FDLI Monograph SERIES

Can We Say That?
A Practical Guide to Substantiating Claims for Food and Consumer Health Products

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Sarah Roller, J.D., R.D., M.P.H., is a partner and chair of the Food and Drug Law practice group at Kelley Drye & Warren LLP. For more than 20 years, Ms. Roller has been providing strategic legal counsel to food and beverage companies, helping them achieve success in the marketplace while navigating the complex web of federal and state public health laws and consumer protection laws governing virtually every aspect of their product formulations, packaging, labeling, and advertising – including the laws enforced by FDA, USDA, FTC, and similar state agencies. In addition, she defends companies when they become the target of a FDA warning letter, FTC access letter, or a false advertising lawsuit. Ms. Roller frequently publishes and lectures on food and drug law issues, and she has served as a lecturer for the FDA Commissioner's training program for incoming FDA fellows. She is recognized as a leading practitioner in the area of Food and Beverage Law by *Chambers USA* and is mentioned in *US Legal 500* for her work in the Marketing and Advertising area. Ms. Roller is a Registered Dietitian and received her Bachelor of Science in Dietetics from the University of Wisconsin and her Master of Public Health from the University of Minnesota.

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About This Monograph

The Food and Drug Administration (FDA) and Federal Trade Commission (FTC) share jurisdiction over consumer health products such as foods, dietary supplements, non-prescription drugs and medical devices, cosmetics and pet care products – and the rules governing what can be said about these products can vary from category to category, from claim to claim, and from audience to audience. In addition to the FDA and FTC requirements, consumer health products are also subject to state and local food and drug laws, including no less than 50 state food and drug statutes and 50 state statutes that are comparable to the FTC Act. Given that these products are essential parts of daily life, consumers, industry and government agencies all have an interest in seeing that these products are labeled and advertised accurately.

Further, recent enforcement actions have evidenced a new and significant degree of cooperation between the FDA and FTC with respect to how these products are promoted to consumers. It is imperative that consumer health product marketers understand the legal and regulatory requirements for product claims.

This Monograph is designed to assist lawyers, regulatory advisors and marketing professionals answer the question *"Can we say that?"* as they design and execute programs to promote foods and other consumer health products. It serves as a practical guide to substantiating the advertising and labeling claims so fundamental to product development, including:

- An overview of the legal and regulatory structures governing foods and other consumer health products
- Key considerations for evaluating marketing concepts and claims
- An outline for establishing effective pre-launch review procedures
- A guide to determining the kinds of substantiation required to support different types of claims
- Discussion of claims and consumer deception issues pertaining to the different categories of foods and other consumer health products
- Discussion of how to challenge questionable claims being made by others

After reading this Monograph, you will be better able to:

- Understand and evaluate the legal and regulatory considerations and risks relating to claims made for specific foods and other consumer health products
- Determine the level of substantiation necessary for particular claims
- Establish an effective claims development, launch and review process
- Assess the viability and most appropriate vehicles for challenging questionable claims

I. Introduction

"Can we say that?" This is a question that confronts companies that make and market consumer products on a daily basis, and a question that lawyers, scientific and regulatory advisors and marketing professionals are regularly called upon to answer as they assist such companies in the design and execution of marketing programs to promote consumer product sales.

"Can we say that?" can be a challenging question to answer, particularly when it concerns marketing communications that are designed to promote food and consumer health products, which are distinguished from others in the marketplace by two significant features. First, these products are subject to the requirements of the Federal Food, Drug and Cosmetic Act (FDCA) and the related implementing regulations administered and enforced by the Food and Drug Administration (FDA).[1] Second, most of these products are marketed and sold directly to consumers for use under conditions that involve no supervision by a medical doctor or other healthcare professional. As a result, the information consumers need to understand the benefits of these products and use them under appropriate conditions must be accurately and effectively conveyed to them through product labels, labeling, print and broadcast advertising, Internet websites and other forms of marketing communications.

Food and consumer health products encompass a diverse range of FDA-regulated products, but all of them function in ways that have a distinctively intimate relationship to the body and personal health of the consumers who use them to care for themselves or consume them through the care they receive from others (e.g., children and pets). Some products in this category are ingested (e.g., foods and nonprescription drugs) and, at least for a time, become an integral part of the body of the consumer as they play their role in nourishing and supporting normal body functions (e.g., conventional foods and dietary supplements), or in treating or alleviating the symptoms of disease (e.g., nonprescription drugs). Other products in this category are applied to the body to enhance its physical appearance (e.g., cosmetics), or are used in close contact with the body to deliver health benefits by mechanical means (e.g., nonprescription devices). More specifically, food and consumer health products encompass a subset of FDA-regulated products that encompasses conventional and fortified foods and beverages, dietary supplements, nonprescription drugs and devices, cosmetics, pet food and pet care products. For purposes of this monograph, this subset of FDA-regulated products is termed "food and drug" (F&D) consumer products.

Because of the distinctively intimate ways in which F&D consumer products benefit consumers, the information and claims characterizing product benefits in labeling, advertising and other forms of marketing communications present uniquely sensitive public health and consumer protection policy concerns. These concerns are evident in the complex and elaborate web of legal and regulatory requirements that govern the marketing practices of companies that make and market F&D consumer products. For example, in addition

[1] Food also encompasses products that are subject to the Federal Meat Inspection Act (FMIA), Federal Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA) and the related implementing regulations administered and enforced by the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA). Foods that are subject to the FMIA, PPIA, and EPIA, also are subject to the overlapping requirements of the FDCA (e.g., food additive regulation). FDA and USDA Food Safety Inspection Service (FSIS) food labeling requirements are similar and generally consistent. The discussion in this monograph focuses primarily on FDA regulations and highlights distinctive FSIS provisions.

to the requirements that govern F&D consumer products under the FDCA,[2] the information and claims on which companies rely to market F&D consumer products is subject to the requirements of the Federal Trade Commission Act (FTCA) and Lanham Act, and other federal laws. In addition, the requirements of these federal laws are layered over an extensive and growing body of state and local laws, including no less than 50 state food and drug statutes and 50 state statutes that are comparable to FTCA.

This complex body of federal and state law imposes many specific requirements on the companies that make and market F&D consumer products. At the same time, in one way or another, most of the laws share a common overarching consumer protection policy objective, which is accomplished by provisions that prohibit companies from using false or deceptive claims to market their products to consumers. In addition, these laws typically deem marketing claims to be "false" or "deceptive" based on standards and evidence establishing that the meaning conveyed to reasonable consumers is inaccurate and inadequately substantiated, rather than on the meaning that a company intended to convey to consumers through the claim or the evidence available to support the intended claim. Ultimately, the laws governing F&D consumer product marketing claims require companies to achieve more than "compliance" with particular regulations issued by FDA, FTC or other agencies, and hold companies responsible for the effectiveness of their marketing communications in conveying product information and benefits in ways that are well understood and align with the expectations of reasonable consumers.

Despite the many laws and regulations that apply to F&D consumer product marketing claims, all told, they provide far greater guidance and certainty to companies concerning the marketing claims that are prohibited than concerning those that are allowed for use in product labeling, advertising and other marketing communications. This means that *"Can We Say That?,"* is a question that cannot be answered well without care, and one that often requires more time and effort to answer than one might at first expect. Seldom can an adequate and defensible legal basis for F&D consumer product marketing claim be established solely from an FDA regulation or guidance document, without considering the requirements and precedents that apply under FTCA and other federal and state consumer protection laws. This also means that for companies to achieve legal compliance and minimize the liability risks associated with F&D consumer product marketing claims, the internal standards and procedures on which companies rely to evaluate and adopt marketing claims must be designed to ensure not only FDA regulatory compliance, but also account for the standards and precedents that apply under FTCA and other federal and state consumer protection laws.

This practical guide is designed to assist lawyers, scientific and regulatory advisors and marketing professionals who are engaged in the development and review of marketing communications for F&D products in answering the critical *"Can we say that?"* question on a sound and reliable basis. Further, this practical guide outlines the basic FDCA regulatory framework governing "food," "dietary supplements," nonprescription (over-the-counter (OTC)) "drugs" and "devices," "cosmetics" and skincare products and pet food and pet care products, and provides a roadmap to help navigate the pre-launch phase review process for F&D consumer product marketing claims, and to do so in a manner that accounts for the FDCA and FTCA requirements, and those that apply under other federal and state consumer protection laws.

This practical guide also is designed in a manner that lends itself to both a cover-to-cover read, beginning with this Introduction, and a review of selected sections that may relate to a F&D consumer product type (e.g., food, dietary supplement, drug, other), specific types of claims (e.g., health claims, green marketing claims, other) or to more general consumer protection principles.

[2] For meat, poultry, and processed egg products, marketing claims in product labeling are subject to FMIA, PPIA and EPIA requirements, respectively.