Title: FDA Advisory Committee Voted Yes on Six Peptides. Now What? The Regulatory Road Ahead

As previously reported, the FDA's Pharmacy Compounding Advisory Committee (PCAC) recently voted in favor of adding six peptides—BPC-157, KPV, TB-500, MOTS-c, Epitalon and Semax—to the list of bulk drug substances that may be used in compounding under Section 503A of the Federal Food, Drug, and Cosmetic Act (the 503A Bulks List). The July 2026 votes represented a significant development for the compounding industry, particularly because FDA staff had recommended against inclusion of the peptides before PCAC reached a different conclusion.

As discussed in our previous article, however, the PCAC votes did not immediately make these peptides lawful for compounding under Section 503A. PCAC serves an advisory role, and FDA retains the authority to ultimately decide whether a substance is placed on the 503A Bulks List. Accordingly, pharmacies should not interpret the favorable votes as authorization to begin compounding BPC-157, KPV, TB-500, MOTS-c, Epitalon or Semax.

With the advisory committee process now completed for these substances, the more important questions are (1) what FDA's next steps will be, (2) how long that process may take, (3) whether FDA could establish some form of interim enforcement posture before completing rulemaking, and (4) what the compounding industry can do in the meantime to influence the ultimate outcome.

The PCAC Vote Is an Important Step, But It Is Not the Final Step

Congress expressly incorporated consultation with PCAC into the process for developing the 503A Bulks List, which gives the Committee an important role in FDA's evaluation of substances nominated for use in pharmacy compounding. PCAC is not simply an outside organization offering an opinion about peptides. It is the federal advisory committee specifically charged with providing FDA advice concerning pharmacy compounding matters, including substances being considered for the 503A Bulks List. Members of the PCAC are selected by the FDA Commissioner or designee among authorities knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine and related specialties.

At the same time, Congress did not give PCAC final regulatory authority. FDA retains responsibility for determining which substances ultimately appear on the 503A Bulks List, and FDA is not legally required to adopt every (or any) recommendation made by its advisory committee.

That distinction is especially important following the July 2026 meeting because FDA staff and PCAC reached different conclusions concerning six peptides. FDA staff raised concerns regarding the available information concerning characterization, safety, effectiveness and other factors, recommending against inclusion. After considering FDA's presentation, available scientific information and public testimony, however, PCAC voted in favor of inclusion.

FDA must now determine how it will reconcile the recommendation of its advisory committee with the concerns expressed by Agency staff during the evaluation process. FDA could ultimately accept PCAC's recommendation, decline to follow it, develop additional

conditions or regulatory safeguards, request or consider additional information or simply take additional time before proceeding with formal rulemaking.

For the peptide industry, the July votes represent an important regulatory victory, but they do not represent the end of the process.

What Happens Next Inside FDA?

The formal pathway for placing a substance on the 503A Bulks List generally requires notice-and-comment rulemaking. FDA evaluates nominated substances based on several factors, including the physical and chemical characterization of the substance, available safety information, evidence regarding effectiveness and the substance's historical use in compounding. Consultation with PCAC forms an important part of that evaluation, but the Agency must still determine whether and how to proceed according to the Committee's recommendations.

If FDA decides to include these peptides, then the Agency would issue a proposed rule. Publication of a proposed rule would provide interested stakeholders with an opportunity to submit comments, scientific information, clinical data and other evidence supporting or opposing inclusion. FDA would then review the administrative record before determining whether to issue a final rule adding one or more of the peptides to the 503A Bulks List.

This distinction between a PCAC recommendation and final rulemaking is critical. The July 2026 votes substantially advanced the regulatory discussion surrounding these peptides, but the votes themselves did not amend the 503A Bulks List. Unless and until FDA takes further action, pharmacies must continue evaluating the legality of compounding these substances under the law and regulatory framework that currently exists.

What Happens to Category 1?

One of the most important short-term questions is whether the favorable PCAC recommendations could affect the interim regulatory treatment of these peptides before FDA completes final rulemaking.

Historically, FDA divided substances nominated for inclusion on the 503A Bulks List into three categories while the Agency evaluated those nominations. Category 1 generally consisted of substances that had been nominated with sufficient supporting information for FDA to evaluate and that did not appear among substances FDA identified as presenting significant safety risks. Under FDA's interim enforcement policy, the Agency generally did not intend to take enforcement action against a compounder solely because a Category 1 substance had not yet been formally placed on the 503A Bulks List, provided that the other conditions of the applicable enforcement policy were satisfied.

This historic framework was particularly important because FDA's evaluation and rulemaking process can take years. Category 1 effectively provided a limited regulatory bridge for certain nominated substances while FDA completed its review.

FDA modified that framework in January 2025. Under the revised policy, substances newly nominated on or after January 7, 2025 are no longer assigned to Categories 1, 2 or

3. Substances nominated before that date, however, remain within the existing categorization framework while FDA continues its evaluation.

A favorable PCAC vote does not automatically move a peptide into Category 1, nor should pharmacies assume that the Committee's recommendation itself creates enforcement discretion. The more important issue is whether FDA will now reconsider or otherwise modify the interim regulatory or enforcement posture applicable to any of these substances while the Agency determines whether to add these substances to the Bulks List.

For compounders, that may be one of the most consequential developments to monitor in the coming months.

How Long Could FDA Rulemaking Take?

Unfortunately, there is no fixed statutory deadline within which FDA must publish a proposed or final rule following PCAC's recommendation. The historical development of the 503A Bulks List demonstrates that the process can be lengthy.

For example, FDA published a proposed rule addressing ten other bulk drug substances in December 2016. The Agency did not publish the corresponding final rule until February 2019, more than two years later. In that final rule, FDA placed six substances on the 503A Bulks List and determined that four others should not be included.

That history does not necessarily mean that BPC-157, KPV, TB-500, MOTS-c, Epitalon and Semax will necessarily face a similar timeline. FDA can move more quickly when an issue receives sufficient regulatory priority, and peptides have generated substantial attention from compounders, physicians, patients and policymakers in recent months. Nevertheless, pharmacies and other stakeholders should not assume that a favorable PCAC recommendation necessarily means that a final rule will follow within several months.

Until FDA provides additional information regarding its intended regulatory approach, there is simply no reliable timetable for final action.

Delay May Be Just as Important as an FDA Rejection

Much of the discussion following the PCAC meeting has understandably focused on whether FDA will accept or reject the Committee's recommendations. That framing overlooks another possible outcome that may be equally consequential for compounders: FDA may simply take a significant amount of time before making a final decision.

FDA continues to evaluate numerous substances that have been nominated for the 503A Bulks List, and the Agency's development of that list has been an ongoing process for many years. As noted above, even where PCAC has completed its consideration of a substance, additional administrative steps remain before FDA issues a proposed or final rule.

From the perspective of a pharmacy attempting to make business decisions, prolonged regulatory uncertainty can have nearly the same practical effect as an unfavorable decision. A favorable PCAC recommendation that remains unresolved for several years does not necessarily provide a pharmacy with an immediate pathway to compound the substance.

Accordingly, the key question following the July meeting is not simply whether FDA ultimately agrees with PCAC. The timing of FDA's next action may be just as important as the substance of that action.

How Often Does FDA Disagree With Its Advisory Committees?

Stakeholders often try to assess how frequently FDA follows advisory committee recommendations as a way to anticipate potential outcomes. Although statistics regarding FDA advisory committees generally may provide some context, those numbers have limited usefulness when evaluating PCAC and the 503A Bulks List.

The Section 503A process is relatively unique. FDA applies a specific statutory framework to bulk substances used in pharmacy compounding, and the number of substances that have completed the entire nomination, advisory committee and final rulemaking process is relatively limited. In addition, substances may remain under consideration for substantial periods before FDA reaches a final regulatory determination.

The more useful historical lesson is that PCAC's recommendations are meaningful but not binding. FDA has repeatedly made clear, including during the recent PCAC meeting, that advisory committees provide advice and recommendations while the Agency retains final decision-making authority. At the same time, the favorable July votes give the peptide industry something it did not have before the meeting: a formal recommendation supporting inclusion from the federal advisory committee specifically charged with advising FDA on pharmacy compounding.

That recommendation should carry meaningful weight during the next stage of the process, particularly where PCAC reached its conclusion after considering the concerns presented by FDA staff.

The Industry Should Not Simply Wait for FDA

The period between PCAC's recommendation and FDA's next regulatory action should not be viewed as a waiting period. To the contrary, this may be one of the most important opportunities for the compounding industry, physicians, patients and other stakeholders to strengthen the scientific and administrative record supporting lawful compounding with these substances.

FDA clearly identified its concerns during the evaluation process. Those concerns included questions surrounding physical and chemical characterization, purity, safety, immunogenicity, effectiveness and the limitations of available clinical information. A favorable PCAC recommendation does not make those concerns disappear, and stakeholders seeking inclusion of the peptides should address them directly rather than simply relying on the Committee's vote.

The industry should therefore continue developing scientific evidence regarding the identity, purity and stability of these substances, while physicians and other clinical stakeholders should consider whether patient experience and outcomes can be documented in a more systematic manner. Information regarding dosing, patient populations, clinical outcomes and adverse events will generally be more persuasive to regulators when it is organized and supported than when it is presented solely through anecdotal accounts.

Formal notice-and-comment rulemaking will create another important opportunity. When FDA opens a docket addressing these substances, stakeholders should provide substantive comments that directly respond to FDA's stated concerns. The objective should not simply be to generate a large number of comments supporting peptides. A detailed submission supported by scientific literature, analytical information, clinical experience and proposed quality controls is far more likely to contribute meaningfully to the administrative record.

Congressional Advocacy Can Also Play a Role

There is also a legitimate role for Congressional education and advocacy. Congress created Section 503A and established the statutory framework under which FDA develops the 503A Bulks List. Members of Congress therefore have an appropriate oversight interest in how FDA administers that process and whether the existing regulatory framework adequately protects patients while preserving access to compounded medications.

The strongest advocacy message may not be that every peptide should simply be available for compounding. Instead, stakeholders should focus on whether appropriately regulated pharmacy compounding can provide a safer alternative to the peptide market that already exists outside traditional pharmacy channels.

Patient demand for peptides did not begin with the July 2026 PCAC meeting, and that demand is unlikely to disappear simply because a particular substance is unavailable through a licensed compounding pharmacy. Consumers can already encounter products marketed through websites and other channels as "research use only" substances, where the identity, potency, purity, sterility, sourcing and storage of the products may be difficult to determine.

That reality presents FDA with a broader public-health question: If substantial patient demand already exists, does restricting pharmacy compounding actually eliminate use, or does it push some of that demand into less regulated channels? The compounding industry has an opportunity to argue that appropriately licensed pharmacies operating under established quality standards, prescription requirements and regulatory oversight may provide a more controlled environment than the gray market that has developed around peptides.

The Strongest Approach May Be toPropose Guardrails

The compounding industry should also consider whether its position is strengthened by proposing meaningful safeguards rather than seeking unrestricted access to peptides. This is another way Congress can play a role, as FDA itself may not have statutory authority to implement guardrails.

FDA has repeatedly emphasized concerns regarding quality, safety and the limitations of available clinical evidence. Instead of dismissing those concerns, stakeholders can identify regulatory mechanisms designed to address them. Depending on the substance and the risks involved, those mechanisms could include enhanced testing requirements, appropriate sourcing standards, certificates of analysis, specific labeling, physician oversight, adverse-event monitoring or other quality controls.

Such an approach changes the regulatory discussion from whether FDA should simply permit or prohibit peptide compounding to whether a framework can be developed that appropriately manages the risks FDA has identified while preserving patient access.

The favorable PCAC votes provide an opportunity to have that discussion.

What Pharmacies Should Do Now

Pharmacies should continue to exercise caution while the regulatory process moves forward. The PCAC votes should not be described in marketing materials as FDA "approval" of BPC-157, KPV, TB-500, MOTS-c, Epitalon or Semax, because FDA has not approved these peptides through the drug approval process or added them to the 503A Bulks List.

Likewise, pharmacies should not make significant operational or financial decisions based solely on an assumption that FDA will quickly implement PCAC's recommendations. Pharmacies interested in the peptide market can certainly begin evaluating the regulatory landscape, sourcing considerations, state pharmacy requirements, applicable compounding standards, policies and procedures, and potential compliance infrastructure. They should, however, distinguish between preparing for a potential future market and assuming that the market is presently lawful.

That distinction is particularly important in an area receiving significant regulatory attention.

The Next Phase May Be More Important Than the Vote

The July 2026 PCAC meeting materially changed the regulatory discussion surrounding peptide compounding. FDA staff entered the process recommending against inclusion of all seven peptides under consideration, yet six substances emerged from the meeting with favorable recommendations from the federal advisory committee charged with evaluating pharmacy compounding issues.

That outcome matters, but it does not resolve what happens next.

FDA must now determine how it will respond to PCAC's recommendations, whether additional evidence or regulatory safeguards are necessary, whether any interim enforcement posture should change, and when the Agency will proceed with rulemaking. At the same time, the compounding industry has an opportunity to continue developing the scientific, clinical and policy record supporting lawful access through regulated pharmacies.

The July vote opened an important regulatory door. Whether BPC-157, KPV, TB-500, MOTS-c, Epitalon and Semax ultimately pass through that door will depend largely on what happens next.

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