What you need to know:
Peptides and compounding

Certain peptides, often referred to as "wellness peptides," have increased in popularity through health and wellness influencers who promote their use for a variety of medical conditions. These products are being sold through online gray markets directly to patients and supported by questionable marketing practices. Importantly, these "wellness peptides" have not been demonstrated to be safe and effective in clinical trials and are not reviewed or approved by the FDA. Compounding these peptides is currently not allowed under federal law.

The FDA is holding a meeting of the Pharmacy Compounding Advisory Committee (PCAC) to discuss and get public feedback on whether some of these so-called "wellness peptides" should be included on the FDA's 503A bulks list. If included, this allows compounding by pharmacies, undermining the U.S. regulatory framework for approved prescription drugs and providing broader access for patients to potentially unsafe products.

Here's what you need to know about "wellness peptides" and drug compounding:

What are peptides?

- Peptides are short chains of amino acids (the building blocks of proteins) that act as signaling molecules in the body.
- Several FDA-approved medicines are peptides, including insulin and GLP-1 therapies. These medicines are studied in clinical trials and thoroughly reviewed by the FDA for safety, efficacy and quality prior to receiving approval.
- The current "wellness peptide" trend refers to a separate group of synthetic compounds often marketed by celebrities and influencers. They are not FDA-approved, meaning their safety, effectiveness and quality have not been reviewed by the FDA.

The unknowns about "wellness peptides"

These compounds have not been subject to the FDA's gold-standard review for approval and their safety and effectiveness have not been established in clinical trials. For many of the peptides being discussed at the PCAC, the FDA **identified significant safety risks** related to their use in compounding, confirming that these products were not appropriate for compounding (category 2).

These safety risks included:

- Sterility/injection risks
- Lack of human clinical trial data
- Purity
- Dosing
- Long-term safety

The regulatory history

The law:

- Under federal law, pharmacy compounders – known as 503A compounders – can compound from bulk drug substances in limited circumstances.
- One of these circumstances is when the bulk drug substance has been identified on a list developed by the FDA through regulation (the "503A bulks list").
- The FDA has issued regulations presenting the factors it considers when adding a substance to the 503A bulks list, including any safety issues raised by the use of the substance in compounding and the available evidence (or lack of evidence) of effectiveness of the compounded product.

Past determinations:

The FDA previously considered several of these "wellness peptides" for inclusion on the 503A bulks list and identified significant safety risks related to their use in compounding. Therefore, under the law, the use of these peptides was prohibited in compounding.

Current state:

- On July 23-24, 2026, the FDA is proposing to discuss these peptides with the PCAC for potential inclusion on the 503A bulks list.
- In the **PCAC meeting materials**, the FDA proposes that the wellness peptides NOT be included on the 503A bulks list.

Coming next:

- While the FDA is generally required to consult the PCAC before issuing regulations adding substances to the 503A bulks list, the vote of the PCAC is not the final outcome.
- Following the PCAC, the FDA would still need to proceed through rulemaking before any substance can be added to the 503A bulks list and be eligible for 503A compounding.

Importantly, if these compounds are added to the 503A bulks list, this does not mean they are FDA-approved. It strictly means that 503A compounding pharmacies can compound these substances under Section 503A of the Federal Food, Drug, and Cosmetic Act.

The bottom line

These substances are not FDA-approved and enabling the mass marketing of unapproved drugs presents serious safety risks for Americans and undermines the incentives for seeking FDA approval. Adding these unapproved products to the 503A bulks list would be an evasion of the FDA approval process and undermines the U.S. regulatory framework for approved prescription drugs.