

# JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 6, No. 1, January 2010

"Can You Handle the Truth?"

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

**Lawrence T. Friedhoff, 2009, 243 pages, Pharmaceutical Special Projects Group, \$22.95**

**Review by Norman M. Goldfarb**

"New Drugs: An Insider's Guide to the FDA's New Drug Approval Process for Scientists, Investors and Patients" really does reveal insider insights that cannot be found in other volumes. As the author makes clear, he has learned from many years of drug development.

The following extracts illustrate the practical contents of the book:

This book has been selected for  
[The First Clinical Research Bookshelf](#)

Always take regulatory advice to heart. Since regulators cannot compel a company to do things in a particular way unless they feel there is a safety risk, they often temper their language. Even relatively mild qualifications like "we suggest" or "we have found it is best" should be heard as "you better do it this way or else."

Each metabolite has the potential for both efficacy and toxicity. Metabolites that do not contribute to efficacy have only potential for toxicity. Therefore, products with multiple, non-efficacious metabolites have a proportionately higher risk of toxicity.

Special attention must be given to impurities and degradants. These must be kept at levels that assure the safety of study participants, but must also be kept at levels greater than or equal to those expected in the marketed product.

Successfully completing a Phase II study by demonstrating efficacy in humans is a pivotal step in the drug development process... Everyone wants to be involved with a winner, and if possible, to be in charge. The increase in value that is so essential to the company often brings out the worst in the personalities involved. Skilled drug-development personnel must have a plan in place to defend their leadership positions or they will often find that new, more "professional" people are suddenly put in charge.

It is impossible to exaggerate the care with which [FDA] reviewers evaluate NDA data. Since the reviewers have a limited ability to check the accuracy of the data submitted, they instead focus on its consistency.

Much has been said about the costs of bringing a new drug to market. The major drug companies quote figures close to a billion dollars for each new drug they develop... My guess is that the very high figure is calculated by totaling annual research and development costs and dividing them by the number of new drugs approved each year... The actual cost of doing the studies required to get one new drug approved is much lower;... between \$45 and \$70 million is typically adequate. Another \$10 million or so may be spent on additional studies that are not required for approval but may be needed to support promotion of a new product.

The book consists of 21 chapters:

- What is a Drug?
- Background

- Finding Potential Drugs: The Initial Preclinical Evaluation
- Ethical Concerns and Legal Considerations
- Initial Human Testing: The IND Application and Phase I Studies
- Phase II Studies
- Phase III Studies
- Late Stage Activities
- A Word on Phase IV Studies
- NDA Submission and The NDA Submission Team
- The NDA Review Process
- The Challenges of Success
- Types of New Drug Applications: 505b1, 505b2 and 505j NDAs
- Inspections by Regulatory Agencies
- Rules of Thumb and Other "Tricks of the Trade"
- Patents, Trademarks and Generic Names
- Special Considerations for Investors
- Case Studies and Personal Anecdotes
- Safety Monitoring
- Who Gets Drugs Approved
- A Final Cautionary Note

The book is available in bookstores.

### **Reviewer**

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or [ngoldfarb@firstclinical.com](mailto:ngoldfarb@firstclinical.com).