Council for Responsible Nutrition

The Science Behind the Supplements

Who We Are

The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing dietary supplement industry manufacturers and ingredient suppliers. CRN member companies produce a large portion of the dietary supplements marketed in the United States and globally, including vitamins and minerals, botanicals, sports nutrition supplements, and specialty supplements such as omega-3 fatty acids, and glucosamine-chondroitin. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug store and discount chains. Our members' products also include those marketed through natural food stores and mainstream direct selling companies. CRN members agree to adhere to a strong code of ethics and to comply with voluntary dosage limits and guidelines for labeling, and manufacture dietary supplements to high quality standards under good manufacturing practices.

Our Mission

To improve the environment for member companies to responsibly market dietary supplements by enhancing confidence among consumers, media, healthcare professionals, and decision makers.

What We Do

CRN provides expertise and action in the areas of legislation, regulation, science, communications, and international affairs. CRN encourages member involvement through numerous committees, working groups and task forces. CRN takes a leadership role in advocating for public policy based on sound science and the ability for consumers to have access to a wide variety of high quality, safe and beneficial dietary supplement products.

What We Believe

CRN follows where the science leads. But when it comes to leading the dietary supplement industry, CRN is at the forefront. CRN member companies make dietary supplements that are safe for the world. CRN makes the world safe for dietary supplements.

For More Information:
Visit the CRN website at www.crnusa.org Or call 202-776-7929

0705-250/0206-250

CRN Member Companies

Voting Members

Access Business Group/Nutrilite
Ada, MI

Accucaps Industries Limited
CANADA

Albion Laboratories, Inc.
Clearfield, UT

American Laboratories, Inc.
Omaha, NE

Archer Daniels Midland Company
Decatur, IL

B&C Nutritional Products, Inc.
Vista, CA

B&D Nutritional Ingredients, Inc.
Carlsbad, CA

BASF Corporation
Mount Olive, NJ

Bayer Corporation
Morristown, NJ

Bio San Laboratories Inc.
Derry, NH

Biotron Laboratories, Inc.
Centerville, UT

Cadbury Adams USA LLC
Morris Plains, NJ

Cardinal Nutrition
Vancouver, WA

Cargill Health & Food Technologies
Minneapolis, MN

Cognis Nutrition & Health
LaGrange, IL

Colorcon
West Point, PA

DSM Nutritional Products
Parsippany, NJ

E.T. Horn Company
La Mirada, CA

Eastman Chemical Company
Kingsport, TN

GBA Health Communications
Boca Raton, FL

General Nutrition Centers, Inc.
Pittsburgh, PA

GNLD International
Fremont, CA

Generichem Corporation
Totowa, NJ

Herbalife International of America, Inc.
Century City, CA

Indena USA, Inc.
Seattle, WA

Iovate Health Science Research
Ontario, CANADA

Kaneka America Corporation
New York, NY

Kemin Health, L.C.
Des Moines, IA

Leiner Health Products, Inc.
Carson, CA

Linnea, Inc.
Easton, PA

Lonza, Inc.
Fair Lawn, NJ

Mannatech, Inc.
Coppell, TX

Mingtai Chemical, LLC
Mountainside, NJ

NBTY, Inc.
Bohemia, NY

Natural Alternatives International Inc.
San Marcos, CA

Nutraceutical Corporation
Park City, UT

Nutramax Laboratories, Inc.
Edgewood, MD

Nutrition 21
Purchase, NY

Omya, Inc.
Lucerne Valley, CA

Perrigo Company
Allegan, MI

Pharmanex LLC
Provo, UT

Pharmavite LLC
Mission Hills, CA

Polyphenolics
Granger, IN

Pronova Biocare, a.s.
NORWAY

Proper Nutrition, Inc.
Reading, PA

Rainbow Light Nutritional Systems
Santa Cruz, CA

Reliv International, Inc.
Chesterfield, MO

Rhodia, Inc.
Cranbury, NJ

Ross Products
Columbus, OH

Shaklee Corporation
San Francisco, CA

Stauber Performance Ingredients
Fullerton, CA

Swiss Caps USA, Inc.
Miami, FL

Unigen Pharmaceuticals, Inc.
Broomfield, CO

VitaTech International, Inc.
Tustin, CA

Weider Nutrition International, Inc.
Salt Lake City, UT

Wyeth Consumer Health
Madison, NJ

Zila Nutraceuticals
Prescott, AZ

Associate Members

Covance Laboratories, Inc.
Madison, WI

Merical Vita-Pak, Inc.
Anaheim, CA

Miami Research Associates
Miami, FL

Monsanto Life Sciences Company
Chicago, IL

NSF International
Ann Arbor, MI

PROSAR
St. Paul, MN

SafetyCall International
Minnetonka, MN

SETCO, Inc.
Anaheim, CA

Shuster Laboratories
Canton, MA

U.S. Pharmacopeia
Rockville, MD

Virgo Publishing Inc.
Phoenix, AZ

International/Correspondent Members

Bioriginal Food & Science Corporation
CANADA

Gumlink A/S
DENMARK

Jamieson Laboratories Ltd.
CANADA

Seven Seas Limited
ENGLAND

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FACT SHEET

Dietary Supplements: Safe, Beneficial and Regulated

Q. Who is the dietary supplement industry?

A. In the U.S., the dietary supplement industry is a $20 billion industry. According to the most recent statistics from the Food and Drug Administration (FDA), there are 29,000 dietary supplement products on the market, up from 25,000 in 1993. Dietary supplement products include vitamins, minerals, botanicals, sports nutrition supplements, weight management products, and specialty supplements. These products are intended to be used as supplements to, not substitutes for, a well-balanced diet and a healthy lifestyle. When used properly, they help promote overall good health and prevent disease. More than 150 million Americans take dietary supplements annually.

Q. Is the dietary supplement industry regulated?

A. Yes. The dietary supplement industry is regulated by FDA and the Federal Trade Commission (FTC), as well as by government agencies in each of the 50 states. The FDA has regulatory authority under the Dietary Supplement Health and Education Act (DSHEA), a 1994 amendment to the Federal Food, Drug and Cosmetic Act that was passed by unanimous consent in both the House and Senate.

Q. Why do some people say the industry is unregulated?

A. When critics say dietary supplements are "unregulated," what they generally mean is that dietary supplements are not regulated like drugs. Dietary supplements have always been regulated as a category of food in this country, and DSHEA did not change that fact. Virtually all facets of dietary supplement manufacturing, labeling and marketing are covered by extensive regulations issued and enforced by FDA and FTC. If dietary supplements were regulated like drugs, there would likely be no dietary supplement industry and the products that did exist would cost what drugs cost.

Q. Is it true that before DSHEA was passed, FDA had pre-market approval authority?

A. No. FDA never had pre-market approval over dietary supplements, and DSHEA did not change that fact. Under the law, dietary supplements marketed in the U.S. before passage of DSHEA are "grandfathered" and assumed to have a history of safe use. If a supplement manufacturer wants to introduce a new ingredient, it must provide FDA with 75 days notice, along with safety information. If FDA has any concerns about the ingredient or submitted safety profile, the agency can request more information or deny the product's entry into the marketplace. Since the passage of DSHEA, FDA has turned down about half of the New Dietary Ingredient notifications filed.

Q. Without pre-market approval, how do we know these products are safe?

A. Pre-market approval is not a guarantee of safety as witnessed by those drug products that have been approved by FDA, only to be later recalled due to safety concerns. Like food products, dietary supplements do not undergo pre-market approval, but that does not mean that companies don't do testing, or that products are unsafe. There are provisions under DSHEA that help protect consumers from potentially unsafe products. But, the overwhelming majority of dietary supplements are safely used by 150 million Americans annually.

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CRN FACT SHEET

Dietary Supplements: Safe, Beneficial and Regulated

Q. What did DSHEA do?

A. DSHEA specifically reaffirmed the status of dietary supplements as a category of food and created a specific definition for dietary supplements. Further, DSHEA provided FDA with additional enforcement authority, including the ability to remove from the market products the agency deems unsafe through: 1) an "imminent hazard" clause which permits FDA to immediately remove a product it considers to present an immediate safety concern and 2) a "significant or unreasonable risk" clause that allows removal of a product considered to pose an unacceptable risk of illness or injury.

Q. Shouldn't companies have to abide by Good Manufacturing Practices (GMPs)?

A. Absolutely. Companies are required to abide by food GMPs while FDA finalizes its rule for GMPs specific to dietary supplements. Responsible companies **do** abide by GMPs – and many observe procedures which go above and beyond what the current GMPs require. Responsible companies in the industry fully support the need for the final GMP rule in order to create a level playing field for companies across the board and help increase consumer confidence in these products. FDA anticipates the final rule will be issued this year and as far as industry is concerned, the sooner, the better.

Q. What is CRN's position on reporting of adverse events?

A. CRN supports legislation for mandatory reporting of **serious** adverse events on a Federal level, allowing for industry involvement in developing a system that provides meaningful information while not inappropriately overburdening FDA or manufacturers. In addition, CRN is continuing to work with and encourage its members to explore ways to improve the industry's overall management of adverse event reports.

Q. Is DSHEA a good law?

A. Yes. DSHEA provides an appropriate framework for regulating the dietary supplement industry – as long as it is enforced. In the past several years, FDA has actively engaged in more vigorous implementation of DSHEA and stronger enforcement actions – these efforts are encouraged and supported by the mainstream dietary supplement industry. Even top officials at FDA have stated they are not asking Congress to change the law, noting they have adequate authority to remove unsafe supplements from the market. DSHEA provides FDA with appropriate regulatory authority while still allowing consumers to have the desired access to a wide variety of affordable, high quality, safe and beneficial dietary supplement products.

DSHEA: It Makes Sense...Let's Make it Work