A Timeline of Dietary Supplement Regulations in the U.S.

c.1915

Early introduction of dietary supplement products such as cod liver oil, herbal remedies, iron tonics, and yeast tablets.

c.1940

Multivitamin and multimineral supplements introduced to the US marketplace.

1976

Proxmire Amendment exempts dietary supplements from regulation as drugs under the Federal Food, Drug, and Cosmetic Act of 1938.

EXEMPT

1985

Food and Drug Administration (FDA) establishes the Center for Food Safety and Applied Nutrition (CFSAN) to centralize efforts related to food safety, nutrition, and labeling regulation, particularly to ensure the safety and proper labeling of dietary supplements, foods, and cosmetics.

FDA Center for Food Safety and Applied Nutrition

1993

Congress establishes the Office of Alternative Medicine at the National Institutes of Health (NIH).

1994

Dietary Supplement Health and Education Act (DSHEA) defines dietary supplements as a category of food and establishes regulations for their safety, labeling, and health claims and mandates FDA demonstrate that a dietary supplement is unsafe rather than require pre-market approval.

1995

Congress establishes the Office of Dietary Supplements (ODS) at NIH to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public.

1997

New Dietary Ingredient (NDI) notifications issued by FDA requiring manufacturers to provide at least 75 days before marketing a dietary supplement that contains a NDI not marketed in the United States before October 15, 1994.

FDA NDI NEW DIETARY INGREDIENT

2002

Public Health Security and Bioterrorism Preparedness and Response Act mandates a chain of possession identification for firms seeking to import components of dietary supplements for further processing and export, and requires certificates of analysis for components thereof intended for export.

2007

Current Good Manufacturing Practices (cGMPs) issued by the FDA for dietary supplements, establishing quality control standards for their manufacturing, packaging, labeling, and storage.

c.2010

Coupled with advancements in manufacturing processes, marketing strategies, and the introduction of new products, dietary supplement industry reaches $50 billion mark in the US.

$50B

2013

Adverse Event Reporting (AER) rule issued by FDA requiring manufacturers to report serious adverse events associated with dietary supplements to the FDA within 15 days.

2023

FDA plans for a unified Human Foods Program (HFP), bringing together the functions of CFSAN, Office of Food Policy and Response (OFPR), and Office of Regulatory Affairs (ORA).

FDA U.S. FOOD & DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS

Nestlé HealthScience

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