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Sommario/riassunto	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 --