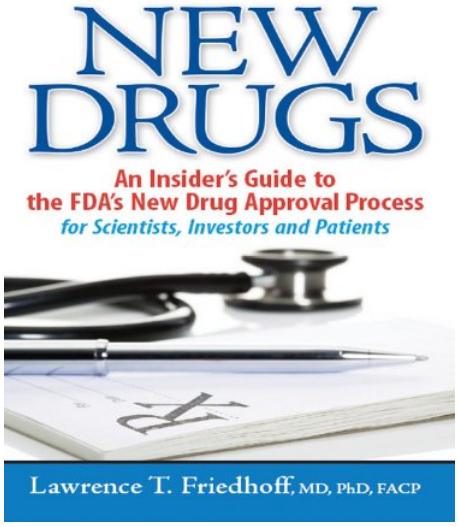
# NyL5z [GET] New Drugs: An Insider's Guide to the FDA's New Drug Approval Process for Scientists, Investors and Patients






Drug development, the processes by which a chemical compound becomes a drug and is approved for sale by the FDA and European and Asian regulators, is not for the faint-of-heart or the shortsighted. Designing and monitoring studies, obtaining and analyzing scientific data, and reconciling clinical results against the ethical constraints and regulatory guidelines of government agencies, requires a complex interaction of in-house specialists and academic and commercial consultants worldwide. Scientific, technical, and tactical considerations play out in an environment where a balance must be struck between the often-competing interests of the corporation, its investors, government regulators, and the safety and well being of intended patients. All the while, dwindling patent protections impose an ever-contracting timeframe for success.Written to be accessible to a wide audience, NEW DRUGS provides a thorough, succinct, and practical understanding of these drug-development processes. If youre involved in the pharmaceutical industry, NEW DRUGS will provide scientific and management tools to increase the likelihood of regulatory approval at each phase of your compounds development. If youre a patient or consumer, NEW DRUGS will enable you to intelligently discuss medications with your health-care provider and empower you to make informed decisions at the pharmacy. If your portfolio, rather than your health, makes you an interested observer of the fortunes of this critical sector of the US economy, NEW DRUGS will help you to decode press releases and annual reports, so that you can recognize and invest in well-run companies with promising products.About the Author:During his 30-year career in pharmaceutical research and development, author Lawrence T. Friedhoff, MD, PhD, FACP has amassed an extraordinary record of industry accomplishments, most notably as the head of the teams that chose, developed, and brought two chemical compounds through regulatory approvals around the world. These new drugs are market blockbusters, each used by millions of patients and each generating well over $1 billion annual revenue worldwide. Dr. Friedhoff's first-hand knowledge of pharmaceutical R&D is extensive and comprehensive: he has held management positions at multi-national corporations developing novel drug compounds, small publicly-traded companies manufacturing generic drugs, start-up ventures, and academic-based research teams writing business plans to obtain venture capital. As an R&D head, he held primary responsibility for choosing drug candidates and preparing comprehensive plans for, as well as managing all phases of, their development, always with an eye towards fulfilling FDA (and often, European and Asian) drug requirements. He has also managed post-FDA-approval activities including collecting and analyzing adverse-event information from consumers, fielding inquiries from patients and healthcare providers, and marketing-related scientific studies. Although the press contains numerous reports of disastrous failed clinical trials, during Dr. Friedhoff's career none of the completed pivotal clinical trials for which he was fully responsible ever failed and all of his new drug applications (NDAs) submitted to the FDA were approved. Few industry professionals have been able match his achievements. Dr. Friedhoff has obtained several patents and has been a frequent and off-cited contributor to the scientific literature. He is also the founder of Pharmaceutical Special Projects Group, LLC, a consortium of independent consultants at whose core are the handful of professionals who have worked together on a variety of successful new drugs under his supervision for nearly twenty years; the team provides various drug-development services to clients and is preparing to bring its own products to market.

Drug development, the processes by which a chemical compound becomes a drug and is approved for sale by the FDA and European and Asian regulators, is not for the faint-of-heart or the shortsighted. Designing and monitoring studies, obtaining and analyzing scientific data, and reconciling clinical results against the ethical constraints and regulatory guidelines of government agencies, requires a complex interaction of in-house specialists and academic and commercial consultants worldwide. Scientific, technical, and tactical considerations play out in an environment where a balance must be struck between the often-competing interests of the corporation, its investors, government regulators, and the safety and well being of intended patients. All the while, dwindling patent protections impose an ever-contracting timeframe for success.Written to be accessible to a wide audience, NEW DRUGS provides a thorough, succinct, and practical understanding of these drug-development processes. If youre involved in the pharmaceutical industry, NEW DRUGS will provide scientific and management tools to increase the likelihood of regulatory approval at each phase of your compounds development. If youre a patient or consumer, NEW DRUGS will enable you to intelligently discuss medications with your health-care provider and empower you to make informed decisions at the pharmacy. If your portfolio, rather than your health, makes you an interested observer of the fortunes of this critical sector of the US economy, NEW DRUGS will help you to decode press releases and annual reports, so that you can recognize and invest in well-run companies with

promising products.About the Author:During his 30-year career in pharmaceutical research and development, author Lawrence T. Friedhoff, MD, PhD, FACP has amassed an extraordinary record of industry accomplishments, most notably as the head of the teams that chose, developed, and brought two chemical compounds through regulatory approvals around the world. These new drugs are market blockbusters, each used by millions of patients and each generating well over $1 billion annual revenue worldwide. Dr. Friedhoff's first-hand knowledge of pharmaceutical R&D is extensive and comprehensive: he has held management positions at multi-national corporations developing novel drug compounds, small publicly-traded companies manufacturing generic drugs, start-up ventures, and academic-based research teams writing business plans to obtain venture capital. As an R&D head, he held primary responsibility for choosing drug candidates and preparing comprehensive plans for, as well as managing all phases of, their development, always with an eye towards fulfilling FDA (and often, European and Asian) drug requirements. He has also managed post-FDA-approval activities including collecting and analyzing adverse-event information from consumers, fielding inquiries from patients and healthcare providers, and marketing-related scientific studies. Although the press contains numerous reports of disastrous failed clinical trials, during Dr. Friedhoff's career none of the completed pivotal clinical trials for which he was fully responsible ever failed and all of his new drug applications (NDAs) submitted to the FDA were approved. Few industry professionals have been able match his achievements. Dr. Friedhoff has obtained several patents and has been a frequent and off-cited contributor to the scientific literature. He is also the founder of Pharmaceutical Special Projects Group, LLC, a consortium of independent consultants at whose core are the handful of professionals who have worked together on a variety of successful new drugs under his supervision for nearly twenty years; the team provides various drug-development services to clients and is preparing to bring its own products to market.