FDA Updates 503A Bulk Drug Substances Framework and Advances Review of Peptide Compounds

Personalized Health Association Provides Industry Perspective as Federal Review of Peptide Compounds Enters Formal Evaluation Phase

WASHINGTON DC, DC, UNITED STATES, April 15, 2026 /EINPresswire.com/ -- The Personalized Health Association (PHA) today responded to the latest developments from the U.S. Food and Drug Administration regarding bulk drug substances nominated for compounding under Section 503A of the Federal Food, Drug, and Cosmetic Act, including category updates and the scheduling of forthcoming Pharmacy Compounding Advisory Committee (PCAC) hearings.

The Agency's actions reflect continued progression from interim categorization toward a formalized evaluation pathway for multiple peptide compounds currently utilized in physician-directed care.

Regulatory Transition and Peptide Review Pathway

FDA's update includes the removal of several peptide substances from interim categories, alongside notice of upcoming PCAC review for potential inclusion on the 503A bulks list.

These include peptides such as:BPC-157, Semax, TB-500 (Thymosin Beta-4 fragment), Epitalon, MOTs-C, KPV, and Dihexa, among others.

Additional compounds widely cited in ongoing policy discussions and scientific literature include:GHK-Cu, DSIP (Delta Sleep-Inducing Peptide), Melanotan II, PEG-MGF, LL-37 (Cathelicidin), and related peptide analogs currently under regulatory consideration.

The Agency has indicated that these substances will be subject to formal evaluation beginning in July 2026, with additional reviews extending into 2027.

While public discussion has accelerated around peptide access, formal regulatory determination remains under FDA review through the PCAC process.

Recent federal signals, including the scheduling of PCAC review and broader policy discussions regarding peptide access indicate that regulatory agencies are actively evaluating near-term

pathways to expand patient access during the interim review period.

Under a framework of enforcement discretion, and consistent with physician oversight and 503A compounding standards, these compounds may be eligible for prescribing and compounding within a regulated, patient-specific context ahead of final PCAC determination.

This evolving framework reflects a growing alignment between patient demand, clinical use, and regulatory pathways, offering the potential for near-term access within a structured and medically supervised environment.

Strategic Leadership and Regulatory Engagement

Lee Rosebush, Lead Strategist for PHA, stated:

“We are now at a critical stage in the regulatory process where years of advocacy are transitioning into formal federal review. Moving these substances into the PCAC framework reflects that progression—establishing a structured pathway for evaluation grounded in safety, clinical use, and scientific data.

This moment marks the point where stakeholder engagement, policy work, and clinical reality converge into a process capable of delivering long-term regulatory clarity.”

Safety, Access, and System Integrity

Jimmy St. Louis, President of PHA, added:

“This transition is fundamentally about safety. Establishing a structured regulatory process creates a pathway for these therapies to move out of gray-market channels and into regulated, quality-controlled environments.

As clearer frameworks emerge, we are seeing a pathway for patients to transition away from unregulated sourcing and back into physician-guided care. That shift has the potential to significantly improve safety while restoring appropriate access.”

Founder Perspective

Bill Moses, Founder and Chairman of PHA, said:

“We are entering a transition from regulatory ambiguity to structured evaluation. The priority now is ensuring that patient–provider decision-making is preserved within a compliant, medically supervised framework.

If properly executed, this pathway allows innovation to advance while strengthening safety,

transparency, and long-term regulatory integrity."

Next Phase: PCAC Review

FDA has scheduled multiple peptide-related substances for review by the Pharmacy Compounding Advisory Committee beginning in July 2026, with additional sessions anticipated into 2027.

PHA will continue to engage constructively throughout this process, supporting:
• Evidence-based evaluation
• High-quality manufacturing and sourcing standards
• Clear regulatory pathways within existing statutory frameworks
• Integration of clinical and real-world safety data

About the Personalized Health Association (PHA)

The Personalized Health Association (PHA) is a national 501(c)(4) advocacy organization advancing safe, responsible access to regenerative and precision medicine. PHA leads federal and state efforts to modernize policies governing adult stem cell, peptide, and regenerative therapies, including advocating for updates to 21 C.F.R. §1271.10(a) to establish a clear, cGMP-based pathway for certain regenerative products to be regulated as 361 HCT/Ps.
PHA represents healthcare providers, accredited regenerative-medicine facilities, compounding pharmacies, peptide-therapy providers, telemedicine platforms, and other healthcare stakeholders committed to high standards of safety, compliance, and evidence-based care. Through coordinated policy leadership, PHA champions physician autonomy and patient access to individualized therapies. Learn more at www.personalizedhealthassociation.org

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