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Pharmaceuticals, Biologics, and Life Sciences

One of the core functions of the U.S. Food and Drug Administration (FDA) is to review marketing applications for regulated products to assure their safety, efficacy, and compliance with other regulatory standards. While this is fundamentally a science-based function, the statutory and regulatory rules the FDA and innovators must follow have proliferated, public and congressional scrutiny has intensified, and the amount of time, effort, and money required to obtain FDA approval has skyrocketed. Thus, product sponsors frequently encounter situations with the FDA that require legal knowledge and specialized advocacy skills to keep an application on, or return it to, a successful approval pathway. Our pharmaceutical attorney advises and assist companies in their dealings with the FDA at all stages of product development and FDA review, covering pre-clinical testing, human safety and efficacy studies, development of appropriate application strategies, and the FDA review process itself.

For new drugs and biologics, we work closely with clients' in-house regulatory and scientific personnel and their outside technical consultants to prepare the least burdensome development and approval strategies, and to ensure that the agency's review of product applications is conducted in conformity with the proper scientific, legal, and regulatory standards.

Incorporating rapidly evolving regulatory policy with novel drug development techniques is critical in expediting the discovery and development of new drugs. The pandemic has changed the drug development paradigm, with the introduction of alternative clinical trial designs and new classes of drugs moving to the forefront of development programs. With our strong background in science and policy, our pharmaceutical attorneys are uniquely situated to guide clients through this exciting time in pharmaceutical development.

Our expertise includes:

- Regulatory strategy planning, such as advising drug companies on FDA requirements pertaining to drug development, product classification, and marketing
- Pre-clinical testing review and protocol development and clinical trial development and review (including design and protocol assistance)
- Preparing submissions to FDA, including:
    - Orphan drug designation request drafting
    - Expedited program applications (e.g., Fast Track, Priority Review, Accelerated Approval, Qualified Infectious Disease Product designations)

  - Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway) application and advice
  - Investigational New Drug (IND) application drafting and planning
  - New Drug Application (NDA) and Abbreviated New Drug Application (ANDA) drafting and planning
  - Drug master file (DMF) applications
  - OTC Monograph Order Request (OMOR)
- Drafting FDA meeting requests, and planning and facilitating meetings with FDA
- Promotion and labeling of pharmaceutical drugs (both prescription and OTC)
- Post-approval product management (e.g., advertising, marketing, reporting requirements, etc.)
- Interacting with and responding to federal and state regulatory inquiries
- Import and export of drug products
- FDA compliance (e.g., annual reports, inspections, etc.)
- Establishing and managing Medical Legal Review Committees for reviews of pharmaceutical companies' commercial/marketing materials to minimize financial, legal, and reputational risk
- Reviewing drug development data as part of due diligence activities in transactions
- Reviewing and assessing emerging legislative/policy issues affecting FDA-regulated products
- Advising on public and private reimbursement strategies
- Patent portfolio advice
- Reviewing pharmaceutical development documents in litigation matters (e.g., discovery)
- Supporting interactions with company C-suites/Boards of Directors
- Reviewing and assessing drug-related agreements (e.g., supply/service agreements, quality agreements, clinical trial agreements, etc.)

Contact Us

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