The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life-Cycle Management

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The Generic Challenge is a must read for pharmaceutical executives and managers, and regulatory, legal, business development, R&D and strategic marketing professionals and anyone who has an interest in the future of the leading American pharmaceutical and biotechnology industries and the high value jobs they provide. It explains clearly and understandably the role of patents, FDA regulation of generic drugs and the Hatch Waxman Act on drug development today and how improvements in innovative drug products provide enhanced benefits to patients while extending the commercial lives of the drugs. There is simply no other book of its kind available on this important subject. Chapters 1-2 cover patents generally and patent enforcement and infringement Chapter 3 covers pharmaceutical, biological and medical device patents Chapters 4-5 cover FDA and drug product exclusivities Chapter 6 covers the Hatch Waxman Act and recent Medicare Act Amendments Chapter 7 puts it all together with Pharmaceutical Life-Cycle Management

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