

Restoring a Legitimate Pathway for Evidence-Based Peptide Review

A statement from Jim LaValle on the FDA's April 15, 2026 update removing 12 peptides from Category 2 and moving them toward formal review through the Pharmacy Compounding Advisory Committee.



Jim LaValle, RPh, CCN, MT

Chair, International Peptide Society (IPS)

Chair, A4M Peptide Certification Course

On April 15, 2026, FDA signaled an important shift by **removing 12 peptides from Category 2** and announcing planned Pharmacy Compounding Advisory Committee consultation on these substances. That list includes BPC-157, Epitalon, KPV, GHK-Cu, and other peptides that have been at the center of ongoing clinical and regulatory debate. FDA has already **placed several on the July 23-24, 2026 PCAC agenda**. This is not automatic approval, and it should not be framed that way. It is, however, a meaningful step toward restoring a legitimate scientific pathway - one that allows these compounds to be evaluated openly, carefully, and with patient safety at the center.

To understand why this matters, it helps to look back at 2023. Beginning in September 2023, FDA placed many of these peptide substances in Category 2 after identifying potential significant safety concerns, including immunogenicity, peptide-related impurities, active pharmaceutical ingredient characterization, and limited human safety data. In practice, that categorization sharply constrained their use in clinical settings and intensified the tension between growing patient interest and limited regulated access.

As a health care professional and pharmacist who has spent four decades studying patterns in real patients,

my view is straightforward: when promising compounds are pushed out of regulated channels, people do not stop searching for solutions. Too often, they move toward poorly sourced products with none of the purity, sterility, dosing, or oversight standards that responsible care requires. A transparent review process is the better path. It protects patients, supports practitioners, and creates a sounder framework for decision-making.

It is also important to emphasize that many of the peptide preparations at issue are handled as sterile compounds requiring precise dosing and controlled clinical oversight. That reality underscores why high-quality sourcing, rigorous safety standards, and proper regulatory oversight are not optional. If these substances are going to be used, they must be evaluated and handled inside a framework that prioritizes quality, sterility, traceability, and clinician accountability.

"This is how we move the field forward - deliberately, transparently, and grounded in evidence."

JIM LAVALLE

What does this recent development mean in practical terms? It signals an opportunity for more appropriate oversight, higher-quality sourcing, and a clearer clinical framework for compounds that, in many cases, have already made a meaningful difference in patient care. Progress in medicine often comes in phases, and this is a solid start. The key question now is which compounds will ultimately meet the standards for safety, efficacy, and clinical use in a way that supports both innovation and patient protection. As this review process unfolds, clinicians will need to stay informed and interpret these regulatory moves through a scientifically grounded, patient-first lens.

At the International Peptide Society, we have approached this work with that responsibility in mind. We have developed more than 70 monographs reviewing the available literature across peptide compounds and their potential clinical applications. That effort has never been about chasing enthusiasm. It has been about building an evidence foundation that helps practitioners judge risk responsibly and understand where peptide therapies may - and may not - fit within modern integrative medicine.

What responsible peptide progress requires

SCIENTIFIC RIGOR

Public review, disciplined interpretation, and clarity about where evidence is established and where it is still emerging.

PATIENT SAFETY

Regulated pathways, pharmacy-quality standards, and clinical oversight that reduce reliance on gray-market sourcing.

PRACTITIONER SUPPORT

Monographs, education, and practical guidance that help clinicians use peptides responsibly and in proper sequence.

REAL-WORLD EVIDENCE

Structured clinical learning that informs future safety, efficacy, and access decisions at scale.

What matters next is a deliberate, transparent, evidence-grounded process that includes careful scientific review, disciplined practitioner education, and continued real-world evidence collection across diverse clinical settings. Peptides are not magic, not casual, and not interchangeable. They belong inside a disciplined clinical framework that respects the body as a system of systems, protects metabolic reserve, and allows innovation and accountability to advance together.

As Chair of IPS (International Peptide Society) the **A4M Peptide Certification Course**, my priority is to help clinicians navigate exactly this kind of shifting landscape with clarity and confidence. Our curriculum is designed to provide a deep understanding of peptide mechanisms, safety considerations, regulatory status, and real-world clinical application so practitioners can make informed decisions rather than relying on hype or fragmented information. I am proud that A4M continues to provide responsible education in this rapidly evolving field. Through the Peptide Certification Course, we remain committed to equipping clinicians with balanced, evidence-informed training so they can integrate peptides into practice ethically, safely, and effectively as new opportunities emerge.

Warm regards,

Jim LaValle, RPh, CCN, MT

Chair, International Peptide Society (IPS)
Chair, A4M Peptide Certification Course
Member, A4M Scientific Advisory Board

Selected official links:

- FDA 503A Categories Update
- FDA PCAC meeting page
- FDA safety-risk summary
- A4M Peptide Therapy Certification