

PANEL 3

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Food Labeling: How to Avoid an FDA or FTC Enforcement Action

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I. INTRODUCTION

Perhaps no other category of consumer products has more direct and sustained implications for consumers than “foods,” which are ingested on a daily basis across the entire lifespan and contribute to an overall diet that determines the extent to which basic metabolic needs for water, energy, and nutrients are satisfied.¹ The safety and nutritional quality of “food” that is marketed to consumers plays a fundamental and influential role in the health and welfare of virtually all consumers on a daily basis. In view of the significant public health and consumer protection interests at stake, the scope and complexity of the body of overlapping federal and state laws and regulations governing the safety, labeling and marketing practices associated with food products may come as no surprise. At the same time, the legal compliance and liability risk management challenges food and dietary supplement companies are facing are growing rapidly and substantially as a result of the convergence of a number of key legal and technological trends which are increasing the uncertainty and risk associated with product marketing practices, including with respect to the information and claims that are disseminated through food labeling.

This Panel will consider legal compliance issues and liability implications in the context of food labeling requirements applicable to food and dietary supplement products under the Federal Food Drug & Cosmetic Act (FDCA), the Federal Trade Commission Act (FTCA), current enforcement policies of the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC), and consumer lawsuits seeking remedies for alleged food labeling violations under state laws. The FDA and FTC have overlapping jurisdiction with respect to food and dietary supplement labeling. This joint jurisdiction operates pursuant to a 1971 Memorandum of

¹ See, e.g., 2010 Dietary Guidelines for Americans, *available at* <http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/PolicyDoc/PolicyDoc.pdf>.

Understanding.² As a general rule, advertising claims for these products are regulated by the FTC. FTC has always retained the authority to regulate food and supplement labeling under Sections 12 and 15 of the FTC Act, which delegate FTC authority to regulate any advertisement that is “misleading in a material respect.”³ With the exception of meat, poultry and processed egg products, which are regulated by USDA’s Food Safety and Inspection Service (FSIS),⁴ the FDA regulates the content of food “labeling”⁵ under FDCA section 403.⁶ Claims made on the Internet, including via the use of metatags, and in promotional videos have been considered both advertising and labeling, and therefore may be the subject of enforcement by either FTC or FDA.

II. FOOD LABELING ENFORCEMENT

Recent enforcement actions challenging food labeling claims have been brought by both FDA and FTC and have underscored the importance of considering both FDCA and FTCA requirements in the context of food labeling compliance programs. Publicity surrounding such FDA and FTC enforcement actions also have inspired a significant number of follow-on consumer class action lawsuits alleging that the same food labeling violates state consumer

² Working Agreement Between FTC and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9,850.01 (1971). *See also Enforcement Policy Statement on Food Advertising* (May 1994), available at <http://www.ftc.gov/bcp/policystmt/ad-food.shtm>. The FTC and the FDA have overlapping jurisdiction to regulate the advertising, labeling, and promotion of foods, over-the-counter drugs, cosmetics and non-prescription medical devices. Under a longstanding liaison agreement between the agencies, the FDA exercises primary responsibility for regulating the labeling of these products, while the FTC has primary responsibility for ensuring that their advertising is truthful and not misleading. The FDA regulates prescription drugs and prescription medical devices.

³ 15 U.S.C. §§ 52, 55 (2006).

⁴ *See* Federal Meat Inspection Act, 21 U.S.C. § 601; Poultry Products Inspection Act, 21 U.S.C. § 451; Egg Products Inspection Act, 21 U.S.C. § 1031 et seq.

⁵ 21 U.S.C. §§ 201(k) (defining “label”), 201(m) (defining “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”).

⁶ 21 U.S.C. § 343 (2006).

protection laws.⁷ During the period since January 2009, FDA enforcement policies have emphasized the importance of food labeling compliance to the advancement of the agency’s public health objectives. In a food labeling enforcement initiative executed in 2010, FDA issued no less than 17 warning letters on a single day which challenged food labeling claims, including a notable number of “front-of-pack” label claims and marketing claims disseminated through internet websites which FDA determined to qualify as food “labeling.”⁸

Since January 2011, FDA has issued numerous warning letters to food manufacturers alleging that food and dietary supplement product labeling violated FDCA section 403 requirements, including requirements governing mandatory label statements (*e.g.*, statement of identity, ingredient labeling, and allergen declaration)⁹, and those governing the conditions of use for nutrient content claims (*e.g.*, antioxidant claims) and health claims.¹⁰ In a few cases, FDA has challenged “natural” claims for food products containing citric acid or other ingredients the agency regards to be synthetic.¹¹ In a number of cases, FDA warning letters have alleged that the

⁷ Sarah Roller and Raqiyyah Pippins, *Marketing Nutrition & Health-Related Benefits of Food & Beverage Products: Enforcement, Litigation & Liability Issues*, 65 FOOD & DRUG LAW JOURNAL 447 (2010).

⁸ *See id.* at 451.

⁹ *See* FDA Warning Letter MIN 11-58 to Donuts Deluxe (Sept. 29, 2011) (product failed to disclose presence of wheat); FDA Warning Letter MIN 11-56 to Magic Mousse, Inc. (Sept. 20, 2011) (product failed to disclose presence of wheat, egg, walnut and milk). FDA Warning Letter CHI-03-11 to Czimer’s Foods, Inc. (Feb. 4, 2011) (product misbranded because offered for sale under the name “Black Bear Burgers” and “Black Bear Steak” but are in fact Elk/Red Deer (*Cervus sp.*) and Brown Bear (*Ursus arctos*), respectively).

¹⁰ *See* FDA Warning Letter MIN 12-21 to CAW Industries (Jan. 31, 2012) (“very powerful antioxidant” claim); FDA Warning Letter 153437 to Goetze’s Candy Company (March 4, 2011) (“fortified with calcium” claim).

¹¹ *See, e.g.*, FDA Warning Letter to Alexia Foods, Inc. (Nov. 16, 2011) (baby portabella mushrooms purported to be “all natural” but contained synthetic chemical preservative).

labeling claims for food or dietary supplement products not only cause the product to be a misbranded food, but simultaneously render the product an unlawful new drug.¹²

Recent FTC enforcement actions against food and dietary supplement manufacturers for statements which specifically appear on food labels serve as an important reminder that industry must account for FTCA requirements in their food labeling compliance programs. For example, recent FTC enforcement actions have challenged the adequacy of the substantiation for food labeling claims including the nutrition and health-related benefits of food products including structure function claims concerning the immunity benefits of vitamins, brain and eye development benefits of omega 3 fatty acids.¹³ One such action, initiated in July 2010, involved a children's probiotic beverage which FTC alleged made unsubstantiated claims including "prevent[ing] upper respiratory tract infections in children," "strengthen[ing] the immune system, thereby providing protection against cold and flu viruses," and "reduc[ing] absences from daycare or school due to illness."¹⁴

III. GENERAL COMPLIANCE PRINCIPLES

Navigating the increasingly complex and dynamic sphere of food and supplement labeling requires companies to ensure that its compliance policies and procedures are well-defined and account for the full range of legal requirements and risk management considerations that arise under the FDCA, FTCA, and related federal and state laws. Given the rise in consumer actions, however, the inquiry can not end here. Compliance policies should also adopt a risk-

¹² See, e.g., FDA Warning Letter W/L 10-12 to NanoLiposomal Nutritionals (Nov. 22, 2011) (alleging website claims regarding diabetes suggested that products could be used for the treatment of diabetes or blood glucose and thus rendered the product an unapproved drug).

¹³ See, e.g., *In the Matter of Kellogg Co.*, FTC Docket No. C-4262 (May 28, 2010) (order modifying earlier orders regarding claims that Kellogg's Frosted Mini-Wheats improved attentiveness and Kellogg's Rice Krispies improved children's immunity).

¹⁴ *In the Matter of Nestle Healthcare Nutrition, Inc.*, File No. 092 3087 (July 14, 2010).

based approach to analyze whether a particular labeling claim may be ripe for consumer action. While complete certainty may not be attainable in today's rapidly changing legal climate, industry would be remiss to assume that compliance with FDA and FTC regulations was sufficient in itself as a matter of food labeling policy.

IV. CONCLUSION

As a result of the previously discussed trends, certain key issue areas have emerged which have generated considerable attention from industry, consumers and enforcement authorities. Such key issue areas include: the use of the term "natural" to describe a product, representations regarding the quality or nutritional health benefits of a particular product, allergen disclosures, and front-of-package labeling statements. While any effective food labeling policy will consider food labeling generally, the current legal climate demands that companies be particularly mindful of the legal and regulatory risks associated with these issues. Given the array of enforcement and legal action available, food and supplement manufacturers should carefully devise a labeling compliance policy to consider labeling issues generally with a particularly critical eye towards key issue areas.