



FACT SHEET

Dietary Supplements: Safe, Regulated and Beneficial

Q. Who is the dietary supplement industry?

A. In the U.S., the dietary supplement industry is a \$46 billion¹ industry. 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 170 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). The FDA has regulatory authority under the Federal Food, Drug and Cosmetic Act as amended in 1994 by the Dietary Supplement Health and Education Act (DSHEA) and in 2006 by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.

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 in 1994, 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 protect consumers from potentially unsafe products. But the overwhelming majority of dietary supplements are safely used by 170 million Americans annually.

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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. It's the law. Responsible companies **do** abide by GMPs—and many observe procedures which go above and beyond what the current regulations require. In June 2007, GMPs specific to dietary supplements were released from FDA. The GMP rule provided a staggered three-year “phase in” compliance period for manufacturers. And for large companies – more than 500 employees – the compliance date was June 2008. Firms with less than 500 employees had to be compliant by June 2009, and for small manufacturers that employ less than 20 employees, the compliance date was June 2010. Responsible companies in the industry have fully supported the need for dietary supplements GMPs in order to create a level playing field for companies across the board and help increase consumer confidence in the quality and safety of these products.

Q. Should serious adverse events associated with dietary supplements be reported to FDA?

A. Yes. CRN and mainstream industry supported the Dietary Supplement and Nonprescription Drug Consumer Protection Act which passed the 109th Congress and was signed into law by President Bush on December 22, 2006. The law requires manufacturers to notify the FDA of all **serious** adverse events associated with an over-the-counter drug or a dietary supplement that they receive. This law strengthens the regulatory structure for dietary supplements and builds greater consumer confidence in this category of FDA-regulated products—thus ensuring and protecting Americans' continued access to safe, beneficial dietary supplements. Consumers have a right to expect that if they report a serious adverse event to a dietary supplement manufacturer—FDA will know about it.

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.