REGULATED PRODUCTS QUICK FACTS

Nearly 20 attorneys focused on regulated consumer products issues

HONORS AND AWARDS

Ranked in *U.S. News-Best Lawyers "Best Law Firms"* for FDA Law, 2012-2014

VENABLE SNAPSHOT

More than 600 lawyers in nine offices

American Lawyer's AmLaw 100

94 practice groups ranked, "Best Law Firms" *U.S. News & World Report-Best Lawyers* 2012-2013

76 attorneys and 29 practice areas ranked, *Chambers USA* 2013

Counsel to 38 of the Fortune 100

QUICK LINKS

Dietary Supplements, Cosmetics and Functional Foods Practice

Return to Venable's Engredea Website

Engredea Website

FOOD AND DRUG LAW RESOURCES

Welcome to Venable's Food and Drug Law Resources page. Here, you will find insightful presentations and resources authored by Venable Food and Drug attorneys covering an array of issues affecting the food and drug industry.

Click on the blue headings below to download the presentations.

PATHWAY TO MARKET

Authors: Todd A. Harrison, Claudia A. Lewis, Michelle C. Jackson, John G. Moore, Heili Kim

Published: *Venable Presentation*

This presentation provides basic steps and issues to consider when bringing a medical food or dietary supplement to market. Specifically, the presentation discusses unique regulations governing entry into the medical food and dietary supplement markets and the pros and cons of each category.

PERMISSIBLE V. IMPERMISSIBLE STRUCTURE/FUNCTION CLAIMS FOR DIETARY SUPPLEMENTS

Authors: Todd A. Harrison, Claudia A. Lewis, Michelle C. Jackson, John G. Moore, Heili Kim

Published: *Venable Presentation*

This presentation provides a detailed overview of structure/function claims, including what they are, how to distinguish them from disease claims, what scientific evidence is necessary to substantiate them, and the technical requirements imposed upon them. Further, the presentation discusses how to assess the quality of your product's scientific evidence, and how the Food and Drug Administration (FDA) will interpret the relationship between your evidence and the claims made.

ADVERTISING: THE FEDERAL TRADE COMMISSION AND PRIVATE RIGHTS OF ACTION

Authors: Todd A. Harrison, Claudia A. Lewis, Michelle C. Jackson, John G. Moore, Heili Kim

Published: *Venable Presentation*

This presentation provides an introductory overview of the Federal Trade Commission's (FTC) role in regulating advertising and the difference between the FTC and FDA's roles. Further, it highlights basic principles to keep in mind when substantiating claims and gives examples of recent federal and state advertising cases.

RESPONDING TO FDA & FTC ENFORCEMENT BASED ON PRODUCT CLAIMS

Authors: Todd A. Harrison, Claudia A. Lewis, Michelle C. Jackson, John G. Moore, Heili Kim

Published: *Venable Presentation*

This presentation describes some of the items to consider in the event that you receive a Warning Letter from the FDA or a Civil Investigative Demand from the FTC, including how to evaluate and fix any suggested violations and respond to the agencies, while mitigating downstream risk. In the event that the investigation ends in a Consent Order, the presentation provides helpful tips on how to negotiate a Consent Order and how to appeal an Administrative Order.

UNITED STATES DIETARY SUPPLEMENT REGULATORY UPDATE

Authors: Todd A. Harrison, Claudia A. Lewis, Michelle C. Jackson, John G. Moore, Heili Kim

Published: *Venable Presentation*

This presentation provides an update of trending legal issues affecting the food and drug industry. Issues discussed include hot topics in FDA Warning Letters, FDA and FTC Consent Decrees, and class actions.

CLAIMING TO BE THE BEST: HOW TO SUBSTANTIATE YOUR CLAIMS

Authors: Todd A. Harrison, Claudia A. Lewis, Michelle C. Jackson, John G. Moore, Heili Kim

Published: *Venable Presentation*

This presentation introduces you to the key players in claim substantiation: the FDA, FTC, The National Advertising Division of the Better Business Bureau, The Electronic Retailing Self-Regulation Program and State Attorneys General. The topics discussed include different types of claims, the substantiation suggested for each type, and recent enforcement trends.

WHAT REGULATORS AND OTHER ATTORNEYS WILL NOT TELL YOU ABOUT FDA, FTC, AND CLASS ACTION LAWSUITS

Authors: Todd A. Harrison, Claudia A. Lewis, Michelle C. Jackson, John G. Moore, Heili Kim

Published: *Venable Presentation*

This presentation is a more concise synopsis of current FDA and California enforcement trends. In particular, it highlights the FDA's current warning letters and California's Proposition 65 rules.

GETTING YOUR INGREDIENT TO MARKET: UNDERSTANDING YOUR REGULATORY OPTIONS

Authors: Todd A. Harrison, Claudia A. Lewis, Michelle C. Jackson, John G. Moore, Heili Kim

Published: *Venable Presentation*

This presentation gives an overview of the kinds of products regulated by the FTC, FDA, and state laws, focusing on food, food additives, drugs, and dietary supplements. The presentation also covers the kinds of claims that can be made about each type of product and the regulatory approval process required in bringing each to market.

FOOD FOR THOUGHT—THE FDA, ORGANICS, AND BIOENGINEERED FOOD

Authors: Todd A. Harrison, Claudia A. Lewis, Michelle C. Jackson, John G. Moore, Heili Kim

Published: *Venable Presentation*

This presentation gives a history of food regulation in the United States, as well as an in-depth overview of labeling and marketing rules for food and drug products. The presentation also covers product differentiation, branding, and domestic and international policy regarding food regulation, as well as legal issues that have arisen in the industry.

CREATING SOPS UNDER THE FINAL GMP RULE TO ASSURE THE IDENTITY, PURITY, STRENGTH AND COMPOSITION OF YOUR PRODUCT

Authors: Todd A. Harrison, Claudia A. Lewis, Michelle C. Jackson, John G. Moore, Heili Kim

Published: *Venable Presentation*

This presentation provides helpful suggestions on creating Standard Operating Procedures, including strategies for product testing, quality control, and monitoring remote operations. Further, it touches on the effect that Good Manufacturing Practices (GMP) compliance has on a business's supply chain.

ADVERTISING LAW TOOL KIT

Authors: Venable's Advertising and Marketing Practice Group

Published: *Venable Publication*

Description: This collection of background information and checklists is designed to help marketers identify potentially problematic advertising practices, including questions to consider when taking a product to market that is, or may be, regulated by the FDA.

LITIGATION: THE LEGAL SHAKEDOWN: THE DIRTY LITTLE SECRET OF CONSUMER CLASS ACTIONS

Authors: Daniel S. Silverman

Published: *Inside Counsel*

Description: This article discusses the prevalence of consumer class action litigation, especially in California, which is well-known by class action attorneys for having consumer-friendly consumer protection statutes, including the Unfair Competition Law (Business & Professions Code Sections 17200 (unfair competition), the False Advertising statute (Business & Professions Code Section 17500, and the Consumer Legal Remedies Act, aka CLRA (Civil Code Section 1750, et seq).

LET THE SELLER BEWARE

Authors: Jeffrey D. Knowles and Daniel S. Silverman

Published: *Electronic Retailer*

Description: Aggressive federal and state regulatory enforcement, competitors increasingly willing to mount self-regulatory and/or Lanham Act challenges, and an uptick in advertising-related consumer class actions has created the most challenging legal environment for markets in decades. Venable partners Jeffrey D. Knowles and Daniel S. Silverman examine the ins and outs of each of these potential threats to marketers in the December issue of *Electronic Retailer* magazine.