

FDA Warning Letter Cites FTC Act and Further Confirms Cooperation Between Agencies

February 16, 2011

On February 1, 2011, the Food and Drug Administration (FDA) issued a warning letter to dietary supplement maker Tennessee Scientific, Inc., relating to a number of product claims on the company's website. The letter states that the products are unapproved drugs and that the claims are unauthorized disease claims. The claims at issue involve treatment and mitigation of a host of diseases including numerous cancers, inflammatory conditions, and heart disease.

What is unusual about this particular warning letter is that the FDA cites the Federal Trade Commission's (FTC) advertising standards as a further basis for challenging the company's conduct. The letter states: "In addition, 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."

FTC enforcement actions pertaining to Nestlé, Iovate and Dannon have garnered significant attention in the food and dietary supplement communities because the consent orders in these cases require the advertiser to obtain FDA approval before making certain health benefit claims in advertising.

For marketers of foods and dietary supplements, the Tennessee Scientific warning letter is notable for the following points:

- it further confirms the high level of cooperation ongoing between the FDA and FTC given that this is the second joint warning letter issued by the agencies in recent months;
- it confirms that websites may be considered both labeling and advertising, and that features such as product name, website name, metatags and clinical study titles on websites may give rise to actionable claims by either agency; and
- by sending a joint letter, the FTC has already established a record that Tennessee Scientific does not have FDA approval for their products or their product claims. Although FTC Consumer Protection Bureau Director David Vladeck recently stated that FDA approval is not a prerequisite to health benefit advertising claims, a joint letter sets an easy stage from which the FTC can take the position that unauthorized disease claims violate the FTC Act. This action further supports the conclusion that the drug-like substantiation provisions in the Nestlé, Iovate and Dannon orders are the new de facto standards for all advertisers making similar claims.

Industry stakeholders should evaluate the substantiation behind their products' health benefit claims in light of these recent developments and fully consider FDA and FTC standards when creating

website or other claims content that could be considered advertising or labeling.