Dietary Supplements Are Safely Regulated

The timeline below shows the steps made since DSHEA was passed to regulate supplements.

1994 The Dietary Supplement Health and Education Act (DSHEA)

- Requires manufacturers to follow Good Manufacturing Practices (GMP) set by the FDA
  - Fully implemented 2008-2010
- Continues to define dietary supplements as Food
- Regulates labels
  - All claims must be truthful and not misleading
  - All ingredients must be on the labels
  - Documentation to prove claims must be maintained
- Approves pre-existing dietary ingredients already on the market as of October 15, 1994
  - Common vitamins, minerals, herbs
  - "Grandfathering" was twice applied to pharmaceuticals already on the market:
    - By the Food, Drug and Cosmetic Act of 1938
    - By an amendment to the Act in 1962 to also exempt existing drugs
- Requires pre-market submission of all New Dietary Ingredients to the FDA
  - The agency questions the majority of submissions
  - The agency has the power to reject applications; and has done so

1997 Food and Drug Administration Modernization Act (FDAMA)

- Provides for health claims based on an authoritative statement by a scientific body of the U.S. government or the National Academy of Sciences
- Such claims may be used only after submission of a health claim notification to FDA

2002 The Public Health Security and Bioterrorism Preparedness and Response Act

- All food manufacturers, including dietary supplement manufacturers, are required to be registered with the government and give advance notification of raw materials imports

2003 The FDA Consumer Health Information for Better Nutrition Initiative

- Provides for qualified health claims where the quality and strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation
  - Such health claims must be qualified to assure accuracy and non-misleading presentation to consumers

2004 The Anabolic Steroid Control Act amendment

- Bans steroid precursors sold as dietary supplements
  - The FDA and DEA have authority to take action against adulterated products

2006 The Dietary Supplement and Nonprescription Drug Consumer Protection Act

- Requires reporting of all serious adverse events (AERs) for both dietary supplements and OTC drugs

2010 The most recent annual report of the American Association of Poison Control Centers

- Published in the journal Clinical Toxicology
- Reports zero reports of accidental deaths from dietary supplements

Full implementation of mandatory federal cGMPs was completed in June

- All manufacturers & suppliers are now bound by FDA standards of safety and documentation

The Dietary Supplement Full Implementation and Enforcement Act

- Introduced in Congress to provide more funding for FDA enforcement of current laws

The Food Safety bill

- Includes enhanced mandatory recall authority for all foods, including dietary supplements
- Expected to pass Congress soon