



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances

[Docket No. HHS-OASH-2026-0496]

RIN 0910-ZD94

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of availability.

SUMMARY: The Secretary of the Department of Health and Human Services (HHS) is announcing the availability of an “Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances.” This document describes the Secretary of HHS’s enforcement policy regarding the use of certain peptide bulk drug substances in compounding pursuant to section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) while the list of bulk drug substances that can be used in compounding under section 503A of the FD&C Act (the 503A bulks list) is developed through rulemaking.

DATES: This announcement is published in the *Federal Register* as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Written comments can be submitted until 2 weeks after date of publication in the *Federal Register* via [regulations.gov](https://www.regulations.gov) on Docket No. HHS-OASH-2026-0496

FOR FURTHER INFORMATION CONTACT: Victoria Marshall, Office of the Assistant Secretary for Health, 200 Independence Avenue SW, Washington, DC, 202-690-7694, OASH-RFI@hhs.gov

SUPPLEMENTARY INFORMATION:

I. Background

HHS is announcing the availability of a draft “Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances.” This document describes the HHS Secretary’s enforcement policy regarding the use of certain peptide bulk drug substances in compounding pursuant to section 503A of the FD&C Act while the list of bulk drug substances that can be used in compounding under section 503A of the FD&C Act (the 503A bulks list) is developed through rulemaking (21 U.S.C. § 353a).

Compounding is generally a practice in which a licensed pharmacist, a licensed physician or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Compounded drugs are not FDA-approved, which means FDA does not review their safety, effectiveness, or quality before they are marketed. Although compounded drugs can serve an important medical need for certain patients, they also may pose risks to patients. However, based on the Pharmacy Compounding Advisory Committee meetings and data regarding utilization of peptides, HHS believes that there is significant interest in the use of these peptides in compounding given the lack of availability of approved products. Therefore, to expand and improve patient access, HHS does not intend to take enforcement action against a State-licensed pharmacy, Federal facility, or licensed physician compounding a drug product using a peptide bulk drug substance found in Appendix A. FDA’s future rulemakings may propose adding some or all of these peptides to the 503A bulks list based on the available evidence.

HHS may revisit application of this interim policy (in whole or in part) if, among other things, a safety signal or product quality issue arises with a compounded drug product within the scope of this policy. The draft Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances does not establish any rights for any person and is not binding on HHS or the public.

This policy contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521) is not required.

III. Electronic Access

Persons with access to the internet may obtain the document at <https://www.hhs.gov/sites/default/files/hhs-503a-peptide-enforcement-discretion-policy-appendix-b.pdf>, or <https://www.regulations.gov>. Use the HHS website listed in the previous sentence to find the most current version of the policy.

Robert F. Kennedy, Jr.,

Secretary,

Department of Health and Human Services.

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