

Recent Dietary Supplement FDA Alerts and Warning Letters

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By Michael H. Cohen

The FDA has the authority to regulate dietary supplements pursuant to the federal Food, Drug, and Cosmetic Act and other laws. FDA provides guidance documents to help the developers of dietary supplements understand their compliance requirements. These guidance documents include the following:

- [Current Good Manufacturing Practice \(CGMP\)](#)
- [New Dietary Ingredients](#)
- [Warning Letters & Safety Information](#)
- [Labeling and Claims](#)
- [Adverse Events Reporting and Recordkeeping](#)
- [General Compliance and Inspection Information for Industry](#)
- [Special Issues/Miscellaneous Items](#)
- [Archived Items of Interest](#)

We've discussed some of the key compliance requirements for dietary supplements previously. We also have a video presentation on the compliance requirements for dietary supplements.

In this article, we discuss a few additional compliance issues.

Navigating FDA and Healthcare Laws for Dietary Supplements: Compliance Made Clear

Learn essential FDA and healthcare compliance requirements for dietary supplements, including labeling, marketing claims, and manufacturing practices. Insights from Cohen Healthcare Law Group.

Dietary Supplement Compliance: Labeling, Marketing, and Manufacturing Strategies for Success

In this video, Michael discusses the importance of making assertive yet compliant claims, adhering to good manufacturing practices, and ensuring ingredient safety to avoid FDA warnings.

FDA oversight of dietary supplements

The FDA coordinates its oversight of dietary supplements with the [Human Foods Program's Office of Food Chemical Safety](#).

Dietary Supplements, and Innovation. FDA regulates the dietary ingredients for dietary supplements and the finished dietary supplement products. FDA's oversight of dietary supplements differs from its oversight of "conventional" foods and drug products.

Based on the Dietary Supplement Health and Education Act of 1994 (DSHEA), the makers and distributors of dietary supplements are not permitted to market products that are "adulterated or misbranded." The burden is on the manufacturers and distributors to evaluate the safety of their products and the labeling of their products before manufacturers and distributors can market their products. Dietary supplements must comply with all the requirements of the Federal Food, Drug, and Cosmetic Act as amended by DSHEA and FDA regulations.

If a dietary supplement is adulterated or misbranded after the supplement reaches the market, FDA can take appropriate actions.

Dietary supplement alerts by the FDA

FDA publishes press releases about recalls of dietary supplements that may risk the health of consumers though not all press releases have recalls. FDA also issues warning letters to companies to inform companies about FDA violations and alert companies about what corrective actions the businesses must take.

In 2024, FDA issued the following notices:

- **Update on FDA launches new directory of ingredients used in products marketed as dietary supplements.** On February 21, 2025, FDA updated FDA's Ingredient Directory, including renaming the web page to be Information on Select Dietary Supplement Ingredients and Other Substances. The changes are in response to feedback from stakeholders. The new directory includes new categories to *"classify the type of FDA action or communication for each listed ingredient; recording the date each listed ingredient was added to the directory; and streamlining the introductory text on the page."*
- **FDA issues draft guidance on new dietary ingredient notification master files for dietary supplements.** On April 3, 2024, FDA announced the availability of a draft guidance for the dietary supplement industry titled "New Dietary Ingredient Notification Master Files for Dietary Supplements." *This guidance document is in response to requests from the dietary supplement industry for "recommendations about Master Files for new dietary ingredient notifications (NDINs)."*

NDINs can help *"facilitate the submission of NDI-related identity, manufacturing, and/or safety information to the FDA for use in evaluating a potential future NDIN."* *"The recommendations in this draft guidance expand upon and replace the recommendations related to Master Files in the FDA's revised draft guidance, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues."*

Ingredient directory

FDA has an ingredient directory to help manufacturers, sellers, and consumers keep current about the ingredients and other substances found in products labeled as dietary supplements. The directory links to FDA's actions and communications which include the *"evaluation of health claims, safety communications, and compliance and enforcement actions."*

The directory comes with this FDA caveat:

"As a reminder, FDA does not approve dietary supplements for safety and effectiveness. This directory is not intended to be a comprehensive list of all ingredients used in dietary supplements and may not include all actions the agency has taken with respect to a particular ingredient."

A sample ingredient in the directory includes the following:

- - Agency actions/statements.
 - **21 CFR 101.72** Health claims: calcium, vitamin D, and osteoporosis
 - Qualified Health Claims: Letter Regarding Calcium and Colon/Rectal, Breast, and Prostate Cancers and Recurrent Colon Polyps (October 2005)
 - 1. Ingredient is the subject of an authorized health claim or qualified health claim.
 - Entry date. April, 2023.
- Dapoxetine (also called Dapoxetineum)
 - Agency actions/statements.
 - Shoreside Enterprises, Inc. Warning Letter (December 2014)
 - Category 4. Ingredient is excluded from the dietary supplement definition under section 201(ff)(3) of the FD&C Act
 - Entry date. April, 2023.

The list of categories includes the following:

1. *"Ingredient is the subject of an authorized health claim or qualified health claim"*
2. *Ingredient is the subject of a safety communication*
3. *Ingredient is not a "dietary ingredient" under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)*
4. *Ingredient is excluded from the dietary supplement definition under section 201(ff)(3) of the FD&C Act*
5. *Dietary ingredient has not met the safety standard in section 402(f)(1)(A) of the FD&C Act*
6. *New dietary ingredient has not met the safety standard in section 402(f)(1)(B) of the FD&C Act*
7. *New dietary ingredient requiring a premarket safety notification under section 413(a)(2) of the FD&C Act but for which no notification has been submitted."*

Additional FDA guidelines for dietary supplements

Additional guidelines for dietary supplements include the following:

- Information for Industry on Dietary Supplements. *"Resources and links for submissions for new dietary ingredient notifications and structure/function claim notifications, applications, guidance, regulations, and other items of interest to industry members."*
- New Dietary Ingredient Notification Process. *"Background information for industry, instructions for submitting premarket notifications, and links to relevant guidance and Federal Register documents."*
- Notifications for Structure/Function and Related Claims in Dietary Supplement Labeling. *"Background information for industry, instructions for submitting notifications, and links to relevant guidance and Federal Register documents."*
- Information for Consumers on Using Dietary Supplements

FDA warning letters for dietary supplements

A few of the more recent warning letters to makers of dietary supplements by the Food and Drug Administration include the following:

- A warning letter was issued on March 4, 2025, to C & A Naturistics by the Center for Drug Evaluation and Research (CDER) for an unapproved drug/misbranded. The letter states that their dietary supplement is actually a drug.
- A warning letter was issued to Pivo IV Inc. on March 6, 2025, by CDER for an unapproved drug/misbranded. The letter states that their dietary supplement is actually a drug.
- A warning letter was issued to IsoThrive Inc. on February 4, 2024, by CDER about objectionable conditions at the facility observed by an FDA clinical investigator.
- A warning letter was issued to Western Innovations, Inc. on 11/13/24 by Human Foods Program about adulterated dietary supplement violations, including Current Good Manufacturing Practice (CGMP) violations.

The Food and Drug Administration has the authority to regulate dietary supplements and their ingredients. FDA provides numerous guidance documents to help manufacturers, medical practitioners, and consumers. When manufacturers fail to comply with the FDA regulations, FDA has the authority to enforce its regulations through warning letters and other actions.