



The Package

Michael Hoelscher



The Package:

FDA's Drug Review Process and the Package Label Tom Brody, 2017-12-01 FDA's Drug Review Process and the Package Label provides guidance to pharmaceutical companies for writing FDA submissions such as the NDA BLA Clinical Study Reports and Investigator's Brochures. The book provides guidance to medical writers for drafting FDA submissions in a way more likely to persuade FDA reviewers to grant approval of the drug. In detail, the book reproduces data on efficacy and safety from one hundred different FDA submissions NDAs BLAs. The book reproduces comments and complaints from FDA reviewers regarding data that are fragmentary, ambiguous, or that detract from the drug's approvability, and the book reveals how sponsors overcame FDA's concerns and how sponsors succeeded in persuading FDA to grant approval of the drug. The book uses the most reliable and comprehensive source of information available for writing FDA submissions, namely text and data from NDAs and BLAs as published on FDA's website. The source material for writing this book included about 80,000 pages from FDA's Medical Reviews, FDA's Clinical Pharmacology Reviews, and FDA's Pharmacology Reviews from one hundred different NDAs or BLAs for one hundred different drugs. Each chapter focuses on a different section of the package label, e.g., the Dosage and Administration section or the Drug Interactions section, and demonstrates how the sponsor's data supported that section of the package label. Reveals strategies for winning FDA approval and for drafting the package label. Examples are from one hundred FDA submissions NDAs BLAs for one hundred different drugs, e.g., for oncology, metabolic diseases, autoimmune diseases, and neurological diseases. This book uses the most reliable and comprehensive source of information available for writing FDA submissions, namely the data from NDAs and BLAs as published on FDA's website at the time FDA grants approval to the drug.

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