Pharmaceutical Compliance and Enforcement Answer Book 2016

Howard L. Dorfman

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Regulation of the pharmaceutical industry by the U.S. Food and Drug Administration (FDA) has increased in the past decade. In particular, passage of the Food and Drug Administration Amendments Act of 2007 has led to heightened supervision.

Pharmaceutical Compliance and Enforcement Answer Book 2016 provides a comprehensive overview of the regulatory issues faced by the different participants in the pharmaceutical industry.

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- The FDAs authority and potential actions to regulate prescription drugs and biologics both before and after approval by the agency
- A facilitys rights and compliance obligations during an inspection by the agency
- How to best evaluate a companys potential of being in violation and what to do to mitigate those risks
- What advertising and promotion of prescription drugs is permitted
- How product liability issues overlap with FDA enforcement initiatives
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Filled with practical suggestions, **Pharmaceutical Compliance and Enforcement Answer Book 2016** provides the attorney and his or her clients with a roadmap to effective compliance with FDA pharmaceutical regulations.

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