THE SAFETY OF SUPPLEMENTS

Extensive Regulations And Science Already Exist On The Safety Of Dietary Supplements

- Dietary supplements are foods. Food safety laws already exist to ensure the safety of foods. The new FSMA laws enhance food safety.
- The safety of dietary supplements is enhanced by the Dietary supplement cGMPs.
- These regulations regulate the safe manufacture of supplements and also protect against contamination and adulteration [21CFR110 and 111]
- The DSHEA law both presumes and defines existing ingredients as being safe and sets up a regulatory structure for all ingredients to ensure safety.
- The safety of vitamins and minerals, which are the majority of supplements used, has been established [Dietary Supplement Fact Sheets, Office of Dietary Supplements, NIH].
- The labeling of supplements is covered by labeling laws [NLEA & DSHEA regulations]
- The Adverse Event reporting regulations provide an additional mechanism for the reporting of serious adverse events associated with supplement use.
- There is both under-reporting and over-reporting of adverse events. In addition, many of the adverse events are not related to the supplement. In any case, the numbers are small relative to supplement use and are not indicative of a general problem.
- New ingredients are covered by the GRAS and NDI portions of existing regulations [FD&C Act, DSHEA

There Needs To Be Increased Education And Enforcement Of Existing Regulations

- There will always be individuals and corporations trying to flout the regulations or are unfamiliar with the regulations, as with any law.

- The regulations covering dietary supplements are enforced by the FDA and other Federal Agencies.

- Enforcement has been stepped up. The FDA is finding significant non-compliance with the regulations. However, FDA compliance is spotty and there is insufficient follow-through. Congress should promote enhanced enforcement through appropriations and other means.
- Both FDA and industry are working to educate industry about the regulations. The industry trade organizations hold a number of educational events each year. FDA participates in these events. The challenge is that many of the individuals and corporations that flout the law don't attend these events.

Dietary Supplements Have Been Safely Regulated Since 1994

DSHEA : The Dietary Supplement Health and Education Act

- Requires manufacturers to follow Good Manufacturing Practices (GMP) set by the FDA
  - GMPs were fully implemented between June 2008 and June 2010
- Continues to define dietary supplements as a special Food category
- Regulates labels
  - All claims must be truthful and not misleading
  - All ingredients must be on the labels
  - Documentation to prove "structure-function" 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:
    - The 1938 Food, Drug and Cosmetic Act & 1962 Kefauver-Harris Amendments
- Requires pre-market submission to the FDA of all New Dietary Ingredients marketed after October 15, 1994
  - The agency questions the majority of submissions
  - The agency has the power to reject applications; and has done so
  - This is analogous to pharmaceuticals where all drugs entering the market after October 10, 1962 require an FDA submission/approval process

SENPA
NATURAL INDUSTRY ALLIANCE

In 2024

As Your Voice In The Natural Products Industry

Our mission is to nourish the human connection as the heart of a changing natural products industry – advocating for, strengthening and uniting the independent natural retailer and manufacturers with their current and future customers, building trust and aligning these retailers as the destination of choice for an enhanced buying experience and natural health education.

Vision Statement

SENPA vision is to nourish the human connection as the heart of the natural products industry through advocacy and education so independent retailers, leading manufacturers and consumers can thrive, in an ever-changing environment, rooted together in our experience of enhanced health and the power of personal relationships.

Be a voice not a number when industry needs you.

www.SOSSUPPLEMENTS.ORG

Dietary Supplements are now Safely Regulated

A Timeline of Dietary Supplement Regulation since 1994

1994 The Dietary Supplement Health and Education Act (DSHEA)*

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1997 The 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; industry supported

2003 The FDA Consumer Health Information for Better Nutrition Initiative*

- 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

The Food Allergen Labeling and Consumer Protection Act*

- Requires label disclosure of the 8 major allergens that cause 90% of all food allergies

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 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 Food Safety Modernization Act*

- Includes enhanced mandatory recall authority for all foods, including dietary supplements
- Expanded facility registration and HACCP (safety handling) rules
- Requires FDA to issue guidance on New Dietary Ingredients (NDIs), per DSHEA

2011 FDA released a new Guidance on its enforcement of NDI regulations

- Requires approval of NDIs by the FDA, not just pre-market notification to the agency
- Redefines NDIs as all *products* containing an NDI ingredient, not just the ingredient itself
- Expands the definition of NDI to include new ingredient processing techniques
- Would encompass tens of thousands of products versus dozens of ingredients
- 2012: FDA notifies Senators Hatch & Harkin that its NDI guidance will be revised & reissued

2014 Introduction of the Designer Anabolic Steroid Control Act (DASCA)*

- Empowers the DEA with new tools to quickly identify and quickly respond when new designer anabolic steroids—illegal drugs—are falsely marketed as dietary supplements

***Industry-supported legislation**

- 20th Anniversary of The Dietary Supplement Health and Education Act (DSHEA)*