Dietary Supplements

FDA regulates both finished dietary supplement products and dietary ingredients. FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA):

- Manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. That means that these firms are responsible for evaluating the safety and labeling of their products before marketing to ensure that they meet all the requirements of DSHEA and FDA regulations.
- FDA is responsible for taking action against any adulterated or misbranded dietary supplement product after it reaches the market.

This section provides detailed information about:

- **Q&A on Dietary Supplements (/Food/DietarySupplements/QADietarySupplements/default.htm)**
  Frequently asked questions about dietary supplements, including definitions, labeling requirements, and regulatory roles and responsibilities.
- **Using Dietary Supplements (/Food/DietarySupplements/UsingDietarySupplements/default.htm)**
  Tips for dietary supplement users, including older supplement users.
- **Report an Adverse Event (/Food/DietarySupplements/ReportAdverseEvent/default.htm)**
  Learn how consumers, health care providers, and others can report a complaint, concern, or problem related to dietary supplements. Includes links to guidance for dietary supplement manufacturers, packers, and distributors.

- **New Dietary Ingredients Notification Process (/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/default.htm)**
  Background information for industry, instructions for submitting premarket notifications, and links to relevant guidance and Federal Register documents.

Ensuring the Safety and Accurate Labeling of Dietary Supplements

Although dietary supplement manufacturers must register their facilities with FDA,* they are not required to get FDA approval before producing or selling dietary supplements. Manufacturers and distributors must make sure that all claims and information on the product label and in other labeling are truthful and not misleading.

Under FDA regulations at 21 CFR part 111, all domestic and foreign companies that manufacture, package, label or hold dietary supplement, including those involved with testing, quality control, and dietary supplement distribution in the U.S., must comply with the Dietary Supplement Current Good Manufacturing Practices (CGMPs) for quality control.

In addition, the manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA all serious adverse event reports associated with use of the dietary supplement in the United States.

FDA regulates dietary supplement labels and other labeling, such as package inserts and accompanying literature. The Federal Trade Commission (FTC) regulates dietary supplement advertising.

Domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States are required to register with FDA. For more information, see **Registration of Food Facilities (/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm).*

Alerts & Safety Information

Visit the **Safety Alerts & Advisories (/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/default.htm)** page in the **Recalls, Outbreaks & Emergencies (/Food/RecallsOutbreaksEmergencies/default.htm)** section for warnings, public health advisories, and other safety information related to dietary supplements.

Popular Topics

- **Safety Alerts and Advisories (/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/default.htm)**
- **Draft Form FDA 3880: Electronic New Dietary Ingredient Notification (NDIN) Submission (/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/ucm356620.htm)**
- **Letter to Herbalife Ltd. Concerning Mischaracterization in Advertisement (/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/ucm427010.htm)**

Guidance

- **Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm381189.htm)**
- **Guidance for Industry: Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm381315.htm)**
- **Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm257563.htm)**
- **Guidance for Industry: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Small Entity Compliance Guide (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm238182.htm)**
- **All Dietary Supplements Guidance (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/default.htm)**

Related Content

- **Energy "Drinks" and Supplements: Investigations of Adverse Event Reports (/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/ucm328536.htm)**
- **Information on Imports, Exports, and Other International Activities (/Food/InternationalInteragencyCoordination/default.htm)**