



Recent Developments in Food and Drug Law, 2016 edition: Leading Lawyers on Dealing with Increased Enforcement, Keeping Up-To-Date with FDA (Inside the Minds)

Jennifer Naeger, Lee Rosebush, Lee Sandler, Shelly Garg, William Garvin, Samuel Louis, Kenya Woodruff

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With all of the hazards surrounding the food and drug industry, maintaining solid records and complying with regulations is more important than ever. Unfortunately, given all of the constant investigative changes and new laws coming out of the courts, it is easy for companies to get lost and fall behind on what they need to keep up with. As their attorney, it is your job to make sure they know what to expect, and how to overcome whatever challenges are thrown their way. *Recent Developments in Food and Drug Law* provides you with an authoritative, insider's perspective on helping clients navigate and comply with guidance changes in manufacturing and labeling practices. Inside, you will find experienced partners from nationwide law firms discussing common FDA violations, including failure to have written procedures and train employees, and outlining the parts of an investigation, including triggers and future avoidance. These lawyers offer you advice on increasing client focus on manufacturing practices, encouraging pharmaceutical companies to develop take back programs for their jurisdictions, and assisting clients in registering as outsourcing facilities. From understanding the Food Safety Modernization Act to overcoming pharmacy compliance issues, these authors stress the importance of educating your clients on reevaluating food safety plans, and divulge best practices for helping clients appropriately label products based on intended use. This book also discusses why your clients should include provisions in manufacturing contracts to ensure that suppliers are liable in the event of compliance failures, and offers advice on developing inspection compliance and response practices.

Inside the Minds provides readers with proven business and legal intelligence from leading C-Level executives and lawyers. Each chapter offers thought leadership and expert analysis on an industry, profession, or topic, providing a future-oriented perspective and proven strategies for success. Each author has been selected based on their experience and C-Level standing within the business and legal communities.

Chapters include:

1. William A. Garvin, Shareholder, Buchanan Ingersoll & Rooney PC-"Current Issues in FDA Investigations, Enforcement, Policies, and Compliance"
2. Jennifer Naeger, Shareholder, Reinhart Boerner Van Deuren sc-"Complexities of the FSMA Demonstrate Clients' Need for Informed Counsel on Food and Beverage Law Issues"
3. Samuel Louis, Partner, Strasburger and Price LLP-"Helping Clients Understand and Comply with New Food and Drug Safety Regulations"
4. Lee H. Rosebush, Partner, Baker Hostetler-"Pharmacy Compliance Issues: The DQSA and More"
5. Lee Sandler, Partner, with Shelly Garg, Associate, Sandler Travis & Rosenberg PA-"Congressional and Regulatory Changes in the Food and Drug Industry Lead to New Compliance Concerns"
6. Kenya Woodruff, Partner, with Suzanne Trigg, Associate, Haynes and Boone LLP-"Balancing Innovation and Compliance in an Evolving Food and Drug Industry: A Spotlight on Current Trends"

Appendices include:

Appendix A: Conagra Plea Agreement

Appendix B: Chemnutra Plea Agreement

Appendix C: Importer Food Safety Vulnerability Assessment: What It Is, and Why You Need It

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