McDermott Will & Schulte

Peptides Under the Microscope: Regulation, Enforcement, and Market Implications

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Agenda

- Peptide market and fundamentals
- Drug compounding overview
- Regulatory landscape and developments
- Enforcement trends
- Medical practice and state law considerations
- Key considerations for investors

What are peptides?

- Peptides are short chains of amino acids (typically 2-50) linked by peptide bonds
  - Occur naturally in the body
  - Involved in many important bodily functions
- Have become popular for use in therapeutics because they can be engineered in highly specific ways, are rapidly metabolized, and can be synthesized chemically
  - Developed for uses including anti-aging, skincare, muscle growth and weight loss, hair growth, and bone loss, among others
  - Can be administered in a variety of ways, including by injection or by mouth

Peptide market at a glance

Global market size of peptide therapeutics:

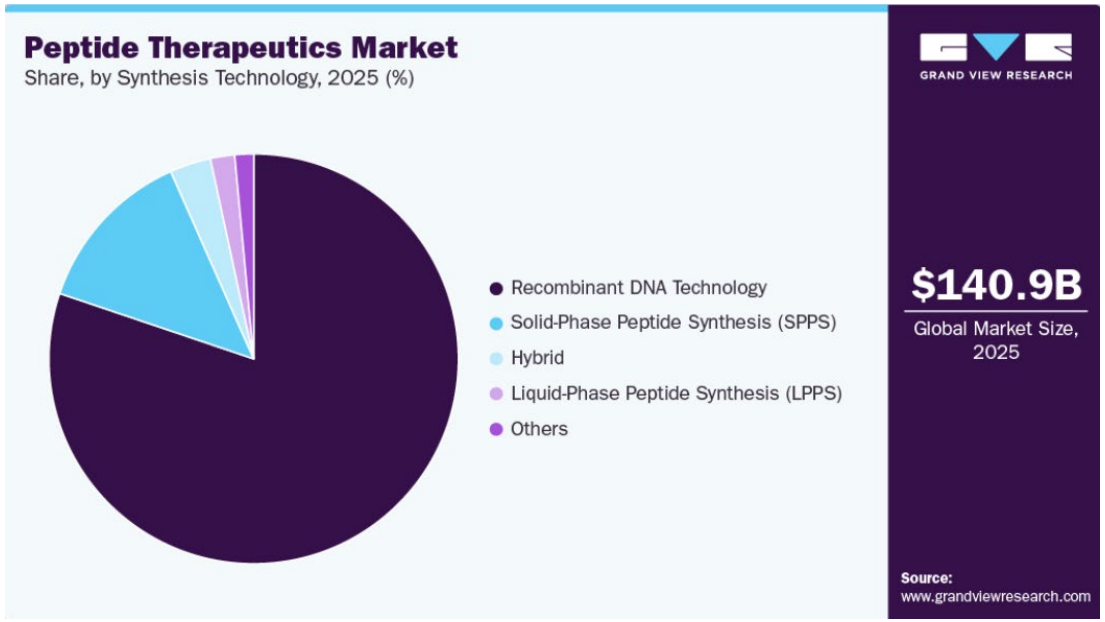
- **2025:** $140.86 billion USD
- **2033 Projection:** $294.58 billion USD; growing at CAGR of 8.73% from 2026-2033
- North America: **61.99% market share**

Key therapeutic areas:

- Metabolic (e.g., diabetes, GLP-1s)
- Oncology
- Endocrine disorders

Market Drivers:

- Demand for targeted, high-efficacy therapies
- Increased prevalence of metabolic disorders (ex. diabetes and obesity)



Grand View Research, *Peptide Therapeutics Market (2026–2033)*, https://www.grandviewresearch.com/industry-analysis/peptide-therapeutics-market

Treatment of peptides by FDA

- FDA does not maintain a separate regulatory category for "peptides"
- Biologics Price Competition and Innovation Act defined “biological product” to include “protein (except any chemically synthesized polypeptide)”
- Further Consolidated Appropriates Act of 2020 removed the parenthetical from the definition

U.S. Food & Drug Admin., *“Deemed to be a License” Provision of the BPCI Act*, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act

Treatment of peptides by FDA

Clarifications on appropriate regulatory pathways for peptides

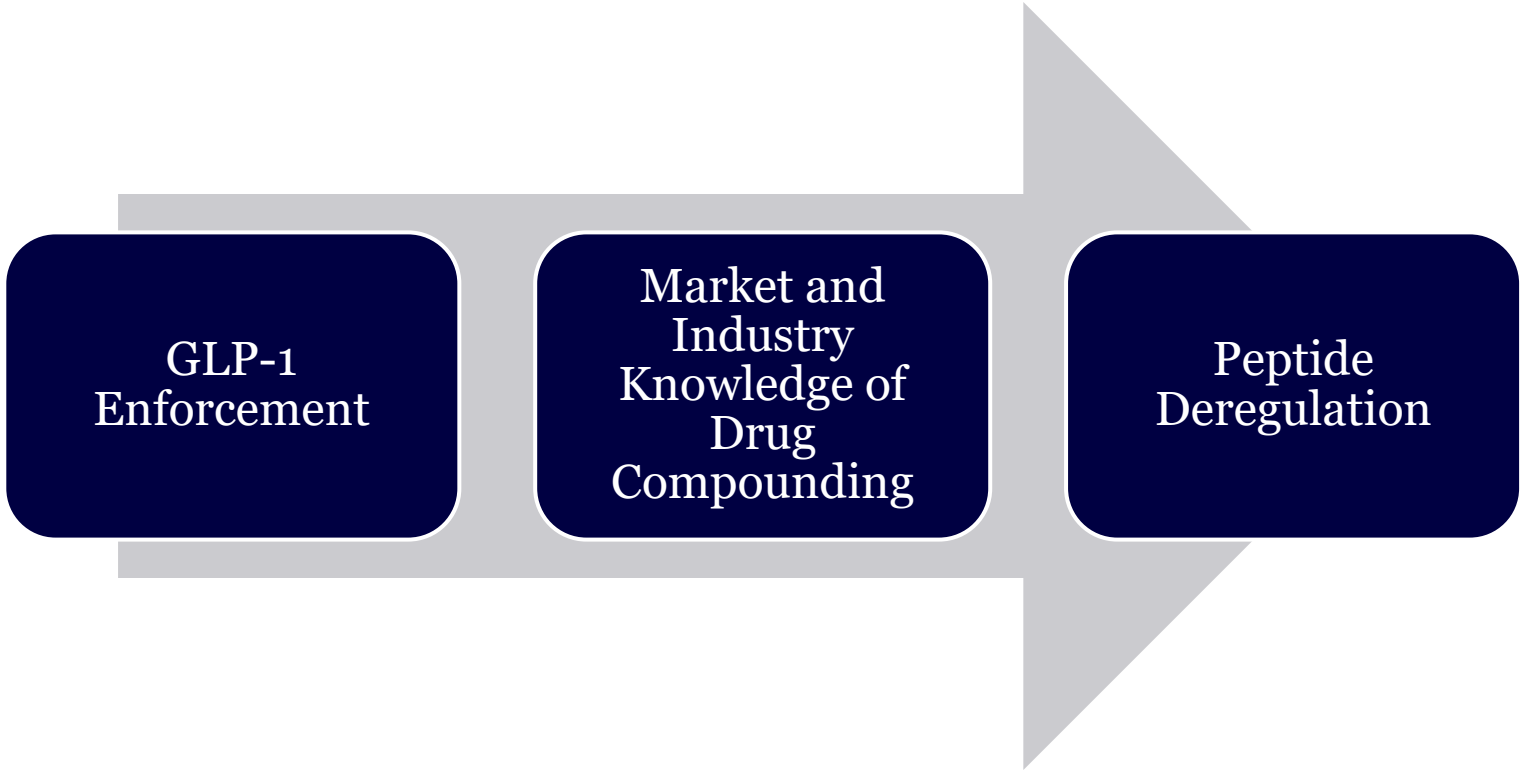
- **2020:** FDA finalized a bright-line interpretation by defining "protein" as any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids
  - Peptides under 40 amino acids would typically be regulated as drugs

- **2023:** Further guidance was released reinforcing the 2020 peptide definition and clarifying that peptides may be regulated as drug products, biologics, devices, or supplementals based on the characteristics of the peptide
  - Peptides need to be individually assessed to determine the appropriate regulatory regime

U.S. Food & Drug Admin., *Definition of the Term "Biological Product"*, https://www.fda.gov/media/135421/download

U.S. Food & Drug Admin., *Clinical Pharmacology Considerations for Peptide Drug Products* (Dec. 2023), https://www.fda.gov/media/171901/download.

Regulatory Drivers of Peptide Compounding Growth



Brief overview of compounding (503A/503B)

Drug compounding

- The combination, mixing, or alteration of ingredients of a marketed drug product to create a medication tailored to the need of an individual patient
- Compounded drugs can provide important medical needs for certain patients (e.g., removing allergens)

Federal Food, Drug, and Cosmetic Act (FD&C Act)

- **Section 503A (compounding pharmacies)**
  - Patient specific – a drug is compounded based on a prescription for a given patient
- **Section 503B (outsourcing facilities)**
  - Bulk compounding – compounded for health care facilities and entities (e.g., physician practices, hospitals)

Compounding boom in the GLP-1 era

- Historically, compounding was conducted on an as-needed basis
- The introduction of GLP-1s into the market had enormous disruptive effects – both market demand and COVID-19 strained supply
- FDA maintains a Drug Shortage List tracking these disruptions in supply of marketed drug products
  - Any product listed as “currently in shortage” is considered **not** “commercially available”
  - During a shortage, certain restrictions concerning the compounding of “essentially copies” are loosened – this is to keep patients from losing access to much needed medications
- Brand manufacturers and the FDA had to grapple with the market-demand driven increase in compounding

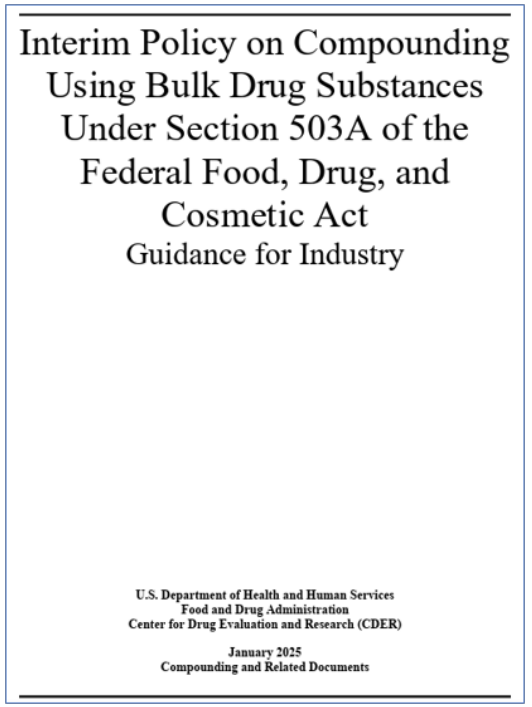
Increased GLP-1 compounding enforcement

Shortages ended

- Enforcement escalated stemming from a number of factors:
  - Patient safety concerns
  - Deceptive marketing proliferation
  - Brand manufacturer pressure
  - Political direction
- In September 2025, FDA issued 55+ Warning Letters to online sellers of compounded GLP-1s and 100+ cease-and-desist letters
- In March 2026, FDA issued an additional wave of Warning Letters

Bulk Drug Lists (503A/503B)

- FDA promulgates Bulk Drug Lists for 503A and 503B compounding that provide insight into the safety of products in the use of compounding and include various peptides
- Historically, nominated products were divided into three categories
  - **Category 1:** adequate support for inclusion on the Bulk Drug Lists
  - **Category 2:** significant safety risks
  - **Category 3:** inadequate information



Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

January 2025
Compounding and Related Documents

§ 216.23 Bulk drug substances that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act.

(a) The following bulk drug substances can be used in compounding under section 503A(b)(1)(A)(i)(III) of the Federal Food, Drug, and Cosmetic Act.

(1) Brilliant Blue G, also known as Coomassie Brilliant Blue G-250.

(2) Cantharidin (for topical use only).

(3) Diphenylcyclopropenone (for topical use only).

(4) N-acetyl-D-glucosamine (for topical use only).

(5) Squaric acid dibutyl ester (for topical use only).

(6) Thymol iodide (for topical use only).

U.S. Food & Drug Admin., *Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act* (Sept. 2024), https://www.fda.gov/media/94155/download

Recent updates

Reversal of compounding restrictions

- January 2025: FDA withdrew Categories 2 and 3 from the Bulk Drugs Lists, which had listed a number of peptide products

intended for it to be temporary. For the reasons that follow, FDA is now ending categorization of newly nominated substances because the Agency believes such a policy no longer serves the guidance's stated objective of preventing unnecessary disruption to patient treatment and, therefore, the balance of public health interests supporting the policy has changed.

However, at this time, until a substance has been evaluated and is identified in a final rule as being included or not included on the 503A bulks list, FDA does not intend to take action against a State-licensed pharmacy, Federal facility, or licensed physician compounding a drug product using a bulk drug substance that is not a component of an FDA-approved drug product, the subject of an applicable USP or NF monograph, or on the 503A bulks list codified at 21 CFR 216.23(a), if all of the following circumstances are present:

(1) The bulk drug substance appears in 503A Category 1 on FDA's website at https://www.fda.gov/media/94155/download. A Category 1 substance may be eligible for inclusion on the 503A bulks list, was nominated before the publication date of this guidance with sufficient supporting information for FDA to evaluate the substance, and has not been identified by FDA as a substance that presents a significant safety risk in compounding prior to the publication of a final rule;

(2) The original manufacturer and all subsequent manufacturers of the bulk drug substance are establishments that are registered under section 510 (including foreign establishments that are registered under section 510(i) of the FD&C Act);

(3) The bulk drug substance is accompanied by a valid COA; and

(4) The drug product compounded using the bulk drug substance is compounded in compliance with all other conditions of section 503A of the FD&C Act.

U.S. Food & Drug Admin., *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act* (Jan. 2025), https://www.fda.gov/media/174456/download

Updated September 27, 2024

503A Category 2: Bulk Drug Substances that Raise Significant Safety Risks

Visit Safety Risks Associated with Certain Bulk Drug Substances for Use in Compounding for a summary of the identified safety risks for bulk drug substances in Category 2, as well as other bulk drug substances that may present significant safety risks.

- BPC-157
- Cathelicidin LL-37
- Cesium Chloride
- Dihexa Acetate
- Domperidone
- Emideltide (DSIP)
- Epitalon
- Germanium Sesquioxide
- GHK-Cu (for injectable routes of administration)
- Ibutamoren Mesylate
- Kisspeptin-10
- KPV
- Melanotan II
- Mechano Growth Factor, Pegylated (PEG-MGF)
- MOTs-C
- Quinacrine Hydrochloride for intrauterine administration
- Semax (heptapeptide)
- Thymosin Beta-4, Fragment (LKKTETQ)

Recent updates

Human Drug Compounding / Certain Bulk Drug Substances for Use in Compounding that May Present Significant Safety Risks

Certain Bulk Drug Substances for Use in Compounding that May Present Significant Safety Risks

Category 2 of the Bulk Substances Nominated Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act

Bulk drug substances used in compounding may present significant safety risks. FDA has identified potential significant safety risks when reviewing nominations for bulk drug substances proposed to be included on the 503A or 503B bulks lists. Such bulk drug substances may appear in category 2 under the following guidance documents:

- Guidance for Industry, Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- Guidance for Industry, Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

The agency also has identified potential significant safety risks associated with certain bulk drug substances that do not appear in category 2 under the interim policies above. A bulk drug substance that FDA has identified as presenting a potential significant safety risk might not appear in category 2 because, for example, its nomination was withdrawn.

U.S. Food & Drug Admin., *Certain Bulk Drug Substances for Use in Compounding that May Present Significant Safety Risks*, https://www.fda.gov/drugs/human-drug-compounding/certain-bulk-drug-substances-use-compounding-may-present-significant-safety-risks

Bulk drug substances under category 2 of the interim policies

Search: Export Excel Show 50 entries

Bulk drug substance	503A category 2, 503B category 2, or both	Date added to category 2	Potential significant safety risks
BPC-157	503A	September 29, 2023	Compounded drugs containing BPC-157 may pose risk for immunogenicity for certain routes of administration and may have complexities with regard to peptide-related impurities and active pharmaceutical ingredient (API) characterization. FDA has identified no, or only limited, safety-related information for the proposed routes of administration. Therefore, the agency lacks sufficient information to know whether the drug would cause harm when administered to humans.
GHK-Cu (for injectable routes of administration)	503A	September 29, 2023	Compounded injectable drugs containing GHK-Cu may pose risk for immunogenicity due to the potential for aggregation and peptide-related impurities. There are limited data in humans to inform safety-related considerations
MOTs-C	503A	September 29, 2023	Compounded drugs containing MOTs-C may pose significant risk for immunogenicity for certain routes of administration and may have complexities with regard to peptide-related impurities and API characterization. FDA has not identified, any human exposure data on drug products containing MOTs-C administered via any route of administration. FDA lacks important information regarding any safety issues raised by MOTs-C, including whether it would cause harm if administered to humans.

Peptides – recent trends

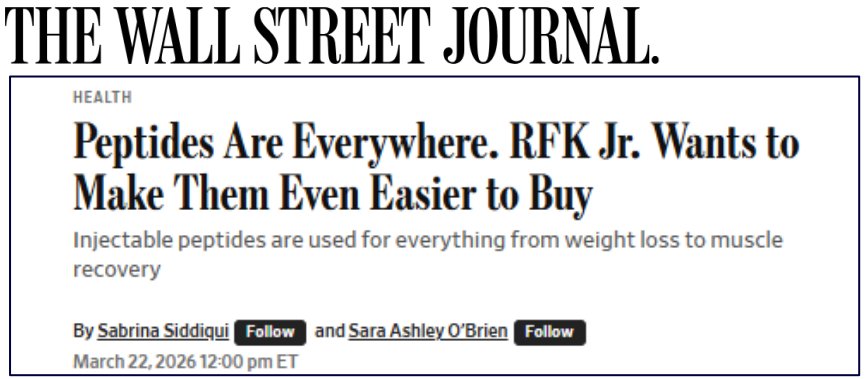
- Given the rise in GLP-1 enforcement trends, compounders have begun looking to other peptides
  - In a recent podcast interview, HHS Secretary Robert F. Kennedy Jr. noted he is a “big fan of peptides”, claimed that the categorization of these peptides in Category 2 was “illegal”, and announced plans to lift restrictions to allow compounding pharmacies to produce peptides
    - These peptides include BPC-157, GHK-Cu, Ipamorelin, TB-500, and CJC-1295, among others

The New York Times

Heeding Kennedy's Wishes, F.D.A. Is Expected to Lift Restriction on Peptides

The peptides, which are increasingly marketed as providing longevity and health benefits, were removed in 2023 from the agency's list of products that compounding pharmacies can sell.

March 31, 2026



THE WALL STREET JOURNAL.

HEALTH

Peptides Are Everywhere. RFK Jr. Wants to Make Them Even Easier to Buy

Injectable peptides are used for everything from weight loss to muscle recovery

By Sabrina Siddiqui Follow and Sara Ashley O'Brien Follow

March 22, 2026 12:00 pm ET

Christina Jewett & Dani Blum, *FDA Is Expected to Lift Restrictions on Peptides, Heeding RFK Jr.'s Views, N.Y. Times* (Mar. 31, 2026), https://www.nytimes.com/2026/03/31/health/peptide-ban-fda-rfk-jr.html

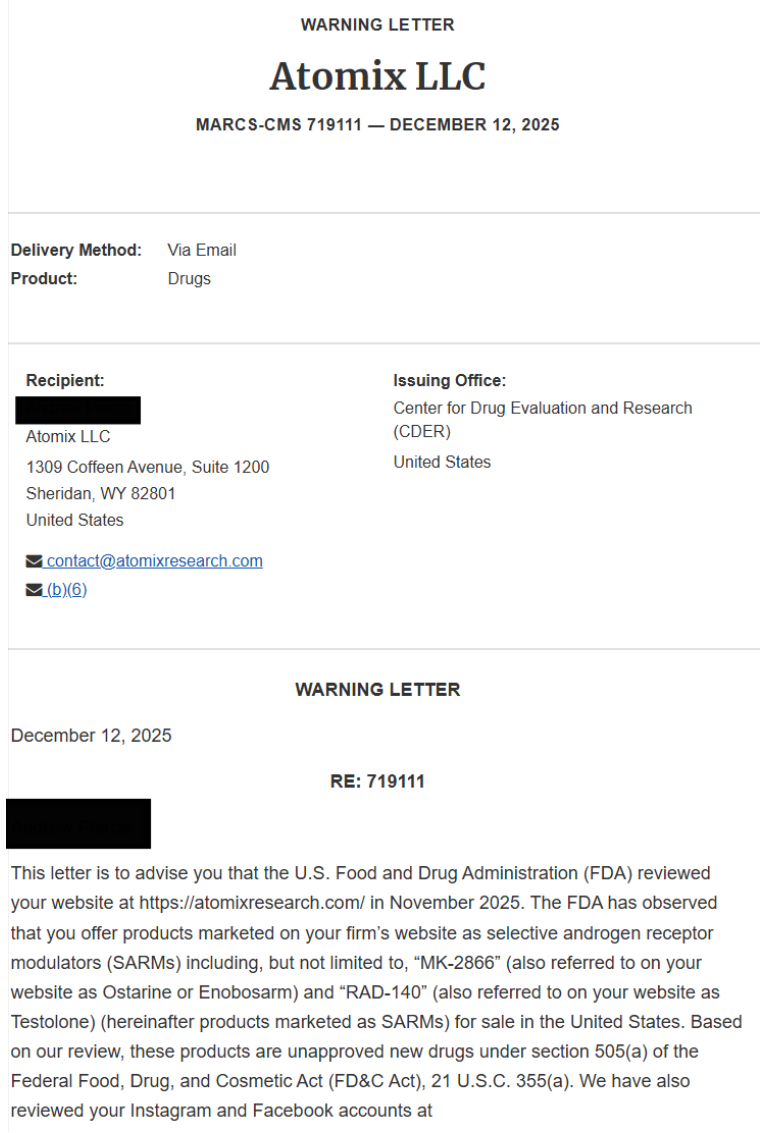
Sabrina Siddiqui, *Peptides Are Everywhere. RFK Jr. Wants to Make Them Even Easier to Buy*, Wall St. J. (Mar. 22, 2026), https://www.wsj.com/health/rfk-jr-china-peptides-market-2ce249df.

Peptides – recent trends

- FDA plans to reconvene the Pharmacy Compounding Advisory Committee, though no meeting has been announced publicly yet
  - Potential topics of interest
    - Whether there is a medical justification for some peptides
    - A vote on which if any peptides should be formally added to the list of products compounding pharmacies can produce
  - The Committee primarily provides advice to the Commissioner on scientific, technical, and medical issues concerning 503A and 503B drug compounding
    - 12 core voting members, including the Chair

Peptides – recent trends

- FDA's official position on peptides is unclear, though recent updates imply some levels of leniency
  - Several Warning Letters have been issued to online sellers marketing selective androgen receptor modulators (SARMS), many of whom also advertise peptide products which were not flagged in the warning letters
    - E.g., the Warning Letter issued to Atomix LLC was framed only around SARMS, even though they also advertise peptides such as PT-141 and BPC-157/TB-50
    - The absence of BPC-157 and similar peptide references may suggest that such products are not on the FDA's current enforcement agenda



WARNING LETTER

Atomix LLC

MARCS-CMS 719111 — DECEMBER 12, 2025

Delivery Method: Via Email
Product: Drugs

Recipient:
[redacted]
Atomix LLC
1309 Coffeen Avenue, Suite 1200
Sheridan, WY 82801
United States
contact@atomixresearch.com
(b)(6)

Issuing Office:
Center for Drug Evaluation and Research (CDER)
United States

WARNING LETTER

December 12, 2025

RE: 719111

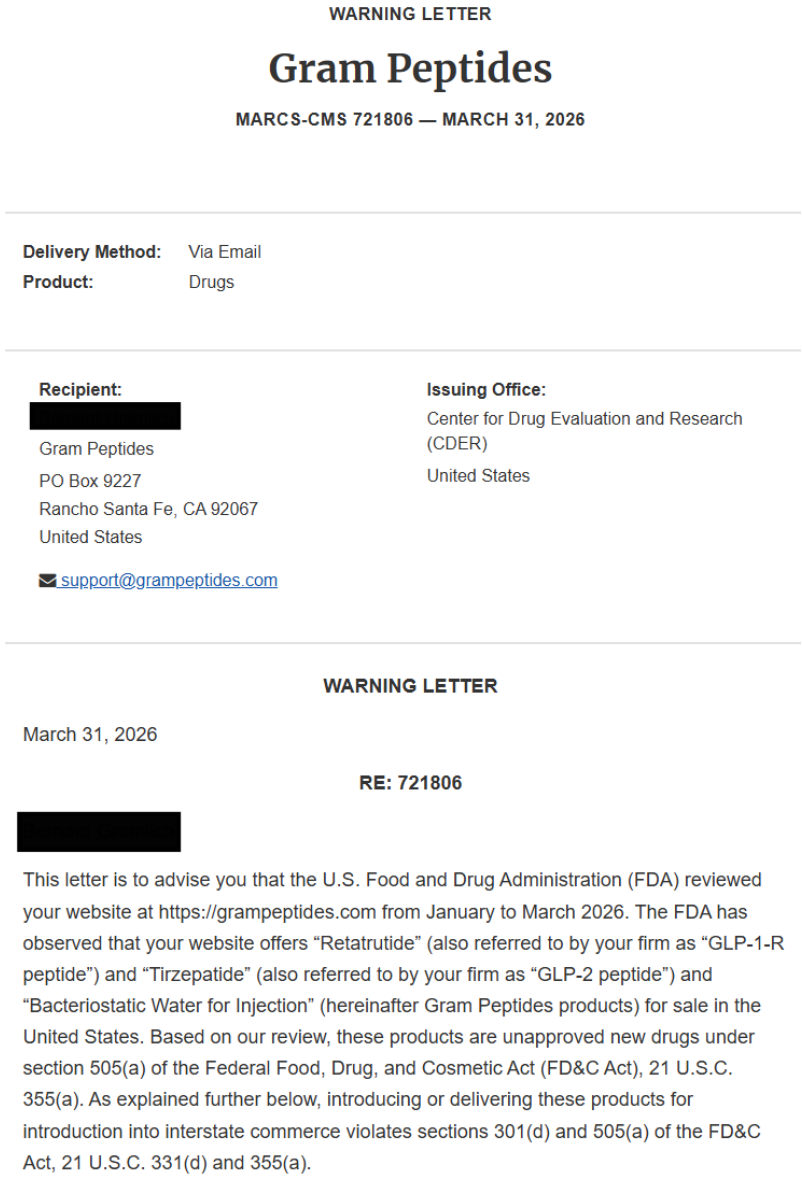
[redacted]

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at https://atomixresearch.com/ in November 2025. The FDA has observed that you offer products marketed on your firm's website as selective androgen receptor modulators (SARMs) including, but not limited to, "MK-2866" (also referred to on your website as Ostarine or Enobosarm) and "RAD-140" (also referred to on your website as Testolone) (hereinafter products marketed as SARMs) for sale in the United States. Based on our review, these products are unapproved new drugs under section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a). We have also reviewed your Instagram and Facebook accounts at

U.S. Food & Drug Admin., *Warning Letter: Atomix LLC – 719111 – 12/12/2025* (Dec. 12, 2025), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/atomix-llc-719111-12122025

Peptides – recent trends

- More recent Warning Letters continue the trend of omission of peptide products
- In March 2026, FDA issued another suite of Warning Letters targeting compounders of medications focusing on GLP-1 products
  - The entities also commercialized peptide products which were not mentioned



WARNING LETTER

Gram Peptides

MARCS-CMS 721806 — MARCH 31, 2026

Delivery Method: Via Email
Product: Drugs

Recipient:
[redacted]
Gram Peptides
PO Box 9227
Rancho Santa Fe, CA 92067
United States

support@grampeptides.com

Issuing Office:
Center for Drug Evaluation and Research (CDER)
United States

WARNING LETTER

March 31, 2026

RE: 721806

[redacted]

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at https://grampeptides.com from January to March 2026. The FDA has observed that your website offers “Retatrutide” (also referred to by your firm as “GLP-1-R peptide”) and “Tirzepatide” (also referred to by your firm as “GLP-2 peptide”) and “Bacteriostatic Water for Injection” (hereinafter Gram Peptides products) for sale in the United States. Based on our review, these products are unapproved new drugs under section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a). As explained further below, introducing or delivering these products for introduction into interstate commerce violates sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).

U.S. Food & Drug Admin., Warning Letter: Gram Peptides – 721806 – 03/31/2026 (Mar. 31, 2026), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/gram-peptides-721806-03312026.

Peptide enforcement & regulation – advertising claims

Advertising and marketing claims of compounded products should avoid the following five categories of claims or actions:	**Same Active Ingredients Claims**: Stating compounded products contain the same active ingredients as FDA-approved drugs
	Equivalency Claims: Implying compounded drugs are equivalent to FDA-approved counterparts (e.g., “same as the brand”, “[Brand product] but now in a convenient form!”)
	Efficacy Claims: Suggesting compounded drugs are "clinically proven" or otherwise efficacious (e.g., “great for weight loss”)
	Implied FDA Approval: Marketing materials implying FDA approval or review (e.g., “the generic version” or “FDA-approved”)
	Company Logos on Product Labels: Materials with company logos implied that the company was the compounder of the product when it is not

Peptide Advertising – FDA Budget

- In FDA's Fiscal Year 2027 budget document, the Agency requested Congress "update the FD&C Act to clarify that a compounded drug is deemed to be misbranded if an advertisement's representation is false or misleading or creates a misleading impression"
- The legislative proposal would codify the FDA's position on direct-to-consumer (DTC) advertising of compounded products in the FD&C Act

DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2027

Food and Drug Administration

U.S. Food & Drug Admin., Fiscal Year 2027 Justification of Estimates for Appropriations, https://www.fda.gov/media/191778/download

Peptide Advertising – FTC

- FTC evaluates peptide advertising based on "competent and reliable scientific evidence" standard
  - Peptides often do not meet this standard due to a lack of published human randomized controlled trial data
  - Qualifying language such as "may help" or "promising, preliminary studies" are not sufficient disclaimers
  - E.g., FTC took action against a telemedicine company for deceptive advertisement of its GLP-1s, in part due to the failure to meet the "competent and reliable scientific evidence" standard and use of fake testimonials

Fed. Trade Comm'n, *Health Products Compliance Guidance* (Dec. 2022), https://www.ftc.gov/business-guidance/resources/health-products-compliance-guidance

Peptide Advertising – Other Enforcement

- Other than the FDA, other agencies and regulatory bodies also regulate different areas of peptides
  - Industry self-regulating bodies such as the Better Business Bureau's National Advertising Division (BBB-NAD) evaluate the truth and accuracy of advertising claims
  - BBB-NAD also refers unresolved cases as well as parties not complying with BBB-NAD decisions to the Federal Trade Commission (FTC) and State Attorneys General

Fed. Trade Comm'n, *Health Products Compliance Guidance* (Dec. 2022), https://www.ftc.gov/business-guidance/resources/health-products-compliance-guidance

BBB Nat'l Programs, National Advertising Division, https://bbbprograms.org/programs/all-programs/national-advertising-division

Peptide Advertising – BBB-NAD

- The BBB-NAD recommended that a manufacturer amend or discontinue its use of claims that its dietary supplements were “clinically proven to significantly increase NAD+ levels, and help maintain them with daily use”
- The BBB-NAD concluded the study results provided by the manufacturer were insufficient to support the broad claim
- The BBB-NAD also recommended that testimonials, influencer advertising and health benefit claims be discontinued unless substantiation could be provided

BBB National Programs
National Advertising Division®

BBB Nat’l Programs, National Advertising Division, https://bbbprograms.org/programs/all-programs/national-advertising-division

Risks/regulations: white labeling of compounded products

White Labeling

- Occurs when compounders produce a product that is then sold by another company under the company's brand name
- FDA Warning Letters stated that the white labeling created a false and misleading implication that the companies are the compounders of the medication products

Compliance Consideration

- Telehealth companies should ensure that white labeled products properly identify the original compounder and do not suggest that they themselves compound the drugs

Peptide enforcement & regulation – state considerations

- **Medical Board Authority:**
  - Broad discretion to enforce “unprofessional conduct”
  - Issue Rulemaking
  - Issue Guidance documents to licensees
- States may also regulate and enforce specific drugs and therapies via their medical (or other professional) practice acts and regulations

Peptide enforcement & regulation – Example: Nevada

Provider under investigation for dispensing peptides at conference

Prompted Investigations by:

Nevada Medical Board	Nevada Pharmacy Board	Nevada Department of Health

Clinical considerations – informed consent and documentation

Consider whether:

- Consent is appropriate for each peptide product or therapy options
- How provider will frame and facilitate and document a discussion of risks and goals of any peptide therapy plan
- Eligibility for peptide therapy (e.g., 18 and older)
- Discussion of alternatives
- Consent should always be documented.

Recommended strong documentation of:

- Baseline condition
- Clinical justification
- Patient response

Clinical considerations – patient monitoring

There are no states with peptide-specific "monitoring statutes." Instead, patient monitoring requirements arise indirectly through:

State medical practice acts (standard of care / unprofessional conduct)	Telehealth laws, regulations and practice standards (wee applicable)

Best Practice: Monitoring expectations vary by peptide type and risk profile, but states consistently expect active clinical oversight, not "set-and-forget" prescribing.

Key considerations for investors

- Regulatory Risk
- Litigation Exposure
- Compliance and Operational Due Diligence
- Market and Competitive Factors
- Financial Considerations
- Strategic and Exit Considerations

Thank you!

PLEASE REACH OUT FOR FURTHER INFORMATION:

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