Generic and Innovator Drugs: A Guide to FDA Approval Requirements

By Donald O. Beers

Generic and Innovator Drugs: A Guide to FDA Approval Requirements By Donald O. Beers

The Fourth Edition provides a complete reference to significant developments in FDA approval requirements, including extensive coverage of innovator drugs, the drug approval process, and patent term extension. Plus, it includes the full text of relevant statutes, regulations, FDA guidelines, memoranda, correspondence, and more. This publication is an invaluable reference for drug company officials, regulatory affairs staffs, and legal counsel.

This one-volume guide contains exhaustive discussions and analyses of all the major regulatory and legal actions from the 1938 FDCA grandfather clause through the Drug Price Competition and Patent Term Restoration Act of 1984 (the Waxman-Hatch Act) to Debarment and the Generic Drug Enforcement Act of 1992.

Major topics covered include:

* FDA approval requirements
* Full new drug applications
* Abbreviated new drug applications and "paper" ANDAs
* Delaying approval of competitive products
* Public availability of NDA data
* The orphan drug amendments
* Debarment
* FDA fraud policy
* Accelerated approvals
* And more.

Generic and Innovator Drugs: A Guide to FDA Approval Requirements

By Donald O. Beers

Generic and Innovator Drugs: A Guide to FDA Approval Requirements By Donald O. Beers

The Fourth Edition provides a complete reference to significant developments in FDA approval requirements, including extensive coverage of innovator drugs, the drug approval process, and patent term extension. Plus, it includes the full text of relevant statutes, regulations, FDA guidelines, memoranda, correspondence, and more. This publication is an invaluable reference for drug company officials, regulatory affairs staffs, and legal counsel.

This one-volume guide contains exhaustive discussions and analyses of all the major regulatory and legal actions from the 1938 FDCA grandfather clause through the Drug Price Competition and Patent Term Restoration Act of 1984 (the Waxman-Hatch Act) to Debarment and the Generic Drug Enforcement Act of 1992.

Major topics covered include:

* FDA approval requirements
* Full new drug applications
* Abbreviated new drug applications and "paper" ANDAs
* Delaying approval of competitive products
* Public availability of NDA data
* The orphan drug amendments
* Debarment
* FDA fraud policy
* Accelerated approvals
* And more.

Generic and Innovator Drugs: A Guide to FDA Approval Requirements By Donald O. Beers Bibliography

- Sales Rank: #8523902 in Books
- Published on: 1995-12
- Original language: English
- Number of items: 1
- Dimensions: 9.50" h x 6.50" w x 2.75" l,
- Binding: Hardcover
- 1500 pages

Editorial Review

From the Publisher
Updated periodically

Users Review

From reader reviews:

Lavonne Ouellette:

Nowadays reading books become more and more than want or need but also work as a life style. This reading habit give you lot of advantages. The benefits you got of course the knowledge the particular information inside the book which improve your knowledge and information. The data you get based on what kind of e-book you read, if you want send more knowledge just go with education books but if you want feel happy read one having theme for entertaining like comic or novel. The Generic and Innovator Drugs: A Guide to FDA Approval Requirements is kind of publication which is giving the reader unstable experience.

Kathryn Botello:

Spent a free time for you to be fun activity to perform! A lot of people spent their free time with their family, or their very own friends. Usually they performing activity like watching television, planning to beach, or picnic inside park. They actually doing ditto every week. Do you feel it? Do you need to something different to fill your current free time/ holiday? Could possibly be reading a book may be option to fill your totally free time/ holiday. The first thing you ask may be what kinds of reserve that you should read. If you want to consider look for book, may be the guide untitled Generic and Innovator Drugs: A Guide to FDA Approval Requirements can be very good book to read. May be it could be best activity to you.

Hye Elliott:

Don't be worry should you be afraid that this book can filled the space in your house, you will get it in e-book means, more simple and reachable. This specific Generic and Innovator Drugs: A Guide to FDA Approval Requirements can give you a lot of good friends because by you looking at this one book you have thing that they don't and make you more like an interesting person. This kind of book can be one of one step for you to get success. This publication offer you information that probably your friend doesn't recognize, by knowing more than additional make you to be great persons. So , why hesitate? Let me have Generic and Innovator Drugs: A Guide to FDA Approval Requirements.

Magdalena McKinney:

Guide is one of source of expertise. We can add our understanding from it. Not only for students but additionally native or citizen want book to know the revise information of year to year. As we know those guides have many advantages. Beside we all add our knowledge, also can bring us to around the world. By the book Generic and Innovator Drugs: A Guide to FDA Approval Requirements we can consider more advantage. Don't one to be creative people? For being creative person must prefer to read a book. Merely choose the best book that acceptable with your aim. Don't always be doubt to change your life with that book Generic and Innovator Drugs: A Guide to FDA Approval Requirements. You can more pleasing than now.

Read Generic and Innovator Drugs: A Guide to FDA Approval Requirements By Donald O. Beers for online ebook

Generic and Innovator Drugs: A Guide to FDA Approval Requirements By Donald O. Beers Free PDF d0wnl0ad, audio books, books to read, good books to read, cheap books, good books, online books, books online, book reviews epub, read books online, books to read online, online library, greatbooks to read, PDF best books to read, top books to read Generic and Innovator Drugs: A Guide to FDA Approval Requirements By Donald O. Beers books to read online.

Online Generic and Innovator Drugs: A Guide to FDA Approval Requirements By Donald O. Beers ebook PDF download

Generic and Innovator Drugs: A Guide to FDA Approval Requirements By Donald O. Beers Doc

Generic and Innovator Drugs: A Guide to FDA Approval Requirements By Donald O. Beers Mobipocket

Generic and Innovator Drugs: A Guide to FDA Approval Requirements By Donald O. Beers EPub

MQ0NWIPO8BX: Generic and Innovator Drugs: A Guide to FDA Approval Requirements By Donald O. Beers