

Legal Is Not Effective

A one-page guide to regulatory status and the five evidence tiers

Between 2023 and 2026, a series of regulatory actions changed which peptides compounding pharmacies may prepare. Those actions are being described as approval. None of them is. The market is treating three separate events as one.

The event	What it means	What it does not mean
Removal from Category 2	The substance is no longer flagged in the significant safety concerns category. In the 2024 and 2026 rounds this followed nominators withdrawing their nominations.	Not a safety clearance, and not permission to compound. It places a substance in a transitional state.
A favorable advisory committee vote	A federal advisory committee recommends the substance for the 503A Bulks List.	Non-binding. In July 2026 the committee voted against its own agency reviewers, who found the evidence insufficient.
Placement on the 503A Bulks List	After rulemaking, compounding pharmacies may use it for patient-specific prescriptions.	Still not FDA approval of a drug. No efficacy finding has been made.

Legality of compounding and clinical effectiveness are two different claims. A compound clearing a regulatory step tells you what cleared the step, not what it does in your body.

THE FIVE EVIDENCE TIERS

Grade any claim on the quality of human data for the use it is actually being sold for.

Tier	What it means
1	Robust human randomized trial evidence for a defined indication, with characterized benefit and risk.
2	Strong or emerging human trial data, but investigational, or approved for a narrow indication and marketed far beyond it.
3	Mechanistically plausible with limited human data, marketed well beyond what that data supports.
4	Predominantly preclinical (rodent and in-vitro), with essentially no controlled human trials for the marketed use. Where most heavily promoted repair and longevity peptides sit.
5	Poor or absent evidence combined with a meaningful safety signal, or unreplicated claims from a single narrow source.

TWO TRAPS BENEATH THE TIERS

The indication gap. Real evidence is routinely attached to a different question: a compound studied for one narrow use is sold for something much broader. Ask whether the studies asked what is being promised.

Measure first: balanceprotocolgps.com

Educational reference from Balance Protocol Institute, Anthony G. Beck, ND, DOM. Not medical advice and not a diagnosis. No compound, dose or source is recommended. Decisions about medications and hormones stay with you and your prescriber.

The product is not always the molecule. Strong literature says nothing about a specific vial: sequence, purity, endotoxin, and quantity are separate questions. Research use only is a regulatory label, not a quality grade.

Do not overcorrect. Sitting outside the approved-drug system does not prove a compound useless. Some have real human data and no sponsor. Read the evidence in both directions.