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control is small enough to show that the new drug is also effective. Drugs approved on this basis may provide important benefits such as improved safety. Because non-inferiority trials are difficult to design and interpret, they have received attention within the research community and FDA. FDA has issued guidance on these trials. GAO was asked to examine FDA's use of non-inferiority trial evidence. This report 1 identifies NDAs for new molecular entities potentially innovative new drugs not FDA approved in any form that included evidence from non-inferiority trials 2 examines the characteristics of these trials and 3 describes FDA's guidance on these trials. GAO reviewed NDAs submitted to FDA between fiscal 1971 and 1994. *FDA Quarterly Activities Report* United States. Food and Drug Administration. Program Information and Analysis Group, 1994. *FDA Quarterly Activities Report* United States. Food and Drug Administration, 1971. **New Drug Approval** Marcia Crosse, 2011-02. This is a print on demand edition of a hard to find publication. Before approving a new drug, the FDA assesses a drug's effectiveness. To do so, it examines info contained in a new drug application (NDA) including data from clinical trials in humans. Several types of trials may be used to gather this evidence. Non-inferiority trials aim to demonstrate that the difference between the effectiveness of a new drug and an active control is small enough to show that the new drug is also effective. FDA has issued guidance on these trials. This report 1 identifies NDAs for new molecular entities potentially innovative new drugs not FDA approved in any form that included evidence from non-inferiority trials 2 examines the characteristics of these trials and 3 describes FDA's guidance on these trials. **Illustrations** **FDA Compliance Program Guidance Manual** United States. Food and Drug Administration, 1995-05-11. Challenges for the FDA Institute of Medicine, Board on Health Sciences Policy, Forum on Drug Discovery, Development, and Translation, 2007-10-02. As the principal agency regulating food, drugs, medical devices, and biological products used by Americans, the U.S. Food and Drug Administration (FDA) serves one of the most critical consumer protection functions of the federal government. The FDA's reach is enormous, regulating products that represent roughly 25 percent of all consumer spending in the United States. Since 1992, however, federal funding for the agency has diminished, and the FDA's Center for Drug Evaluation and Research (CDER) currently relies on the fees it receives from the industry it regulates to fund the majority of its drug regulation functions. Prescription drug safety is receiving heightened press coverage and congressional scrutiny as a result of recent highly publicized events such as the recall of Vioxx because of its link to heart attacks and the link between certain antidepressants, selective serotonin reuptake inhibitors (SSRIs), and an increased risk of suicidal ideation in children. To address these concerns, the FDA in 2005 commissioned the Institute of Medicine (IOM) to conduct an independent assessment of the current U.S. drug safety system. In September 2006, the IOM committee released its report, *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, which included 25 recommendations for improving the system for drug safety review. The committee identified four major vulnerabilities in the U.S. drug safety system: 1) chronic underfunding; 2) organization problems, particularly inadequate integration of pre- and postmarket data review; 3) a range of technical problems related to the

insufficient quantity and quality of postmarket data and inadequate capability to systematically monitor the risks and benefits of drugs after marketing and 4 unclear regulatory authority and insufficiently flexible regulatory tools Since the IOM report was issued the FDA has taken a number of steps toward implementing the recommended improvements Like many government agencies however the FDA is financially strained by its existing responsibilities and fully implementing the recommended improvements to the drug safety system would require significant financial commitments The IOM report addressed some of the costs associated with its recommendations but left many unanswered questions about the resources required to fully achieve the envisioned improvements To better understand the types and magnitude of resources required to achieve the goals of the IOM report the IOM's Forum on Drug Discovery Development and Translation convened a 1 day symposium in March 2007 Challenges for the FDA The Future of Drug Safety Workshop Summary explains the presentations and discussions in seven key areas addressing the FDA's resource challenges strengthening the scientific base of the agency integrating pre and postmarket review enhancing postmarket safety monitoring conducting confirmatory drug safety and efficacy studies enhancing the value of clinical trial registration and enhancing the FDA's postmarket regulation and enforcement **FDA Drug Approval** United States. General Accounting Office,1995 FDA Regulatory Affairs Douglas J. Pisano,David S. Mantus,2008-08-11 Examines harmonization of the US Federal Food Drug and Cosmetic Act with international regulations as they apply to human drug and device development research manufacturing and marketing The Second Edition focuses on the new drug approval process cGMPs GCPs quality system compliance and corresponding documentation requirements Written in FDA Premarket Approval United States. General Accounting Office,1992

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 **FDA Papers** ,1970 **FDA's Reviews of New Drugs** United States. General Accounting Office,1988

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