

# Compounding Peptides: It's Complicated

## A briefing for physicians and other prescribers

Compounding pharmacies frequently get requests from prescribers to compound a medication that is prohibited under Section 503A of the Federal Food, Drug & Cosmetic Act. When a compounding pharmacist must decline to fill a prescription for a particular compounded medication, that's usually the reason.

A current "hot" product in the anti-aging and integrative medicine world is **peptides**, many of which were reclassified in March 2020 by federal law as biologics. Traditional compounding pharmacies cannot compound substances that are classified as biologics. In addition, *most peptides do not meet any of the other legal requirements for compounding.* **Under federal law (Section 503A), to be eligible for use in a compounded product, an active ingredient must meet one of the following criteria:**

1. Be an active ingredient in an FDA-approved drug product.
2. Have a USP or National Formulary drug monograph.
3. Appear on the Section 503A Interim or Final Bulks List published by FDA.

As a result, most peptides are off limits for traditional compounding, as they are either classified as biologics or don't meet one of the three criteria above. Unfortunately, that

Courtesy of:

March 2020 law reclassified both **tesamorelin** and **HCG** as biologics, so they may no longer be compounded.

However, there are some peptides that, because of their smaller molecule size (specifically, 40 amino acids or fewer), do not meet the definition of a biologic, yet *do* meet one of the three legal criteria for use in compounding. One is **semaglutide**. Others include, for example, **sermorelin** and **bremelanotide**. Semaglutide is the active ingredient in an FDA-approved drug product.

The issue is complicated by the fact that a drug manufacturer now markets an FDA-approved semaglutide product, which may be protected by U.S. patents. Thus, compounding using semaglutide API, depending on the formulation, may be considered "essentially a copy" of an FDA-approved drug, and therefore *impermissible* for compounding. However, the FDA approved semaglutide product has been on the FDA Drug Shortage List since March of 2022, which may render it *permissible* for use in compounding.



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Because peptides are popular, it is important to ensure that the medications are compounded from a reputable compounding pharmacy that requires prescriptions and meets the other requirements of Section 503A of the Federal Food, Drug & Cosmetic Act.

There may be online pharmacies or peptide distributors that do not require a prescription, and/or use unacceptable, research-grade ingredients in their injectable drug products. Research-grade peptides are not

appropriate for human use and may contain substances not suitable for injectable use. It is unclear where and under what conditions these products are produced, which makes it very difficult for a state board of pharmacy or FDA to regulate them.

*Wise prescribers will stay away from any entity that prepares or distributes peptide products for individual patients without a prescription. They're not compounding pharmacies, and they're likely violating state and/or federal law.*

*If you have questions about the appropriateness of a substance for compounding, or for the legitimacy of a distributor, contact your local compounding pharmacy. They'll be glad to guide you.*

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*The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers.*

*In traditional compounding, pharmacists create a customized medication, most often from pure ingredients, for an individual patient pursuant to a prescription. Pharmacists' ability to compound medications from pure ingredients is authorized in federal law and for good reason: Manufactured drugs don't come in strengths and dosage forms that are right for everyone, and prescribers need to be able to prescribe customized medications when, in their judgment, a manufactured drug is not the best course of therapy for a human or animal patient.*

*Every day, APC members play a critical role in patients' lives, preparing essential, custom medications for a range of health conditions, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, animal health, and others.*

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