Recent Developments in Food and Drug Law, 2015 Edition: Leading Lawyers on Dealing with Increased Enforcement, Keeping Up-To-Date with FDA (Inside the Minds)

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Recent Developments in Food and Drug Law provides an authoritative, insider's perspective on helping clients incorporate evolutions in FDA policies and practices into their strategies. Featuring experienced partners from law firms across the nation, these experts discuss the impact of recent legislation, such as the Food Safety Modernization Act and Hatch-Waxman Act, on industry regulations and reveal best practices for responding to investigation notices. These top lawyers offer advice on remaining transparent when dealing with government agencies, overcoming challenges in false labeling and advertising litigation, and avoiding documentation issues. From developing successful investigation strategies to participating in FDA registration processes, these experts stress the importance of implementing strong regulatory compliance programs and divulge best practices for advising clients about changes in the law. 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 ever-changing 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. Diane Romza-Kutz, Partner, Husch Blackwell LLP - "Food and Drug Industry Regulations Increase Impacting Industry While Resources Remain the Same"
2. Brian J. Malkin, Senior Counsel, McGuireWoods LLP - "The FDA's Ever-Broadening Regulatory Oversight Creates Need for Increased (and More) User Fees: How Will This Affect Enforcement, the Increasing Need for Sponsor Self-Regulation, and the FDA's Regulatory Priorities?"
3. Paul D. Swanson, Shareholder, Lane Powell PC - "The Challenges of Regulating Food Safety and Litigating Food Mislabeling and False Advertising Claims"
4. James S. Trainor, Partner, White & Case LLP - "Increasing Antitrust Litigation Emphasizes the Importance of Litigating to Verdict"

Appendices Include:

Appendix A: Department of Health and Human Services
Appendix B: Generic Drug User Fee Act Program Performance Goals and Procedures
Appendix C: Lost Prescription Drug Savings From Use of REMs Programs to Delay Generic Market Entry
Appendix D: Standardizing Shared REMs
Appendix E: Guidance for Industry Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

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