

MAKE Wellness Bioactive Peptides Compliance Summary

For independent pharmacies & compliance officers | Prepared by Peptide Partners

OTC - NO RX REQUIRED

LEGAL IN ALL 50 STATES

Bottom line: MAKE Wellness bioactive peptides are food-derived dietary supplements classified under GRAS (Generally Recognized as Safe) and governed by DSHEA. They are not OTC drugs, not synthetic peptides, and not research-only compounds. They are fully legal in all 50 states - no state board approval, special licensure, or regulatory review required. Any pharmacy may carry and recommend them today under standard retail pharmacy licensure.

Side-by-Side: Compounded Injectables vs. MAKE Bioactive Peptides

Category	Compounded Injectable Peptides	MAKE Wellness Bioactive Peptides
Regulatory pathway	503A/503B compounded drug; subject to FDA drug enforcement	Dietary supplement under DSHEA & GRAS; 21 CFR Part 111
Delivery route	Subcutaneous or IV injection	Oral capsule / powder - no needles, no sterile compounding
Prescription required?	Yes - Rx only	No - sold OTC, no prescription needed
DEA scheduling	Some analogs face scheduling risk	Not scheduled; no DEA license required
Manufacturing	Compounding pharmacy; PCAB accreditation often required	FDA-registered, cGMP-certified nutraceutical facility
Ingredient origin	Synthetic API; bulk peptide raw materials	Naturally derived; food-protein amino acid sequences (GRAS)
State legality	Varies; compounding regulations differ by state	Legal in all 50 states - no exceptions, no special authorization
FDA enforcement	Active (2023-2025): BPC-157, TB-500, semaglutide analogs targeted	None - MAKE products are not in any FDA enforcement category

Key Regulatory Distinctions

GRAS & DSHEA CLASSIFICATION

MAKE Wellness products are food-derived dietary supplements governed by GRAS and DSHEA (1994). They are not OTC drugs, not synthetic peptides, and not research-only compounds. They follow the same legal framework as vitamins, protein powders, and nutraceuticals.

NOT A COMPOUNDED DRUG

The FDA's 2023-2025 enforcement actions targeted compounded injectable peptides (BPC-157, TB-500, semaglutide analogs). MAKE products require no compounding, no sterile preparation, and no 503A/503B designation - they are an entirely separate category.

LEGAL IN ALL 50 STATES

No state board approval, special licensure, or regulatory review is required. Any pharmacy in any state may carry and recommend MAKE Wellness products under standard retail pharmacy licensure - effective immediately, with no additional steps.

CGMP MANUFACTURING

Manufactured in FDA-registered, cGMP-certified nutraceutical facilities with three testing checkpoints: raw materials, in-process, and finished goods. No DEA registration required. No controlled-substance classification.

Applicable Regulatory Framework

DSHEA (1994)	Dietary Supplement Health and Education Act
GRAS	Generally Recognized as Safe (food-derived ingredients)
21 CFR Part 111	cGMP for dietary supplements
21 CFR Part 101	Food labeling requirements
FD&C; Act §201(ff)	Definition of dietary supplement
503A/503B	Compounding framework (does not apply to MAKE)

Common Compliance Questions

Can my pharmacy carry these without any special license or state board approval?

Yes - immediately, with no additional steps. MAKE Wellness products are food-derived dietary supplements under GRAS and DSHEA. Your standard retail pharmacy license is all that is required. There is no state board approval process, no special authorization, and no regulatory review needed in any of the 50 states.

Are these affected by the FDA's 2023-2025 injectable peptide enforcement actions?

No. The FDA actions targeted compounded injectable peptides (BPC-157, TB-500, semaglutide analogs) prepared by compounding pharmacies. MAKE products are orally delivered, food-derived dietary supplements - a completely separate regulatory category with no active enforcement concerns and no overlap with the compounded injectable framework.

How are these different from "research only" or synthetic peptides?

MAKE Wellness bioactive peptides are naturally derived short-chain amino acid sequences found in food proteins - not synthetic APIs, not research-only compounds, and not investigational substances. They are formulated for human consumption as dietary supplements and have been on the market legally under GRAS and DSHEA for years.

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