



**Recent Developments in Food and Drug Law, 2014
ed.: Leading Lawyers on Dealing with Increased
Enforcement, Keeping Up-To-Date with FDA
Requirements, ... Compliance Practices (Inside the
Minds)**

Multiple Authors

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Recent Developments in Food and Drug Law provides an authoritative, insider's perspective on adapting to major changes in FDA regulations and enforcement procedures. Featuring experienced partners from law firms across the nation, these experts guide the reader through the rise of FDA inspections and propose key strategies for helping clients manage compliance issues. These top lawyers offer advice on recognizing the triggers for investigations, responding to warning letters, and establishing an internal audit system. From navigating emerging trends in labeling practices to analyzing developments in pharmaceutical regulations, these experts emphasize the need to keep abreast of the FDA's increased safety concerns. The different niches represented and the breadth of perspectives presented enable readers to get inside some of the great legal minds of today, as these experienced lawyers offer up their thoughts on the keys to success within this dynamic area of law.

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. Bryan M. Haynes, Partner, Troutman Sanders LLP - "Understanding the Tobacco Control Act and FDA Investigative Process"
2. Ralph S. Tyler, Partner, Venable LLP - "Avoiding FDA Compliance Problems and Managing Them When They Occur"
3. David Abramowitz, Partner, Locke Lord LLP - "Keeping an Eye on FDA's Increased Focus on Safety and Efficacy"
4. Shahnam Sharareh, PharmD, JD, Partner, Fox Rothschild LLP - "New Food and Drug Law Enforcement Challenges: Where Do We Stand?"
5. Carey B. Nuttall, Partner, Patton Boggs LLP - "Pharmacy Compounding Issues in Today's Marketplace"
6. Brandon W. Neuschafer, Partner, Bryan Cave LLP - "Recent Developments in Food Labeling"
7. Roger Morris and Lisa Davis, Partners, Quarles & Brady LLP - "Generic Drugs and Biosimilars Lower Costs and Raise Legal Questions"
8. Theodora McCormick, Partner, Sills Cummis & Gross PC - "Food Advertising and Labeling Trends Spark Concerns About Compliance and Litigation"
9. Lisa Mueller, Partner, Michael Best & Friedrich - "Helping Clients Understand Biosimilar Product Regulations and the Biosimilar Litigation Process"
10. Suzan Onel, Partner, K&L Gates LLP - "Where the "App" World and FDA Collide: Current Status of the FDA's Regulation of Medical Device Software and Mobile Medical Apps"
11. Lauren A. Tulli, Member Attorney, Cozen O'Connor - "A Prescription for Responsibility: The FDA Looks to Expand the Scope of Potential Liability for Drug Company Officials"

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