

Herbal Supplement Industry Fights Back

COMPANY FILES SUIT AGAINST THE FTC TO PROTECT RIGHT TO SHARE HISTORICAL USE CLAIMS WITH CONSUMERS.

Editorial Staff

Houston attorney Richard Jaffe, Esq., filed the suit on behalf of New Mexico-based Native Essence Herb Company and its owners, Mark and Marianne Hershiser.

"Herb sellers should be able to tell consumers that an herb has a long historical use to treat a disease," said Jaffe, a perennial health care litigator and the author of *Galileo's Lawyer*, an inside look at the battles between government and complementary and alternative medicine. "The FTC's prohibition of this kind of truthful information is unreasonable and unconstitutional."

According to the suit, "The FTC's dietary supplement advertising guidelines with respect to claims concerning the historical use of herbs violate the First Amendment," and "Plaintiffs can accurately and completely quote or provide a link to information contained on any informational federal government website concerning herbs or herbal remedies." The suit also seeks "a preliminary and permanent injunction barring the FTC from enforcing its policies prohibiting truthful statements concerning the historical use of herbs against the Plaintiffs and all other persons or companies."

In April, the FTC informed Native Essence that its Web site "contained false, leading or unsubstantiated claims," including claims that Native Americans and other cultures have used some of the listed herbs for hundreds or thousands of years. The FTC, which had received no consumer complaints, threatened to file an injunction against the company - despite the Hershisers' contention that much of the historical information posted on their site is taken from federal government Web sites. The commission also sent a stipulated consent agreement requesting all proceeds from the sale of specific herbs unless Native Essence could demonstrate it lacked adequate funds to do so.

The Hershisers removed the historical information from the company Web site, but then chose to file suit against the FTC rather than acquiesce to the commission's demands. They hope the courts will decide herbal companies can provide consumers with information taken from government Web sites and other recognized legitimate sources.

"What (the Hershisers) did was put on their Web site information from studies done around the world," said Jaffe. "(Mark Hershiser) doesn't make this stuff up. And a substantial portion of what he was posting is from federal government Web sites. But the argument is that if the government posts this information on a Web site it's OK, but it's not OK if you're a company trying to sell herbs."

"This is a precedent-setting case," added Jaffe. "The issue has never been litigated; it not only affects the Hershisers, but all companies which sell herbal products."

The FTC guideline, *Dietary Supplements: An Advertising Guide for Industry*, addresses historical claims in section II C (2), "Claims Based on Traditional Uses":

In assessing claims based on traditional use, the FTC will look closely at consumer perceptions and specifically at whether consumers expect such claims to be backed by supporting scientific evidence. Advertising claims based solely on traditional use should be presented carefully to avoid the implication that the product has been scientifically evaluated for efficacy. The degree of qualification necessary to communicate the absence of scientific substantiation for a traditional use claim will depend in large part on consumer understanding of this category of products. As consumer awareness of and experience with "traditional use" supplements evolve, the extent and type of qualification necessary is also likely to change.

There are some situations, however, where traditional use evidence alone will be inadequate to substantiate a claim, even if that claim is carefully qualified to convey the limited nature of the support. In determining the level of substantiation necessary to substantiate a claim, the FTC assesses, among other things, the consequences of a false claim. Claims that, if unfounded, could present a substantial risk of injury to consumer health or safety will be held to a higher level of scientific proof. For that reason, an advertiser should not suggest, either directly or indirectly, that a supplement product will provide a disease benefit unless there is competent and reliable scientific evidence to substantiate that benefit. The FTC will closely scrutinize the scientific support for such claims, particularly where the claim could lead consumers to forego other treatments that have been validated by scientific evidence, or to self-medicate for potentially serious conditions without medical supervision.

According to Jaffe, no case law exists to support enforcement of the guideline. A complete copy of *Dietary Supplements: An Advertising Guide for Industry* is available online at www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.shtm#IIc.

Sources: Law Offices of Richard A. Jaffe, June 25, 2008; Associated Press, June 28, 2008.

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