Working Together

How growing FDA and FTC collaboration changes the regulatory landscape for food and dietary supplement marketers.

BY JOHN E. VILLAFRANCO, RAQIYYAH R. PIPPINS, AND KRISTI L. WOLFF; KELLEY DRYE & WARREN LLP

Increased collaboration between FDA and the FTC is creating a notable shift in regulatory enforcement that blurs the jurisdictional lines between the agencies. This growing partnership also requires a new assessment of potential liabilities for companies making health-benefit claims for their products.

For example, on February 1, 2011, FDA issued a warning letter to dietary supplement maker Tennessee Scientific Inc.[1] alleging that certain claims on the company's website constituted unauthorized disease claims, which also caused the dietary supplement products to be unapproved drugs. What is unusual about this particular warning letter is that FDA cited FTC advertising standards as a further basis for challenging the company's conduct. More specifically, after citing alleged violations of the Food, Drug and Cosmetic Act ("FDCA"), the letter states: "it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating the claims are true at the time they are made." While the FTC is not a signatory of the letter, the letter requests that Tennessee Scientific respond to the FTC regarding the potential violations of the FTC Act.

FDA's warning letter to Tennessee Scientific is the latest example of a growing confluence of FDA and FTC regulation, which has been occurring since the beginning of the Obama Administration.[2] While FDA and the FTC share jurisdiction for regulating the promotion of food and dietary supplement products, for decades the agencies have worked

under a Memorandum of Understanding ("MOU")[3] that provides FDA with primary responsibility for product labeling and the FTC with primary responsibility for advertising. "Labeling" is defined by the FDCA to include "all labels and other written, printed or graphic matter (1) upon any article or any of its container or wrappers, or (2) accompanying such article."[4] Traditionally, FDA has interpreted labeling broadly to include anything involved in informing the sales transaction, including written material sold with a product (or near a product in a store), and, in some cases, product websites.[5] "Advertising" has been interpreted to include all promotional materials other than the product label, such as print advertisements, commercials, and product websites.

In practice, industry has considered the regulatory standards for labeling and advertising claims to be as separate and distinct as the statutes under which FDA and the FTC garner the authority to regulate such claims in the first instance.[6] For example, generally speaking, marketers traditionally interpreted the FTC's food and dietary supplement marketing enforcement policy as permitting claims to be used in commercials, and other forms of advertising that are not authorized for use on labels or in labeling under FDA jurisdiction.[7] Simply put, marketers believed that there were more-restrictive standards for labeling claims. They understood the FTC to have distinct substantiation standards that, while deferential to FDA, permitted the use of truthful, but effectively qualified, health-benefit information that could not be used in labeling (e.g., representations involving "health claims" that have not specifically been authorized by FDA, or claims involving the term healthy, even though the product did not meet FDA's nutritional profile for the term). Recently, however,

there has been an unprecedented level of FDA and FTC collaboration that requires industry to rethink its understanding of the FTC's enforcement policy regarding food and dietary supplement marketing campaigns.

Early in the Obama Administration, the FDA and FTC expressed a commitment to interagency collaboration in regulating the promotion of food, beverage, and dietary supplement products, and established "working groups" to share information regarding marketing activities for such products.[8] Consistent with this commitment to monitoring food and dietary supplement marketing, FDA Commissioner Dr. Margaret Hamburg initiated a number of organizational and policy changes within FDA, including the creation of an "Office of Foods"[1] responsible for, among other things, "leading FDA efforts to…ensure that food labels contain clear and accurate information on nutrition."[1] Simultaneously, FTC Bureau of Consumer Protection Director David Vladeck expressed his intent to be more active in food and dietary supplement advertising, beginning with efforts to "strengthen" the substantiation standards for health-benefit claims through use of more-specific language in consent orders. Mr. Vladeck also warned industry to anticipate "increase[d] [interagency] coordination with respect to strategic planning and case selection," which he expected to "enhance the enforcement efforts of both agencies."[9]

The agencies delivered on Mr. Vladeck's warning with a series of joint FDA and FTC activities, which have transformed the liability and risk-management considerations for food and dietary supplement marketers. The primary area of collaboration between FDA and the FTC has been their review of health-benefit claims for functional foods and dietary supplements (e.g., "claims that such [products] will boost the immune system, assist with memory and brain function, boost metabolism, protect the heart, or afford other physical or mental health benefits."[10]) While not an exhaustive list, notable interagency collaborations in the past eight months include the following:

- FDA warning letters referencing potential violations of the FTC Act, which document FDA's position that certain claims present in advertising materials within the FTC's jurisdiction would not be approved by FDA for use in labeling. For example, FDA's aforementioned warning letter to Tennessee Scientific Inc. warns that certain claims that FDA considers to be in violation of the FDCA also may violate the FTC Act and directs Tennessee Scientific Inc. to reply to the FTC regarding the company's substantiation for such marketing claims.

- FTC orders requiring marketers to gain FDA approval prior to using certain claims in advertising regulated by the FTC. For example, the final consent orders pertaining to Nestlé Healthcare Nutrition,[11] Iovate Health Sciences U.S.A.,[12] and The Dannon Company,[13] and a proposed consent order submitted to POM Wonderful LLC,[14] include language that would require specific disease claims to be "specifically permitted in labeling for [a] product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990" before the claim could be used in the advertising for such product.

- Press releases announcing the FTC and FDA's simultaneous investigation of specific companies to assess violations of the FDCA and FTC Act. For example, in November 2010, the FTC sent letters to four marketers of caffeinated alcohol drinks, citing evidence "suggesting that alcohol containing added caffeine presents unusual risks to health and safety" and warning that marketing of such beverages may constitute an unfair or deceptive practice, in violation of the FTC Act.[15] On the same day, FDA announced that it was sending letters to the same four companies, warning that, as used in their products, caffeine is an "unsafe food additive" under the FDCA.[16]

These deliberate and coordinated enforcement activities confirm the high level of cooperation between FDA and the FTC and significantly change the liability risks

associated with food and dietary supplement marketing strategies in several ways. First, agency collaboration reinforces the importance of marketers considering FDA labeling standards and guidance documents for all health-benefit claims, even where the health-benefit claims are used solely in FTC-regulated advertising. Second, increased FDA and FTC coordination heightens the risk of companies having to financially defend against FDA and FTC enforcement simultaneously. Finally, regulatory actions like the Tennessee Scientific warning letter confirm that product websites are receiving heightened scrutiny and may be viewed by regulators as both labeling and advertising. Companies that reference websites on product labels must be especially careful to ensure that the information on the referenced website is consistent with both FTC advertising and FDA labeling standards, including website names, meta-tags, and clinical study titles and summaries.

The increase in FDA-FTC collaboration also illustrates the need for clarity regarding the appropriate use of FDA- or FTC-specific definitions and standards across agencies. For example, the FDA has formal definitions for terms such as *health claims,*[17] *disease claims,*[18] and *healthy,*[19] and often issues guidance documents regarding its position on the appropriate classification of products and ingredients for the purpose of FDA regulation. As FDA and FTC increase interagency collaboration, industry would benefit from the FTC formally clarifying whether it will be adopting FDA's definitions and guidance documents as the standard for FTC regulation as well.

Approach with Caution

It is no secret that marketers are striving for ways to legally and effectively educate consumers about the health benefits provided by food and dietary supplement products. Increased FTC and FDA collaboration, however, requires marketers to consider advertising strategies that can sustain heightened scrutiny. Until further clarity is provided regarding the application of FDA's labeling standards to FTC-regulated advertising, industry should fully consider FDA and FTC standards when creating website or other product-related promotional materials using health-benefit claims. The agencies' efforts to harmonize FDA and FTC regulation of health-benefit claims may require industry to harmonize its labeling and advertising substantiation review as well. N

View references online at NutritionalOutlook.com/1105/GlobalRegulations

John E. Villafranco *is a partner and* ***Raqiyyah R. Pippins*** *and* ***Kristi L. Wolff*** *are associates in the advertising and marketing practice at Kelley Drye & Warren LLP in Washington, DC.*