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FOOD & BEVERAGE LAW: NEWS AND ANALYSIS

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For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

Mark Anstoetter
816-474-6550
manstoetter@shb.com

or

Madeleine McDonough
816-474-6550
202-783-8400
mmcdonough@shb.com

FTC WARNING LETTERS: A NEW ERA OF ENFORCEMENT?

The Federal Trade Commission (FTC) recently announced that it had sent warning letters to 11 companies that promote omega-3 fatty acid dietary supplements. The letters indicated that the companies should review their product labeling and packaging claims, as well as product advertising, to ensure that the claims are adequately substantiated.

The commission's issuance of these letters is significant because of the FTC's action to regulate dietary supplement labeling claims, an area that has for nearly four decades been regulated by the Food and Drug Administration (FDA).

Commission Takes Aim at Ad Links Between Omega 3 and Children's Visual and Mental Development

According to a February 16, 2010, press release,[1] the FTC's Division of Advertising Practices in January sent warning letters to 11 companies that promote supplement products containing omega-3 fatty acids intended for use by children ages 2 years and older. The letters reference an investigation the FTC conducted last fall into claims made by Northwest Natural Products (NNP) for possible violations of sections 5 and 12 of the Federal Trade Commission Act (FTC Act)[2] in connection with the advertising and promotion of three dietary supplements in NNP's L'il Critters line of Gummy Fish vitamins for children.

Following the FTC's investigation into whether NNP had adequate substantiation for the claims it was making, NNP modified all marketing materials for its products, including product packaging and labeling. NNP also discontinued dissemination of print advertisements and Web site materials for Gummy Fish that contained the claims at issue.

The omega-3 letters indicate that FTC staff has identified various express and implied claims on product packaging and in advertising representing that the products boost, improve, enhance, or support brain and vision function and development in children. The FTC recommends that the unnamed letter recipients review their companies' advertising, product packaging and labeling, as well as other promotional materials to ensure that any claims made for the products at issue are adequately substantiated with competent and reliable scientific evidence. The 11 companies were given two weeks to respond to the FTC describing any actions taken in response to the letters to ensure compliance with the FTC Act.

Omega-3 Action Blurs Jurisdictional Lines

Under a 1971 Liaison Agreement, the FTC and FDA share "complementary jurisdiction" over dietary supplement marketing.[3] The FTC serves as the primary regulator of advertising for foods (including dietary supplements), while FDA exercises primary enforcement responsibility for claims made in food and dietary supplement "labeling."[4] FTC Guidance further explains the division of regulatory jurisdiction between the agencies as follows:

> As applied to dietary supplements, the FDA has primary responsibility for claims on product labeling, including packaging, inserts, and other promotional materials distributed at the point of sale. The FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials. Marketing on the Internet is subject to regulation in the same fashion as promotions through any other media.[5]

The FTC's omega-3 warning letters object not only to claims and statements made in dietary supplement advertising, but also to claims made on product labels and packaging. As a result, the warning letters present an unusual instance of the FTC exercising regulatory authority over supplement product labels, which has historically been an area subject to only FDA regulatory enforcement under the 1971 agreement between the agencies.

Still, the FTC is not alone in blurring the clearly defined lines of regulatory jurisdiction governing claims made for FDA-regulated products. In 2001, FDA issued a warning letter to Ocean Spray for claims made on the company's Web site, referred to in the FDA's letter as "labeling."[6] Even though content on a company's Web site has traditionally been viewed as advertising that would fall within FTC's bailiwick, FDA has continued to take the position that certain statements made on a company's Web site can be "labeling" subject to FDA's enforcement authority, e.g., where the Web site address is provided on a product label or if the Web site serves as a portal for product sales.[7]

Implications for Industry

The FTC's recent issuance of warning letters concerning claims made on dietary supplement labels represents a further blurring of the complementary jurisdictional lines agreed to by the FTC and FDA. It is likely that the FTC will continue exercising enforcement action over claims made on the labels of FDA-regulated products under its FTC Act authority, rather than waiting for FDA to take action against a product for being misbranded under the Federal Food, Drug, and Cosmetic Act (FDCA).

Accordingly, industry can no longer assume that the FTC will adhere to the jurisdictional boundaries established by the 1971 agreement and must ensure that both labeling and advertising claims comply with the substantiation requirements of the FTC Act. Moreover, in light of FDA's position that Web content can be considered product labeling, companies should also ensure that any statements or claims made on company Web sites, and possibly in all advertisements, are made in accordance with the FDCA and FDA regulations.

Finally, while the FTC's issuance of warning letters targeting claims on product labeling is not in line with its 1971 agreement with the FDA, it is consistent with statements made by an FTC staff attorney at a January 2010 conference sponsored by the Food and Drug Law Institute.

During that conference, Christine Lee DeLorme, an attorney with the Division of Advertising Practices at the FTC indicated that the commission will be closely scrutinizing claims related to omega-3 fatty acids, probiotics, fiber products, antioxidants, and products marketed for use by children. The recently issued warning letters cover two of those categories— products marketed for use by children and claims related to Omega-3 fatty acids. As a result, companies that manufacture products that fall within any of these categories are on notice that they may well be subject to FTC scrutiny.

This analysis was prepared by Sarah Sunday, Of Counsel, in SHB's Washington, D.C., office.

Endnotes

1 Press Release, Federal Trade Commission, FTC Warning Marketers of Children's Omega-3 Fatty Acid Supplements That Claims About Brain and Vision Benefits May Be Deceptive (Feb. 16, 2010) available at http://www.ftc.gov/opa/2010/02/omega.shtm.

2 15 U.S.C. §§ 45 and 52. Section 5 of the FTC Act prohibits unfair trade practices while section 12 prohibits the dissemination of false advertisements.

3 *See* Federal Trade Commission, In the Matter of Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Proposed Rule; at 1 n. 1 (Aug. 27, 1998) (citing FTC-FDA Liaison Agreement, 4 Trade Reg., Rep. (CCH) ¶ 9851); *see also* FDA MOU 225-71-8003, Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration.

4 The Federal Food, Drug and Cosmetic Act defines "labeling" as "all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

5 Federal Trade Commission, Dietary Supplements: An Advertising Guide for Industry, (Apr. 2001), p. 1.

6 *See* Food and Drug Administration Warning Letter to Robert Hawthorne, President, Ocean Spray Cranberries, Inc. (Jan. 19, 2001), available at http://www.fda.gov/downloads/ICECI/EnforcementActions/WarningLetters/2001/UCM069236.pdf.

7 *See, e.g.*, Food and Drug Administration Warning Letter to Ken Powell, Chairman of the Board and CEO (May 5, 2009), available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm162943.htm (indicating that FDA views the company's Web site as labeling for the product because the Web site address appears on the product label).

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
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