November 11, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances (Docket No. HHS-OASH-2026-0496)

Dear Secretary Kennedy:

On behalf of the American Academy of Family Physicians (AAFP), which represents 124,500 family physicians and medical students across the country, we appreciate the opportunity to comment on the draft notice published in the Federal Register on October 30, 2026, regarding Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances.

The AAFP strongly supports rigorous pre- and post-market testing of medications and biological agents to establish their safety and effectiveness, with clinical benefits measured by meaningful patient health outcomes. Consistent with our longstanding policy on Medication, Device, and Biologic Agents Testing and Selection, we believe that decisions regarding access to medications must be grounded in sound scientific evidence and established regulatory standards.

The AAFP is concerned that the proposed enforcement discretion policy would permit the compounding of six peptide substances before their safety and effectiveness have been adequately established. While we recognize the importance of patient access to emerging therapies, patient demand alone is not sufficient justification for making unapproved substances available for clinical use. The FDA's review processes are intended to protect patients from treatments that may be unsafe or ineffective.

We recognize that compounding plays an important role in meeting patients' medical needs when commercially available medications are not appropriate. However, we are concerned that FDA's Center for Drug Evaluation and Research (CDER) recommended against adding any of the six peptides covered by this policy to the 503A bulks list. HHS has pointed to additional information about the peptides and argued that some of FDA's safety concerns are

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theoretical rather than based on documented harm. However, this does not necessarily mean the peptides are safe. **The absence of documented harm should not be equated with affirmative evidence of safety**, especially when there is limited clinical evidence. The AAFP believes that unresolved questions regarding these substances should be addressed through FDA's scientific and regulatory review processes, rather than through an interim enforcement discretion policy that permits their use while those evaluations remain ongoing.

Although the proposed policy includes conditions related to product quality, manufacturing, and adverse event reporting, these safeguards cannot replace the need for evidence that the substances themselves are safe and effective. While these requirements may help reduce some risks associated with compounded medications, they do not address the underlying concerns about these peptides.

For these reasons, the AAFP urges HHS not to move forward with the draft enforcement discretion policy and instead allow FDA to complete its review of these substances through the established 503A regulatory process. We appreciate HHS's efforts to improve patient access to needed treatments but believe that ensuring medications are safe and effective must remain a priority. For additional questions, please contact Kate W. Gilliard, JD, Sr. Manager, Federal Policy & Regulatory Affairs at kgilliard@aafp.org.

Sincerely,



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American Academy of Family Physicians, Board Chair

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