

Compliance Tips for Nutritional Supplement Companies: Navigating FDA and FTC Regulations

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Nutritional supplements are becoming big business, but sellers of these products must follow the law if they wish to operate without interference. The Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) regulate the marketing of nutritional supplements. The two agencies have a set of rules, laws, and guidelines that they expect those in the business of selling supplements to follow. This article is an overview of what those rules are and what happens if you don't follow them.

Key Compliance Requirements for Nutritional Supplement Companies

The dietary supplement industry has unique regulatory issues because of the stringent FDA and FTC standards it must meet. This document outlines essential steps necessary for maintaining compliance in this complex, paper-based realm.

1. Adhering to FDA Labeling and Ingredient Disclosure Requirements

All labels on dietary supplements must be accurate and complete, according to the FDA. This ensures that consumers know what is in a product and how it is supposed to function.

- - **Accurate Ingredient Labeling:** The FDA requires that all ingredient lists on supplement labels be in descending order by weight. For clarity, each ingredient must be identified with its common name. **Supplement Facts Panel:** Every product that is a supplement must contain a Supplement Facts panel. This panel tells you the serving size for the product, the amount per serving, and the % Daily Value for each nutrient, if they have established a value. The panel's presence is about more than just following rules; it's about helping consumers make choices.
 - **Caution Statements:** Some ingredients found in dietary supplements, such as iron, carry health risks and require that warnings be placed on the product label. Ensure that any necessary warning statements are visible and legible to the consumer.

An FDA action was faced by a supplement company for an inaccurate label that failed to include certain ingredients. The company avoided problems in the future by updating its label to meet the FDA's requirements.

Key Action: Verify that all supplementary materials contain precise ingredient lists; a complete and informative Supplement Facts panel; and any and all precautionary statements that are required to keep consumers safe.

2. Making Compliant Health Claims in Supplement Advertising

Prompted by public complaints, the FTC investigates potentially deceptive advertising. When the FTC seeks an injunction against an advertiser, it must prove that the advertising is misleading. The advertisers can then defend their claims. If the FTC wins, substantial penalties can follow.

- - **Differentiating Structure-Function Claims from Disease Claims:** How a nutrient supports normal body functions is what the nutrient claim is all about. For example, many of the dietary supplements on the market today make claims like “supports healthy immune function.” These days, you won’t find many dietary supplements on the market making the good old-fashioned “cure”-related claims of the past. And that’s just as well, since most “cure” claims that were made in the past, such as the “cure” for “rheumatism,” in the 1960s, or the “cure” for “bad nerves,” in the 1950s, were not supported by solid scientific evidence.
 - **Substantiating Claims with Scientific Evidence:** Reliable scientific evidence must support all health claims, and in most instances, this means clinical studies. The FTC does not look kindly on health claims that are propped up by anecdotal evidence or that consist of no evidence at all.
 - **Avoiding Misleading Testimonials:** Consumer experiences must be used as the basis for writing testimonials. Those written on the basis of experiences of atypical results must carry a disclaimer to clarify that results can and do vary from person to person. Indeed, the use of the word “guaranteed” in any testimonial is a definite no-no.

Case Study: *A nutritional supplement firm was warned by the FTC for using testimonials that suggested unreal results. The company sidestepped any further trouble by rewriting the testimonials to reflect “typical” experiences. For more on the [FTC’s guidelines](#) concerning health claims, visit.*

Key Action: Only use health claims that are substantiated by science and make sure that any testimonials you use meet the guidelines set by the Federal Trade Commission.

3. Ensuring Ingredient Safety and Compliance with FDA’s cGMP Standards

Manufacturers of nutritional supplements must comply with the FDA’s Current Good Manufacturing Practice (cGMP) standards to ensure that the products they make are safe and of high quality.

- - **cGMP Requirements for Supplement Manufacturing:** The cGMP quality standards cover all aspects of the life of a dietary supplement from the very beginning—when the ingredients are being sourced—to the very end—when the supplement is ready for people to take. At each stage from sourcing to production, there is quality control. And with cGMPs, nothing is taken for granted. Manufacturers are required to document and to verify that what is supposed to happen at each step does indeed happen. If you want to know more about cGMPs, a good place to start is the FDA’s own explanation at the link given.
 - **Testing for Ingredient Purity and Potency:** Regular testing of raw materials and finished products is a must for manufacturers to verify ingredient purity and potency. Testing is necessary to make sure that what goes into products and the products themselves are free from any and all harmful contaminants. Testing is also necessary to verify that manufacturers are making only the label claims that they are allowed to make.
 - **Quality Assurance and Record-Keeping:** Keeping cGMP compliance is all about documentation. Maintain detailed records of every batch—production dates, ingredient sources, quality tests—that support traceability from finished product back to individual raw materials.

A dietary supplement manufacturer was penalized for not conforming to the FDA’s current good manufacturing practices (cGMPs), which led to the recall of its products. The company bore the brunt of this cGMP penalty, and we presume it did what most of us would do when recovering from a penalty: It built a quality assurance (QA) system. Regardless of the state of its QA system before the penalty, the company today complies with the cGMPs and is now presumably maintaining a state of

control in its quality department.

Key Action: Adhere to cGMP standards for all manufacturing processes. This includes testing of all ingredients and ensuring quality control throughout the entire system.

4. Complying with FDA and FTC Requirements for Supplement Marketing

The marketing of supplements is regulated by both the FDA and the FTC. Their shared concerns? Truthful representation. Transparent labeling. Accurate information for consumers.

- - **Avoiding Disease Claims in Marketing:** Unless they are FDA-approved as drugs, supplements cannot make disease claims. You should be making structure-function claims that tell the audience what the supplement is doing in normal, healthy people—that is, in the kind of people who would be taking your supplements. If you want to know what the FDA thinks a supplement can claim, go to the website of the FDA.
 - **Using Qualified Health Claims Carefully:** Health claims that are qualified need a disclaimer that describes the level of scientific support for the claim. Be careful with these, as they require evaluation by the FDA (and sometimes the FTC) and can be complex to implement correctly.
 - **Disclosing Material Connections:** The FTC mandates that companies reveal any significant connections—like payments or complimentary products—when they utilize endorsements or testimonials in their marketing. Clear and upfront disclosure preserves the vital element of consumer trust.

A warning from the FTC was issued to a supplement company for making health claims on its website that were not approved. The company still operates and now complies with the FTC's guidance on making health claims. According to the FTC, when making health-related claims, the standard for the supplements is that they not only have to work but also be safe. If the company makes a structure claim, the way it works should be in line with what science has shown. If the company makes a health claim, the supplement should not have serious side effects or any effects that outweigh the benefits.

Key Action: Do not make disease claims, use health claims that are not misleading and that qualify your statements, and disclose any material connections you have in endorsements.

Common Legal Risks and Penalties for Supplement Non-Compliance

Failing to comply with FDA and FTC standards can result in penalties, product recalls, and damage to one's reputation.

For more information on FDA and FTC compliance for nutritional supplements, see:

- [FDA Dietary Supplement Labeling Guide](#)
- [FDA cGMP Requirements](#)
- [FTC Health Claims Guidance](#)

Compliance with FDA and FTC regulations is necessary for brands in the nutritional supplement sector to safeguard their identity and prevent regulatory scrutiny. Adhering to the standards set for labeling and advertising, as well as following the good manufacturing practices laid out by the FDA, allows supplement companies to compete with confidence and without legal threat in a largely unregulated marketplace.