

## EZASSI SIGNALS

# Dietary Supplement Manufacturing Compliance (United States)

## Regulatory Signals · September 2026

A Regulatory watch on what is changing, or being enforced, in the obligations that land on a US dietary supplement manufacturing, packaging, labeling or holding facility: cGMP enforcement, import alerts, adulteration, New Dietary Ingredient policy, product listing and state laws on who may buy. Eight signals from one cycle.

| # | SIGNAL                                                                                                                                                                                                                          | CONFIDENCE | HORIZON                  | STATUS   |
|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------------------------|----------|
| 1 | Six Part 111 Warning Letters in Eight Months Point to a Sustained FDA Enforcement Tempo Against Dietary Supplement Manufacturers                                                                                                | High       | Immediate (0-3 months)   | Verified |
| 2 | Three Dietary Supplement Import Alerts Updated in a Five-Week Window Signal a Coordinated FDA Border-Enforcement Push Across cGMP, Drug Adulteration, and Kratom                                                                | Medium     | Immediate (0-3 months)   | Review   |
| 3 | Cluster of Hidden-Drug Adulterant Recalls and Notifications Across Sexual-Enhancement and Weight-Loss Categories Points to a Persistent Finished-Product Testing Gap                                                            | High       | Immediate (0-3 months)   | Review   |
| 4 | Tejocote Identity Substitution Recall Confirms an Active Botanical-Ingredient Safety and Supplier-Qualification Hazard                                                                                                          | Medium     | Immediate (0-3 months)   | Verified |
| 5 | FDA's March 2026 Public Meeting, April 2026 Industry Comments, and 2026 Priority Deliverables Together Signal That NDI Scope for Novel Production Methods Is Approaching a Regulatory Decision Point                            | Medium     | Short-term (3-12 months) | Review   |
| 6 | California's Signing of AB 2030 Creates a Two-State Age-Restriction Pattern, Establishing Operational Age-Verification Obligations for Sellers of Weight-Loss and Muscle-Building Supplements                                   | High       | Immediate (0-3 months)   | Verified |
| 7 | Companion House and Senate Mandatory Listing Bills in 2026, Alongside a Unified Agenda Proposed-Rule Entry, Establish Mandatory Product Listing as the Most Advanced Federal Legislative Threat to Supplement Manufacturers     | Medium     | Short-term (3-12 months) | Verified |
| 8 | Proposition 65 Lead Notices in September 2026 Targeting Supplement Powders and Named Supplement Brands Signal That Multi-Party Distribution-Chain Enforcement Is an Active Exposure for California-Facing Supplement Businesses | Medium     | Immediate (0-3 months)   | Review   |

Every signal rests on two or more dated events. Confidence is published as a band. Where a signal sits below High, the reasoning names the evidence that is missing. Status says where the evidence stands: Verified, Review, or Inconclusive — we looked, and the evidence does not yet support a firmer call.

SIGNAL 1 OF 8

## Six Part 111 Warning Letters in Eight Months Point to a Sustained FDA Enforcement Tempo Against Dietary Supplement Manufacturers

**HIGH** Immediate (0–3 months) · Enforcement & Compliance Signals · Verified

FDA issued at least six warning letters citing serious 21 CFR Part 111 violations at dietary supplement manufacturing, packaging, and holding facilities between February and August 2026, each preceded by a Form 483, indicating that cGMP enforcement against supplement facilities is operating at an elevated and consistent pace.

### REASONING

This watch tracks recurring Part 111 citations across facilities as a signal threshold. Six facilities — Hearthly Foods, Nupack, Nature's Elements, Nutratch, Flax & More, and American Pharma Mfg. — each received a warning letter in 2026, each following a Form 483 issuance, each citing serious Part 111 violations. The run of six actions across distinct facilities and multiple inspection dates (March 2025 through March 2026) establishes a pattern of sustained enforcement tempo rather than an isolated action. The findings note that the individual Part 111 subsections cited in each letter are not available from the search results reviewed, so a recurring specific sub-citation cannot be reported; the signal rests on the frequency and structure of the enforcement actions, not on a specific regulatory subsection. Confidence is High because the pattern across facilities is strong, but the absence of subsection-level detail prevents identification of the specific recurring deficiency.

### PATTERN

Hearthly Foods, Inc. warning letter dated February 10, 2026, following a March–April 2025 inspection; Nupack Inc. warning letter dated March 20, 2026, following an August–September 2025 inspection; Nature's Elements, Inc. warning letter dated April 7, 2026, following an October 2025 inspection; Nutratch, LLC warning letter dated June 4, 2026, following a September–October 2025 inspection; Flax & More Corporation warning letter dated May 12, 2026, following an October 2025 inspection; American Pharma Mfg. Inc. warning letter dated August 4, 2026, following a March 2026 inspection. Each action followed issuance of a Form 483 and each cites serious Part 111 violations.

### IMPLICATION

A facility operating under 21 CFR Part 111 faces an elevated probability of receiving a Form 483 during any FDA inspection and, if observations are unresolved, a warning letter. The enforcement tempo documented here suggests FDA is conducting and completing supplement cGMP inspections at a rate that produces multiple public enforcement actions per quarter. A facility that has not been inspected recently, or that has open Form 483 responses, should treat the near-term inspection risk as material.

### RECOMMENDED ACTION

Conduct an internal Part 111 gap assessment now, benchmarking current SOPs against each of the 21 CFR Part 111 subparts (batch production records, master manufacturing records, component specifications,

laboratory controls, finished-product testing, and records retention under 111.610(a)), and document corrective actions before any scheduled or unannounced FDA inspection.

#### SOURCES & WHAT THEY SIGNAL

- [FDA Warning Letter — American Pharma Mfg. Inc. \(August 4, 2026\)](#) — Most recent confirmed Part 111 warning letter in the monitoring period; establishes that FDA inspected a California supplement manufacturer in March 2026 and escalated to a warning letter.
- [FDA Warning Letter — Flax & More Corporation \(May 12, 2026\)](#) — Second facility in the 2026 run; inspection October 2025, warning letter May 2026, Part 111 cited.
- [FDA Warning Letter — Nutratech, LLC \(June 4, 2026\)](#) — Third facility; confirms pattern continues into June 2026 enforcement cycle.
- [FDA Warning Letter — Nature's Elements, Inc. \(April 7, 2026\)](#) — Fourth facility; October 2025 inspection, April 2026 warning letter.
- [FDA Small Entity Compliance Guide — Part 111 cGMP](#) — Confirms record-retention requirements under 21 CFR 111.610(a) as an active compliance benchmark FDA uses in inspections.
- [FDA Warning Letter — Nupack Inc. \(March 20, 2026\)](#) — Fifth facility; August–September 2025 inspection, March 2026 warning letter.
- [FDA Warning Letter — Hearthly Foods, Inc. \(February 10, 2026\)](#) — Earliest 2026 warning letter in the run; also cites adulteration under FD&C Act section 402(g)(1), linking Part 111 noncompliance to adulteration status.

## SIGNAL 2 OF 8

## Three Dietary Supplement Import Alerts Updated in a Five-Week Window Signal a Coordinated FDA Border-Enforcement Push Across cGMP, Drug Adulteration, and Kratom

**MEDIUM** Immediate (0–3 months) • Enforcement & Compliance Signals • Review

FDA updated Import Alerts 54-14, 54-16, and 54-15 between mid-August and late September 2026, covering Part 111 cGMP failures, active pharmaceutical ingredients in supplement products, and kratom respectively, indicating that detention-without-physical-examination authority is being actively maintained across the primary enforcement pathways for imported supplements and bulk ingredients.

### REASONING

This watch specifies Import Alerts 54-14, 54-16, 54-15, 54-18, and 54-12 as priority tracking targets and calls for a triggered review on any red-list addition to 54-14 or 54-16. Three of those five named alerts were updated within a five-week window (August 14 to September 21, 2026). The updates were not all to the same alert — they span different enforcement theories (cGMP, drug adulteration, botanical hazard). That breadth across theories and the compressed timeframe is the pattern. Confidence is not higher because the findings confirm alert update dates but do not establish the number of red-list additions, specific firms added, or detention counts for each alert; the signal rests on confirmed alert activity, not on a verified spike in detentions.

### PATTERN

Import Alert 54-16 updated August 14, 2026, covering DWPE for dietary supplements containing active pharmaceutical ingredients; Import Alert 54-15 updated August 17, 2026, covering DWPE for kratom and *Mitragyna speciosa* products, including bulk dietary ingredients; Import Alert 54-14 updated September 21, 2026, covering DWPE for foreign supplement facilities with Part 111 deficiencies, specifically citing vitamin C drops and adulteration under FD&C Act section 402(g)(1).

### IMPLICATION

Any facility that imports finished supplement products, semi-finished goods, or bulk dietary ingredients from foreign suppliers faces active DWPE risk on three independent grounds: the supplier's cGMP status (54-14), the presence of undeclared drug substances in the product (54-16), and kratom or *Mitragyna speciosa* content (54-15). A single shipment can be detained on any one of these grounds without physical examination. Supplier qualification programs must address all three alert pathways, not only the most obvious one for the ingredient category.

### RECOMMENDED ACTION

Verify that every active foreign supplier is absent from the red lists of Import Alerts 54-14, 54-16, and 54-15, and establish a quarterly review schedule tied to the alert publication dates, using the FDA import-alert index as the primary tracking source.

### SOURCES & WHAT THEY SIGNAL

- [FDA Import Alert 54-14 \(updated September 21, 2026\)](#) — Confirms DWPE authority for foreign supplement facilities with Part 111 deficiencies; updated September 21, 2026, establishing the alert is actively maintained.

- [FDA Industry Import Alert Index — Dietary Supplements \(Import Alert 54-16, August 14, 2026\)](#) — Lists Import Alert 54-16 as DWPE for food and supplement products containing active pharmaceutical ingredients; date confirms active maintenance in the monitoring period.
- [FDA Import Alert 54-15 — Kratom / \*Mitragyna speciosa\* \(updated August 17, 2026\)](#) — Confirms DWPE for finished supplements and bulk dietary ingredients containing kratom, citing significant-or-unreasonable-risk adulteration theory under FD&C Act section 402(f)(1)(B).

SIGNAL 3 OF 8

## Cluster of Hidden-Drug Adulterant Recalls and Notifications Across Sexual-Enhancement and Weight-Loss Categories Points to a Persistent Finished-Product Testing Gap

**HIGH** Immediate (0–3 months) · Enforcement & Compliance Signals · Review

FDA issued or listed at least eight recalls or health-fraud notifications between August and September 2026 for dietary supplement products containing undeclared pharmaceutical or pharmacologically active substances — including sildenafil, tadalafil, amino tadalafil, sibutramine, fluoxetine, DNP, and unspecified hidden ingredients — spanning both sexual-enhancement and weight-loss product categories.

### REASONING

This watch tracks undeclared drug ingredients and adulteration patterns as a core concern. Eight distinct product-level enforcement entries appear within approximately six weeks: biQ-FEL and X10 (sildenafil/tadalafil, September 15); LUZE Fit (sibutramine, September 15 database entry) and DEEP (amino tadalafil, September 15 database entry); Lipofit Extreme 2.0 (fluoxetine/DNP, August 31); and ZUBB, Esbelta Intense Loss, B. MAGI, and DMagic Plus (hidden ingredients, August 12–September 4). The two earlier January 2026 entries for Silintan (meloxicam) and Modern Warrior (1,4-DMAA, aniracetam, tianeptine) extend the pattern further back. No single entry tells the full story; taken together, they show that hidden-drug adulteration is not confined to one product type or one drug class — it runs across categories and drug families simultaneously. Confidence is High because the FDA sources are primary (recall notices, FDA databases, weight-loss notifications page), the pattern is consistent across sources, and the timeframe is compressed.

### PATTERN

biQ-FEL 500 mL recall for undeclared sildenafil and tadalafil, September 15, 2026; X10 Natural Enhancement Supplement listed on FDA health-fraud recalls with the same undeclared ingredients; LUZE Fit listed in FDA Health Fraud Product Database for sibutramine, and DEEP listed for amino tadalafil, September 15, 2026; Lipofit Extreme 2.0 Fat Burner recalled for undeclared fluoxetine and DNP, August 31, 2026; ZUBB (September 4), Esbelta Intense Loss (August 18), B. MAGI and DMagic Plus (August 12) listed on FDA Weight Loss Product Notifications page for hidden ingredients; Silintan and Modern Warrior listed in January 2026 for undeclared meloxicam, 1,4-DMAA, aniracetam, and tianeptine.

### IMPLICATION

FDA's adulteration enforcement is sweeping across sexual-enhancement, weight-loss, and metabolic/cognitive product categories simultaneously. For a manufacturer or contract manufacturer producing any of these product types, finished-product release testing that relies solely on a supplier's certificate of analysis is insufficient — the pattern shows drug adulterants reaching finished products. Additionally, Import Alert 54-16 (active pharmaceutical ingredients in supplements) maps directly onto this domestic recall pattern, meaning the same risk presents at the border for imported products.

**RECOMMENDED ACTION**

Require accredited third-party finished-product testing for undeclared drug substances (including PDE-5 inhibitors, sibutramine analogues, stimulants, and prescription-class compounds) for any product in the sexual-enhancement, weight-loss, or metabolism/cognitive categories before release, and audit supplier qualification records for each ingredient used in those formulations.

**SOURCES & WHAT THEY SIGNAL**

- [FDA Weight Loss Product Notifications](#) — Lists ZUBB, Esbelta Intense Loss, B. MAGI, and DMagic Plus between August 12 and September 4, 2026, for hidden ingredients, showing that weight-loss adulteration notifications continued at pace through the monitoring period.
- [FDA Recall — A&P Creations LLC / biQ-FEL \(September 15, 2026\)](#) — Primary recall notice confirming undeclared sildenafil and tadalafil in a product marketed as a dietary supplement.
- [FDA Health Fraud Product Database](#) — Lists LUZE Fit for sibutramine and DEEP for amino tadalafil, extending the hidden-drug pattern to a second product cluster.
- [FDA Health Fraud Recalls Page](#) — Lists Lipofit Extreme 2.0 (fluoxetine/DNP, August 31, 2026), X10 (sildenafil/tadalafil), Silintan (meloxicam), and Modern Warrior (1,4-DMAA, aniracetam, tianeptine), establishing the pattern across multiple product categories and drug classes.

SIGNAL 4 OF 8

## Tejocote Identity Substitution Recall Confirms an Active Botanical-Ingredient Safety and Supplier-Qualification Hazard

**MEDIUM** Immediate (0–3 months) • Enforcement & Compliance Signals • Verified

FDA's September 2026 recall of Niwali Tejocote products for yellow oleander substitution, combined with FDA's separately maintained warning that tejocote and Brazil seed products are a known substitution target, establishes yellow oleander contamination as a recurring botanical-identity hazard requiring active ingredient verification controls, not a one-time incident.

### REASONING

A single recall is an entry-level finding. What elevates this to a signal is that FDA's recall notice states the products appeared to be *Thevetia peruviana* rather than tejocote, and FDA separately maintains a broader advisory stating that products labeled as tejocote or Brazil seed have been found to contain yellow oleander. Two independent FDA sources — a specific recall and a category-level advisory — point in the same direction: botanical identity substitution in this ingredient class is a systemic supply-chain problem, not an isolated mislabeling. The cardiac glycoside hazard (severe neurologic, gastrointestinal, and cardiovascular effects, potentially fatal) makes this a high-severity adulteration concern. Confidence is held at Medium because both sources are FDA primary sources, but the findings do not establish the frequency of prior incidents or the number of suppliers affected.

### PATTERN

Global Mix Inc. recall of Niwali Tejocote Capsules and Niwali Tejocote Pieces, September 21, 2026, after FDA analysis identified the product as *Thevetia peruviana* (yellow oleander) rather than tejocote; FDA states all parts of yellow oleander contain cardiac glycosides capable of severe or fatal effects. FDA's health-fraud page separately describes a broader issue with products labeled as tejocote or Brazil seed being substituted with yellow oleander.

### IMPLICATION

Any facility sourcing tejocote or Brazil seed — whether as a finished product ingredient or as a botanical raw material — must treat species-level identity verification as a non-delegable quality obligation. A certificate of analysis from a supplier is insufficient if it does not include botanical authentication (e.g., microscopy, HPTLC, or DNA barcoding). Under 21 CFR Part 111, a facility bears responsibility for establishing component specifications and verifying that components meet those specifications before use; yellow oleander substitution in a tejocote ingredient is a direct Part 111 component-qualification failure and an independent adulteration ground.

### RECOMMENDED ACTION

If tejocote or Brazil seed is in any active or proposed formulation, require species-level botanical authentication testing (HPTLC or DNA barcoding) from an accredited laboratory on every incoming lot before use, and audit whether current component specifications for those botanicals include identity criteria sufficient to distinguish tejocote from *Thevetia peruviana*.

**SOURCES & WHAT THEY SIGNAL**

- [FDA Recall — Global Mix Inc. / Niwali Tejocote \(September 21, 2026\)](#) — Primary recall notice confirming FDA laboratory analysis identified yellow oleander in place of tejocote; establishes the specific substitution event and the cardiac glycoside hazard.
- [FDA Health Fraud Scams — Tejocote / Brazil Seed Advisory](#) — FDA's broader advisory confirming that yellow oleander substitution in tejocote and Brazil seed products is a recognized category-level hazard, not limited to the Niwali recall.

SIGNAL 5 OF 8

## FDA's March 2026 Public Meeting, April 2026 Industry Comments, and 2026 Priority Deliverables Together Signal That NDI Scope for Novel Production Methods Is Approaching a Regulatory Decision Point

**MEDIUM** Short-term (3-12 months) · [Regulatory Agency Actions](#) · [Review](#)

FDA's commitment to release final NDI guidance in 2026, its convening of a public meeting on the scope of dietary-ingredient categories including fermentation and synthesis, and the Council for Responsible Nutrition's post-meeting comments identifying manufacturing method and ingredient identity as the central unresolved questions collectively indicate that a formal FDA position on whether fermentation- or synthesis-derived ingredients require NDI notification is likely to emerge before the end of 2026.

### REASONING

Three independent events point in the same direction: (1) FDA's Human Foods Program stated a 2026 deliverable of releasing final guidance on safety and identity information required in NDI notifications; (2) FDA held a public meeting on March 27, 2026 specifically addressing the meaning of 'dietary substance for use by man to supplement the diet by increasing total dietary intake' and new production methodologies including fermentation; and (3) CRN submitted April 27, 2026 comments after the meeting identifying manufacturing method and ingredient identity for proteins, peptides, enzymes, and microbials as the central open questions. The Unified Agenda also carries a proposed-rule-stage entry (0910-AI91) on whether an ingredient is excluded from the dietary supplement definition. The NDI master-file guidance remains at draft stage, meaning the full framework is not yet finalized. Confidence is held at Medium because the deliverable commitment and meeting have occurred, but no final guidance has been published in the findings, and the timing of the proposed rule under 0910-AI91 is uncertain.

### PATTERN

FDA Human Foods Program 2026 Priority Deliverables commit to releasing final NDI guidance during 2026 and streamlining NDI notification review; FDA held a public meeting on March 27, 2026, specifically addressing 'dietary substance' definition, new production methodologies, proteins, enzymes, and microbials, with written comments due April 27, 2026; CRN submitted comments April 27, 2026 identifying manufacturing method and ingredient identity as central issues for FDA to resolve; FDA's decision tool states that a new manufacturing method significantly changing chemical composition is relevant to NDI analysis; Unified Agenda entry 0910-AI91 lists a proposed-rule-stage item on rulemaking to provide by regulation that an ingredient is not excluded from the dietary supplement definition; NDI master-file guidance remains listed as draft as of September 2026; according to FDA's submitted NDI notifications page, at least one fermentation-derived dietary ingredient (described as an astaxanthin-rich carotenoid fermentation product associated with LCY Biosciences) appears in the NDI notification system, though the submission date of May 20, 2025 could not be independently confirmed in public sources as of September 2026.

**IMPLICATION**

Manufacturers using fermentation, precision fermentation, synthesis, or cell-culture methods to produce dietary ingredients should not assume their production method is categorically excluded from NDI notification requirements. FDA's public meeting and the Unified Agenda entry signal that the agency is building toward a formal position. Once final guidance or a proposed rule is published, a comment window will open and compliance timelines will become concrete. Acting before that window closes — by auditing the production methods and ingredient histories in a current portfolio — preserves the ability to influence the final rule and to prepare NDI notifications if required.

**RECOMMENDED ACTION**

Map every ingredient in the current product portfolio that is produced by fermentation, synthesis, or cell culture against the FDA NDI decision-tree criteria and the pre-October 15, 1994 marketing-status threshold, and prepare a written analysis of each ingredient's NDI status before the final guidance or proposed rule is published.

**SOURCES & WHAT THEY SIGNAL**

- [FDA Guidance Documents — NDI Master Files \(Draft, April 2024\)](#) — Confirms that the NDI master-file guidance remains at draft stage as of September 2026, meaning the complete NDI framework has not yet been finalized.
- [FDA Algorithm/Decision Tree for NDI Notification Determination](#) — Establishes that FDA's existing decision framework already treats a new manufacturing method that significantly changes chemical composition as a factor in NDI analysis.
- [FDA Submitted 75-Day Premarket NDI Notifications — LCY Biosciences Fermentation Product](#) — Shows that a fermentation-derived dietary ingredient (astaxanthin-rich carotenoid fermentation product) appears to have entered the NDI notification system, establishing that the issue is live, not hypothetical; the specific submission date of May 20, 2025 could not be independently confirmed in public sources as of September 2026 and should be verified against the FDA NDI notification list directly.
- [Reginfo.gov — 2026 Unified Agenda, HHS/FDA Proposed Rule 0910-AI91](#) — Formal regulatory-agenda signal that FDA is at proposed-rule stage on rulemaking addressing whether an ingredient is excluded from the dietary supplement definition.
- [FDA Human Foods Program 2026 Priority Deliverables](#) — FDA's stated commitment to release final NDI guidance in 2026 and to develop streamlined NDI review methods, establishing a concrete agency deliverable timeline.
- [FDA Public Meeting — Exploring the Scope of Dietary Supplement Ingredients \(March 27, 2026\)](#) — Confirms FDA convened a formal public meeting specifically addressing the dietary-substance definition, new production methodologies, and ingredient categories including proteins, enzymes, and microbials.
- [CRN Comments on FDA Public Meeting on Scope of Dietary Supplement Ingredients \(April 27, 2026\)](#) — Industry's post-meeting submission identifies manufacturing method and identity determination for proteins, peptides, enzymes, and microbials as the unresolved core questions, confirming what FDA's final guidance will need to address.

SIGNAL 6 OF 8

## California's Signing of AB 2030 Creates a Two-State Age-Restriction Pattern, Establishing Operational Age-Verification Obligations for Sellers of Weight-Loss and Muscle-Building Supplements

**HIGH** Immediate (0–3 months) · Legislative & Statutory Activity · Verified

California signed AB 2030 on September 28, 2026, prohibiting sale or giveaway of over-the-counter weight-loss and muscle-building dietary supplements to persons under 18 and requiring age verification, making California the second state — after New York, effective April 2024 — to enact such a restriction, and the Second Circuit's November 2025 decision upholding New York's law removes the most immediate legal obstacle to multi-state enforcement.

### REASONING

This watch specifies a triggered review upon a second state enacting an age-restriction law after California, treating a multi-state pattern as the key threshold. That threshold is now met: New York's law is confirmed effective April 2024, California's AB 2030 was signed September 28, 2026, and the Second Circuit upheld New York's law on November 13, 2025, removing a key legal challenge that could have stayed enforcement. California's law explicitly covers products 'labeled, marketed, or otherwise represented' for weight loss or muscle building, and the legislative analysis identifies specific ingredients including creatine, green tea extract, raspberry ketone, Garcinia cambogia, and green coffee bean extract. CRN acknowledged post-enactment that broad scope creates uncertainty about coverage, while CSPI supported the measure. The pattern is two enacted state laws, a surviving Second Circuit challenge, and active industry concern about product-scope uncertainty — that combination warrants High confidence.

### PATTERN

New York General Business Law § 391-OO prohibition on selling weight-loss or muscle-building supplements to persons under 18, effective April 2024, with age-verification requirement at retail; New York Department of State consumer alert dated April 2, 2025, confirming the law is in effect; Second Circuit decision in *Council for Responsible Nutrition v. James*, November 13, 2025, upholding New York's law against CRN's challenge; California Governor signed AB 2030 on September 28, 2026, extending the restriction to California with age-verification and delivery-seller provisions; California Senate Judiciary analysis identifies creatine, green tea extract, raspberry ketone, Garcinia cambogia, and green coffee bean extract among potentially covered ingredients; CRN criticized AB 2030 as overly broad; CSPI supported the measure.

### IMPLICATION

Sellers, distributors, and manufacturers whose products are labeled, marketed, or otherwise represented for weight loss or muscle building must now operate age-verification programs in at least two states, with a product-scope definition broad enough to reach commonly marketed ingredients. The Second Circuit's ruling means that the constitutional arguments that could have stayed enforcement have already failed once. Any manufacturer whose labeling, marketing copy, or website describes a product's weight-loss or muscle-

building function should assess whether that product falls within California's and New York's covered categories — the obligation turns on how the product is represented, not only its ingredient composition.

#### RECOMMENDED ACTION

Audit all product labels and marketing materials for weight-loss and muscle-building representations, map each affected product against the ingredient lists in AB 2030's legislative analysis and New York's § 391-OO, and implement age-gating at point-of-sale and on delivery platforms for California and New York before enforcement commences.

#### SOURCES & WHAT THEY SIGNAL

- [New York General Business Law § 391-OO](#) — Primary statutory text of New York's supplement age-restriction law; confirms prohibition on sales to persons under 18 and age-verification requirement at retail.
- [California Senate Judiciary Committee Analysis — AB 2030](#) — Legislative analysis identifies the covered product scope, including specific ingredients (creatine, green tea extract, raspberry ketone, Garcinia cambogia, green coffee bean extract) relevant to manufacturers assessing coverage.
- [CRN Newsroom — California AB 2030 Signed \(September 28, 2026\)](#) — Confirms California Governor signed AB 2030 on September 28, 2026, and reports CRN's post-enactment criticism of the law's broad scope.
- [CSPI Statement — California AB 2030](#) — Confirms public-interest group support for the measure, indicating political and advocacy momentum behind further state-level enactments.
- [Second Circuit Decision — Council for Responsible Nutrition v. James \(November 13, 2025\)](#) — Court decision upholding New York's law against CRN's constitutional challenge, removing the principal legal obstacle to enforcement of state age-restriction laws for supplements.
- [New York Department of State Consumer Alert \(April 2, 2025\)](#) — Government enforcement notice confirming New York's law took effect April 2024 and is being communicated to consumers.

SIGNAL 7 OF 8

## Companion House and Senate Mandatory Listing Bills in 2026, Alongside a Unified Agenda Proposed-Rule Entry, Establish Mandatory Product Listing as the Most Advanced Federal Legislative Threat to Supplement Manufacturers

**MEDIUM** Short-term (3–12 months) · Legislative & Statutory Activity · Verified

H.R. 8370 (introduced April 20, 2026) and S. 3677 (introduced January 15, 2026) — both requiring manufacturers, packers, and distributors to list each dietary supplement with FDA before or upon introduction into commerce — together with the Unified Agenda entry 0910-AI91 on dietary-supplement definition rulemaking, establish mandatory product listing as a bicameral legislative priority that, if enacted, would create a new pre-market disclosure obligation on the entity of record.

### REASONING

Companion bills in both chambers are a recognized signal of legislative seriousness, even when neither has been reported out of committee. H.R. 8370 was introduced April 20, 2026 and referred to Energy and Commerce; S. 3677 was introduced January 15, 2026 and referred to HELP. Both bills place the obligation on the same party — the manufacturer, packer, or distributor whose name appears on the label — and both treat the U.S. agent as responsible for foreign entities. This alignment across chambers on scope and responsible-party definition indicates coordinated bill drafting. The Unified Agenda proposed-rule entry 0910-AI91 on the dietary-supplement definition provides an additional administrative-track signal pointing in the same direction. Confidence is held at Medium because neither bill has been marked up, reported, or enacted in the findings reviewed, and the Unified Agenda entry is at proposed-rule stage with no published NPRM confirmed. Paired bills in committee are a genuine legislative signal but carry real uncertainty about passage timeline.

### PATTERN

H.R. 8370 introduced April 20, 2026, requiring each dietary supplement marketed in the United States to be listed with FDA; responsible person defined as the manufacturer, packer, or distributor on the label, or U.S. agent for foreign entities; referred to House Energy and Commerce Committee; S. 3677 introduced January 15, 2026, with parallel text; referred to Senate HELP Committee; H.R. 7366 (Dietary Supplement Regulatory Uniformity Act) introduced February 4, 2026, to affirm federal preemption of state supplement regulation; Unified Agenda 0910-AI91 lists a proposed-rule-stage item on whether an ingredient is excluded from the dietary supplement definition; existing facility registration requirement confirmed as currently operative and distinct from proposed product listing.

### IMPLICATION

If either the House or Senate listing bill advances to markup, the responsible person named on every supplement label — typically the manufacturer or the entity that contracts with the manufacturer — would face a new pre-introduction registration and listing obligation. For private-label manufacturers and contract manufacturers, the identity of the label entity becomes an active compliance-structure question. Manufacturers whose labels bear their own name should begin building the data infrastructure (product

identity, ingredient disclosure, responsible-person information) that a listing system would require, so that compliance is not a new operating burden if a bill passes quickly.

#### RECOMMENDED ACTION

Assign a regulatory-affairs owner to track markup schedules for H.R. 8370 before the House Energy and Commerce Committee and S. 3677 before the Senate HELP Committee, and simultaneously build or audit an internal product-registry dataset (label identity, formulation, responsible person) that could serve as the submission basis if mandatory listing becomes effective.

#### SOURCES & WHAT THEY SIGNAL

- [H.R. 8370 — Dietary Supplement Listing Act of 2026 \(House\)](#) — House bill introduced April 20, 2026, requiring manufacturer-level product listing with FDA; defines responsible person and the listing trigger for products entering commerce after January 1, 2027.
- [S. 3677 — Dietary Supplement Listing Act of 2026 \(Senate\)](#) — Senate companion bill introduced January 15, 2026, with parallel mandatory-listing framework; confirms bicameral coordination on the legislative proposal.
- [H.R. 7366 — Dietary Supplement Regulatory Uniformity Act \(February 4, 2026\)](#) — House bill to affirm FDA preemption over state supplement regulation; directly relevant to manufacturers assessing state law compliance exposure concurrent with federal listing proposals.
- [Reginfo.gov — 2026 Unified Agenda, HHS/FDA Proposed Rule 0910-AI91](#) — Administrative-track signal that FDA is at proposed-rule stage on the dietary supplement definition, which intersects with the legislative listing proposals.
- [FDA Questions and Answers on Dietary Supplements — Facility Registration](#) — Confirms that existing facility registration is separate from and insufficient to satisfy the proposed product-listing obligation, clarifying the incremental burden the bills would impose.

## SIGNAL 8 OF 8

## Proposition 65 Lead Notices in September 2026 Targeting Supplement Powders and Named Supplement Brands Signal That Multi-Party Distribution-Chain Enforcement Is an Active Exposure for California-Facing Supplement Businesses

**MEDIUM** Immediate (0–3 months) • Enforcement & Compliance Signals • Review

At least one confirmed Proposition 65 sixty-day notice filed September 25, 2026 — naming a dietary supplement powder and listing multiple entities including an online marketplace alongside product-associated companies — indicates that Proposition 65 lead-exposure enforcement is reaching supplement products sold through e-commerce channels and naming parties beyond the manufacturer.

### REASONING

Notice 2026-04594 is a confirmed primary-source filing from September 25, 2026, naming Turtle Bear Holdings, LLC; Pattern Inc.; and Amazon.com Services LLC in connection with dietary supplement powders and an alleged lead exposure without required Proposition 65 warning. The naming of an online marketplace alongside product-associated companies is the analytically significant element: it signals that Proposition 65 noticing parties are pursuing the distribution chain, not only the manufacturer or brand holder. A second database entry appears in the attorney general's searchable results listing Organic Muscle Inc. in connection with a notice for a dietary supplement product and lead compounds, though its filing date cannot be confirmed from the findings as falling within the July–September 2026 window, and the specific product name and listed chemical(s) associated with that entry could not be independently verified in the available sources. Two entries in the database pointing at supplement products and lead, one of which is confirmed filed in the monitoring period, create a pattern that meets the two-event threshold. Confidence is held at Medium because the second notice's filing date is unconfirmed in the findings, the product details of the second entry could not be confirmed in public sources as of September 2026, the notices do not state test concentrations or whether litigation was filed, and the role of each named entity is not specified in the available source excerpts.

### PATTERN

Proposition 65 Notice 2026-04594 filed September 25, 2026, naming Turtle Bear Holdings LLC, Pattern Inc., and Amazon.com Services LLC for alleged lead exposure from dietary supplement powders without required warning; Organic Muscle Inc. appears in the California attorney general's 60-day notice search results in connection with lead compounds and a dietary supplement product, though the specific product name and chemical details of that entry could not be confirmed in available public sources as of September 2026.

### IMPLICATION

Supplement manufacturers and distributors selling into California through online marketplaces face Proposition 65 noticing risk that extends to the marketplace platform itself. For a manufacturer, this means that the entity of record on Amazon or a similar platform may receive a notice even if the notice also names the platform. Supplement powders — which are among the most common heavy-metal exposure vehicles due to botanical ingredient sourcing — are a targeted product form. A manufacturer whose products contain

botanicals, protein concentrates, or mineral ingredients sourced from supply chains with known heavy-metal exposure should treat California Proposition 65 lead compliance as an active operational matter.

#### RECOMMENDED ACTION

Commission Proposition 65 lead (and cadmium, arsenic, and mercury) testing for all supplement powder products sold into California, compare results against current Proposition 65 no-significant-risk levels and maximum allowable dose levels, and evaluate whether current label warnings are sufficient or whether reformulation or supply-chain changes are required.

#### SOURCES & WHAT THEY SIGNAL

- [California Attorney General — Proposition 65 60-Day Notice Search Results](#) — Database listing showing Organic Muscle Inc. in connection with a lead-related notice for a dietary supplement product; the specific product name and chemical details of this entry could not be confirmed in available public sources as of September 2026 and should be verified directly against the attorney general database.
- [California Proposition 65 60-Day Notice 2026-04594 \(September 25, 2026\)](#) — Primary confirmed notice filed September 25, 2026, naming dietary supplement powders, lead as the listed chemical, and multiple parties in the distribution chain including an online marketplace.

PUT A WATCH ON YOUR QUESTION

## A watch on your question runs every cycle.

These signals came from one cycle of a standing watch. Name a company, a market or a regulation, and the watch keeps running whether or not anyone opens the platform. Every signal arrives rated for confidence and horizon, with the dated events behind it and the sources that carry the weight.

See all the samples and tell us your question at [ezassi.com/ezassi-signals-sample-library](https://ezassi.com/ezassi-signals-sample-library).

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