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Gray Zone Between FDA And FTC Nutraceutical Regulation

Law360, New York (August 13, 2013, 8:53 PM ET) -- As we have come to expect in our litigious society, the rise of nutraceuticals in the consumer market has led to a concomitant rise in litigation over nutraceutical labeling and marketing. A nutraceutical, in the broadest sense, refers to any food product that claims to have health or medicinal benefits. These range from isolated nutrients and dietary supplements to genetically engineered foods, herbal products and processed foods.

The often hyperbolic claims touted in labeling and advertising for these products provide fertile ground for "consumer fraud"-type claims, particularly in states like California that broadly define a cognizable injury, and generally permit class actions to pursue remedies for such injuries. Nutraceutical manufacturers frequently assert federal preemption as a defense to these actions, but the applicable law and regulatory authority are far from clear.

This article briefly discusses the overlapping authority of the U.S. Food and Drug Administration and the Federal Trade Commission over the labeling, advertising and promotion of nutraceuticals.

Regulatory Authority of FDA Vs. FTC — Dangers of Overlap and Falling Through the Cracks

The FDA's authority to regulate nutraceuticals stems from the Federal Food, Drug and Cosmetic Act (FDCA) as amended by the Dietary Supplement Health and Education Act. The FTC's authority emanates from the Federal Trade Commission Act (FTC Act).

The two agencies operate under a liaison agreement under which the FTC possesses primary enforcement responsibility for claims made in advertising, while the FDA has primary enforcement responsibility for claims made in labeling and packaging.

The difference between labeling and advertising, however, is not always clear. The FDA has stated that in certain circumstances, information about FDA-regulated products that is disseminated over the Internet by a regulated company can be considered labeling, in line with the definition in Section 201(m) of the FDCA, especially when consumers may purchase the product directly from the website.

Additionally, some courts have interpreted “labeling” to include any visual, audio or other material that bears a strong contextual relationship to the product and is distributed at the point of sale. These actions have blurred the lines as to which agency has regulatory authority and oversight.

While the agencies have published guidance regarding the intersection of authority between the FDA and the FTC, the guidance not only fails to address all areas of the underlying source of uncertainty but also has quickly become outdated by rapidly changing trends in health food development, promotion and methods of communication (i.e.,. blogs, social media, etc.).

In recent years, methods of purchasing nutraceuticals have grown to include infomercials, websites and even cell phone apps. There are new vehicles for marketing, such as blogs and social media (i.e.,. Twitter, Facebook, etc.). The social media and Internet boom has particularly amplified the confusion surrounding the distinction between labeling versus advertising.

One example of the blurred line involves Phusion Projects LLC, makers of Four Loko, a caffeinated alcoholic beverage allegedly linked to injuries and deaths. Both the FDA and the FTC sent warning letters to Phusion Projects on Nov. 17, 2010, stemming from the same alleged acts.

Additionally, in 2011, the FTC required packaging and label changes for Four Loko drinks due to claims made regarding the percent alcohol volume by can, even though the FDA ostensibly has primary enforcement over labeling and packaging.

Likewise, there are multiple instances of the FDA sending warning letters to dietary supplement companies concerning claims made on websites, which most would consider advertising rather than labeling, and thus, within the purview of the FTC.

In the recent case of Wilson v. Frito-Lay North America Inc., 2013 U.S. Dist. (N.D. Cal. Apr.1.2013), the U.S. District Court for the Northern District of California considered whether company websites identified on product labeling constitute “labeling” under the FDCA. Plaintiffs claimed the statement “Visit our website @ fritolay.com” printed on a bag of chips transformed every statement on that Frito Lay website into labeling.

The court acknowledged that statements not actually printed on a label can be “labeling” but only if those statements serve the purpose of labeling, which is to supplement or explain the product. The court found that none of the website language was labeling because it did not explain or supplement the product and because consumers were not told the website would inform them of the details of the products’ nutritional facts.

Somewhat surprisingly, the plaintiffs neither raised nor did the court discuss the FTC's authority over advertising and the application of that authority to language on the website, which reasonably could be construed as advertising.

Missing in Action — Regulatory Guidance for Marketing by Social Media

Both the FTC and the FDA have treated social media as advertising, and the FTC has touched on the issue in its guidance. Despite requests, the FDA has yet to release guidance about marketing via social media, opting instead to address the issue on a case-by-case basis.

It has long been a matter of speculation whether "liking" on Facebook or "retweeting" on Twitter may be construed as an endorsement of the content. Recently, the FDA issued a warning letter to AMARC, a dietary supplement company, for "liking" an unapproved claim regarding its product, PolyMVA, on Facebook.

Specifically, the warning letter alleged that PolyMVA was being promoted as a drug and pointed to, among other things, a March 10, 2011, post, which was “liked” by PolyMVA. The post, by a third party, stated: “PolyMVA has done wonders for me. I take it intravenously 2x a week and it has helped me tremendously. It enabled me to keep cancer at bay without the use of chemo and radiation…Thank you AMARC[.]”

The FDA's warning letter suggests that it interprets a Facebook "like" as an endorsement of the statement. Here, the FDA's attention to the supplement company's Facebook activity may have been because it was making unapproved drug claims.

Advertising of drugs, as well as advertising of a dietary supplement as a drug (i.e., claiming it can diagnose, treat, cure or prevent a disease) is within the FDA's purview; the FTC, however, has the authority to regulate advertising of food and dietary supplements.

It remains to be seen whether the FDA's scrutiny of Facebook activity will extend to other types of third-party claims (i.e., nondrug claims) regarding dietary supplements or food products.

Congress Is Seeking Guidance from FDA

In the FDA Safety and Innovation Act, a bill signed into law in July 2012, Congress gave the FDA a July 2014 deadline by which to issue regulatory guidance on the appropriate use of social media for promotion of "medical products that are regulated by [the FDA]."

The agency has been studying the issue since 1996. "Medical products" is not defined in the act, but in a 2009 public hearing announcement by the FDA on this topic, it indicated that the agency interprets "medical products" to include "prescription drugs for humans and animals, prescription biologics, and medical devices." Thus, the guidance may not extend to foods and dietary supplements.

There has been much speculation that the FDA will not meet the deadline, continuing to leave manufacturers and marketers in the dark. Meanwhile, what about the FTC's authority to regulate advertising? Is social media promotion of nutraceuticals, labeling or advertising? Or both?

Despite the lack of concrete rules, some insight into the FDA's thoughts on the issue can be gleaned from the numerous hearings, notices and FDA enforcement actions (including untitled letters and warning letters) that address promotion through product websites, sponsored internet links, online banners and Facebook.

Additionally, the FDA did issue one draft guidance document discussing social media in the context of unsolicited requests for off-label information, but that guidance was limited to prescription drugs and medical devices.

FTC Issues Some Guidance for Use of Social Media

Earlier this year, the FTC updated its guidelines regarding e-commerce disclosures, specifically instructing that companies should be mindful that consumers will be reading the content on various types of devices (i.e., computer, smartphone and tablet) and that all disclosures need to be clear and conspicuous regardless of the device.

Additionally, the FTC provided a template on how to disclose ads within posts on social media platforms. For instance, social media posts by a paid spokesperson, including space-constrained messages such as tweets, need to disclose that it is a paid endorsement, as well as state typical results if the statement is a testimonial.

This will affect advertisers, social media participants, bloggers and startup companies, to name a few. And it stands to reason that the FTC will also expect digital advertising regarding nutraceutical products to contain full disclosure of nutritional facts and any other required information, even under Twitter's 140-character limit.

One intriguing issue that remains unclear is the extent to which a company may be responsible for posts by third parties regarding results with products. If the claim is made on a page belonging to the company, does the company have to follow up with a statement that results are not typical and may vary? What if a tweet is retweeted? Neither the FDA nor the FTC have officially weighed in on these issues unique to social media.

Does the Liaison Agreement Clarify or Confuse Agency Roles?

The purpose of the liaison agreement between the FDA and the FTC is to reduce the duplication of regulation and conserve agency resources by eliminating confusion as to which agency regulates what. But increased collaboration between the two agencies has left the jurisdictional lines hazier than ever.

In recent years, the FDA and the FTC expressed a renewed commitment to interagency collaboration in regulating the promotion of food, beverage and dietary supplement products. The agencies established “working groups” specifically to share information regarding marketing activities for such products, which seems to indicate that agency roles in regulating nutraceutical companies may well become more intertwined and less clear-cut over time.

Examples of such collaboration include a 2011 FDA warning letter sent to Tennessee Scientific in which the FDA cited FTC advertising standards as a partial basis for challenging the company's conduct and requested the company respond to the FTC regarding potential violations.

Similarly, the FTC's warning letter to Phusion Projects referenced the FDA's warning letter sent the same day, stating "FDA's warning that caffeine is an 'unsafe food additive' as used in Four Loko, is a relevant consideration in the FTC's analysis of whether the marketing of caffeinated alcohol products such as Four Loko and Four Maxed is deceptive or unfair under the FTC Act. In the past, the FTC has accorded significant weight to FDA findings regarding product safety and efficacy."

Other examples of interagency collaboration include FTC orders requiring marketers to gain FDA approval before making certain claims in advertising regulated by the FTC and press releases announcing the FTC and the FDA's simultaneous investigation of specific companies to assess violations of the FDCA and the FTC Act.

More Questions Than Answers as to Agency Roles and Nutraceuticals

In short, the waters remain murky as to which regulatory body clearly regulates what when it comes to nutraceutical product marketing. What is clear is that the FDA and the FTC have a symbiotic relationship. The agencies' increased cooperation likely means heightened regulatory scrutiny of the nutraceutical arena.

And of course, with increased regulation comes increased litigation and increased financial risks associated with defending against FDA and FTC enforcement. While the regulatory consequence of an FDA or FTC warning letter may not seem terribly severe on its own, the reality is that these letters are public information and, therefore, frequently the genesis of consumer class action claims.

Until there exists a clear distinction between what constitutes labeling and advertising in nutraceutical marketing and which regulatory body has authority, nutraceutical manufacturers would do well to closely monitor the two agencies' actions and statements, as well as litigation trends involving nutraceuticals. Companies, their marketing teams and their legal counsel should be proactive in understanding the law and regulatory environment and should consider creating compliance programs that will help ensure that marketing efforts are regularly evaluated for conformity.

In the meantime, manufacturers and marketers of nutraceuticals should strive for compliance with both FDA and FTC regulations and guidelines and should expect product websites and social media pages to continue to receive heightened scrutiny by one or both agencies. When in doubt, the manufacturer should follow a "double dose" of precaution by anticipating overlap between the FDA and the FTC.

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