

3 FDA Legal Traps When Marketing your Dietary Supplement Product

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Ask an FDA Legal Expert

The world of dietary supplement claims and labeling requires a hard look at the kinds of claims FDA allows and FDA for dietary supplements.

It is not simply about how much you pay to get X number of labels reviewed. That kind of bottom-feeding, discount chain mentality gets a lot of companies X'd out of the market every year.

Consider the case of Seymour Heart, MD, the successful physician and You Tube personality who privately branded his dietary supplements. He got a label, wonderful, and was proud that he got the font size right and put the address of the manufacturer on it.

But then, he had made 11 different claims on the label, and that was something the FDA regulatory consultant did not review.

The FDA regulatory consultant vendor did not conduct any review of FDA warning letters for each particular claim.

Nor the FDA regulatory consultant talk about substantiation requirements that each of FDA and FTC impose on every dietary supplement claim, whether the claim is on the label itself or on the website or other marketing materials.

Dr. Heart got a nice flat fee deal and then later found himself in the crosshairs of regulatory enforcement for making drug claims for his product.

Now it's your turn.

See our previous post:

DIETARY SUPPLEMENT LEGAL REVIEW COULD SAVE YOUR COMPANY

If you want to sell healthcare products online, the legal hurdles can be steep.

FDA Legal Trap # 1: FDA Looks to Intended Use, Giving FDA Broad Enforcement Discretion

The intended use doctrine gives FDA a trump card over enforcement activity.

Because FDA is not limited to the definition of “labeling” in determining the “intended use” of a product, FDA can look to anything it deems relevant.

As well, FTC can enforce if it determines that the advertising is untruthful or misleading.

Therefore, materials on other websites that include promotional statements by the Company, can be considered evidence of intended use.

If a television spot or radio ad or newspaper ad, brochure, website, or other piece of marketing collateral, contains disease claims, then, FDA will take the claims that are not structure/function claims and use intended use doctrine to prove a violation. Any states sponsored, approved, endorsed, or repeated by the dietary supplement company on its own website or in social media sites are fair game for intended use.

See our previous post:

FDA TAKES AGGRESSIVE STANCE ON DIETARY SUPPLEMENT PROMOTION AND LABELING

The FDA has taken an aggressive stance on dietary supplement promotion and labeling in recent warning letters involving dietary supplement manufacturers’ and distributors’ response to consumer [...]

FDA Legal Trap # 2: Misbranding Dietary Supplements

FDA considers a dietary supplement “misbranded” if the product “labeling” is false or misleading in any way, or makes inappropriate claims. “Labeling” means not only the label on the box, but also any written, printed or graphic material accompanying the product (including the website).

Inappropriate claims include *disease* (or *therapeutic*) claims—those that claim a product will diagnose, cure, mitigate, treat, or prevent disease. If you make a disease claim, then the product gets regulated as a drug, which requires prior proof of safety and efficacy before selling the product in interstate commerce.

The most common *permissible* claims for dietary supplements are *structure/function* claims. These describe **the role of a substance intended to maintain the structure or function of the body, or general well-being from consumption of a nutrient or dietary ingredient.**

“Disease” is defined as “damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition.”

For example: the claim, “shrinks tumors” is a disease claim, and “supports the immune system” is a structure/function claim.

See our previous post:

MISLEADING ADVERTISING OF HEALTH PRODUCTS TRIGGERS FTC COMPLAINT AND PENALTIES

Dietary supplement manufacturers, medical device manufacturers and distributors, and makers of cosmetics should have legal review of their website advertising and marketing claims for Federal [...]

FDA Legal Trap #3: Misunderstanding Structure/Function Claims

One point is misunderstanding is about what the structure/function has to look like. There are certain magic words that are helpful—for example, here are some common structure/function claims: “energy boosting,” “ease stress,” “maintains a healthy body and mind,” or claims that use terms such as “stimulate,” “maintain,” “support,” “regulate,” or “promote” in association with a body system, organ, or function affected by the supplement, so long as the statements do not suggest disease prevention or treatment or use for a serious health condition a consumer lacks the ability to evaluate.

However, FDA looks at the overall meaning of the claim, not at whether certain terms such as, “supports,” are used. For example, when FDA published the structure/function final rule, it explained that “maintains healthy lungs in smokers” would be a disease claim, because it implies prevention of tobacco-related lung cancer and chronic lung disease.

FDA lists ten different ways that a product can make a prohibited disease claim. These include a claim that the product: has effect on a disease or a symptom of a disease; is a substitute for a drug; or has a role in the body’s response to a disease. Also, a claim that consumers would understand to refer to a disease, is a disease claim. For example, “controls blood sugar in persons with insufficient insulin” would be considered an impermissible disease claim as it could easily be understood to refer to treatment of diabetes.

Also where FDA regulates certain claims for OTC drugs, these are considered drug claims.

FDA Legal Trap #4: Neglecting Substantiation of Dietary Supplement (or Cosmetics) Claims

Both FDA and FTC require that all statements regarding a product need to be truthful and non-misleading. Among other things, this means that the advertiser must have adequate substantiation or underlying evidence for the intended use. Normally, this means the claim must be supported by “competent and reliable scientific evidence.”

FDA and FTC define “*competent and reliable scientific evidence*” as: “tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.”

In determining whether this standard has been met, FDA considers four issues:

1. The meaning of the claim(s) being made.
2. The relationship of the evidence to the claim.
3. The quality of the evidence.
4. The totality of the evidence.

Testimonials and other anecdotal evidence are insufficient to substantiate a claim. A testimonial can include:

descriptions of experiences of individuals using a dietary supplement product or ingredient. It might also include descriptions of the use of the product or ingredient by others, for example, by other cultures in the past or present. It might consist of an opinion or statement of an expert or someone who endorses the product. Anecdotal evidence generally would not be sufficient to substantiate claims regarding a diet.

FDA regards the following factors as important to establish whether information would constitute “competent and reliable scientific evidence.”

- Does each study or piece of evidence bear a relationship to the specific claim(s)?
- What are the individual study’s or evidence’s strengths and weaknesses? Consider the type of study, the design of the study, analysis of the results, and peer review.

- If multiple studies exist, do the studies that have the most reliable methodologies suggest a particular outcome?
- If multiple studies exist, what do most studies suggest or find? Does the totality of the evidence agree with the claim(s)?

Some of the issues that typically present substantiation issues include:

- Claims that the product is “clinically proven.”
- Claims about evidence (and the evidences do not meet FDA’s rigorous criteria above).
- Claims about expected results.
- Claims about mechanism or scientific process.

Unsubstantiated or inadequately substantiated claims are not only problematic from the FDA perspective; they can also generate lawsuits from private plaintiffs, including consumers and competitors. Law firms representing plaintiffs are actively looking for new entrants to the dietary supplement market and scrutinizing their websites and marketing materials for potential fodder for large, class-action lawsuits.

[1] Similarly, FTC considers: (1) Type of product (i.e., products related to consumer health or safety require greater substantiation); (2) Type of claim (claims that are harder for consumers to assess require more substantiation; this includes “health claims that may be subject to a placebo effect or technical claims that consumers cannot readily verify for themselves”); (3) Benefits of a truthful claim; (4) Cost/feasibility of developing substantiation for the claim; (5) Consequences of a false claim (including physical injury if the consumer relies on an unsubstantiated claim of therapeutic benefit); (6) Amount of substantiation that experts in the field believe is reasonable (the FTC looks to “accepted norms in the relevant fields of research” including those developed by a government or authoritative body).

FTC notes that claims can be *implied* by the advertising material as well as made *expressly*. In assessing the implied claims, the FTC looks to the “net impression” conveyed by all elements of an ad, including the text, product name, and depictions.

FTC also requires that disclosure of any necessary qualifying information be presented clearly and prominently so that it is actually noticed and understood by consumers. Similarly, where there are limited studies, and there are “significant limitations to each of the studies and a better controlled study is necessary to confirm whether the effect is genuine:” Disclosure of qualifying information must be clear and prominent.

See our previous post:

DIETARY SUPPLEMENTS, COSMETICS, MEDICAL DEVICES – WHY SUBSTANTIATING CLAIMS MATTERS

Substantiating claims matters whenever you bring a dietary supplement, cosmetic (or skin care product), or medical device to market – why?

The Structure/Function Notification to FDA

The manufacturer must prepare a notification to FDA no later than 30 days after the first marketing of the product that the manufacturer is making the structure/function statement in accordance with the applicable regulation (21 CFR § 101.93(a)).

Among other things, the manufacturer will need to include the structure/function disclaimer: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.” FDCA §403(r)(6). The statement must be “prominently displayed and in boldface type.” *Id.* The regulation is very specific about the *text*, *placement*, and *typesize* of the disclaimer.

The disclaimer itself is necessary, but not sufficient, to keep the product within the bounds of dietary supplement classification. In other words, simply putting the mandatory disclaimer on the label will not prevent FDA enforcement if FDA reasonably concludes that the “intended use” is as a drug.

Some Other Dietary Supplement Legal Hot Buttons

Other dietary supplement legal hot buttons include:

- Failing to disclose the compensation paid to an expert who endorses the product
- Overstating what consumers generally can expect from the product
- Over hyping the product with terms such as “best,” “miracle”
- Referencing any disease (obesity, anxiety, depression, insomnia, hypertension, high blood pressure, gastrointestinal disorder such as leaky gut syndrome....) or symptom of disease
- Making too many claims
- Using “clinical proven”
- Using OTC claims such as “antiviral” or “antibiotic”
- Using the term “inflammation”
- Making duplicate claims and being careless in terms of implied disease claims
- Talking about a scientific process or mechanism of action which makes the product sound like it has drug-like properties of effects
- Comparing the dietary supplement to a drug, or suggesting that the dietary supplement can substitute for the drug, or is “more effective” than the drug
- Not doing a substantiation review to see whether the product in fact has the evidentiary backing that FDA and FTC both demand
- Failing to get a legal read on each and every claim, and instead assuming that the product is “safe” and therefore beyond FDA scrutiny
- Underestimating the power of FDA and/or FTC to make the company’s life miserable once enforcement action is initiated, and relying on the false assumption that the worst thing that can happen is a warning letter.

Get Your Claims and Labels Reviewed for FDA Compliance

When you want to get your dietary supplement to market, it’s tempting to pay a vendor simply to get a label reviewed. When you do that, it’s likely your dietary supplement product will skip a whole bunch of regulatory hoops that, if left unaddressed, could become fodder for later enforcement activity.

Contact an FDA attorney who is knowledge about the ins and outs of dietary supplement regulation and laws governing product claims for dietary supplements.

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Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.