Generic and Innovator Drugs: A Guide to FDA Approval Requirements (Beers, Generic and Innovator Drugs)

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Completely updated, the new ***Seventh Edition*** of ***Generic and Innovator Drugs: A Guide to FDA Approval Requirements*** provides indispensable and practical insights into the **FDA** approval process.

You'll find comprehensive coverage of:

- Abbreviated **new drug applications**
- **505(b)(2) new drug applications**
- Delaying approval of competing products
- **FDA** approval of **biologic drugs**

No other book can cover the **drug approval process** as thoroughly, answering important questions like these:

- What is required to extend the patent of an **FDA**-approved product?
- When must a generic manufacturer notify the innovator manufacturer when submitting an **ANDA** or **505(b)(2)** application?
- When does the **FDA** delay approvals because of patent claims, and when does it ignore patents?
- How can one challenge an **FDA** exclusivity decision?
- When can a manufacturer safely sell a drug without prior **FDA** approval?
- In what circumstances can a generic manufacturer obtain **FDA** permission to file an **ANDA** for a variant of an existing drug?
- When will the **FDA** waive or reduce prescription drug user fees?
- How can a company or an individual avoid debarment?
- What steps are necessary to comply with the **FDA**'s Fraud Policy?
- When and how can a drug company take advantage of **FDA** accelerated approval procedures?
- What are the labeling requirements for exporting approved drugs?
- How does the **FDAAA of 2007** affect the drug and biologic approval requirements?

Generic and Innovator Drugs: A Guide to FDA Approval Requirements provides step by step guidance of the approval process and expert interpretation of:

- *The Hatch-Waxman Act (Drug Price Competition and Patent Restoration Act)*
- *The Medicare Prescription Drug, Improvement, and Modernization Act*
- *The Food and Drug Administration Modernization Act*
- *The FDA Export Reform and Enhancement Act*
- *The Food and Drug Administration Amendments Act of 2007*
- And more!

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