

Legal Framework for Adaptogens, Nootropics & Botanicals



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Agenda

- Statutory & regulatory foundations (FD&C Act, DSHEA, FTC Act)
- Drug vs. Supplement vs. Food — How FDA Decides
- Ingredient pathways: GRAS, Food Additive, ODI vs. NDI
- Claims & substantiation standards (FDA vs FTC)
- Labeling & cGMP compliance
- Importation basics & FSVP
- Possible enforcement actions and key compliance takeaways

Adaptogens, Nootropics & Botanicals — At a Glance

- **Botanicals** - plant-derived ingredients that may be regulated as foods, dietary supplements, cosmetics, or drugs depending on intended use, formulation and claims.
 - **Adaptogens:** Descriptive term for a subset of botanicals promoted to help the body adapt to stress.
 - **Nootropics:** Descriptive term for a subset of botanicals (and some synthetics) promoted to enhance cognition.

Regulators

- **FDA:** FD&C Act; DSHEA; 21 C.F.R. Parts 101, 111, 117, 190.
- **FTC:** Federal Trade Commission Act; advertising substantiation.
- **USDA:** Organic program (7 C.F.R. Part 205).
- **CBP / FDA OIO:** Import clearance, PREDICT, import alerts.
- **State Attorneys General:** Enforcement under UDAP laws (false/deceptive marketing).
- **California Proposition 65 (HSC § 25249.6):** Requires warnings for exposures to listed carcinogens/reproductive toxins above safe harbor levels.

Statutory Definitions

- Drug: 21 U.S.C. 321(g)(1)
 - A “drug” includes (1) articles recognized in the official compendia (United States Pharmacopoeia, National Formulary, or Homeopathic Pharmacopoeia), (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals, (3) articles (other than food) intended to affect the structure or function of the body, and (4) articles intended for use as components of any of these categories.
 - Often claims drive classification: disease claims = drug.

Statutory Definitions

- Dietary Supplement: 21 U.S.C. 321(ff)
 - a product (other than tobacco) intended to supplement the diet that contains one or more dietary ingredients, such as a vitamin, mineral, herb or other botanical, amino acid, or other dietary substance.
 - The product must be intended for ingestion, not represented as a conventional food or as a sole item of a meal or the diet, and it must be labeled as a “dietary supplement.
 - May make structure/function claims with DSHEA disclaimer; disease claims = drug.

Statutory Definitions

- Conventional Food: 21 U.S.C. 321(f)
 - Articles used for food or drink for humans or animals, chewing gum, and articles used as components of food or drink.
 - Consumed for taste, aroma, or nutritive value.

Statutory Definitions

- Cosmetic: 21 U.S.C. 321(i)
 - Articles applied to the human body for cleansing, beautifying, promoting attractiveness, or altering appearance, and their components.
 - Cosmetic claims only; structure/function or disease claims = drug.

Intended Use & Classification

- FDA classifies products based on intended use, which is inferred from multiple factors. The most common are:
 - Claims: Disease claims almost always make a product a drug.
 - Composition: Certain ingredients (e.g., drug actives, compendia-listed) can independently trigger drug status.
 - Route: Ingestion aligns with foods/supplements, topical with cosmetics, and injectables or inhaled forms with drugs.
- FDA may also consider the totality of circumstances — including labeling, marketing, and overall consumer context — when determining classification.

Drug Preclusion

- An article that has been approved as a drug (or biologic), or is the subject of substantial clinical investigations made public, generally cannot later be marketed in supplements or conventional foods — unless it was first marketed as a food or supplement before drug approval/IND.

Dietary Supplements — Ingredient Pathways (ODI vs. NDI)

- Old Dietary Ingredients (ODIs):
 - Marketed in the U.S. before October 15, 1994.
 - No NDI notification required.
 - Firm must keep evidence of pre-1994 marketing (labels, catalogs, invoices).
- New Dietary Ingredients (NDIs):
 - Not marketed before Oct. 15, 1994.
 - Require NDI notification to FDA 75 days before marketing (21 C.F.R. § 190.6).
 - Exemption:
 - NDI notification not required if the ingredient is already present in the food supply as an article of food in a form not chemically altered.

Conventional Foods — Ingredient Pathways (GRAS vs. Food Additive)

- GRAS (Generally Recognized as Safe):
 - Ingredient is generally recognized, by qualified experts, as safe under intended conditions of use.
 - Can be self-determined or submitted as a GRAS Notice to FDA (public inventory).
- Food Additive:
 - Any substance added to food that is not GRAS is a food additive.
 - Requires premarket approval via Food Additive Petition to FDA.
 - Process is lengthy, resource-intensive, and rarely used compared to GRAS.

Botanicals Across Product Classes

- Drugs: Botanical Drug Development Guidance (2016);
 - requires NDA approval, with full safety/efficacy data.
 - *Examples:* Croton lechleri (source of crofelemer, anti-diarrheal), Camellia sinensis extract (sin catechins, HPV treatment).
- Supplements: Treated as dietary ingredients under DSHEA;
 - NDI/ODI requirements, structure/function claims only
 - Examples: ashwagandha, rhodiola, bacopa.*

Botanicals Across Product Classes

- Foods: Botanicals may be added if they are GRAS or approved as food additives.
Examples: tea (Camellia sinensis), chamomile, spices/herbs as flavorings.
- Cosmetics: Botanicals allowed if intended only for cleansing, beautifying, or appearance; cannot make structure/function or disease claims.
Examples: aloe vera (skin conditioning), calendula (soothing lotions).

Claims & Substantiation

- FTC: competent & reliable scientific evidence
- FDA: structure/function claims w/disclaimer
- Case: FTC v. POM Wonderful (2015)

Supplement Labeling

Supplement Labeling Requirements (not exhaustive)

– Unique to Supplements

- Statement of Identity (“Dietary Supplement”)
- Supplement Facts panel (21 C.F.R. § 101.36)
- DSHEA disclaimer (for structure/function claims)
- Domestic address/phone for adverse event reporting (21 U.S.C. § 343(y))

– General Food Labeling Requirements (also apply to supplements)

- Net Quantity of Contents
- Other Ingredients list (excipients, fillers)
- Allergen disclosure (FALCPA)
- Name & place of business (manufacturer/packer/distributor)
- Lot/batch code (traceability)
- Warning statements (where required)

Food Labeling

Food Labeling Requirements (not exhaustive)

- Unique to Foods
 - Statement of Identity (common/usual name or standard of identity)
 - Nutrition Facts panel (21 C.F.R. § 101.9)
 - Ingredient statement (21 C.F.R. § 101.4)
- General Food Labeling Requirements
 - Net Quantity of Contents
 - Allergen disclosure (FALCPA)
 - Name & place of business (manufacturer/packer/distributor)
 - Lot/batch code (traceability)
 - Warning statements (if required — e.g., juice pasteurization, phenylketonurics)

cGMP Compliance

- Supplements: 21 C.F.R. 111
- Foods: 21 C.F.R. 117 (HARPC)
- Drugs: 21 C.F.R. 210/211
- Inspection authority: 21 U.S.C. 374

NDI Decision Tree

- 1) Is ingredient a statutory dietary ingredient?
- 2) Marketed pre-10/15/1994? (ODI)
- 3) If not, file NDI unless exempt
- 4) Assess chemically altered status

NDI Triggers

- Novel extraction/solvent system
- Fermentation analogs
- High concentration isolates
- Nanomaterials or novel delivery forms

NDI Notification — Core Elements

- Identity: what the ingredient is (taxonomy, plant part, manufacturing process).
- Specifications & Quality: composition, purity, contaminants, stability.
- Intended Use: serving size, conditions of use, estimated exposure.
- Safety Evidence: history of use, toxicology, human studies, margin of safety.
- References: 21 C.F.R. § 190.6 and FDA's NDI Guidance for Industry.

FDA Review of NDIs

- Possible outcomes: acknowledgment, objection, incomplete
- Objections: identity/safety gaps, drug preclusion
- Timeline: 75-day statutory period

ODI Documentation

- Evidence required: catalogs, sales records, labels, published references (pre-10/15/1994).
- Firm should maintain proof of ODI status

GRAS vs Food Additive

- GRAS: expert consensus, scientific procedures
- GRAS notice: voluntary, public inventory
- Food additive petition: costly, rare

Importation Basics

- Importer Roles
 - Importer of Record: Responsible for U.S. Customs entry, duties, and paperwork.
 - FSVP Importer: Required under FSMA for foods/supplements; must verify foreign suppliers meet U.S. safety standards.
- Prior Notice
 - Importers must submit advance notice of food/supplement shipments
- FDA's PREDICT System
 - Risk-based electronic screening tool.
 - Uses shipment data, importer history, and country/product risk factors to target shipments for inspection.
- Detention Without Physical Examination (DWPE)
 - FDA can place a firm, product, or country on an Import Alert.
 - Shipments are automatically detained unless the importer provides proof of compliance.

FSVP Compliance

- Legal Basis
 - Foreign Supplier Verification Program (FSVP) is a FSMA requirement under 21 U.S.C. § 384a.
 - Applies to importers of foods and dietary supplements.
- Core Duties
 - Hazard Analysis: Identify known or reasonably foreseeable hazards in each imported food/supplement.
 - Supplier Evaluation: Assess supplier's food safety practices, compliance history, and risk profile.
 - Verification & Corrective Actions: Activities may include onsite audits, sampling/testing, review of records;
 - Qualified Individual Oversight: FSVP must be developed and overseen by a "Qualified Individual" with training or equivalent job experience.
- Documentation
 - Written FSVP records must be maintained and made available to FDA during inspection.

Case Study: Cognitive Beverage

- Main Ingredients
 - *L-theanine, Bacopa extract*
- Regulatory Pathway
 - Marketed as a conventional food/beverage.
 - Ingredients must be GRAS (self-GRAS or notified) or otherwise permitted as food additives.
- Claims (assuming substantiated)
 - Likely ok: “support focus/alertness.”
 - Prohibited: “Improves ADHD symptoms” / “Treats memory loss.”

Case Study: Adaptogen Capsule

- Ingredients
 - *Ashwagandha extract, Rhodiola*
- Regulatory Pathway
 - Marketed as a dietary supplement under DSHEA.
 - Must qualify as an ODI or have a valid NDI notification if not grandfathered (unless covered by the food supply exemption)
- Claims
 - Permissible: “Supports stress response” / “Helps maintain a sense of calm.”
 - Prohibited: “Treats anxiety” / “Relieves depression.”

Possible Enforcement Actions

- FDA: Warning Letters (disease claims, labeling violations)
- FTC: Consent Orders (inadequate substantiation, deceptive ads)
- State Attorneys General: Consumer Protection & Prop 65 Actions (false/misleading marketing; chemical exposure warnings in California)
- Retailers & Platforms: Gatekeeping Requirements & Content Moderation

Key Compliance Takeaways

- Confirm classification (drug/supplement/food)
- Check for drug preclusion
- Document ODI/NDI or GRAS pathway
- Confirm compliant labels & claims
- Maintain import/FSVP dossiers
- Monitor enforcement actions

Thank you!

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