PEPTIDE REGULATION IN 2026:

WHAT YOU NEED TO KNOW TO REMAIN COMPLIANT

Interest in compounded drugs has expanded rapidly in recent years. Fueled by growing demand for GLP-1 weight loss medications and personalized formulations, the U.S. compounding market, presently valued at USD 6.45 billion, is project to reach over ten billion annually by 2034.[1] Alongside FDA approved drugs, compounded peptides prepared under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) have become a visible part of modern clinical practice.

Beyond GLP-1s, U.S. consumers are increasingly seeking a range of other peptides, including many substances that are prohibited for human use. Driven by promises of longevity, improved physical fitness and performance, as well as broad online marketing and distribution, celebrity promotion, and even professional endorsement by licensed practitioners, peptides are now widely available through online channels. This ease of access, combined with limited regulatory enforcement, has contributed to a proliferation of online offerings spanning lawful drug products, legally ambiguous compounds, and clearly unlawful substances.

A simple Google search reveals numerous peptide marketers and sellers, including telehealth providers, compounding pharmacies, medical spas, medical practices, wellness websites, and yes—a cornucopia of unregulated vendors. In a digital world where FDA-approved drugs, compounded products, and substances that are outright prohibited for human use often appear side by side, the line between what lawful and what isn't is not always clear to prescribers, compounders, or patients. Additionally, the ease with which these products can be purchased further contributes to the mistaken assumption that availability equates to legality or regulatory approval.

How does one, then, determine which **legal framework governs a given peptide, and whether—or under what conditions—it may be lawfully administered to humans?** As FDA regulatory attorneys, we are frequently asked whether a substance may be prescribed, whether a given script may be formulated, or whether a particular peptide can be made or sold for human use. Here, we share a few lessons drawn from our experience working with peptides and compounded drug products.

As is customary in this field, a brief disclaimer is in order. This article is not legal advice. *(As attorneys, we are bound to say this at least once in a piece like this.)* It is also not medical advice, nor is it an endorsement or a condemnation of peptide drugs, pharmaceutical compounding, or branded drug products. Rather, what we offer is a brief overview of the regulatory landscape governing these products and what, in many respects, could be characterized as the "wild west" of the U.S. peptide market today.

We begin with the basics, including what peptides are, how the FDA classifies them, and how they fit within the drug regulatory framework . . .

How FDA Regulates Peptide Drugs or Biologics

Peptides are the building blocks of proteins; they are short chains of amino acids that occur naturally in the human body and in nature, and play key roles in various biological functions, including hormone signaling, immune response, tissue repair, and metabolism. Peptides can be isolated, chemically modified, or synthesized by various chemical and biotechnological methods for application in medicine, pharmacy, and research.

FDA regulates peptides under its authority to oversee both drugs and biologics. Under federal law, a "drug" is defined broadly to include any article intended to diagnose, treat, cure, mitigate, or prevent disease, or to affect the structure or any function of the human body.[2] Peptides, *depending on their intended use*, can meet this definition and thus fall under the FDA's jurisdiction. Once FDA jurisdiction is established, the agency determines whether a given peptide is regulated as a drug or biologic.

Drugs are regulated under the FD&C Act and must generally proceed through one of two approval pathways—the New Drug Application (NDA) for brand-name drugs or the Abbreviated New Drug Application (ANDA) pathway for generics—before they may be lawfully marketed in the United States. Biologics, on the other hand, are regulated under the Public Health Service Act (PHSA), and require a Biologics License Application (BLA).

Whether a peptide is regulated as a drug or as a biologic is governed by statute and corresponding regulation. This distinction is critical for compounding because only *drugs*—but not biologics—can be lawfully compounded. In practice, this distinction will often turn on peptide length and structure, with shorter peptides generally regulated as drugs and longer peptides, including proteins, as biologics.[3]

In either case, unless an exemption applies, neither drugs nor biologics may be lawfully introduced into interstate commerce without FDA approval. If, for example, a drug product is marketed without an approved NDA or ANDA, FDA may deem it an unapproved new drug, misbranded, or adulterated, and may subject it to enforcement action. Federal law prohibits the introduction of *adulterated*, *misbranded*, or *unapproved drugs* into interstate commerce,

> Under federal law, drugs are articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of the human body.

with potential civil or criminal consequences. Accordingly, drugs must meet applicable quality standards, be accurately labeled, and follow the appropriate FDA approval pathway before they are marketed or sold for human use.[4]

The distribution of unlicensed biological products is similarly prohibited under the PHSA, and because that statute incorporates the FD&C Act's adulteration and misbranding provisions by reference, such products may also be subject to enforcement under this act.[5]

So where does traditional pharmaceutical compounding fit within this regulatory framework?

The federal legal framework governing the compounding, prescription, and administration of drugs for human use is primarily established under the FD&C Act, as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA) and the Drug Quality and Security Act (DQSA). Under federal law, compounded drugs qualify for specific exemptions from the FD&C Act's new drug approval, adulteration, and misbranding provisions, provided they meet certain statutory conditions. For traditional compounding pharmacies, these exemptions and conditions are set forth in Section 503A.

Under this section, compounded *drugs* are exempt from the federal *new drug* approval requirements, as well as certain labeling with adequate instructions of use and current good manufacturing practice requirements (cGMP), provided they meet all statutory requirements and if the compounding is performed in accordance with specific conditions. FDA guidance summarizes these conditions into ten core requirements,[6] including that compounded drugs must be prepared by a licensed pharmacist or physician pursuant to a valid prescription for an identified individual patient, or—if compounded in advance—only in limited quantities based on a documented history of receiving such prescriptions within an established pharmacist–patient–prescriber relationship.

Other core requirements include preparing compounded drugs using bulk drug substances and ingredients that meet applicable safety and manufacturing standards; not compounding drugs that have been withdrawn or removed from the market for safety or effectiveness reasons, or that have been identified by the HHS Secretary as demonstrably difficult to compound; and also not compounding regularly or in inordinate amounts drug products that are "essentially copies of commercially available drug products."[7]

As defined under Section 503A, the term "essentially a copy" does not include "a drug product in which there is a change made for an identified individual patient that produces a significant difference for that patient, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product."[8] FDA guidance elaborates on what the agency intends to consider to be "essentially a copy",[9] while also explaining that for a drug to be commercially available it has to be a "marketed drug product."[10]

Whether a drug is considered "commercially available" becomes relevant when a pharmacy, for example, compounds a drug product that is no longer marketed but has not been withdrawn for safety or effectiveness reasons or when there is an FDA-declared drug shortage. Take, for example, the peptide drug sermorelin. Although sermorelin is not currently FDA-approved, it may be lawfully compounded pursuant to a valid prescription because it was previously approved by FDA and later voluntarily discontinued for business reasons, not for safety concerns.

It's worth noting that because sermorelin was FDA-approved "for something," and was not withdrawn from the market for safety reasons, it may be lawfully *prescribed* for any indication the prescribing professional deems appropriate. In general terms, medical discretion allows for off-label prescribing but this discretion doesn't extend to substances that have never been FDA-approved or that are not permissible for compounding. In those circumstances, the issuance of a prescription by a licensed practitioner does not "authorize" a pharmacy to compound or dispense the product.

Ensuring precise regulatory compliance—rather than following the pack—not only promotes patient safety and safeguards against enforcement action, but also ensures you won't need a peptide to sleep soundly while running your business.

When a drug shortage exists, as occurred with the prolonged shortages of branded tirzepatide and semaglutide drug products, FDA guidance states that the drug will not be considered "commercially available." As a result, it will not be treated as "essentially a copy," meaning that—at least subject to FDA's enforcement discretion—a pharmacy may compound products that would otherwise be considered essentially copies of branded products.

Absent a drug shortage, "essentially a copy" considerations primarily come into play when a pharmacy compounds a product using the same active pharmaceutical ingredient (API) an FDA approved drug. Pharmacies that prepare formulations using bulk drug substances containing the same API as branded drugs should be attentive not only to regulation but also to potential litigation by branded drug manufacturers. In practice, these issues arise most often in the GLP-1 context, where pharmacies respond to prescriber requests for compounding formulations that differ from branded products in ways intended to establish a patient-specific, clinically significant difference. Common examples of such formulations include modifications based on excipient sensitivities or allergies, dosage strengths not commercially available, alternative dosage forms, or formulations combined with additional active or inactive ingredients.

Here emphasize that while following FDA guidance confers protection with respect to *federal* enforcement, compliance with state-specific laws, regulations or guidance—including those from boards of pharmacy—is also required. In California, for example, regulations adopted by the State Board of Pharmacy in June 2025 impose an affirmative duty on the pharmacist beyond what is stipulated under federal law, requiring them to verify and document that any compounded preparation differing from a commercially available drug is clinically justified for the identified patient.[11]

Compliance with federal law or FDA guidance, while important, will also not necessarily prevent pharmacies from being sued by brand-name manufacturers seeking to prevent or discourage compounded drugs—including lawfully compounded products—from being made. This dynamic is illustrated by the hundreds of demand letters and lawsuits brought by manufacturers of semaglutide and tirzepatide against 503A pharmacies, 503B outsourcing facilities, weight-loss clinics, medical spas, and telehealth providers, advancing a range of evolving legal theories.

What about compounding peptides listed on FDA's interim bulks list?

One of the requirements for compounded drugs under Section 503A to qualify for exemptions from federal new drug approval, labeling, and cGMP requirements is that they be compounded using bulk drug substances that comply with United States Pharmacopeia standards, are components of FDA-approved drugs, or appear on FDA's Section 503A bulk drug substances list.

As promulgated by regulation, the 503A bulk list is considerably small, comprised of only six substances. FDA has, for the past several years, been evaluating additional bulk drug substances for possible inclusion on this list, but thus far remains engaged in an ongoing, substance-by-substance review process of many substances—including numerous peptides. While it does this, FDA has exercised enforcement discretion to permit state-licensed pharmacies and physicians to compound certain substances, but only those identified in *Category 1* of its interim bulk substances list, provided specified conditions are met.[12]

Those conditions include: (i) registration of the bulk substance manufacturer under Section 510 of the FD&C Act; (ii) availability of a valid certificate of analysis for the bulk substance; and (iii) full compliance with all other applicable requirements of Section 503A.[13] Category 1 bulk drug substances are those that have been nominated for inclusion on FDA's bulks list with sufficient supporting information and without significant safety risks identified. Peptides such as Sermorelin Acetate, and coenzymes like beta-Nicotinamide Adenine Dinucleotide (NAD+) and glutathione are included in this category.

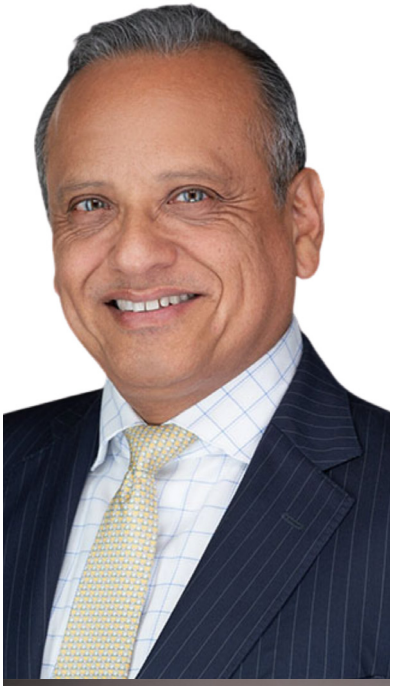
In contrast, despite their widespread availability on the open market, many peptides popular in biohacking and longevity circles like BPC-157, Thymosin Beta-4, or CJC-1295, cannot be lawfully compounded for human use at present. This is because they do not meet the statutory criteria for compounding, fall outside FDA's discretionary policy exemption, or have been identified by FDA as presenting significant safety risks for human use.

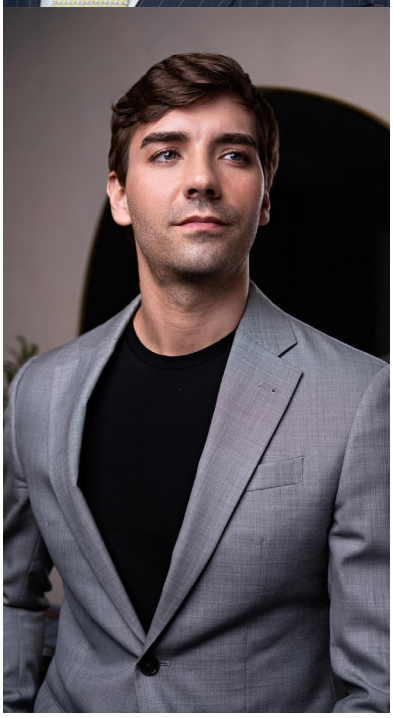
To further complicate matters for compounders, prescribers, and patients, FDA's determinations regarding Category 1 status may depend not only on the substance itself, but also on its route of administration. In practice, a peptide that is prohibited for injectable use may, for example, be permitted in a topical formulation. Less common routes of administration—such as intranasal or transdermal—may not be explicitly addressed in guidance

or regulation and can require more nuanced regulatory analysis.

What the future holds

While patients and prescribing clinicians may be eager to access or offer cutting-edge therapies, the highly regulated world of pharmaceutical compounding is not the place to "move fast and break things". While there are plenty of opportunities for smart and lawful business strategies, navigating this constantly evolving market and regulatory landscape requires careful consideration so as to not end up as a target of a state board of pharmacy investigation or an FDA/FTC enforcement action. As regulations continue to evolve in this area, it is important to obtain real-time information regarding what can be lawfully compounded and dispensed from reliable regulatory sources. We believe enforcement actions will increase in 2026, but thoughtful players in this field will also find attractive opportunities in 2026, if they are well advised.





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1. GlobeNewswire, *U.S. Compounding Pharmacies Market Size on Track to Hit $10.93 Billion by 2034*, August 18,2025
2. 21 U.S.C. § 321(g).
3. The PHSA provides the statutory definition of what constitutes a "biological product." That definition includes a "protein" that is "applicable to the prevention, treatment, or cure of a disease or condition of human beings." **42 U.S.C. § 262(i)(1).** Federal regulations further clarify that a protein is "any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size." 21 CFR 600.3(6). Applying this framework, FDA exercises scientific and regulatory judgment to determine whether a particular peptide qualifies as a biologic or is instead regulated as a drug.
4. A drug may be considered ***adulterated*** if, for example, it is contaminated or fails to meet standards for strength, quality, or purity. *See* 21 U.S.C. § 351 et seq. A drug may be ***misbranded*** if its labeling is false or misleading, lacks adequate directions for use, or otherwise fails to meet specific labeling requirements. 21 U.S.C. § 352 et seq.
5. 42 U.S.C. at §262(j) (The FD&C Act, 21 U.S.C. 301 et seq., including the requirements under sections 505(o), 505(p), and 505–1 of such Act [21 U.S.C. 355(o), (p), 355–1], applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act.). See *also* 21 U.S.C. §§ 331 et seq.
6. Pharmacy Compounding of Human Drug Products Under Section 503A of the FDCA, Guidance (January 2016),
7. *See* §503A et seq.
8. *Id.*
9. **U.S. Food & Drug Admin.,** Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry at 5-7 (Jan. 2018)
10. ***Id* at 5.**
11. 16 C.C.R. § 1731.1(e); See also *California Board of Pharmacy's New "Essentially a Copy" Rules: What GLP-1 Compounders Need to Know*, Jesse Dresser, Esq, Frier Levitt, August 18, 2025.
12. FDA, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A* (Jan. 2025).
13. *Id.*