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## **Regulatory Spotlight: Peptides**

As interest in therapeutic peptides continues to grow across wellness and medical markets, businesses involved in the manufacturing, distribution, and administration of peptides must proceed with caution. Companies are increasingly facing scrutiny under both federal and state law, particularly from the U.S. Food & Drug Administration (FDA), the Federal Trade Commission (FTC), and various state pharmacy regulatory boards.

### What Are Peptides — and Why Are They Risky to Market?

Peptides are short chains of amino acids that can have pharmacological effects, often used in the fitness community, regenerative medicine, and hormone therapy. While their popularity is expanding, so too is scrutiny by federal and state regulators.

Companies marketing peptides for wellness, anti-aging, weight loss, or performance enhancement must understand that these substances are typically regulated as prescription drugs or biologics, not dietary supplements or cosmetics. As such, they are subject to rigorous FDA approval requirements, including clinical trials. Improper labeling or marketing could trigger civil penalties, injunctions, or even criminal liability.

### Misbranding Claims

Peptide products can be considered misbranded under the Federal Food, Drug, and Cosmetic Act (FDCA) if their labels:

- Are false or misleading;
- Fail to list ingredients;
- Omit adequate directions for use; or
- Contradict how the product is marketed.

Even disclaimers like “not for human consumption” or “for research use only” do not necessarily protect businesses if actual marketing practices suggest otherwise.

### How Are Peptides Different from Dietary Supplements

While both peptides and supplements fall under FDA purview, the regulatory paths differ sharply:

- Dietary supplements: Not subject to pre-market FDA approval, but must comply with labeling and safety rules.
- Peptides: Regulated as drugs/biologics; require pre-market approval and clinical evidence of safety and efficacy.



### What Should Companies Do?

If you're involved in the peptide space, compliance is critical. Here are a few things we recommend:

- Conducting a legal review of product labeling, advertising, and manufacturing/distribution practices;
- Ensuring that all partners are licensed and compliant with state and federal supply chain rules;
- Avoiding ambiguous marketing strategies or unsubstantiated medical claims;

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