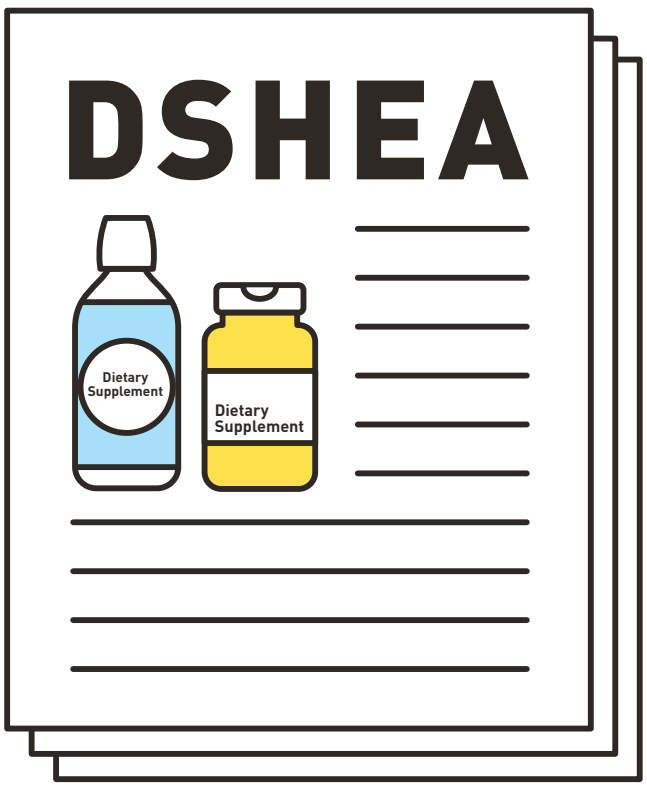
Dietary Supplements: How FDA Helps Keep You Safe



The Law

The Dietary Supplement Health and Education Act of 1994 (DSHEA) defined dietary supplements and set out FDA's authority regarding these products. Under DSHEA:

- **FDA does not have the authority to approve dietary supplements for safety and effectiveness or their labeling before they are sold in stores or online.**
- Dietary supplement companies are responsible for ensuring that their products are safe and label claims are truthful and substantiated.
- Dietary supplement companies can introduce new dietary supplements to the market without receiving approval from FDA. In fact, they often can introduce dietary supplements to the market without even notifying FDA.

FDA Regulates

Even though FDA does not approve dietary supplements, there are product **manufacturing and labeling requirements** in place that supplement companies are required to follow.

FDA oversees the dietary supplement marketplace by:

- Periodically **inspecting** dietary supplement manufacturing facilities to verify that companies are meeting all manufacturing and labeling requirements.
- **Monitoring** adverse event reports and complaints received from industry, healthcare professionals, and consumers.

FDA Takes Action

When a product is found to be unsafe or otherwise not in compliance with FDA requirements, FDA can:

- Work with the company to bring the product into **compliance**.
- Ask the company to voluntarily **recall** the product.
- Take action to **remove** a dangerous product from the market.

U.S. FOOD & DRUG ADMINISTRATION

Learn more at www.fda.gov/dietarysupplements.

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