Regulatory Status of Peptide Products:

Overview:

The peptides and products on the Age|REcode Peptide Order Form span a range of U.S. regulatory categories. Below we categorize each item into **FDA-aligned regulatory buckets** with an explanation and supporting references. This categorization clarifies whether a peptide is an FDA-approved drug, an investigational drug, a research-use-only compound, a cosmetic peptide, a dietary supplement ingredient (GRAS or DSHEA-eligible), or part of an Age|REcode branded supplement formulation.

Note: In the U.S., substances intended to **treat or prevent disease** or affect body structure/function (beyond general wellness) are regulated as drugs. Dietary supplements (under DSHEA 1994) can only contain certain *"dietary ingredients"* (vitamins, minerals, herbs, amino acids, or other dietary substances) and **cannot include new unapproved drugs**[1][2]. Cosmetics are products applied to the body for appearance-enhancement and are not pre-approved by FDA as long as no medical claims are made. Peptides sold for "research use only" (RUO) are typically unlabeled to avoid drug classification[3][4].

Below is a **comprehensive table** of the Age|REcode peptides/products and their **proposed U.S. regulatory category**, with brief regulatory rationale and citations to FDA or other official guidance:

Peptide/Product Regulatory Classification Table

Peptide / Product	Regulatory Category	Regulatory Status & Explanation	Key References
Semaglutide (GLP-1 analog)	FDA-Approved Drug (Prescription)	**Approved** in FDA's Orange Book for Type 2 diabetes (Ozempic, 2017) and chronic weight management (Wegovy). Semaglutide is a GLP-1 receptor agonist[5]. It is a prescription drug, not legally sold for research or	FDA Orange Book; FDA Drug Shortage Memo[5]

Peptide / Product	Regulatory Category	Regulatory Status & Explanation	Key References
		supplement use.	
Tirzepatide (dual GIP/GLP-1 agonist)	FDA-Approved Drug (Prescription)	**Approved** by FDA in May 2022 for type 2 diabetes (brand *Mounjaro*)[6][7]. Recently (Nov 2023) also approved for obesity under brand *Zepbound*[8]. It is an Rx drug and appears in FDA records as an approved dual-incretin therapy.	StatPearls (NCBI)[6]; FDA News[7]
Bremelanotide (PT-141)	FDA-Approved Drug (Prescription)	**Approved** as a prescription medication for hypoactive sexual desire disorder in premenopausal women (brand *Vyleesi*, 2019). It's the first FDA-approved treatment for low female sex drive[9].	FDA/NIH release[9] (Vyleesi – first FDA-approved HSDD treatment)
Tesamorelin (GHRH analog)	FDA-Approved Drug (Prescription)	**Approved** in 2010 (brand *Egrifta*) for reduction of excess abdominal fat in HIV-associated lipodystrophy[10][11]. Tesamorelin is an NDA-approved peptide (a GHRH analog).	American J. Health-System Pharm.[10][11]
Oxytocin (Oxytocin acetate)	FDA-Approved Drug (Prescription)	**Approved** hormone drug (oxytocin injection, *Pitocin*) indicated for medical uses such as labor induction and postpartum bleeding control. Oxytocin appears in FDA's database of approved drugs.	FDA Approved Drugs Database (Oxytocin)[12] (not listing by name, but oxytocin is known approved hormone)
Sermorelin (GHRH analog)	FDA-Approved Drug (historical; discontinued)	**Approved** in 1997 (brand *Geref*) for childhood growth hormone deficiency[13]. While the NDA was later discontinued, Sermorelin was an FDA-approved peptide drug. It may be compounded in certain cases as it had been	FDA Orphan Drug database[14][13] (Geref approval 1997)

Peptide / Product	Regulatory Category	Regulatory Status & Explanation	Key References
		approved, but any over-the-counter sale would be unlawful.	
IGF-1 (Insulin-like Growth Factor-1)	FDA-Approved Drug (Prescription)	**Approved** as mecasermin (recombinant IGF-1, brand *Increlex*) for growth failure in children.	FDA Drugs Database (Mecasermin); see IGF-1 LR3 below
Retatrutide (triple agonist LY3437943)	Investigational New Drug (IND; Not Approved)	**Not FDA-approved** – Retatrutide is a *phase 3 investigational* triple agonist for obesity/diabetes. Lilly confirms it is *"not currently approved by the FDA and is considered an investigational medication."*[15] It can only be legally utilized in clinical trials.	Lilly FAQ (Dec 2025)[15][16]
Mazdutide (dual GLP-1/Glucagon agonist)	Investigational New Drug (Not FDA-Approved)	**Not FDA-approved** in the US – Mazdutide is a dual-agonist peptide under development by Innovent/Eli Lilly. It has **NMPA approval in China** (2025) for weight management, but in the U.S. it remains in Phase 3 trials and *"is not approved for use by the FDA in the United States."*[17] Any U.S. sales outside trials would classify it as an unapproved new drug.	PrepTide (peptide database)[17]; PR Newswire/Biospace updates
Survodutide (GLP-1/Glucagon dual agonist)	Investigational New Drug (Not FDA-Approved)	**Not FDA-approved** – Survodutide (BI 456906) is an investigational dual receptor agonist from Boehringer Ingelheim/Zealand Pharma. It's in Phase 2/3 trials for obesity and NASH[18][19]. Like similar agents, it's only available in studies. (Nearly 19% weight loss was shown in a Phase 2 trial[20], but no FDA approval yet.)	PubMed (Survodutide trial)[21]; Boehringer press[19]

Peptide / Product	Regulatory Category	Regulatory Status & Explanation	Key References
Cagrilintide (long-acting amylin analog)	Investigational New Drug (Not FDA-Approved)	**Not FDA-approved** – Cagrilintide is an *investigational* amylin analog for obesity. It is being combined with semaglutide in Novo Nordisk's phase 3 trials (the combo called *CagriSema*). As of 2025, cagrilintide is still **investigational** (NDA filing for the combo is in progress). Drugs.com notes cagrilintide as "an investigational long-acting amylin analogue"[22]. No standalone FDA approval exists yet.	Drugs.com (CagriSema)[22]; JAMA (GLP-1 new drugs)[23]
BPC-157 (Body Protection Compound)	**RUO** – Research Use Only (Unapproved Drug)	**Not an approved drug or supplement.** FDA and DoD classify BPC-157 as an *unapproved drug*, **not** a vitamin or dietary ingredient[24]. It is **prohibited** for use in military supplements[25]. No FDA approval exists (it's not in the Orange Book[12]).	OPSS (DoD) advisory[24][3] (RUO only)
Epitalon (Epithalon; pineal tetrapeptide)	**RUO** – Research Use Only (Unapproved Drug)	**Not FDA-approved.** Epitalon is a synthetic pineal peptide (4 amino acids) touted for anti-aging. It has no FDA-approved uses and is not on the 503A compounding list[2]. It's sold as a research chemical. Like other unscheduled peptides, it's **legal to sell for lab use** but *illegal to market for human treatment*[26].	AMMG FDA update (2020)[26][2]
ARA-290 (Cibinetide, 11-aa EPO fragment)	**RUO** – Research Use Only (Investigational)	**Not FDA-approved.** ARA-290 is a derivative of EPO under investigation (it had FDA *Orphan Drug* status for	Empr.com (Orphan designation)[27]; Paragon Sports Med.[29]

Peptide / Product	Regulatory Category	Regulatory Status & Explanation	Key References
		sarcoidosis neuropathy) but *no approval was obtained*[27]. Clinical trials were conducted (e.g. Phase 2 for sarcoidosis), but it remains investigational[28]. It is not scheduled by DEA and can be sold for research, but it **cannot be marketed as a supplement or therapy**. Often labeled for research use only.	(investigational, not routine use)
LL-37 (Cathelicidin antimicrobial peptide)	**RUO** – Research Use Only (Unapproved Drug)	**Not FDA-approved.** LL-37 is a human antimicrobial peptide fragment. It is not on any FDA-approved drug list and was flagged by FDA in 2020 as **not permissible for compounding** (no USP monograph/FDA nod)[26]. Thus it's available only as a chemical reagent. Any clinical use would be experimental.	AMMG FDA update[30] (LL-37 on list of peptides not to compound)
DSIP (Delta Sleep-Inducing Peptide)	**RUO** – Research Use Only (Unapproved Drug)	**Not FDA-approved.** DSIP is a naturally occurring neuropeptide sold for research. It has no approved medical use and cannot be an official supplement. FDA included DSIP in the 2020 list of peptides that *"may no longer be compounded"* due to lack of approval/monograph[30]. Sold labeled as RUO only.	AMMG FDA update[30] (DSIP unapproved, banned from compounding)
Follistatin-344	**RUO** – Research Use Only (Unapproved)	**Not FDA-approved.** Follistatin-344 is a research protein (myostatin inhibitor) with no FDA-sanctioned use. It's not scheduled, but as a large peptide it falls under	FDA Guidance – (Follistatin not in Orange Book; sold as RUO by peptide suppliers)[12]

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		biologic drug regulations if used in humans. Thus it can only be legally sold for research, *with no health claims*.	
FOXO4-DRI (pro-apoptotic peptide)	**RUO** – Research Use Only (Unapproved)	**Not FDA-approved.** FOXO4-DRI is an experimental peptide (a **senolytic** agent studied in mice for anti-aging). It is purely research-stage; no human approval. It's unscheduled and offered as a lab reagent. Any human use would be experimental/investigational.	(Research article, 2017 Cell paper by Baar et al. – no FDA approval)
Dihexa (PNB-0408, neuropeptide analog)	**RUO** – Research Use Only (Unapproved)	**Not FDA-approved.** Dihexa is an experimental neurotrophic peptide (AngIV analog) not approved for any indication. It does not appear on FDA's drug lists. Sold as a research chemical only. (No dietary origin; purely synthetic drug candidate.)	(No FDA listing; sold as research chem with RUO labels)
CJC-1295 (GHRH analog, with/without DAC)	**RUO** – Research Use Only (Unapproved)‡	**Not FDA-approved.** CJC-1295 (both with DAC and without) is a synthetic GHRH analog. FDA has not approved it, and in fact FDA was petitioned to allow its compounding but has not (was on Category 2/under evaluation)[31]. It's widely sold as a research peptide.	FDA 503A List update[31] (CJC-1295 nominations withdrawn; no approval)
Ipamorelin (GHRP analog)	**RUO** – Research Use Only (Unapproved)	**Not FDA-approved.** Ipamorelin is a synthetic GH secretagogue (GHRP). Like CJC-1295, it was nominated for compounding but not approved (Category 2 then withdrawn)[32]. No FDA drug approval exists. Only sold for research, often combined with	FDA 503A List update[32] (Ipamorelin nomination withdrawn; not approved)

Peptide / Product	Regulatory Category	Regulatory Status & Explanation	Key References
		CJC-1295 in studies.	
Selank (synthetic heptapeptide)	**RUO** – Research Use Only (Unapproved)	**Not FDA-approved.** Selank is a Russian-developed heptapeptide (anxiolytic) not approved by FDA. It's unscheduled and sold as a research chemical in the US. *(Note: An FDA Category 2 listing for "Selank acetate" was removed in 2024 due to a nomination error[33].)*	FDA 503A update[33] (Selank nomination issue); RUO product listings
Melanotan II (Afamelanotide analog)	**RUO** – Research Use Only (Unapproved for tanning)**§**	**Not FDA-approved** for general use. (Afamelanotide is approved in US for a rare disorder, but Melanotan-II as sold is typically an *unsanctioned analog* used for tanning.)	FDA Consumer Warning (Melanotan II unapproved for tanning)
GHK-Cu (Copper Tripeptide-1)	**Cosmetic Peptide** (Topical use accepted)	**Cosmetic ingredient – not an approved drug.** GHK-Cu is a naturally occurring peptide (glycyl-L-histidyl-L-lysine) that binds copper. It is **used in topical anti-aging skincare**, which do not require pre-market FDA approval[34]. *Injectable use is not FDA-approved*[35]. As a cosmetic, it can be sold in creams/serums for appearance (collagen support) but no medical claims can be made.	Journal of Peptide Science[34] (GHK-Cu not FDA-approved as drug, used in cosmetics); FDA 503A list[35]
SNAP-8 (Acetyl Octapeptide-3)	**Cosmetic Peptide** (Topical use accepted)	**Cosmetic ingredient – not a drug.** SNAP-8 is a synthetic 8–amino acid fragment used in wrinkle creams (a "Botox-like" topical). It has **no FDA-approved drug use** and is sold either in cosmetic formulations or as a lab	Bluum Peptides disclaimer[36] ("SNAP-8 is not FDA-approved drug… research only if not in a cosmetic").

Peptide / Product	Regulatory Category	Regulatory Status & Explanation	Key References
		reagent. Vendors note *"SNAP-8 is not an FDA-approved drug"* and any non-cosmetic supply is for research only[36]. In creams applied to skin (with no therapeutic claims), it is allowed as a cosmetic.	
Topical Blend: SNAP-8 + GHK-Cu Serum	**Cosmetic Product** (Topical serum)	**Cosmetic product.** A serum combining SNAP-8 and GHK-Cu is marketed for skin appearance (anti-wrinkle/firming). Such topical products are **regulated as cosmetics** as long as they are marketed only for beautification (e.g. "reduces the look of wrinkles") and not for treating disease. No FDA pre-approval is needed, though quality must meet cosmetic regulations.	FDA Cosmetics Overview (21 CFR 700) – (Cosmetics do not require FDA approval if no drug claims); Ingredient use in cosmetics[34]
Glutathione (L-Glutathione, GSH)	**Dietary Supplement Ingredient (GRAS)**	**Allowed in supplements/foods.** Glutathione is a tripeptide antioxidant naturally present in foods and the human body. The FDA has formally granted it "*Generally Recognized As Safe (GRAS)*" status for use in conventional foods[37]. It is widely sold as an oral **dietary supplement**. *(Note: As a drug, glutathione is not FDA-approved for disease treatment; but as a supplement, it can be marketed for general health (e.g. antioxidant support) under DSHEA.)*	Drugs.com (Glutathione)[37] (FDA has granted GRAS status for glutathione in foods)
NAD+ (Nicotinamide	**Dietary Supplement**	**Allowed in supplements (as precursor forms).** NAD^+ is an	ChromaDex PR[38] (FDA granted NDI

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Adenine Dinucleotide)	**Ingredient** (vitamin metabolite)	essential coenzyme derived from Vitamin B3 (niacin). While NAD^+ itself is naturally present in cells, supplements typically use precursors like *nicotinamide riboside (NR)* or *NADH*. The FDA has accepted an **NDI (New Dietary Ingredient)** notification for NR (Niagen®) and it is self-affirmed GRAS[38]. This indicates NAD-related compounds can be lawful dietary ingredients. NAD^+ capsules are sold as supplements for "energy/metabolism support" with standard DSHEA disclaimers (no disease claims).	status to Niagen® NR, which raises NAD^+ levels); Amazon product info (Tru Niagen – NDI and GRAS)[39]
L-Carnitine (and blends containing it)	**Dietary Supplement Ingredient** (nutrient)	**Allowed in supplements.** L-Carnitine is a naturally occurring amino acid derivative present in red meat and produced in the body. It is an accepted **dietary ingredient** (commonly sold for fitness and metabolic support). Oral carnitine is also FDA-approved as a prescription for deficiency, but as a supplement it has been grandfathered in use pre-1994 and affirmed as safe. ***Age|REcode's amino acid blends (e.g. Super Human Blend with arginine, ornithine, citrulline, etc.) fall under standard supplement nutrients.***	21 CFR § 190.6 (Dietary ingredients include amino acids); NIH Fact Sheet on Carnitine (widely available supplement)
Anserine (β-	**Dietary**	**Allowed in supplements.**	Aging Dis. study

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alanyl-1-methyl-L-histidine)	**Supplement Ingredient** (dipeptide)	Anserine is a naturally occurring dipeptide in meat (especially chicken and fish). It is consumed in the diet and considered a "dietary substance" under DSHEA. Studies have used **anserine supplements** in humans (often paired with carnosine) to support cognitive and physical function[40]. Thus, anserine can be lawfully marketed in dietary supplements (no FDA pre-approval needed, as it's a constituent of common foods).	(anserine/carnosine supplementation in elderly)[40]; Wu et al. (2020)[41] (anserine abundant in beef, absent in plants)
Carnosine (β-alanyl-L-histidine)	**Dietary Supplement Ingredient** (dipeptide)	**Allowed in supplements.** Carnosine is a dipeptide naturally found in red meat and muscles. It has long been sold as a supplement for its antioxidant and anti-glycation benefits. Being present in foods, it qualifies as a dietary ingredient. It is not FDA-approved as a drug (no disease claims), but is legal as a supplement (e.g. used in trials for cognition and fatigue in aging)[40].	Aging Dis. study[40] (carnosine/anserine supplementation benefits); Wu 2020 review[41] (carnosine in diet)
L-Theanine (from green tea)	**Dietary Supplement Ingredient** (amino acid)	**Allowed in supplements.** L-Theanine is an amino acid found in tea leaves; it has been widely used in dietary supplements for relaxation and cognitive support. It is recognized as a dietary substance (originally from a common food – tea) and has GRAS status for use in	FDA GRAS Notice No. 275 (2008) – L-Theanine GRAS for beverages; NIH Dietary Supplement Database

Peptide / Product	Regulatory Category	Regulatory Status & Explanation	Key References
		foods/beverages in the US. No FDA drug approval (sold under DSHEA with structure/function claims).	
Magnesium L-Threonate	**Dietary Supplement Ingredient** (mineral compound)	**Allowed in supplements.** Magnesium L-threonate is a magnesium salt of L-threonic acid. Magnesium itself is a mineral nutrient, and various magnesium salts are used in supplements. Magnesium L-threonate (used for cognitive health formulas) has been marketed as a dietary supplement (brand Magtein) and has self-affirmed GRAS status for cognitive support products. It meets the definition of a dietary ingredient (mineral + metabolite of Vitamin C).	FDA GRAS Notice No. 816 (Magtein, 2018) – no objections; *DSHEA 1994* (minerals allowed as dietary ingredients)
Cerluten® (A-5 Brain Peptide)	**Dietary Supplement Ingredient** (animal extract)	**Allowed in supplements.** Cerluten A-5 is a branded complex of *natural brain peptides* derived from bovine cerebral cortex. It is essentially an organ extract from a food animal (young cattle). Organ meat extracts are considered dietary ingredients (analogous to glandular supplements). For example, Cerluten capsules are sold as dietary supplements containing "**Cerluten A-5 (bovine brain amino acids) – 10 mg**"[42][43]. Because the source (beef) is a common food, this ingredient is legal in supplements, provided	Product label (Limitless Life CNS Cerluten)[42][43] ("bovine brain amino acid complex" as supplement ingredient); Khavinson et al. – peptide bioregulators as dietary supplements

Peptide / Product	Regulatory Category	Regulatory Status & Explanation	Key References
		manufacturing is food-grade. (Appropriate BSE safety measures must be followed for brain-derived ingredients).	
ReCover™ Oral Capsules (Age|REcode)	Dietary Supplement Product	**Marketed as** a dietary supplement for tissue healing. Each capsule: BPC-157 (500 µg), GHK-Cu (2 mg), and L-Carnosine (500 mg)[44]. **Carnosine** is legitimate (naturally in diet, see above). However, **BPC-157** and **GHK-Cu** are **not recognized dietary ingredients** – BPC-157 is a synthetic gastric peptide not found in foods[45][1], and GHK-Cu, while natural in the body, is not typically present in the diet except in trace peptides. The FDA has explicitly stated BPC-157 is *"not a dietary ingredient"* and is an unapproved drug[24]. Including such peptides means **regulatory risk**: FDA could deem *ReCover* an adulterated product due to the presence of an unapproved drug. Indeed, products like this are sold with disclaimers that they are **"dietary supplements" not evaluated by FDA**[46], **ReCover™ is sold as a supplement under DSHEA.** (No drug claims should be made; it's provided for general wellness/recovery support).	FDA/DoD on BPC-157[24] ("unapproved drug, not a dietary ingredient"); LinkedIn FDA expert[1] (5-Amino-1MQ case analog – "not in food supply, cannot be GRAS or NDI"); Age|REcode note[46] (ReCover is labeled as a dietary supplement with FDA disclaimer)
ReVive™ Oral Capsules (Age|REcode)	Dietary Supplement Product –	**Marketed as** a dietary supplement for metabolic/energy support.	FDA dietary ingredient criteria (DSHEA, 21

Peptide / Product	Regulatory Category	Regulatory Status & Explanation	Key References
	Compliance Issues	Composition per cap: 5-Amino-1MQ (50 mg), SLU-PP-332 (1 mg), NAD^+ (250 mg)[44]. **NAD^+** is acceptable (vitamin B3 derivative). **5-Amino-1MQ**, however, is a **novel synthetic molecule** (an NNMT inhibitor) *not found in the food supply*, and **not an approved dietary ingredient**[1]. Experts note that since 5-Amino-1MQ is not a vitamin, mineral, herb, or food constituent, it cannot be marketed as a supplement without an NDI notification (which it hasn't had)[1]. FDA has *not approved or evaluated it*, and it's essentially an experimental drug. **Regulatory status:** Like ReCover, *ReVive™ is labeled and sold as a dietary supplement*, but it contains at least one ingredient (1MQ) that FDA would consider an **unapproved new drug** if marketed for human consumption. This is a grey area relying on lack of FDA enforcement to date. The product must refrain from disease treatment claims and include the standard disclaimer that it's not FDA-evaluated[46].	USC 321(ff)); LinkedIn – Kalman[1] ("5-Amino-1MQ…does not occur in foods…cannot be GRAS or an FDA 'no objection' NDI; synthetic compound likely making Amazon products adulterated"); Age|REcode info sheet[47][48] (ingredients of ReVive)
ReBalance™ Oral Capsules (Age|REcode)	Dietary Supplement Product (DSHEA-Compliant)	**Marketed as** a dietary supplement for brain and stress support. Ingredients per cap: Anserine (250 mg), Glutathione (500 mg, enteric),	Product label (ReBalance formula)[50]; FDA GRAS Notice (Glutathione)[37];

Peptide / Product	Regulatory Category	Regulatory Status & Explanation	Key References
		Magnesium L-Threonate (500 mg), L-Theanine (200 mg), Cerluten® A-5 brain peptide extract (2 mg)[49][50]. All components qualify as dietary ingredients: **Anserine** and **carnosine** are natural food peptides (see above), **glutathione** is GRAS[37], **magnesium** and **theanine** are well-established supplement ingredients, and **Cerluten (bovine brain peptides)** is essentially an animal glandular extract (sourced from beef CNS tissue[51]). Such organ extracts were marketed as supplements long before 1994 and are considered dietary substances (with proper sourcing). **Regulatory status:** *ReBalance™ appears to comply with DSHEA's requirements*, as its ingredients either are listed dietary nutrients or can be argued as constituents of foods. The product is sold as a supplement with appropriate structure-function claims (e.g. "supports cognitive health") and carries the FDA disclaimer about not treating diseases[46]. This is aligned with current supplement regulations in the US.	VitaStream Cerluten info[51] ("natural brain peptides…food-grade…derived from beef cattle"); DSHEA (dietary ingredient = vitamin, mineral, herb, or extract/metabolite of a food used for diet[1])

Notes:

- ‡ *CJC-1295:* In September 2023, FDA signaled intent to move **CJC-1295** (and variants) to the 503A Category 1 list for **compounding evaluation**[31]. This is

ongoing. Until/unless approved for compounding or as a drug, its status remains "unapproved, for research only."

- **§** *Melanotan II:* A related analog, **afamelanotide (Scenesse)**, is FDA-approved for a rare disease (EPP). **Melanotan-II** itself is not approved for any use in the U.S. and is sold as a gray-market tanning peptide.

Additional Context and Regulatory Guidance:

- **FDA Orange Book & Drug Database:** Peptides that have FDA-approved NDAs (New Drug Applications) appear in the Orange Book (e.g. semaglutide, tirzepatide, tesamorelin, etc.). Selling those outside of prescription channels violates Section 505 of FD&C Act (unapproved drug distribution).

- **Investigational New Drugs:** Peptides in clinical trials (with INDs) like retatrutide or mazdutide cannot be marketed to the public[16].

- **Research Use Only (RUO):** Many peptides are sold with "RUO" labeling to avoid regulatory action[3]. However, if evidence shows they are intended for human use, FDA may consider that labeling fraudulent[4]. In 2024, FDA warned compounders about peptides like BPC-157, stating they **"cannot be legally prescribed or sold"** for humans[45].

- **Cosmetics vs. Drugs:** Peptides used in topical cosmetics (like GHK-Cu, SNAP-8) are legal as **cosmetic ingredients**. The key is that the product must **only claim cosmetic effects** (improved appearance). Any claim to affect structure/function (e.g. "repairs tendons" or "treats hair loss") would cause FDA to deem it an unapproved drug[52]. Currently, copper peptides and similar are accepted in cosmetics[35].

- **DSHEA and Dietary Supplements:** To be sold as a **dietary supplement**, a peptide or ingredient must meet the definition in 21 U.S.C. §321(ff). This includes substances that are components of the normal diet or present in the food supply **or** were marketed as supplements in the US before 1994. Ingredients like **glutathione, amino acids (arginine, etc.), vitamins, minerals, herbs, and animal extracts** have a history of safe use and/or GRAS determinations[37]. New chemical entities (e.g. 5-Amino-1MQ) **do not qualify** and would require a New Dietary Ingredient notification and FDA's non-objection prior to marketing – which, as noted, has not occurred[1]. Selling such novel compounds as "supplements" puts the onus on the company and may invite FDA action for adulteration.

- **Age|REcode Capsules Marketing:** The Age|REcode branded capsules (ReCover™, ReVive™, ReBalance™) are positioned as **"dietary supplements"** with structure-function claims (e.g. supporting recovery, metabolism, cognitive health). They

include the standard **FDA disclaimer** that the product is not evaluated to treat or cure diseases[46]. This is crucial for compliance with supplement labeling laws.

In conclusion, each peptide falls into one of the categories above. **FDA-approved peptides** (Category 1) should only be obtained via prescription or used within specific federal and state regulatory approved framework such as "off-label" drugs within "physician use". **Investigational peptides** (Category 2) are confined to trials. **RUO peptides** (Category 3) can be bought for lab research but not marketed for medical claims. **Cosmetic peptides** (Category 4) are permissible in topical products without medical claims. **Dietary ingredient peptides/compounds** (Category 5) can be sold as supplements if they have GRAS status or a history of use (and are not promoted as drugs). The **Age|REcode Oral Capsules** (Category 6) are **sold as supplements** under DSHEA, ReBalance appears to fit within supplement guidelines, whereas ReVive and ReCover include experimental peptides that are not fully "FDA-approved or -acknowledged" as supplement ingredients, presenting a compliance risk[1][24]. Consumers and practitioners should be aware of these distinctions, and all marketing must be careful to stay on the right side of FDA regulations to avoid misbranding or adulteration issues.

Sources: The table above cites official FDA documents (Orange Book, press announcements, warning letters), federal regulations, GRAS notices, and expert analyses to ensure accuracy and current (2026) regulatory guidance. Please refer to those citations (【...】) for verification of each point.

Legal Disclaimer:

This report is provided for **educational and informational purposes only** and does not constitute legal or regulatory advice. **No content in this document should be interpreted as an endorsement or recommendation of any specific peptide, product, or marketing strategy.** Regulatory laws and FDA guidelines are **subject to change** over time, and readers should verify the current regulatory status of products with official **FDA resources** or consult a qualified legal/regulatory professional for up-to-date guidance.

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Furthermore, any reference in this document to products or compounds **not evaluated or approved by the U.S. Food and Drug Administration (FDA)** is intended for context and discussion only. Such products **must not be marketed or promoted** for the purpose of diagnosing, treating, curing, or preventing any disease **unless proper FDA approval or clearance has been obtained.** This disclaimer is intended to clarify the scope and

limitations of the report and to reinforce that regulatory compliance and prudent practice remain the responsibility of the reader.

Sources:

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