

2026 FDA Guidance: What Dietary Supplement Brands Need to Know

Comprehensive 2026 guide details DSHEA, 21 CFR Part 111 GMPs, NDI notifications, labeling, and FDA enforcement trends for supplement brand compliance

IRVINE, CA, UNITED STATES, March 25, 2026 /EINPresswire.com/ -- Qalitek Laboratories, an ISO 17025-accredited testing laboratory with regulatory consulting capabilities serving dietary supplement brands across North America, today published its 2026 FDA Dietary Supplement Regulatory Update — offering supplement brands a comprehensive overview of U.S. regulatory requirements, recent enforcement trends, and key compliance priorities.



The Dietary Supplement Health and Education Act (DSHEA) of 1994 established the regulatory framework for dietary supplements, classifying them as a category of food rather than drugs. While FDA approval is not required before marketing, DSHEA mandates that supplements be safe, labels must be truthful and not misleading, and structure/function claims must be substantiated.

FDA's Current Good Manufacturing Practice (cGMP) regulations, codified in 21 CFR Part 111, set the quality standards manufacturers must follow. These regulations require written procedures for all manufacturing operations, identity testing of all incoming ingredients, complete batch production records, and finished product testing. Enforcement of Part 111 has intensified in recent years, with increased inspections and the use of import alerts for GMP violations.

"The regulatory landscape for dietary supplements continues to grow more complex, and 2026 is no exception," said Nour Abochama, Vice President of Operations at Qalitek Laboratories. "FDA's enforcement priorities focus on GMP compliance, new dietary ingredient (NDI) notifications, and label claim substantiation. Brands that invest in quality systems and testing documentation are better positioned, while those that don't face increasing risks — from warning letters and import

alerts to Amazon suspensions."

New Dietary Ingredient (NDI) notifications remain a critical compliance area. Supplements containing an ingredient not marketed in the U.S. before October 15, 1994, must submit an NDI notification to FDA at least 75 days before marketing. Brands that fail to submit required notifications are in violation of DSHEA.

Labeling requirements under DSHEA and 21 CFR Part 101 include a Supplement Facts panel, statement of identity, net quantity, manufacturer/distributor information, directions for use, and proper disclaimers for structure/function claims. Claims must include a statement that they have not been evaluated by FDA and that the product is not intended to diagnose, treat, cure, or prevent any disease.

For supplement brands selling on Amazon, FDA compliance and Amazon's platform requirements are increasingly intertwined. Amazon's documentation requirements — including Certificates of Analysis, GMP documentation, and label reviews — are designed to ensure products meet FDA regulatory standards.

"Brands that understand the regulatory framework — DSHEA, 21 CFR Part 111, and FDA enforcement priorities — can make informed compliance decisions and anticipate regulatory trends, not just respond to current requirements," added Abochama.

RESOURCES

Full article: Qalitex FDA Dietary Supplement Regulations 2026

ABOUT QALITEX LABORATORIES

Qalitex Laboratories is an ISO 17025-accredited analytical testing laboratory with facilities in Irvine and San Diego, California. The laboratory provides COA testing, heavy metal analysis by ICP-MS, microbiology testing per USP <61> and <62>, preservative efficacy testing, and ICH-guided stability studies. Qalitex also offers regulatory compliance support for dietary supplement brands, cosmetics companies, and consumer goods manufacturers. Testing programs meet 21 CFR Part 111, California Proposition 65, Amazon supplement compliance, and Health Canada NHP standards, with standard turnaround times starting at 48 hours.

Nour Abochama

Qalitex Laboratories

+ +1 949) 881-6661

[email us here](#)

Visit us on social media:

[LinkedIn](#)

[Instagram](#)

[Facebook](#)

This press release can be viewed online at: <https://www.einpresswire.com/article/901698834>

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2026 Newsmatics Inc. All Right Reserved.