

RESEARCH BRIEFING · UPDATED JUNE 2026

The 2026 Peptide Regulatory Tracker

The FDA Category 2 changes, the PCAC 503A review, GLP-1 shifts, and the enforcement wave — a plain-English briefing on what actually changed in 2026, and what's legal, gray, or gone.

Prepared by **OmegaLabz** for the peptide research community. This document reports on scientific and regulatory news for laboratory research professionals. It is **not legal or medical advice**, and no product is intended for human or animal consumption.

THE HEADLINE CHANGE

01 12 peptides removed from Category 2

On **April 15, 2026**, the FDA/HHS announced the removal of **12 peptides from Category 2** of the §503A bulk drug substances list — the “significant safety risks / do-not-compound” bucket — effective on or about **April 22, 2026**. Affected compounds include BPC-157, TB-500, MOTS-c, GHK-Cu (injectable), Melanotan II, Semax, PEG-MGF, and CJC-1295, among others whose nominations were withdrawn.

READ THIS TWICE

02 Removal ≠ approval to compound

Removal from Category 2 does not equal approval to compound. These peptides now sit in a **regulatory gray zone — not banned, not authorized.** Each must still clear **PCAC review** and then formal **notice-and-comment rulemaking** before compounding becomes legal. Nothing here makes any peptide legal to sell or compound today.

The practical takeaway: the “schedule change” is real, but it is a procedural step, not a green light. Realistically, legal compounding status is **months-to-years out**, and PCAC recommendations are **non-binding** — even a favorable vote requires FDA agreement plus rulemaking.

THE CALENDAR

03 PCAC 503A review schedule

- **July 23–24, 2026 — PCAC Meeting (FDA White Oak, MD)**
Jul 23: BPC-157, KPV, TB-500, MOTS-c · **Jul 24:** Emideltide (DSIP), Semax, Epitalon
- **Before end of Feb 2027 — Second PCAC Round**
GHK-Cu, Melanotan II, Cathelicidin (LL-37), Dihexa acetate, PEG-MGF

DON'T MISS THE WINDOWS

04 Time-sensitive deadlines

Jun 30, 2026

Deadline to request an **oral presentation** at the July PCAC meeting

Jul 9, 2026

Deadline for **written comments** to the Committee

Jul 23–24

The **PCAC meeting** itself

STATUS SNAPSHOT

05 Where key compounds stand

COMPOUND	2026 STATUS	NEXT MILESTONE
BPC-157	Gray zone	PCAC Jul 23
TB-500	Gray zone	PCAC Jul 23
MOTS-c	Gray zone	PCAC Jul 23
DSIP (Emideltide)	Gray zone	PCAC Jul 24
Semax	Gray zone	PCAC Jul 24
Epitalon	Gray zone	PCAC Jul 24
GHK-Cu	2nd round	PCAC by Feb 2027
PEG-MGF	2nd round	PCAC by Feb 2027

THE OTHER HALF OF THE STORY

06 GLP-1s: the shortage exemption is ending

As the national shortage resolves, the FDA is **removing GLP-1s (semaglutide, tirzepatide) from the 503B list**. Compounded semaglutide and tirzepatide now carry a **compliance risk** absent patient-specific documentation of a “significant difference” from the branded product. The shortage-exemption window that fueled the compounded-GLP-1 boom is closing.

ENFORCEMENT SIGNAL

07 The market is consolidating

In **March 2026, Peptide Sciences** — among the largest U.S. “research use only” peptide vendors — voluntarily shut down. Weeks later, on **April 7, 2026**, the FDA’s CDER issued **seven warning letters in a single day** to online peptide sellers, establishing that “research use only” language is **not, by itself, a legal position** — regulators judge the surrounding claims. The takeaway for the market: rising enforcement pressure, and a premium on suppliers with genuine quality documentation and durable, compliant operations.

BOTTOM LINE

08 What to watch

The **July 23–24 PCAC outcome** sets the multi-year direction for which peptides ever reach legal compounding. Until rulemaking follows a favorable vote, the status quo holds: a gray zone, not a green light. Track the meeting, read the quality documentation (COAs, HPLC purity), and treat any source that over-claims as a source that hasn’t read the April letters.

SOURCES

Orrick — FDA removes 12 peptides from Cat 2 & schedules PCAC · FDA — July 23–24 2026 PCAC meeting notice · FDA Law Blog — FDA’s Pep(tide) Rally · Lengea Law — BPC-157, TB-500 & 5 others under 503A review · Frier Levitt — removal from Do-Not-Compound list · National Law Review — what FDA’s actions mean for peptide compounding · Health Law Alliance — FDA targets RUO labeling (April 2026 warning letters).



Stay ahead of the next change.

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