Buchanan Ingersoll & Rooney PC

FDA & BIOTECHNOLOGY – Pharmaceuticals

The Science and the Law of Bringing New Therapies to Market

In bringing new drug therapies to market – and keeping them there – you can't separate the science from the law. That's why our Food and Drug Administration (FDA) and Biotechnology team blends great depth in both the legal and scientific issues pharmaceutical companies face throughout a drug's entire lifecycle.

How We Can Help You

We can provide you with a wide spectrum of FDA-related services. Like an experienced pilot, we're here to get you safely to your destination – an FDA-approved drug successfully brought to market and sustained throughout its lifecycle. Having represented both branded and generic pharmaceutical companies involved in prescription drugs and biologics, we understand the interplay of science and law in helping your products be successful.

The Right Experience for Every Piece of the Puzzle

Few firms can match the level of industry, science and FDA experience we offer. Many of our attorneys have worked for the FDA, as well as pharmaceutical companies and research institutes, as scientists or legal counsel. Our team includes a former associate chief counsel for the FDA, a former in-house counsel to a leading pharmaceutical company, and individuals with advanced degrees in life sciences. We also have a founder and co-chair of the BioNJ Legal, Compliance and Regulatory Forum. This connection gives our clients access to networking opportunities and best-practice learnings from top companies within the New Jersey life science community. And that's just a start.

Developing and marketing pharmaceutical products requires assembling the pieces of an intricate puzzle. That's why our team works so closely with groups across the firm who have the experience to help complete the picture. Our Government Relations, Healthcare, Intellectual Property, Corporate and Litigation teams are ready to jump in when we need them. And of course, we partner with your in-house legal counsel, scientists, technologists, and management teams because – after all – nobody knows your products and your goals like you do.

Guiding You through Clinical Trials, Including Real World Evidence

We can provide you with legal strategies for developing drugs that have the optimal chance of successful passage through the FDA-review process. That process includes informed consent and managing clinical trial disclosure requirements under the federal Sunshine Act and other government requirements.

Pre- & Post-Approval Communications

We will help you promote your products in a way that won't get you in trouble. Our group can counsel you on all aspects of pre-approval and post-approval communications, including:

Lawful pre-approval communications and dossier development to obtain managed care approval, including competent and reliable scientific evidence • Advisory board management • Medical journal articles, speaker programs and scientific conventions • State and federal laws on spend disclosure, spending limits and prohibitions and compliance program adherence • Social media, websites, journal advertisements, visual aids and more

Drug Safety Issues

On the critical issue of drug safety, we can help you:

Challenge FDA administrative actions through correspondence, citizen petitions and litigation
Assess risks • Draft protocols for awareness and assessment of adverse events
Report adverse events • Handle "Dear Doctor" letters and labeling updates

Regulatory Compliance, Now and Long-Term

We're ready to help you comply with all regulatory requirements at every phase of a drug's lifecycle, from development and manufacturing through marketing and distribution and beyond. We can help you establish and maintain ongoing compliance programs designed to reduce the risk of product liability and Lanham Act or other claims, assist with ongoing market access, and assist with listing and paying agencies – including listings in formularies. We can review and revise labeling when needed. And we'll help you stay ahead by keeping you informed of developments at the FDA, the Federal Trade Commission (FTC), and the U.S. Department of Justice (DOJ) that may affect you.

Managing Government and Internal Investigations

If a government investigation occurs, we will guide you through it. We frequently represent clients before the DOJ, the FTC, state attorneys general and various other federal and state regulatory agencies. If you are subpoenaed to testify as witnesses, we will help you thoroughly prepare. We can also assist you in dealing with congressional oversight investigations and hearings. Part and parcel of this, we can assist you in any crisis management situation that may arise for your products, such as product malfunctions, failures or product supply issues. We can handle notifications to healthcare providers and distributors, inquiries by regulators, media management and more.

Commercial Contracts

Our Commercial Contracts group has extensive experience drafting and negotiating commercial contracts for pharmaceutical companies, including Supply Agreements, Development Agreements, Manufacturing Agreements, Licensing Agreements, Distribution Agreements, and Quality Agreements. The Commercial Contracts group works closely with the FDA and Biotechnology group to ensure that the regulatory aspects of the contracts are accurate, while working closely with clients to ensure their interests are protected.

ADVANCING OUR CLIENTS' GOALS

Keeping a Drug Company Fully Compliant as it Brings New Drugs to Market

We counseled a prescription drug company selling branded and generic drugs on the requirements of the Food and Drug Administration Amendments Act (FDAAA). These included requirements for clinical trial disclosures and best practices for correcting past errors in the submission of New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs).

Advancing the Science in Stem Cell Studies

Our lawyers helped a university researcher prepare an Investigational New Drug (IND) application for Phase 1 stem cell studies. Our client received the necessary FDA clearance.

Generic v. Brand Name Drugs

To receive FDA approval to market a generic drug before the expiration of patents related to the brand-name drug, a generic applicant must provide certification that a patent submitted to FDA by the brand-name drug's sponsor is invalid, unenforceable, or will not be infringed by the generic product. This is called a Paragraph IV certification, referring to a section of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments. Our team assisted a client in complex litigation regarding a Paragraph IV certification and whether a generic drug is entitled to 180-day exclusivity.