Life Sciences Regulatory

Life Sciences

We routinely handle regulatory issues that arise for life sciences companies developing new drugs, biologics, devices, supplements and other products which require FDA approvals, such as informed consent, clinical trial concerns, IND and IDE requirements, jurisdictional issues, approval timing and strategies, priority and breakthrough therapy reviews, market and data exclusivity questions, orphan drug issues, GMP and GCP compliance matters, among many others. In financings, IPOs and M&A transactions, we advise clients on diligence, valuation and post-acquisition strategies and regulatory components, merger clearance matters, consortia issues and enforcement actions by United States and European Union (EU) regulatory authorities, review regulatory disclosures and assist in drafting SEC filings. The firm also has a depth of experience preparing compliance policies and procedures for our clients to govern their interactions with healthcare professionals, CME grants and charitable donations, Sunshine Act compliance and their support of various funding initiatives.

Furthermore, as one of the largest and most respected law firms in Washington DC, we often draw upon our lawyers familiar with public policy to advise companies and trade associations on a number of current issues facing the life sciences industry including drug pricing and reimbursements, enforcement, healthcare policy and legislation that affects patent protection for pharmaceuticals.

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