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**Food and Drug Administration**



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**MOVIPREP Drug Profile, 2023** DrugPatentWatch,2023-08-15 MOVIPREP Drug Profile 2023 This report focuses on MOVIPREP and covers the following critical aspects of this drug United States patents FDA Paragraph IV patent challenges District Court patent litigation European supplementary protection certificates SPCs Clinical trials Drug prices Annual sales revenues Finished product suppliers

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**KAZANO Drug Profile, 2023** DrugPatentWatch,2023-08-15 KAZANO Drug Profile 2023 This report focuses on KAZANO and covers the following critical aspects of this drug United States patents Expired United States patents FDA Paragraph IV patent challenges District Court patent litigation European supplementary protection certificates SPCs Clinical trials Drug prices Finished product suppliers

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Approved Drug Products With Therapeutic Equivalence Evaluations EDURANT Drug Profile, 2023

DrugPatentWatch, 2023-08-15 EDURANT Drug Profile 2023 This report focuses on EDURANT and covers the following critical aspects of this drug United States patents Expired United States patents District Court patent litigation European supplementary protection certificates SPCs Clinical trials Drug prices Finished product suppliers Raw active pharmaceutical ingredient API sources *Biosimilars for Cancer Treatment* Shvetank Bhatt, Harish Dureja, Samir Gunvantbhai Patel, Archita Samir Patel, Kamal Dua, 2024-07-01

The book delves into the role of biosimilars in the field of cancer treatment It also discusses the application of biosimilars in various cancer types from colorectal and cervical to prostate gastric lung pancreatic breast hepatocellular ovarian and blood cancers It contains chapters that focus on the clinical trials of biosimilars providing insights into the latest research and developments This book serves as a valuable resource for clinicians researchers and anyone seeking a comprehensive understanding of the intersection between biosimilars and cancer treatment

**Biosimilars** Hiten J. Gutka, Harry Yang, Shefali Kakar, 2018-12-13 This book provides a comprehensive overview of the biosimilar regulatory framework the development process and clinical aspects for development of biosimilars The development path of a biosimilar is just as unique as a development path of a new drug tailored by the mechanism of action the quality of the molecule published information on the reference product the current competitive environment the target market and regulatory guidance and most importantly the emerging totality of evidence for the proposed biosimilar during development For the ease of readers the book comprises of six sections as follows Section I Business Health Economics and Intellectual Property Landscape for Biosimilars Section II Regulatory Aspects of Development and Approval for Biosimilars Section III Biopharmaceutical Development and Manufacturing of Biosimilars Section IV Analytical Similarity Considerations for Biosimilars Section V Clinical aspects of Biosimilar Development Section VI Biosimilars Global Development and Clinical Experience Chapters have been written by one or more experts from academia industry or regulatory agencies who have been involved with one or more aspects of biosimilar product development The authors and editors have an expertise in commercialization and pricing of biosimilars intellectual property considerations for biosimilars chemistry manufacturing controls CMC and analytical development for biosimilars regulatory and clinical aspects of biosimilar development Besides the industry practitioners the book includes several contributions from regulators across the globe

**Approved Drug Products with Therapeutic Evaluations** DIANE Publishing Company, 1995-09 Identifies drug products approved on the basis of safety over the counter OTC drug products that require approved applications as a condition of marketing drug products with approval under Sect 505 of the Act products that have never been marketed have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons

**Biopharmaceuticals** Basanta Kumara Behera, 2020-12-07 Biopharmaceuticals Challenges and Opportunities This book

highlights how the traditional microbial process technology has been upgraded for the production of biologic drugs how manufacturing processes have evolved to meet the global market demand with quality products under the guidelines of internally recognized regulatory bodies It also carries information on how armed with a deeper understanding of life threatening diseases biopharmaceutical companies and the life sciences industry have developed formal and informal partnerships with researchers in institutes universities and other R the use of diversified groups of host cells belonging to animals plants microbes insects and mammals stem cell therapy and gene therapy supply chain management of biopharmaceuticals and the future scope of biopharmaceutical industry development This book is the latest resource for a wide circle of scientists students and researchers involved in understanding and implementing the knowledge of biopharmaceuticals to develop life saving biologic drugs and to bring awareness to the development of personalized treatment that can potentially offer patients a faster diagnosis fewer side effects and better outcomes Features Explains how the traditional cell culture methodology has been changed to a fully continuous or partially continuous process Explains how to design and fabricate living organs of body by 3D bioprinting technology Focuses on how a biopharmaceutical company deals with various problems of regulatory bodies and develops innovative biologic drugs Narrates in detail the updated information on stem cell therapy and gene therapy Explains the development strategies and clinical significance of biosimilars and biobetters Highlights the supply chain management of biopharmaceuticals

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