

# The Four Worlds of Peptide Regulation

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**ABSTRACT** — The same peptide molecule can be a prescription drug, a compounding-pharmacy preparation, a dietary supplement or natural health product, and a cosmetic — four legal lives determined not by chemistry but by route of administration, the claim on the label, and the jurisdiction. This paper maps the four regulatory worlds in the United States and Canada, explains the doctrines that separate them (including the US drug-preclusion rule), and gives readers a practical test for placing any peptide product they encounter.

## 1. One Molecule, Four Legal Lives

Peptides are short chains of amino acids — the same chemistry whether they appear in an injectable drug vial, a capsule, or a face cream. Regulation does not follow the molecule; it follows what is claimed, how it enters the body, and where it is sold. The result is that a single compound can be simultaneously lawful in one presentation and unlawful in another, in the same country, on the same day. Understanding this is the single most useful skill a consumer, clinician, journalist, or investor can bring to the category — and almost no marketing material will teach it, because ambiguity sells.

| World                            | Governing regime (US / Canada)                                 | What may be claimed                                  | Typical peptide examples                            |
|----------------------------------|----------------------------------------------------------------|------------------------------------------------------|-----------------------------------------------------|
| <b>1. Prescription drug</b>      | FDA NDA/BLA · Health Canada DIN                                | Diagnose, treat, cure, prevent disease — as approved | Semaglutide, tirzepatide, insulin, teriparatide     |
| <b>2. Compounded preparation</b> | US 503A/503B bulks framework · provincial pharmacy law         | Per prescription; no marketing claims                | The 2026 review peptides (pending rulemaking)       |
| <b>3. Supplement / NHP</b>       | DSHEA (US) · Natural Health Products Regulations, NPN (Canada) | Structure/function only — never disease              | Collagen peptides, creatine, casein/whey bioactives |
| <b>4. Cosmetic</b>               | MoCRA (US) · Cosmetic Notification (Canada)                    | Appearance only — never physiology beneath the skin  | Topical GHK-Cu, palmitoyl peptides, argireline      |

## 2. World One: Prescription Drugs

The peptide drug is now the centre of the pharmaceutical industry. Tirzepatide posted USD \$36.5 billion in 2025 sales — the best-selling drug in the world — and its manufacturer guided \$80–83 billion for 2026, with an oral small-molecule GLP-1 expected within the year. Drug status is earned through controlled trials, facility inspection, and an approved label; it confers the exclusive right to make disease claims. Everything else in the peptide world is defined by its distance from this standard.

## 3. World Two: The Compounding Channel

US compounding pharmacies may prepare drugs from bulk substances only if those substances sit on (or are proposed in good standing for) the FDA's 503A bulks list, or appear in an approved drug. Most wellness peptides never entered that system: FDA placed them in 'Category 2' — substances with significant safety concerns — which made them effectively off-limits. That placement is what the 2026 reclassification (WP-002) partially reversed. The key point for readers: compounding legality is a moving, procedural question — a

pharmacy either can or cannot source a given bulk substance today, and 'under review' does not mean 'available.'

## 4. World Three: Supplements & Natural Health Products

The US supplement regime (DSHEA, 1994) permits structure/function claims — 'supports joint comfort' — without pre-market approval, but with two hard walls: no disease claims, and the drug-preclusion doctrine, under which an ingredient first studied or approved as a drug is generally barred from supplements. This is why collagen peptides (food-derived, long food history) are comfortably lawful while injectable-drug-adjacent peptides cannot simply be 'put in a capsule.' Canada is stricter and slower: every natural health product needs a pre-cleared Natural Product Number (NPN), a process that runs twelve to eighteen months but produces a government-reviewed licence for specific claims — an underappreciated trust asset.

## 5. World Four: Cosmetics

A cosmetic may change your appearance; the moment its marketing claims to change your physiology, it becomes an unapproved drug. Topical peptides — copper tripeptides, palmitoyl signal peptides — live lawfully here, provided claims stay on the appearance side of the line ('reduces the look of fine lines'). Canada requires a Cosmetic Notification within ten days of first sale; the US Modernization of Cosmetics Regulation Act (MoCRA) added facility registration and safety substantiation. The regime is fast and permissive precisely because the claims are modest — a trade every honest brand should understand it is making.

## 6. A Practical Placement Test

For any peptide product, ask four questions in order. **(1) Route:** is it injected? If yes, it is a drug or it is unlawful — there is no third option in either country. **(2) Claim:** does the marketing name a disease, or physiology beneath the skin? Then it is being marketed as a drug, whatever the label says. **(3) Licence:** does it carry a DIN, NPN, or appear in an approved drug? **(4) Seller:** is the seller identifiable, inspectable, and in a jurisdiction where the first three questions have answers? A product that fails the test is not necessarily dangerous — but it is unregulated, and the consumer is the quality-control department.

## 7. Case Study: One Tripeptide, Four Lives

GHK-Cu — a naturally occurring copper tripeptide (WP-004) — illustrates the whole map. As a topical cosmetic with appearance claims it is lawful in both countries today. As an oral supplement it sits in a contested space. As an injectable sold online it was unlawful, and remains so while FDA rulemaking proceeds — its April 2026 removal from Category 2 changed its review status, not its legality. And as a potential future drug it would require the full approval pathway no one has yet funded. Same molecule; four worlds; four different answers.

## References & Sources

- [1] US FDA — Interim policy on bulk drug substances under Section 503A; Category framework.
- [2] Federal Register, Docket FDA-2025-N-6895 (April 22, 2026) — removal of 12 peptides from Category 2.
- [3] Dietary Supplement Health and Education Act of 1994 (DSHEA); FDCA §201(ff)(3)(B) (drug preclusion).
- [4] Health Canada — Natural Health Products Regulations (SOR/2003-196); NNHPD licensing guidance.
- [5] Health Canada — Cosmetic Regulations (C.R.C., c. 869); Cosmetic Notification requirements.
- [6] Modernization of Cosmetics Regulation Act of 2022 (MoCRA).
- [7] Eli Lilly FY2025 results and FY2026 guidance (public filings and earnings communications, Feb 2026).



Companion papers: WP-002 (the 2026 reclassification), WP-004 (GHK-Cu), WP-005 (grey-market formulary).

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