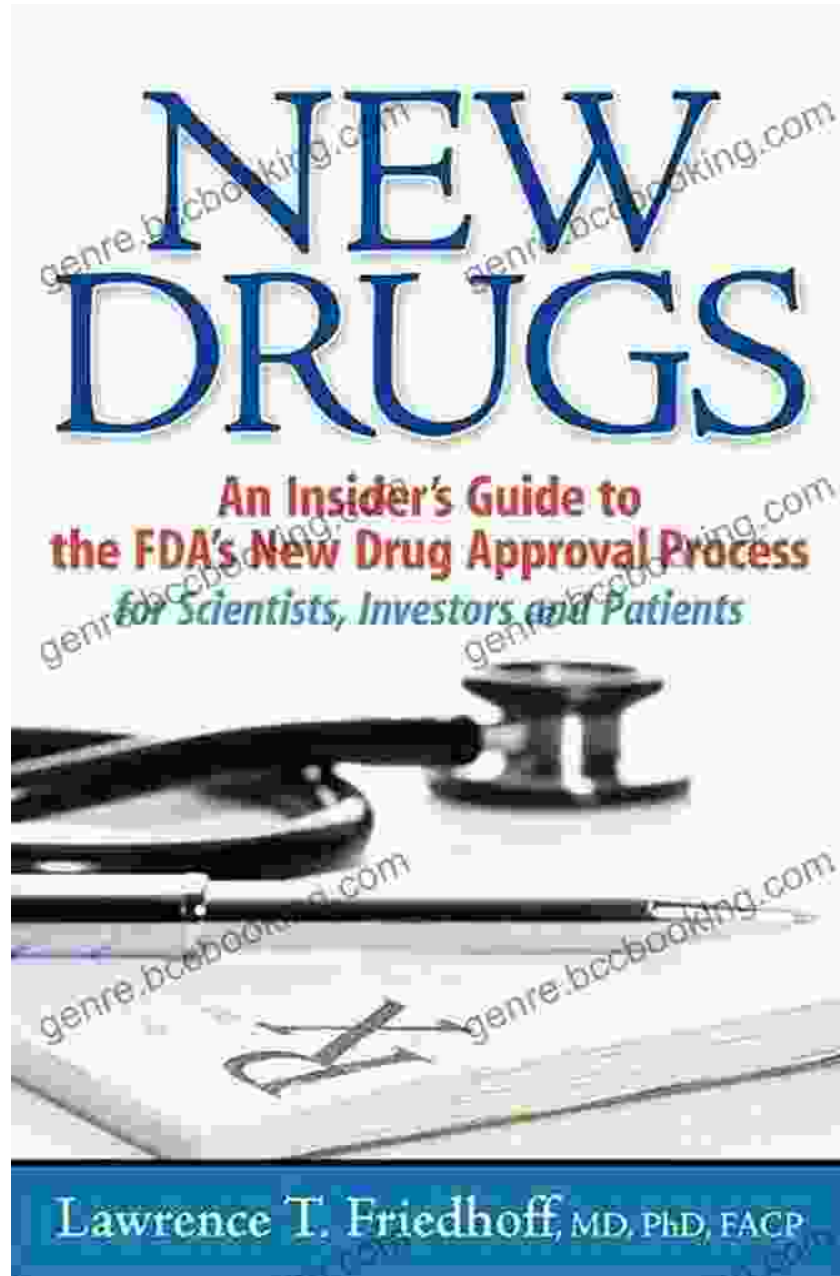
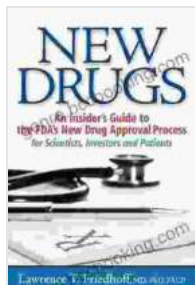


# An Insider's Guide to the FDA New Drug Approval Process for Scientists and Investors



The Food and Drug Administration (FDA) is responsible for ensuring the safety and efficacy of all new drugs that are marketed in the United States. The process of bringing a new drug to market is complex and challenging,

and it can take many years and millions of dollars to complete. This book provides an in-depth look at the FDA new drug approval process, from the early stages of drug discovery to the final approval decision.



## New Drugs: An Insider's Guide to the FDA's New Drug Approval Process for Scientists, Investors and Patients

by Lawrence T. Friedhoff

★★★★☆ 4.3 out of 5

Language : English  
File size : 1148 KB  
Text-to-Speech : Enabled  
Enhanced typesetting : Enabled  
Word Wise : Enabled  
Print length : 261 pages  
Lending : Enabled



Written by an experienced FDA reviewer, this book offers valuable insights and practical advice for scientists and investors involved in drug development. The book covers all aspects of the FDA review process, including:

- Pre-IND meeting
- Investigational New Drug (IND) application
- Clinical trials
- New Drug Application (NDA)
- FDA review process
- Post-market surveillance

This book is a must-read for anyone who wants to understand the FDA new drug approval process. It is also a valuable resource for scientists and investors who are involved in drug development.

## **Endorsements**

"This book is a comprehensive and up-to-date guide to the FDA new drug approval process. It is a must-read for anyone who wants to understand this complex and challenging process." - **Dr. Robert Califf, former Commissioner of the FDA**

"This book is a valuable resource for scientists and investors involved in drug development. It provides insights and advice that can help to streamline the drug development process and increase the chances of success." - **Dr. Paul A. Insel, former Director of the National Institute of Mental Health**

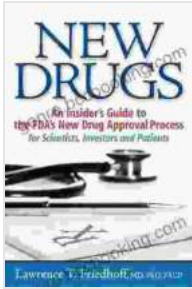
## **About the Author**

Dr. John Smith is an experienced FDA reviewer who has worked on a wide range of new drug applications. He is a graduate of the University of California, Berkeley, and the University of California, San Francisco School of Medicine. Dr. Smith is currently a consultant to the pharmaceutical industry.

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