



Council for Responsible Nutrition

The Science Behind the Supplements

What's on the Horizon for
Dietary Supplement
Regulation & Oversight

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Dietary supplements are regulated as food



**Adverse Event
Reporting**

Claims

**Good
Manufacturing
Practices**

**No pre-market
approval**

BACKGROUND: DIETARY SUPPLEMENT REGULATION

- The Dietary Supplement Health and Education Act of 1994 (DSHEA) established the first legal framework specifically for dietary supplements.
 - *Definition of “dietary supplement.”*
 - *Provided FDA with additional enforcement authority, including the ability to remove adulterated (unsafe) products from the market.*
 - *Authorized FDA to establish Good Manufacturing Practices (GMPs).*
 - *Allowed use of “structure/function” claims.*
 - *Premarket notification of “new” dietary ingredients (NDIs).*



WHAT IS A DIETARY SUPPLEMENT?

DSHEA defined “dietary supplement” as a product intended to supplement the diet that contains one, or any combination, of the following substances:



- (A) vitamin;
- (B) mineral;
- (C) herb or other botanical;
- (D) amino acid;
- (E) dietary substance for use by man to supplement the diet by increasing the total dietary intake; or,
- (F) concentrate, metabolite, constituent, or extract of any of these ingredients.

CONSUMER USAGE

Or, as we like to say,

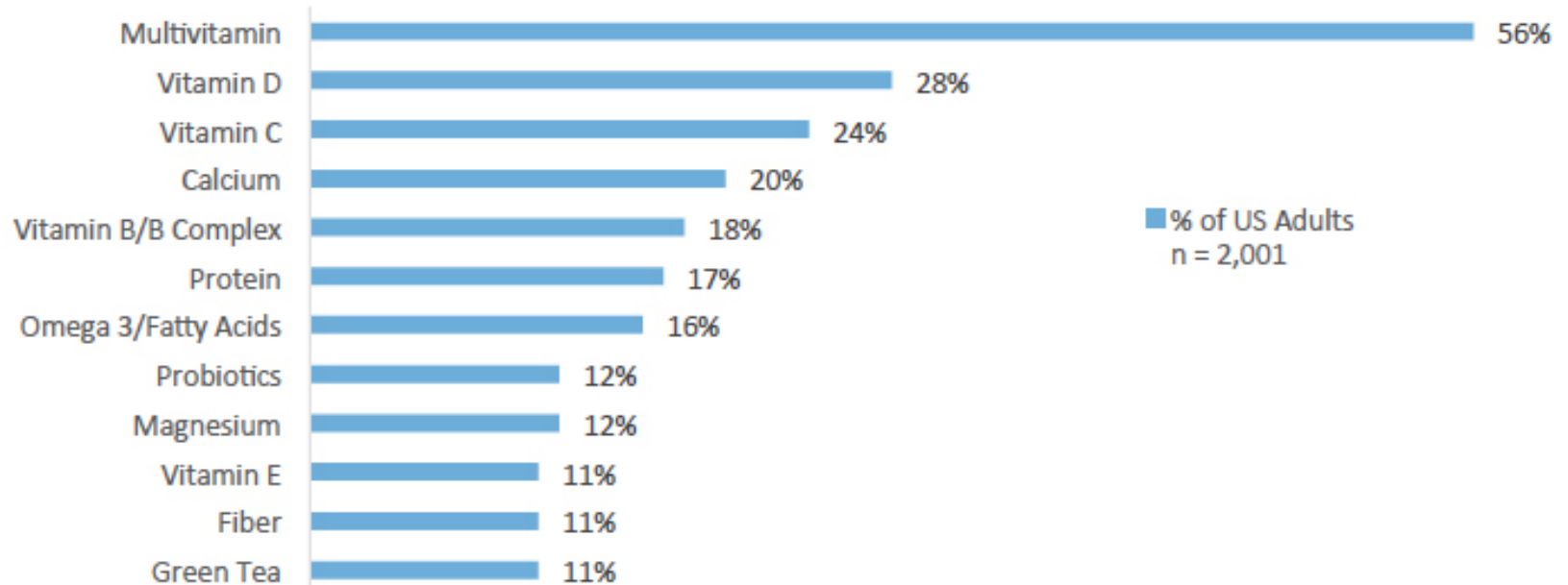


"MORE THAN
170 MILLION
AMERICANS"

76%

of Americans take dietary supplements

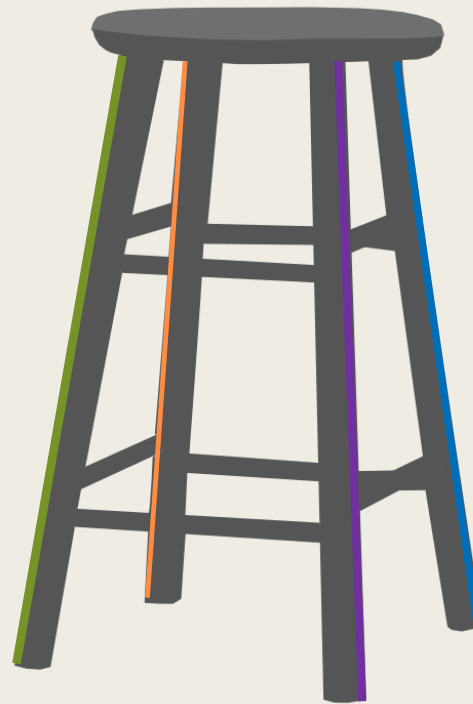
Most Popular Supplements Among U.S. Adults



DIETARY SUPPLEMENT REGULATION

1. The ingredients are **safe**.

2. The ingredients are **effective**—the product does what the marketer says it will do.



3. The product is manufactured in a manner that assures **quality**.

4. The product is **monitored** in the marketplace.



FACT

**The Food & Drug Administration (FDA)
regulates dietary supplements**

↙
Safety

↓
Quality

↘
Labeling



About the Regulation

Regulated as a category of food

Intentionally different than drug regulation

Supplements are not drugs and cannot claim to treat, prevent, or cure disease

FDA inspects manufacturing facilities

FDA has authority to remove unsafe products, do recalls, and close facilities

Mandatory serious adverse event reporting to FDA required by law



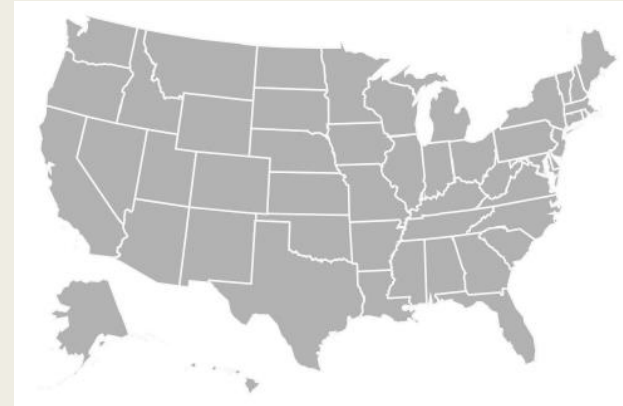
FACT

The Federal Trade Commission (FTC) regulates supplement advertising

Advertising **must be truthful** and not misleading

Advertisers must have **adequate substantiation** for all objective product claims before disseminating an ad

STATE REGULATION



- Many states have statutes modeled after the Federal Food, Drug, & Cosmetic Act (FD&CA).
- In areas where there is not express preemption or a clear conflict, states can enact additional laws and regulations.
 - *States expressly prohibited from adopting nutritional labeling requirements that are not identical to the FD&CA § 403A(a) and FDA’s implementing regulations.*
 - *The Biotech Labeling Solutions Act (July 2016) requires labeling of genetically modified ingredients and prevents states from doing the same.*

RECENT STATE LEGISLATION

- Recent state legislation has targeted the sales to minors of creatine, weight-loss products, and energy drinks.
- Also restrictions on ingredients like pure powdered caffeine and synthetic food dyes, and packaging (requiring a tether between plastic bottles and their caps).



STATE REGULATION

- The Safe Drinking Water and Toxic Enforcement Act, known as Proposition 65.
 - *Ballot initiative in 1986; requires a “person doing business” in the state to provide a “clear and reasonable warning” for exposures to certain chemicals; applies to dietary supplements and other foods.*
- Manufacturers can shift the burden to warn to retailers.
- New regulations require a warning prior to purchase.
 - *Applies to both brick-and-mortar and internet retail sites.*

WARNING: This product contains a chemical known to the State of California to cause cancer.

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.



STATE ATTORNEYS GENERAL



- State Attorneys General have broad jurisdiction to regulate, especially in the area of consumer protection/fraud.
- Example of recent enforcement actions:
 - *NY AG investigation involving four retailers and store-brand herbal supplements (Feb. 2015).*
 - Led to the formation of a still-active bipartisan state AG working group on supplements.
 - *VT and OR AG investigation into the sale of products containing BMPEA and picamilon.*
 - OR AG lawsuit against GNC ongoing.
- Collaboration with FTC
 - *Three joint actions with ME AG; additional actions with CT and NY AGs .*

IMPACT OF NEW ADMINISTRATION

- Possible new regulatory landscape
 - *FDA Commissioner Gottlieb focused on opioid crisis and drug approval process.*
 - *Exec. Order aimed at regulatory rollback.*
 - *Concerns about food safety rollout (global and domestic), lack of enforcement (FDA, FTC).*
- Democratic State AGs taking an activist role; ready to step in if they perceive lack of federal enforcement.
- Not only targeting manufacturers, but also retailers.



WHAT'S AHEAD?



- Class actions fueled by increased calls for transparency: country of origin, level of processing, the presence or absence of ingredients (GMOs, fiber, e.g.).
 - *Growing Proposition 65 list, plus new warning regulations effective in August 2018.*
- New Nutrition/Supplement Facts Label
 - *Industry concerns regarding the definition of fiber and disclosure of added sugar.*
- Increased focus on ingredients of concern
 - *Quality assurance/identity testing protocols for complex ingredients, like herbs and botanicals that go beyond the minimum federal requirements.*
 - *Weight-loss, bodybuilding, and sexual enhancement products.*
- Continued interest from State AGs and State Legislatures

BOTTOM LINE:

Compliance is a shared responsibility



RETAILERS



INDUSTRY



REGULATORS



CRN's Mission . . .

...to sustain and enhance a climate for our members to responsibly develop, manufacture, and market dietary supplements, functional food and their nutritional ingredients.



CRN SELF-REGULATORY INITIATIVES

- Code of Ethics
 - Voluntary Guidelines/Best Practices:
 - ✓ *Iodine in prenatal vitamins*
 - ✓ *Melatonin*
 - ✓ *Caffeine*
 - ✓ *Probiotics*
 - ✓ *Enzymes*
 - ✓ *Safe upper levels*
 - CRN/NAD Initiative
- Joint Activities:
 - ✓ *Standardized Information on Dietary Ingredients (SIDI) Protocol*
 - ✓ *Supplement **OWL**®*
 - Resources:
 - ✓ *FDA Warning Letters Database*
 - ✓ *FTC Warning Letters Compilation*
 - ✓ *National Advertising Division (NAD) Decisions Compilation*

THE VOICE OF RESPONSIBLE INDUSTRY



Dietary Supplement Industry and U.S. Anti-Doping Agency Warn Consumers about Dangerous, Illegal Ingredients Known as SARMs— Groups support strict enforcement action by FDA



A Mislabeled Product Is an Illegal Product

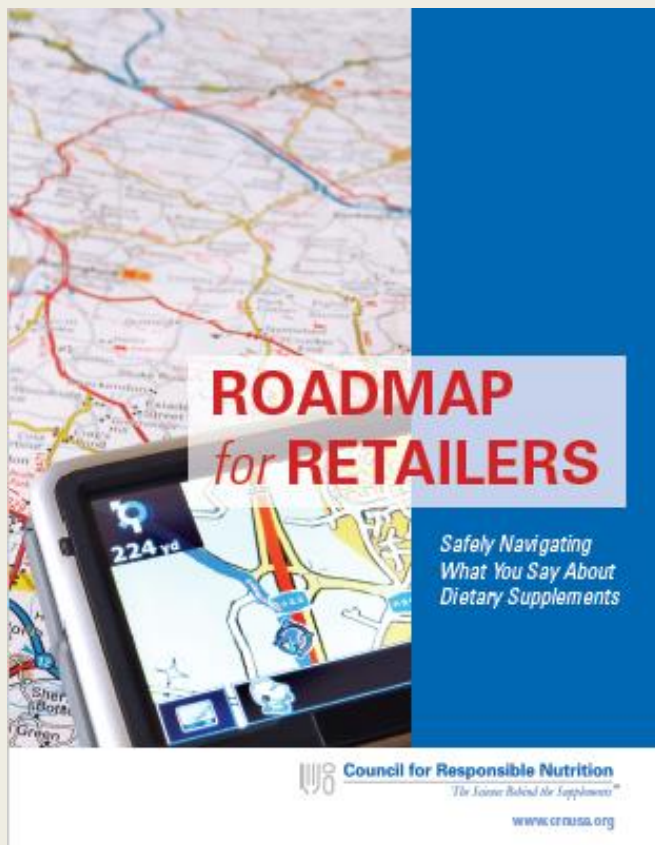
INCREASED TRANSPARENCY & ACCOUNTABILITY

- Guiding Principles of CRN:
 - *No response will solve all the issues being raised or pacify all the industry's critics.*
 - *Focus on measures that allow responsible companies to distinguish themselves from less reputable firms can help consumers navigate the marketplace and solidify confidence in reputable companies.*
 - *Viable proposals must have widespread support and agreement within the industry.*
 - *Whatever policies or proposals are advanced may require some sacrifice and additional burdens on companies.*

- Collaboration with regulators and retailers, and other third-party stakeholders.

TAKEAWAYS FOR RETAILERS

- Know the law, know your regulators.



<http://www.crnusa.org/roadmap-retailers-what-you-can-and-cannot-say-about-supplements>

- Monitor industry developments, and FDA and FTC activity

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CRN: The Short Report

- Utilize industry self-regulatory initiatives.

THANK YOU!

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