clear labeling requirements are necessary to promote patient safety and guide health care providers, including pharmacists, in educating patients about their use. FDA should also assess whether adding any of the requirements in the enforcement policy to the process for adding future substances to the 503A Bulks List would be warranted if a patient safety benefit is observed.

Accordingly, APhA urges HHS and FDA to: (1) withdraw the current enforcement discretion policy while FDA completes its review of the PCAC recommendations and relevant scientific evidence; (2) continue the established 503A Bulks List process, including appropriate rulemaking; (3) clearly communicate that enforcement discretion does not constitute FDA approval, a determination of safety or effectiveness, or inclusion on the 503A Bulks List; (4) strengthen adverse event reporting[6] and labeling requirements applicable to products compounded under any future enforcement discretion policy; and (5) continue to support

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[5] *USP Statement on Quality and Safety Considerations for Unapproved Peptides*, USP (Nov. 3, 2026). Available at: https://www.usp.org/news/usp-statement-on-quality-and-safety-considerations-for-unapproved-peptides.

[6] FDA Listening Session, APhA (Feb. 27, 2026). Available at: https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=spIshLGRap8%3d (noting that FDA should clearly explain what FAERS data represents and its limitations, so the public can interpret and use the information appropriately).

research regarding the safety, effectiveness, dosing, appropriate patient populations, and potential clinical uses of these substances.

The current lack of sufficient human data should not be interpreted as demonstrating that these substances lack potential clinical benefit. Rather, it underscores the need for additional research to characterize their safety, effectiveness, dosing, appropriate patient populations, and potential risks. If evidence develops to support inclusion of nominated substances on the 503A Bulks List, pharmacists will be integral to compounding and education on such preparations. Therefore, APhA supports continued research on these substances for patients and health care providers to better understand their potential uses and any corresponding risks or benefits.

The risk of this approach most heavily falls on the pharmacist. When a patient experiences an adverse event, the pharmacist will be held responsible, even if they complied with every condition of the draft policy and met all applicable compounding standards. The draft enforcement discretion policy does not provide any liability protection for pharmacists or pharmacies that compound these products, exposing them to both state regulatory action and civil liability. In light of these unaddressed liability concerns, APhA reiterates its request that HHS rescind this draft policy.

Thank you for the opportunity to submit comments on this draft policy. If you have any questions or would like to meet with APhA and our nation's pharmacists, please contact Michael Baxter, APhA's Vice President, Government Affairs, at mbaxter@aphanet.org.

Sincerely,



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APhA Executive Vice President and CEO