

Guest Column – September 2003

FTC Law and Supplement Advertising—Who’s Minding the Store?*

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Usually when we consider regulatory compliance for dietary supplements, we of course think of FDA law and specifically the Dietary Supplement Health and Education Act (“DSHEA”). The FDA primarily governs the formulation, ingredients, manufacture and labeling of supplements while advertisements are governed by a “sister” agency, the Federal Trade Commission (“FTC”). In general, the two agencies have shared jurisdiction under a long-standing memorandum of understanding, and they work closely together as to the monitoring of dietary supplements. The FTC has primary responsibility for claims in advertising, including print ads, TV and radio ads, infomercials, catalogs, and other direct marketing materials—such as the Internet.

The two agencies have issued joint open letters to the industry, e.g., cautioning joint enforcement actions against marketers of opportunistic products like Herbal Cipro and Stress Less supplements in the wake of 9/11 and again after the Iraq war. Your web pages must also be free of deceptive promotions, and include only claims for which there is adequate substantiation. Indeed, the FTC conducts periodic “surf days” when it examines the Internet for ads in violation. For the last 3 or 4 years, the FDA and FTC have also co-operated in a “Cyber Sting” strategy called Operation Cure.all, which begins with the FTC’s close scrutiny of Internet websites.

It is important to note that it is not only the manufacturer and the advertiser who have responsibility for the regulatory compliance of a dietary supplement advertisement. The FTC has stated that “all parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims.” Thus, everyone involved in promoting supplement products should be familiar with the basic FTC principles for advertising. In the past, the FTC has taken action against ad agencies, distributors, retailers, catalog companies, and infomercial producers, in addition to supplement manufacturers.

The fundamental rules are that a) the advertisement--in its net impression to the reasonable consumer--must be truthful and not misleading, and b) before crafting an ad, advertisers must have adequate substantiation for all objective product claims. Substantiation for claims may be based on a literature review of studies published by others, on an animal study, or even on documented traditional use. However, among other caveats, for any of these sources,

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the formulation, exact ingredient, and serving size must be identical to that in your product, the evidence must be relevant to the health benefit you are claiming, and your claim must include clear qualifiers to show the limits of the available evidence. For instance, traditional use substantiation could support the following claim: “Although not scientifically studied, the *Aloe vera* plant has been used for centuries by Native Americans to promote energy and mental clarity.”

The basic requirements for every material claim about a product are that it must not be deceptive or misleading, and “competent and reliable” scientific evidence is needed. Before creating advertising claims for a dietary supplement, many marketers think they first need to conduct a double-blind, placebo-controlled human clinical trial. This “Gold Standard” of substantiation is not necessary, but for a very strong claim including the phrase “clinically proven,” generally the FTC would expect at least one such controlled human clinical trial, performed at a U.S. university, and ideally published in a peer-reviewed journal. Be cautious in using the words “proof” or “clinical tests” because these can be red flags to the Commission. But the FTC has always used the guideline that marketers “set their own bar”; if only preliminary animal studies have been performed then “Animal studies indicate....” is accurate.

Now we know that an advertiser is responsible for the substantiation and accuracy of implied claims as well as express claims in ads, but what are examples of “implied” claims? Examples: There is no mention of “breast cancer” in the ad, but the well-recognized pink ribbon symbol appears prominently. The words “arthritis” and “inflammation” do not occur in the advertising copy for an aloe supplement, but there is a large picture of a skeleton with hot red fire emanating from every joint. Note: As to labels, under the final FDA regulation on structure/function claims (published on January 6, 2000), the name of the product may not convey an implied disease claim, e.g., D-Congest, or Rx Rheum, or ArthriCure.

Marketers often wonder: How can I use testimonials or endorsements in my ad? Do I need a disclaimer with each testimonial, and what other kinds of disclosures are required in an ad? Anecdotal evidence of a health benefit or efficacy of a supplement product—based solely on the experience of individual consumers—is generally not sufficient to substantiate an ad claim. Also, if other substantiation fails to show that an individual experience is representative or typical, then a disclaimer is necessary. The disclaimer must be clear and conspicuous. For example, after the claim “I blasted off 40 pounds in 2 weeks,” the vague “Results may vary” in fine print is not a sufficient disclaimer. Rather, adequate qualification would be a prominent disclaimer immediately adjacent to the quotation, in the same size print, reading, “These results are not typical. Average weight loss achieved in a clinical study was 7 pounds in 2 weeks.”

For a spokesperson or endorser, the ad must disclose any material connection between the endorser and the advertiser—any personal, financial, or managerial connection, e.g., if the endorser also happens to be an officer of the company. For an expert, make sure that the endorsement is not misleading in any respect, that the expert’s qualifications are relevant and appropriate for the claim being made, and that the expert has conducted adequate examination of the product and its effects and a review of the scientific literature. For example, “Dr. Flimsy” stating that “aloe improves joint mobility and flexibility” is deceptive and misleading, implying an M.D., especially if a) Ms. Flimsy is only a Doctor in the sense that she has a Ph.D. . . . in Art History!, and b) if Dr. Flimsy is the sister of the company president, whereas that relationship is not disclosed. Please see my own disclaimer below!

Marketers need to be aware of and in compliance with FDA law as well as FTC law for dietary supplement promotional materials. The reason is the principle of intended use. By regulation, the FDA may consider any materials accompanying a product for “indicia” or indications of its intended use. Although the FDA has primary responsibility for labeling (including container labels, box labeling, package inserts, and fliers distributed at the point of sale), that agency is authorized to examine all materials (including ads) surrounding the product to determine the intent for its use by the consumer. In case law, specifically judicial opinions dating back to the 1960s, federal courts have looked to the advertising of a product to determine intent of use, and FDA category of the product. For example, an aloe supplement with a letter-perfect label (compliant with DSHEA and all of the accompanying FDA regulations) could nonetheless be considered an unapproved new drug by the FDA, if its promotional materials stated, “A great natural alternative to OTC cold and flu medications.” The result would be a Warning Letter, and subsequently a seizure action or injunction is possible.

<u>Structure/Function Claim- Intended as Supplement</u>	<u>Disease Claim—Intended as a Drug</u>
Aloe supports cartilage and joint function.	Aloe prevents and treats arthritis.
Aloe helps maintain good digestion and intestinal flora.	Aloe relieves irritable bowel syndrome.
Aloe helps maintain healthy blood pressure.	Aloe reduces high blood pressure.

FTC law can be complicated, but there are pamphlets and guidebooks available, where you can read more about “do’s and don’ts” for advertisements of dietary supplements. In fact, the FTC itself published an excellent booklet (in November 1998) entitled, “Dietary Supplements: An Advertising Guide for Industry.” I call this the “Green booklet” because of its botanical-colored cover, and it contains several hypotheticals and case studies. Also, for guidance documents, announcements, and other materials, go to the FTC website at www.ftc.gov. It has a very useful home page and also a search option.

Given that there is strong scientific evidence that aloe has excellent therapeutic, disease treatment benefits, it is very frustrating for marketers of aloe supplements that such disease claims may not be used. However, remember that DSHEA stands for the Dietary Supplement Health and Education Act, and Section 5 of DSHEA provides for a type of “safe harbor” for disease claims in the form of educational information about a dietary ingredient. Sometimes called “Third-party Literature” because usually it is written by someone independent from the marketer, this Section 5 Literature allows for a company to publish scientific, medical information about Aloe that includes therapeutic benefits. But there’s a Catch-22: Section 5 literature may not be an advertisement or promotional in any way . . . but that’s a story for another issue.

*** This article is not meant, and should not be construed, as a legal opinion, or legal advice, but rather is intended to provide some examples and general principles as to advertisements for dietary supplements, based on Federal Trade Commission law.**