under what code are peptides restricted by fda

Peptides are not restricted as a single “class”; instead, they are regulated as drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act), primarily via the statutory definition of “drug” in 21 U.S.C. 321(g), the compounding provisions in Sections 503A and 503B of the FD&C Act, and related FDA guidance on bulk drug substances and synthetic peptides. In practice, most of the “peptide restrictions” people encounter come from how FDA classifies bulk drug substances (Category 1/2/3) under 503A/503B, and from the fact that unapproved peptides marketed for human use are considered unapproved new drugs under 21 U.S.C. 355. [1] [2] [3] [4]

Core statutory hook

- The primary legal hook is the definition of “drug” in the FD&C Act, codified at 21 U.S.C. 321(g)(1). [4]
- Under 21 U.S.C. 321(g)(1), any article (other than food) intended to affect the structure or function of the body, or intended for diagnosis, cure, mitigation, treatment, or prevention of disease, is a “drug,” which squarely covers therapeutic peptides. [4]
- Once classified as drugs, peptides fall under the general “new drug” provisions in 21 U.S.C. 355, meaning they require an approved NDA/ANDA unless they are being lawfully compounded under Section 503A/503B or otherwise exempt. [3] [1]

503A / 503B compounding framework

- The specific “restriction” mechanism for many gray-zone peptides is the compounding framework in Sections 503A and 503B of the FD&C Act (these are sections of the statute itself, not the CFR), as implemented in FDA’s “bulk drug substances” lists. [2] [5] [1]
- Section 503A allows traditional pharmacies to compound for individual patients when the bulk substance either has a USP/NF monograph, is a component of an FDA-approved drug, or appears on FDA’s 503A Bulks List (Category 1 list). [5] [1]
- FDA’s category system for nominated bulk substances (Category 1 = may be compounded, Category 2 = significant safety concerns, Category 3 = insufficient data) is the main administrative vehicle used to “restrict” specific peptides by making them ineligible for compounding under 503A/503B. [6] [1] [2]

Category 2 “restricted” peptides

- Category 2 of the “Bulk Drug Substances Nominated Under Sections 503A or 503B” list identifies substances that “may present significant safety risks” and therefore are generally not eligible for routine compounding; multiple peptides were placed here in 2023. [2] [5] [6]

- This Category 2 placement is an FDA policy action under its 503A/503B authority; it does not create a separate criminal statute, but it effectively prohibits 503A/503B facilities from compounding these peptides, making their pharmacy supply chain illegal if compounded. [1] [6] [2]
- Examples include BPC-157, TB-500, CJC-1295 and others that were moved into Category 2, though HHS has since announced that many of these will be shifted back to Category 1, restoring compounding eligibility. [7] [8] [6]

Synthetic peptide guidance

- FDA's "Guidance for Industry: ANDAs for Certain Highly Purified Synthetic Peptide Drug Products" clarifies that FDA treats any alpha-amino-acid polymer of 40 or fewer residues as a "peptide," not a protein, for regulatory purposes. [3]
- That guidance further states that such peptides are regulated as drugs under the FD&C Act unless they fall within the statutory definition of a "biological product" under the Public Health Service Act (e.g., certain peptide vaccines). [3]
- The guidance is non-binding but operationally important because it channels many synthetic peptides into the small-molecule drug/NDA-ANDA pathway rather than the biologics/BLA pathway. [3]

What is *not* the basis of restriction

- Peptides as a class are not scheduled under the Controlled Substances Act; they are generally not "controlled substances" in the CSA sense, with the main exception being separate statutory treatment for human growth hormone (somatropin) under a distinct provision (21 U.S.C. 333(e)). [9]
- The common "research chemical / not for human consumption" labeling is a marketing strategy, not a formal legal category; if a peptide is intended for human use, FDA still treats it as a drug under 21 U.S.C. 321(g) and the unapproved new drug provisions. [1] [4]

Practical summary for your use case

- At the statutory level, peptides are restricted under the FD&C Act via:
  - 21 U.S.C. 321(g)(1) (definition of "drug"). [4]
  - 21 U.S.C. 355 (new drug approval requirement). [1]
  - Sections 503A and 503B (compounding exemptions and conditions). [2] [1]
- At the policy/guidance level, the main "restriction code" people reference is FDA's Category 2 bulk substance designation for compounding under the 503A/503B framework. [6] [2]
- The synthetic peptide guidance document (FDA, 2017) provides the operational definition of "peptide" (≤40 amino acids) and confirms they are regulated as drugs unless they qualify as biological products. [3]

For your own regulatory strategy: are you more concerned with 503A/503B compounding constraints, or with pathways for NDA/ANDA approval of a novel peptide entity?

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1. https://rethinkpeptides.com/articles/how-the-fda-regulates-peptides-a-complete-framework-overview
2. https://www.fda.gov/drugs/human-drug-compounding/certain-bulk-drug-substances-use-compounding-may-present-significant-safety-risks
3. https://www.fda.gov/media/107622/download
4. https://formblends.com/research/guides/peptide-legality-regulatory-guide
5. https://a4pc.org/news/2023-10/fda-puts-some-peptides-off-limits
6. https://meto.co/blog/peptides-legal-again-2026
7. https://www.mypeptidematch.com/blog/fdas-overlooked-peptide-regulations-what-patients-need-to-know
8. https://www.linkedin.com/posts/mansihukmani_breaking-hhs-secretary-rfk-just-announced-activity-7433283286224760832-WNqP
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