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Alliance for Pharmacy Compounding

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August 25, 2026

Kyle Diamantas, J.D.
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Matthew J. Lash, J.D.
Acting Director
Office of Compounding Quality and Compliance
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Considerations for an FDA compliance framework for peptides

Dear Acting Commissioner Diamantas and Mr. Lash:

The Pharmacy Compounding Advisory Committee has recommended that six peptide-related bulk drug substances be included on the Section 503A Bulks List. The Alliance for Pharmacy Compounding recommends that FDA concur with those recommendations but not rush immediately to final rulemaking. Instead, FDA should establish an extended interim framework under which compounding of the PCAC-recommended substances would be permitted through the Agency's exercise of enforcement discretion, subject to defined safeguards.

Those safeguards should address API sourcing and quality, professional oversight and prescribing, patient disclosure, serious adverse-event reporting, traceability, and limited utilization data collection. They are intended to address identified risks from the outset, not to serve as an experiment on patients. The extended interim period would give FDA a controlled, regulated pathway now while also allowing the Agency to refine implementation as experience and data accumulate.

We believe this approach is preferable to attempting now to resolve every operational question through final rulemaking. It gives FDA meaningful control over the conditions under which these substances may be compounded, provides ongoing safety and utilization visibility, and preserves flexibility to determine later whether, when, and how further rulemaking is warranted.

I. Recommendation and legal basis

A flourishing illicit peptide market already exists and presents a threat to public health. APC believes that a regulated, guardrail-based compounding strategy better protects patients than either blanket prohibition or blanket approval of the peptides under consideration. The framework proposed here

would apply only to peptide substances affirmatively recommended by PCAC and specifically designated by FDA for this interim pathway.

Section 503A(c) directs FDA, through the Secretary, to identify by regulation bulk drug substances that may be used in compounding and requires consultation with PCAC.[1] APC is not asking FDA to bypass that process or permanently add these substances to the 503A Bulks List without rulemaking. The question is what FDA may do in the meantime – and for how long – while it considers the appropriate permanent regulatory treatment.

FDA's January 2025 Interim Bulks Guidance reflects the Agency's longstanding use of enforcement discretion in this setting.[2] For more than a decade, FDA generally did not prioritize enforcement against Section 503A pharmacies using properly nominated Category 1 substances while formal evaluation remained pending. Category 1 itself is not statutory; it is an administrative enforcement-discretion policy, and some substances remained within that interim structure for years. Just as important here, FDA has repeatedly exercised enforcement discretion in the compounding context subject to defined conditions. Examples include:

- FDA's Category 1 interim bulks policy, under which enforcement discretion has applied only to qualifying nominated substances and only when the pharmacy otherwise complies with Section 503A and the conditions of FDA's interim policy;
- FDA's temporary COVID-19 policy permitting certain Section 503A pharmacies to compound drugs for hospitalized patients before receipt of patient-specific prescriptions, subject to conditions that included adverse-event reporting and other limitations;
- FDA's transition periods after drugs came off the shortage list, including the GLP-1 transition periods, during which the Agency temporarily exercised enforcement discretion as to the essentially-a-copy restriction while other applicable compounding requirements remained in force; and
- FDA's enforcement-discretion policies concerning the Section 503A interstate-distribution limitation, under which the Agency has defined the circumstances in which it would or would not prioritize enforcement of the statutory 5% limitation.

These examples are directly relevant to the proposal here: FDA has not merely declined enforcement in the abstract; it has defined the conditions under which regulated parties may rely on an enforcement-discretion policy. APC is asking FDA to use that same tool for the PCAC-recommended peptides.

FDA therefore may define a separate enforcement-discretion policy for these PCAC-recommended peptides and specify the conditions that must be met for a pharmacy to come within it. That principle is consistent with FDA's broader authority to set enforcement priorities, recognized in *Heckler v. Chaney*, 470 U.S. 821 (1985).[3]

The important distinction is this: APC is not asserting that every safeguard proposed below is independently required by Section 503A for all compounded medications. We are recommending that FDA make compliance with these safeguards a condition of this particular enforcement-discretion policy. Because the policy would rest on enforcement discretion rather than permanent regulation, FDA could revise or refine the conditions as experience warrants.

The framework also should be durable. FDA need not set an arbitrary expiration date or treat final rulemaking as the automatic next step. The policy can remain in place for as long as FDA determines it is useful, legally appropriate, and protective of public health, with periodic review of safety information, utilization, compliance, and supply-chain performance.

II. Proposed conditions of extended enforcement discretion

We recommend that FDA announce that it generally does not intend to take enforcement action based solely on the use in Section 503A compounding of a designated PCAC-recommended peptide, provided the pharmacy and the bulk drug substance meet the conditions below. The framework should not alter traditional compounding with substances already permissible under Section 503A by virtue of an FDA-approved drug component, an applicable USP/NF monograph, an existing FDA enforcement policy, or final inclusion on the 503A Bulks List.

A. Supply-chain and sourcing safeguards

Require peptide API to be purchased only through an FDA-registered repackager, relabeler, or reseller that has completed vendor validation and Certificate of Analysis validation.

A pharmacy participating in this interim framework should be permitted to obtain a designated peptide API *only* through an FDA-registered repackager, relabeler, or reseller that has itself performed and documented appropriate vendor validation of the API manufacturer and validation of the manufacturer's Certificate of Analysis.

That purchasing-channel requirement is a central safeguard of the proposed framework. The repackager, relabeler, or reseller would provide the pharmacy with lot-specific documentation, including the validated CoA and information sufficient to establish provenance. Direct pharmacy purchases from an API manufacturer, or purchases through an entity that has not completed those validation steps, would not qualify for the enforcement-discretion pathway.

Section 503A already requires bulk drug substances to be manufactured by an establishment registered under Section 510, and such manufacturers are subject to applicable CGMP requirements. We recommend that FDA build on that baseline by establishing a substance-specific **Green List** identifying, for each designated peptide, FDA-registered API manufacturers that FDA has inspected or otherwise deemed to be cGMP-compliant.

Under this approach, the two safeguards would work together: the API manufacturer would need to appear on FDA's Green List for the designated peptide, and the pharmacy could obtain that API only through an FDA-registered repackager, relabeler, or reseller that had completed and documented vendor and CoA validation.

This structure intentionally places the primary vendor-qualification and CoA-validation functions upstream with FDA-registered entities already subject to FDA oversight, while preserving the pharmacy's responsibility to determine that the API received is suitable for the formulation, route of administration, dose, and applicable USP and state-law requirements. For purposes of this framework, supply-chain readiness would exist only when at least one qualifying Green List

manufacturer is available and the API can be obtained through an FDA-registered repackager or reseller meeting these validation requirements.

A staged Green List also would create an economic incentive for legitimate manufacturers to invest in validated processes, analytical methods, stability work, and impurity characterization. As additional manufacturers meet FDA's expectations, FDA could add them to the list. Over time, a reliable supply of appropriately manufactured API could displace research-grade material now circulating in the illicit markets.

B. Professional oversight and patient transparency

Limit compounding to valid, patient-specific prescriptions reflecting prescriber judgment

Peptide compounding under the interim framework should occur only pursuant to a valid patient-specific prescription reflecting the medical judgment of a licensed prescriber and the professional responsibilities of a licensed pharmacist. It should not be driven by consumer demand, casual internet marketing, research-chemical promotion, or office-stock purchasing. Nothing happens until a prescription is written.

The prescription should reflect an individualized clinical decision and an actual prescriber-patient relationship. The purpose should be to substantiate professional judgment, not to create a new federal practice-of-medicine regime or invite FDA to second-guess legitimate clinical decisions.

Provide enhanced patient disclosure

Patients receiving medications under this special framework should receive clear information that the preparation is compounded, is not FDA-approved, and that evidence regarding the active ingredient may be limited. The disclosure should support informed decision-making without stigmatizing the practice of pharmacy compounding or undermining prescriber judgment.

Important information about this compounded medication

> *This medication was prepared by a licensed compounding pharmacy based on a prescription from your licensed healthcare practitioner.*
>
> *This compounded preparation is not FDA-approved. The active pharmaceutical ingredient in this preparation has not been determined by FDA to be safe and effective for any indication.*
>
> *Available evidence of safety for this active ingredient may be more limited than for FDA-approved drug products or more established compounded therapies.*
>
> *The active ingredient used to prepare this medication was obtained through an FDA-registered repackager or reseller that documented the API's source from a manufacturer meeting FDA's requirements for this active ingredient, completed vendor validation and Certificate of Analysis validation, and confirmed that the material was labeled for use as an active pharmaceutical ingredient, not as research-grade or laboratory-use-only material.*
>
> *Use this medication only as directed by your prescriber. Contact your prescriber or pharmacist promptly if you experience side effects, unexpected symptoms, or concerns. Serious adverse events may be reported to your prescriber, your pharmacist, or FDA's MedWatch program.*

C. Safety reporting, traceability, and utilization data

Require serious adverse-event reporting and records sufficient for traceability and recall

As a condition of the interim policy, participating pharmacies should report serious adverse events through MedWatch and maintain records sufficient to support product investigations, traceability,

and recalls. We emphasize *serious* adverse events. Requiring reports of every minor, expected, transient, or clinically insignificant event could generate large volumes of low-value information and obscure the signals regulators most need to see.

Serious adverse-event reports also need denominator context. Ten reports have very different implications if they arise from 500 prescriptions than if they arise from 500,000. Limited, de-identified aggregate utilization data would give FDA that context without requiring patient-level information, proprietary pharmacy business data, or monitoring of individual prescribing patterns.

Use OPEN as the mechanism for limited utilization reporting

APC proposes that OPEN, coordinated by Emory University's Rollins School of Public Health through APC's existing research collaboration with Drs. Hui Shao and Donghai Liang, serve as the mechanism for collecting and analyzing utilization information for FDA-designated peptide APIs. APC's broader Compounding Dispensing Data initiative would remain voluntary; participation in OPEN for these designated APIs would be mandatory only for pharmacies electing to compound under the interim framework.

The required data set should remain deliberately small and limited to fields ordinarily available from dispensing systems:

- FDA-designated API name;
- dosage form and strength;
- patient gender, where available; and
- month of fill.

Emory would aggregate and analyze the data independently. FDA, other regulators, manufacturers, and the public would receive aggregate, de-identified analyses from the Emory Rollins School partners, rather than raw pharmacy- or patient-level data. Data handling would comply with HIPAA and applicable federal and state privacy requirements. Participation would not constitute FDA, Emory, or APC endorsement or certification of any individual preparation, pharmacy, prescriber, or prescribing practice.

APC would support recruitment, onboarding, training, technical assistance, and pharmacy engagement, while Emory would retain control of analytic methods and findings. Any project budget should reflect both Emory's scientific and data-management responsibilities and APC's operational implementation role.

D. Continued enforcement against unlawful peptide activity

Creation of a narrow regulated pathway should be accompanied by continued FDA enforcement against actors operating outside it, including sellers of illicit or misbranded substances marketed for human use under labels such as "For Research Use Only." A lawful pathway with meaningful conditions gives patients, prescribers, pharmacists, API manufacturers, and regulators an alternative to that market and draws a clearer line between actors participating in a regulated healthcare system and those choosing to operate outside it.

III. Why the interim framework should be extended and ongoing

The proposed safeguards are designed to address identified risks from the beginning: FDA-registered and appropriately qualified API sources improve supply-chain accountability; patient-specific prescribing and documentation reinforce professional oversight; disclosure supports informed

consent; serious adverse-event reporting improves safety visibility; and OPEN provides the denominator needed to interpret those reports responsibly.

The reason to maintain the framework for a sustained period is not to discover whether those protections are worthwhile. It is to allow the regulated pathway to operate long enough for a legitimate supplier base to deepen, for longitudinal safety and utilization information to accumulate, and for FDA to refine implementation details based on real-world experience.

A prolonged enforcement-discretion framework also gives FDA flexibility that immediate rulemaking does not. The Agency can adjust conditions, respond to emerging safety signals, and add qualifying Green List manufacturers without locking the model into permanent regulation.

There is therefore no policy reason to treat rulemaking as an automatic or imminent next step. If the framework is protecting patients, improving supply-chain accountability, generating useful data, and giving FDA meaningful visibility, the Agency should be able to maintain it while those benefits continue. If FDA later determines that rulemaking is warranted, it will have better information about which safeguards should be retained, modified, or omitted.

IV. Conclusion

PCAC's affirmative recommendations give FDA an opportunity to move beyond a binary choice between an unregulated marketplace and unconditional authorization to compound these substances.

There is a third path: an extended enforcement-discretion framework conditioned on meaningful safeguards for API quality, professional oversight, patient transparency, serious adverse-event reporting, traceability, and limited utilization data. It can protect patients now while giving FDA the time and evidence needed for later regulatory decisions.

APC stands ready to work with FDA, Emory University, pharmacy stakeholders, API manufacturers, and others to develop the operational details necessary to implement and sustain this framework responsibly.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer

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[1] 21 U.S.C. § 353a(c).

[2] U.S. Food and Drug Administration, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry* (January 2025).

[3] *Heckler v. Chaney*, 470 U.S. 821 (1985).