

Peptide Therapy

A library document that treats each peptide as its own medicine: approved indication versus compounded copy versus research chemical, what the July 2026 FDA advisory vote did and did not do, and why “peptide therapy” is not a diagnosis.

Jupiter & Palm Beach County, FL

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How to use this book

If someone sold you “peptides” the way a store sells vitamins, start at Chapter 1. If you already know the name of the vial, jump to that chapter. If you compete, read Chapter 11 before you inject anything.

About NovaGenix

The clinic’s current peptide roster, offered when clinically appropriate and legally available: sermorelin, ipamorelin, tesamorelin, BPC-157, TB-500, NAD+, and PT-141. Evaluation does not guarantee a prescription. Availability tracks FDA compounding rules, which moved in 2023–2026 and will move again.

Hub: novagenix.org/more/peptide · cornerstone post: [Peptide therapy in Jupiter](#).

1. A peptide is not a protocol

A peptide is a short chain of amino acids. Insulin is a peptide. Semaglutide is a peptide. So is an unapproved research sequence sold in a research-chemical vial. Grouping them as “peptide therapy” is like grouping penicillin and bleach as “liquids.”

Useful questions, every time: What is the sequence? Is there an FDA-approved finished product? What is the labeled indication? If compounded, is the bulk substance eligible under 503A/503B right now?

What human outcome data exist? What does WADA say?

2. Three regulatory buckets

Bucket	Example at this clinic	What that means
FDA-approved finished drug	Tesamorelin (Egrifta) for HIV lipodystrophy; Vyleesi (bremelanotide) for premenopausal HSDD	Reviewed label, manufacturing file, boxed warnings where they exist
Compounded peptide	Sermorelin, and others when a lawful compounding rationale exists	Not FDA-approved as a finished product; legality depends on 503A bulk-substance status and a patient-specific prescription
Unapproved / investigational	BPC-157, TB-500, ipamorelin (no approved product)	Human evidence thin; FDA has flagged impurities, immunogenicity, and injectable-route gaps for some nominated peptides

A compounded copy of an approved drug is still not the approved drug. A research vial from the internet is not a compounded prescription.

3. What the July 2026 FDA peptide vote actually did

In July 2026 an FDA advisory committee recommended certain peptide bulk substances — NovaGenix’s public post names six substances under consideration, including a vote recommending BPC-157 toward possible 503A-list inclusion — for further regulatory handling. That vote is **nonbinding**.

It is not an approval. It is not a finding of safety and effectiveness. It is not permission to market “BPC for tennis elbow.” Agency staff can still oppose a listing on evidentiary grounds. Final inclusion on the 503A bulk list is a separate FDA action.

Read the clinic’s patient version: [What the July 2026 FDA peptide vote actually means for patients](#).

4. Sermorelin — a GHRH analogue without a current brand

Sermorelin is a fragment analogue of growth hormone–releasing hormone. It asks a working pituitary to release GH, which can raise IGF-1. It is not somatropin.

Geref, a historical branded sermorelin product, was withdrawn for commercial reasons, not because the molecule was banned. Today’s clinic preparations are compounded. They are not FDA-approved finished drugs, and they do not inherit pediatric GHD labeling as an adult anti-aging license.

Do not promise weight loss, muscle, or sleep as established indications. Monitor IGF-1 and glucose-related risk when a physician uses it at all.

Page: [Sermorelin therapy](#).

5. Ipamorelin — ghrelin-receptor secretagogue, no approved product

Ipamorelin is a growth-hormone secretagogue at the ghrelin receptor, not a GHRH analogue. It is not FDA-approved for any indication. Its 503A bulk-substance status has moved: Category 2 interim list in September 2023, nomination withdrawn and removed in September 2024, referred for further review. Treat current compounding legality as a living fact, not a brochure line.

FDA concerns on the peptide class include impurities, immune reactions, unnatural amino acids, and thin safety files for some injectable uses. “Clean GH pulse without cortisol” is a marketing sentence, not a completed human program.

Page: [Ipamorelin therapy](#).

6. Tesamorelin — the one with a real label

FDA-approved tesamorelin (Egrifta / Egrifta WR) reduces excess *visceral* abdominal fat in adults with HIV-associated lipodystrophy. That is the indication. It is not a general obesity drug, not a belly-fat aesthetic product, and not interchangeable with a GLP-1.

Mechanism: GHRH analogue → pituitary GH → IGF-1. Monitor glucose and IGF-1. A compounded tesamorelin is not the approved product.

7. BPC-157 — preclinical gravity, thin human data

BPC-157 is a synthetic sequence derived from a gastric protein. Animal and cell work on tendon-cell migration, vessels, and gut protection is why the internet will not shut up about it. Human evidence is small: a modest knee-pain report, a prospective hamstring study on ClinicalTrials.gov. That is a signal, not a sports-medicine standard of care.

Not FDA-approved for any indication. July 2026 committee activity toward a 503A pathway is not approval. WADA 2026 Prohibited List: S0 non-approved substances. FDA has cited limited human safety information and impurity/immune concerns for injectable peptides in this neighborhood.

Page: [BPC-157 in Jupiter](#).

8. TB-500 and the “Wolverine stack”

TB-500 is the research nickname usually attached to a thymosin-beta-4 fragment. It is not an FDA-approved drug. Combining it with BPC-157 as a “Wolverine stack” is clinic slang, not a labeled regimen and not a reason to skip diagnosis of the actual tendon.

If a physician considers either peptide, the honest frame is investigational / compounded-if-lawful, with no promise of faster surgical recovery.

9. PT-141 — approved for one group of women; off-label elsewhere

Bremelanotide (PT-141) as **Vyleesi** is FDA-approved for acquired, generalized HSDD in premenopausal women who meet label criteria. It is a melanocortin-receptor agonist given subcutaneously. It is not a PDE5 inhibitor.

Not approved for men, postmenopausal women, or erectile dysfunction. NovaGenix may discuss compounded PT-141 off-label for selected men as part of ED care; that product is not Vyleesi. Blood pressure rises transiently; nausea is common; do not use with uncontrolled hypertension or relevant cardiovascular disease without a physician who has looked at the label warnings.

10. NAD+ is not a peptide

NAD+ is a coenzyme in redox and sirtuin-adjacent metabolism. People ask about it in the same consult as peptides, which is why it lives on this list. An IV or injection does not restore youth. Human outcome data vary by route and endpoint. Treat it as a separate evidence file.

Page: [NAD+ at NovaGenix](#).

11. Athletes: WADA, NCAA, and “my doctor prescribed it”

A prescription does not create a therapeutic-use exemption. BPC-157 is on the WADA 2026 Prohibited List as a non-approved substance. Growth-hormone secretagogues and related agents are a separate anti-doping problem. NCAA banned-substance lists are not identical to WADA but they are not casual.

Clinic post: [NCAA banned peptides and steroids — 2026 football season](#).

12. How physician-led peptide care is structured at NovaGenix

1. Name the complaint in ordinary language (sleep, recovery, visceral fat in an indicated population, desire, a specific tendon) — not “I want peptides.”
2. Check whether an approved drug already does that job (tesamorelin, Vyleesi, a GLP-1, a PDE5 inhibitor).
3. Check current compounding legality for anything else.
4. Labs when the axis demands them (IGF-1, glucose, and anything the history requires).
5. Stop rules: if the goal has not moved in a defined window, stop.

NovaGenix pages and posts

Peptide pages

[Peptide hub](#)

[Sermorelin](#)

[Ipamorelin](#)

[Tesamorelin](#)

[BPC-157](#)

[PT-141](#)

[NAD+](#)

Posts

[Beginner peptide guide](#)

[July 2026 FDA vote](#)

[NCAA / athlete warning](#)

[Tesamorelin vs HGH](#)

Compare two peptides side by side

[Tesamorelin vs. sermorelin](#)

[Sermorelin vs. ipamorelin](#)

[Is tesamorelin the same as HGH?](#)

[What is ipamorelin / CJC-1295?](#)

Repair and recovery peptides

[TB-500](#)

[The “Wolverine stack”](#)

[Regenerative medicine, Jupiter](#)

[Schedule a consultation](#)

[Dr. Timothy Mackey, D.O.](#)

Guidelines, labels, and research

- Egrifta / tesamorelin prescribing information — HIV-associated lipodystrophy indication
- Vyleesi (bremelanotide) prescribing information — premenopausal HSDD
- FDA compounding / 503A bulk-substance process; July 2026 advisory committee materials
- FDA statements on peptide impurities, immunogenicity, and injectable-route data gaps
- WADA 2026 Prohibited List (S0 and related classes)

- McGuire et al. 2025 narrative review of BPC-157 for musculoskeletal healing (preclinical-heavy)
- Lee et al. 2021 small human knee-pain BPC-157 report
- ClinicalTrials.gov listings for BPC-157 hamstring protocols

Institutes

Regulatory and anti-doping

[FDA](#)

[WADA](#)

[NCAA](#)

Explainers

[MedlinePlus](#)

[Endocrine Society](#)

Other clinics — comparison, not endorsement

Peptide telehealth brands often sell stacks by nickname. Compare whether an M.D./D.O. is accountable, whether the product is an approved drug or a compounded peptide with a current legal basis, and whether athletes are warned off WADA-listed substances.

FAQ

▼ Are peptides legal?

Some are approved drugs. Some may be compounded when the bulk substance and prescription meet current federal rules. Some are neither. “Legal” is a property of a specific product and use, not of the word peptide.

▼ **Will sermorelin replace HGH?**

No. Different molecule, different regulation, different evidence.

▼ **Can I buy BPC-157 online and tell the clinic later?**

Research-chemical vials are not a clinic prescription. Athletes can lose eligibility. Contamination is not hypothetical.

▼ **Is NAD+ a peptide?**

No.

Glossary

- **503A / 503B** — compounding pharmacy vs outsourcing facility.
- **GHRH** — growth hormone–releasing hormone.
- **Secretagogue** — a substance that causes another hormone to be secreted.
- **S0** — WADA class for non-approved substances.

Disclaimer

Education only. Peptide compounding rules change. This book is not a finding that any named peptide is currently compoundable or appropriate for a given patient. [Medical disclaimer](#).

Florida 72-hour advertising notice for free/discounted exam offers applies to how visits are sold.

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