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U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
Submitted electronically via regulations.gov

RE: Docket No. HHS-OASH-2026-0496 — Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances (91 Fed. Reg. 68526, October 30, 2026)

The Kentucky Board of Pharmacy ("the Board") appreciates the opportunity to comment on the Department's interim enforcement discretion policy concerning six peptide bulk drug substances: BPC-157, Epitalon, KPV, MOTS-c, Semax and TB-500. The Board regulates pharmacy practice in the Commonwealth of Kentucky, including the compounding pharmacies and nonresident pharmacies that may operate under this policy.

The Board supports traditional, patient-specific compounding when conducted within the scope of applicable federal and state law. As the Board explained in its June 10, 2026, comments to the Pharmacy Compounding Advisory Committee (Docket No. FDA-2025-N-6895), the Board has concerns regarding compounding operations that increasingly resemble manufacturing and regarding the broad use of substances that lack an FDA-approved counterpart without the body of safety and efficacy evidence ordinarily generated through the drug approval process. The interim policy raises those concerns directly. It also creates gaps and challenges for state boards of pharmacy that the Department should address now, because the policy has already taken effect.

Summary of recommendations

Primary recommendation: The Department should not proceed with the interim enforcement discretion policy. It should instead proceed through the rulemaking Congress required under section 503A(c).

If the Department nonetheless retains the policy, the Board recommends that it:

1. Place in the docket the utilization data and other evidence the Department relied on in departing from FDA's scientific review, including any data showing the policy will reduce use of research-use-only and illicitly sourced peptides.

2. State expressly that the policy does not preempt, displace or otherwise alter state law, and does not authorize or permit compounding that is prohibited under applicable state law.
3. Establish a practical mechanism for providing the reports required under the policy to state boards of pharmacy, share relevant FDA inspection findings with those boards, and clarify how compliance with each condition will be documented, monitored and enforced.
4. Address the scale of production and interstate distribution while the section 503A memorandum of understanding and 5 percent limit remain suspended, including specific criteria that distinguish patient-specific compounding from manufacturing.
5. Clarify conditions that are ambiguous or internally inconsistent so that state regulators, compounders and other stakeholders can apply the policy consistently.
6. Extend FDA's GLP-1 green list framework to the six peptides covered by the policy and make the list transparent so that regulators can verify that the original manufacturer identified on a certificate of analysis is on the list and that the ingredient a pharmacy uses can be traced to that manufacturer.

Comment 1: The interim policy should not substitute for the rulemaking Congress required

Congress specified how a bulk drug substance without a USP or NF monograph, and without an FDA-approved counterpart, becomes eligible for 503A compounding. It must appear on a list the Secretary develops "through regulations issued by the Secretary under subsection (c)" (21 U.S.C. 353a(b)(1)(A)(i)(III)). Subsection (c) requires the Secretary to consult the Pharmacy Compounding Advisory Committee and to promulgate the list "in consultation with the United States Pharmacopoeia Convention" (21 U.S.C. 353a(c)(1)–(2)). FDA has followed that process since the first bulks list rule in 2019 (21 CFR 216.23).

The Board does not question the Department's authority to set enforcement priorities. The Supreme Court has held that an agency's decision not to bring an enforcement action under the Food, Drug, and Cosmetic Act is generally committed to its discretion (*Heckler v. Chaney*, 470 U.S. 821 (1985)). The Court noted, however, that it was not deciding a case in which an agency adopts a general policy so extreme as to amount to an abdication of its statutory responsibilities.

The Board does not contend this policy has reached that point. But an open-ended, categorical commitment not to enforce, for six named substances, functions in practice much like placement on the bulks list. It does so without the statutory findings, USP

consultation or notice-and-comment record that a listing rule requires. The policy also took effect before comment, with a two-week comment period that followed publication.

Congress chose rulemaking, with advisory committee review, USP consultation and public comment, as the way to decide whether substances like these may be compounded. That process exists for exactly this situation, where FDA's scientific reviewers and its advisory committee disagree. The Board therefore recommends that the Department:

- Not move forward with the interim enforcement discretion policy.
- Proceed instead with a proposed rule under section 503A(c) addressing each of the six peptides, so that the evidence can be reviewed on a full public record.
- Confirm that USP will be consulted, as section 503A(c)(2) requires, before any of the peptides is listed.

If the Department retains the policy despite these concerns, the Board asks that it adopt the recommendations in Comments 2 through 7.

Comment 2: The Department should publish the evidence it relied on

The policy departs from FDA's own scientific review. For each of the six peptides, the Center for Drug Evaluation and Research (CDER) recommended against listing. At the July 24, 2026, Advisory Committee meeting, FDA's presentation on Epitalon and Semax cited poor physical and chemical characterization, insufficient human safety data, immunogenicity risk, a possible long-term cancer concern for Epitalon, and abuse and bleeding signals for Semax.

Appendix B explains the departure by pointing to evidence that was not before CDER: lot-specific certificates of analysis from FDA-registered facilities, newly "documented and quantified" historical use, and human studies. None of that evidence appears in the docket. Without it, commenters, state regulators and FDA itself cannot evaluate whether the evidence answers CDER's concerns.

The policy also departs from FDA's existing interim framework. Under FDA's January 2025 guidance, a substance qualifies for interim enforcement discretion only if FDA has not identified it as presenting a significant safety risk. These six peptides were in Category 2, reserved for substances with significant safety risks, from September 2023 until April 22, 2026. They left Category 2 because the nominations were withdrawn, not because FDA found the risks resolved.

The policy also rests on an untested premise. The Secretary "has determined that this limited enforcement-discretion policy will discourage the continued, widespread use of

certain research-use-only peptides supplied by foreign manufacturers." The Board is not aware of any data showing that people who now buy research-use-only or illicit peptides will switch to compounded products once those products are available. Compounded peptides require a prescription, a prescriber visit and pharmacy pricing, while research-use-only products are sold online without any of these. Patients may continue to use both channels, and the policy could expand overall demand rather than redirect it. The policy offers no evidence on this point and no plan to measure whether it works.

The Board recommends that the Department:

- Place in the docket the utilization data and studies cited in Appendix B, with confidential commercial information redacted as needed.
- Reopen or extend the comment period for at least 30 days after that evidence is posted.
- Explain how each of CDER's specific safety findings has been addressed.
- Publish any data supporting the conclusion that the policy will reduce use of research-use-only and illicit peptides.
- Identify the measures the Department will use to track whether that use actually declines, and report the results publicly.

Comment 3: The policy should state that it does not displace state law

The policy speaks only to federal enforcement, but it is silent on state law. Licensees may read it as authorization to compound these peptides. In states whose law tracks section 503A, that reading would be wrong, and the policy should say so.

Kentucky is an example. Its compounding regulation, 201 KAR 2:076, Section 3(5), adopts the same three tests as section 503A(b)(1)(A)(i). Preparations compounded for human use must comply with a USP or NF monograph, be compounded from a component of an FDA-approved drug, or be compounded from a component on FDA's list of bulk drug substances. The regulation makes no exception for federal enforcement discretion, and a violation is unprofessional conduct under KRS 315.121. A Kentucky-permitted pharmacy that meets every condition of the policy may still violate Kentucky law.

The same gap already exists for substances in FDA's Category 1, which are compounded under federal enforcement discretion but are not on the bulks list. The peptide policy widens that gap to substances FDA's own reviewers found unsafe for listing.

State authority here is well established:

- Enforcement discretion is a decision not to prosecute. It creates no federal right to compound that could conflict with state law.
- The Federal Food, Drug, and Cosmetic Act contains no express preemption provision for prescription or compounded drugs. The Supreme Court has applied a presumption against preemption in this field (*Wyeth v. Levine*, 555 U.S. 555 (2009)).
- Detailed federal health and safety regulation does not by itself displace stricter state and local rules, and an agency's statement that it does not intend to preempt is dispositive on implied preemption of the field (*Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985)).
- FDA's own guidance states that it expects state boards of pharmacy to continue their oversight and regulation of pharmacy practice.

The Board recommends that the Department add an express statement that the policy does not preempt, displace or alter any state law, and does not authorize compounding that state law prohibits. A pharmacy should be required to comply with the law of every state into which it ships.

This statement matters. Under *Hillsborough County*, agencies are expected to make their intentions clear when they intend federal requirements to be exclusive, and an agency's disclaimer of preemption carries decisive weight. Without one, compounders may argue that state rules stand as an obstacle to the policy. In *Bryant v. Stein*, 732 F. Supp. 3d 485 (M.D.N.C. 2024), appeal filed (4th Cir. July 2024), a federal court held that state requirements re-imposing restrictions FDA had considered and rejected in a risk evaluation and mitigation strategy were preempted, because Congress had charged FDA with balancing safety and patient access.

That reasoning does not reach this policy, and the Department should say so. *Bryant v. Stein* rested on a risk evaluation and mitigation strategy issued under express statutory authority for an FDA-approved drug. The peptide policy is a nonbinding statement of enforcement priorities with no force of law, and it reflects no federal judgment about state compounding requirements. Obstacle preemption also turns on the purpose of Congress, not of an agency. In section 503A, Congress required that bulk drug substances be added through rulemaking, and Kentucky's regulation follows that requirement. The same court upheld state requirements addressing general patient safety, the practice of medicine and reporting to state health authorities, the traditional state role the policy should preserve.

Comment 4: The conditions depend on state oversight without any mechanism for it

Several of the policy's ten conditions can be verified only through inspection and records review, which in practice falls to state boards. The policy gives states no tools, data or federal support to do that work.

- **Reports to states (condition 5).** Compounders must report products compounded, serious adverse events and quality problems "to FDA and to the States where the products are compounded and sent." The policy does not say which state agency receives the reports, in what format, or how often. Many state boards have no system to receive or analyze them. Reporting to state health authorities falls within the states' traditional health and safety role, and a federal court has upheld such a requirement against a preemption challenge (*Bryant v. Stein*, 732 F. Supp. 3d 485 (M.D.N.C. 2024)).
- **MedWatch data.** Reports submitted to FDA through MedWatch are not routed to the state boards that license the reporting pharmacy.
- **Certificate of analysis review (conditions 3 and 4).** Appendix B sets a detailed testing standard that includes orthogonal identity methods, nitrosamines, residual TFA and endotoxins. Verifying it requires analytical expertise that state pharmacy inspectors generally do not have.
- **Oral bioavailability (condition 8).** Compounders of oral products must keep documentation of "adequate" oral bioavailability in humans. There is no standard against which an inspector can judge that documentation.
- **Documentation.** The policy does not identify the records a compounder must keep or what evidence is enough to show that a condition is met. It also does not say how a compounder will be treated if it claims to meet the conditions but cannot produce documentation to prove it. Without consistent criteria, state boards will evaluate the same conditions in different ways, producing inconsistent oversight and enforcement.

As the Board noted in its June 2026 comments, state boards are structured to regulate professional practice and patient-specific dispensing, not to provide the scientific and manufacturing oversight that FDA exercises over new drugs. The Board recommends that the Department:

- Name a receiving point for state reports, specify a standard format, and give state boards access to MedWatch reports involving compounders they license.
- Commit FDA to inspect compounders relying on the policy, using its authority under section 704 of the Act.

- Publish periodic summaries of reports received under condition 5.
- Identify the records compounders must maintain and produce on request, including the source and identity of each bulk drug substance, manufacturer verification, certificates of analysis, lot-specific testing, compounding records and distribution records.
- State that a compounder that cannot produce documentation showing it meets each condition is outside the policy.
- Provide standardized documentation expectations and inspection guidance for state boards, so that the same conditions are evaluated the same way in every state.
- Share relevant FDA inspection findings and compliance information with the board that licenses the inspected pharmacy and with the boards of states into which it ships, using FDA's existing authority to share non-public information with state officials under 21 CFR 20.88. This matters most when an out-of-state pharmacy ships into a state whose board has limited ability to inspect it.

Comment 5: Nothing limits scale or interstate distribution

The policy places no limit on volume or on shipping across state lines. In the current regulatory setting, that leaves high-volume, multi-state peptide compounding without any federal check.

Section 503A(b)(3)(B) limits a compounder's out-of-state distribution to 5 percent of its total prescription orders, unless its state has entered a memorandum of understanding with FDA. FDA has suspended the standard memorandum and deferred enforcement of the 5 percent limit until a final rule is issued. Until then, a single 503A pharmacy may ship compounded peptides nationwide in any quantity, relying on the policy for federal non-enforcement.

That is the manufacturing-like model the Board described in its June 2026 comments. Products prescribed one patient at a time, often through telehealth, can reach national scale without the approval, current good manufacturing practice and post-market surveillance that apply to manufacturers. The receiving state's board may have little ability to inspect the out-of-state pharmacy or trace adverse events back to it.

The line between traditional compounding and manufacturing should not be left to case-by-case interpretation. Section 503A requires that a drug be compounded for an identified individual patient based on a valid prescription, or in limited quantities before receipt of a prescription based on an established history of such prescriptions (21 U.S.C. 353a(a)). A

pharmacy can meet that requirement on paper while operating in a way that is functionally indistinguishable from large-scale production and distribution.

The Board recommends that the Department:

- Limit the policy to compounding that stays within the 5 percent interstate threshold in section 503A(b)(3)(B), whether or not FDA is currently enforcing that limit.
- Require compounders relying on the policy to notify each state into which they ship that they are doing so.
- Clarify that the policy does not cover compounding for office stock, resale, centralized filling or distribution through third parties, consistent with condition 10's patient-specific prescription requirement.
- Adopt specific operational criteria that distinguish patient-specific compounding from manufacturing or wholesale distribution, including the timing of compounding relative to receipt of the prescription, the volume and frequency of compounding, centralized fulfillment arrangements, the use of third-party entities and the geographic scope of distribution.

Comment 6: Several conditions need clarification

Some conditions are ambiguous or conflict with each other. Compounders cannot reliably comply with them, and regulators cannot consistently apply them.

Provision	**Issue**	**Requested clarification**
Semax route (Appendix B) and device limit (condition 9)	Semax is limited to intranasal use, but the only device that may be co-packaged with any covered product is a 510(k)-cleared syringe	Whether nasal spray devices are permitted for Semax, and if so, under what standard
Epitalon "intermittent courses" (Appendix B)	The term is not defined	A maximum course length and a minimum interval between courses
Oral bioavailability (condition 8)	"Adequate" oral bioavailability in humans is not defined, and no acceptable form of documentation is described	The evidence that satisfies the condition, or removal of oral routes until a standard exists

Certificate of analysis (conditions 3 and 4)	Compounders must rely on a COA meeting the Appendix B testing standard, but the policy does not say how a pharmacy should verify it	Whether independent testing is expected, and what a pharmacy must do when a COA is incomplete
Reseller validation (condition 4)	A repacker or reseller must "validate" the manufacturer and its COA, with no standard for that validation	Minimum validation elements, and whether the compounder must keep them on file
Labeling (condition 6)	The required statement does not say the product is not FDA-approved	Add "This product has not been approved by FDA" to the required statement

Comment 7: FDA's GLP-1 green list should be extended to the peptides and made usable by regulators

FDA has already built a tool for this problem. On September 5, 2025, FDA announced a “green list” import alert to stop GLP-1 active pharmaceutical ingredients from unverified foreign sources. Under Import Alert 66-80, revised October 9, 2026, GLP-1 bulk drug substances offered for import may be detained without physical examination unless the firm and product appear on the green list. A firm is added only when FDA's evaluation indicates that its active ingredient appears to comply with current good manufacturing practice.

FDA's reasons for the GLP-1 green list apply equally to the six peptides. FDA found that 21 percent of the 48 GLP-1 ingredient sites it inspected or assessed were not in compliance. It described sites that register, offer ingredients for import, refuse records requests and then deregister. It also noted that 503A compounders are exempt from current good manufacturing practice, so problems with ingredient quality may go undetected. The peptides covered by the policy are synthetic ingredients, largely sourced abroad, used by the same 503A compounders.

Condition 4 of the policy requires the original manufacturer to be registered under section 510, to comply with current good manufacturing practice, and to be identified with its physical site on the certificate of analysis. Registration, however, is not evidence of compliance, and neither a compounder nor a state inspector can confirm compliance from a certificate of analysis. The green list provides that confirmation, but only if regulators can use it. The current list appears in an import alert written for FDA field staff and organized by

country and product code. It gives state inspectors no practical way to match the manufacturer named on a certificate of analysis to a facility FDA has verified.

A manufacturer's presence on the list is necessary but not sufficient. Inspectors must also be able to confirm that the ingredient a pharmacy actually used came from that manufacturer and matches the certificate of analysis. The list should therefore carry enough identifying information to match the manufacturer named by the pharmacy to the manufacturer on the certificate of analysis and to the pharmacy's purchasing records.

The Board recommends that the Department and FDA:

- Extend the green list approach of Import Alert 66-80 to the six peptides, so that peptide ingredients from manufacturers FDA has not evaluated are detained at import.
- Make the green list transparent and searchable for state regulators and compounders, listing each firm's name, FDA Establishment Identifier, physical address and the specific ingredients covered.
- Add as a condition of the policy that the original manufacturer named on the certificate of analysis appear on the green list for that peptide.
- Require compounders to keep, under written policies and procedures, documentation showing that the manufacturer and source of each lot were verified at procurement and at use, including purchase invoices and lot-matched certificates of analysis.

Conclusion

The Board shares the Department's concern about patients obtaining research-use-only peptides from unregulated foreign sources. The right way to address that problem, however, is the rulemaking Congress required, not an open-ended interim policy. As written, the policy has no end date, rests on evidence not in the public record, assumes without data that it will reduce use of research-use-only products, is silent on state law, depends on state oversight it does not support, and places no limit on scale.

The Board respectfully asks the Department not to move forward with the interim policy and to proceed instead with the rulemaking that section 503A requires. If the Department retains the policy, the Board asks that it adopt the recommendations in Comments 2 through 7. The Board would welcome the opportunity to work with the Department and FDA on these issues.

Sincerely,

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Authorities cited

- HHS, Enforcement Discretion Policy Regarding 503A Compounding Using Certain Peptide Bulk Drug Substances, 91 Fed. Reg. 68526 (Oct. 30, 2026), with Appendices A and B
- 21 U.S.C. 353a(b)(1)(A)(i)(III), (b)(3)(B) and (c) (govinfo)
- 21 CFR 216.23
- 21 CFR 20.88, Communications with State and local government officials
- *Heckler v. Chaney*, 470 U.S. 821 (1985)
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- *Bryant v. Stein*, 732 F. Supp. 3d 485 (M.D.N.C. 2024), appeal filed (4th Cir. July 2024)
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- FDA, Category 2 bulk drug substances
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- FDA, Memorandum of Understanding Addressing Certain Distributions of Compounded Drugs
- FDA, FDA Launches Green List to Protect Americans from Illegal Imported GLP-1 Drug Ingredients (Sept. 5, 2025)
- FDA, Import Alert 66-80, Detention Without Physical Examination of GLP-1 Receptor Agonist Bulk Drug Substances (rev. Oct. 9, 2026)
- 201 KAR 2:076, Compounding
- KRS 315.121

- Kentucky Board of Pharmacy, Comments to the Pharmacy Compounding Advisory Committee, Docket No. FDA-2025-N-6895 (June 10, 2026)