Hogan Lovells

Transaction and Securities Disclosure Support and Due Diligence

When purchasing a pharmaceutical or biotechnology product or business, or when you obtain financing for a purchase for product development activities, you need to ensure that your regulatory issues due diligence is handled properly.

In working with our clients, we frequently serve as special FDA counsel to companies, issuers, and underwriters in conjunction with initial public offerings and follow-on offerings. We perform due diligence valuations and due diligence reviews of regulatory issues, including the relevant product pathway for the product through the FDA, the EMEA/EMA, or other regulatory bodies. We also provide input on the regulatory issues presented in disclosures, including risk factors associated with offerings.

Additionally, we help draft descriptions of the FDA regulatory process for drugs, including biologics and animal drugs/veterinary medicinal products, and carry out similar analyses on regulatory processes in other countries, particularly those in the EU.

In our role as regulatory counsel, we work in conjunction with our colleagues in the Corporate and Securities practice to provide opinion letters on the regulatory sections of a prospectus.

Representative experience

Contacts

Robert F. Church,
Los Angeles

Susan S. Lee,
Washington, D.C.

Michael N. Druckman,
Washington, D.C.

Practices

Pharmaceuticals and Biotechnology Regulatory

Routinely conduct due diligence of FDA and foreign regulatory law for a wide variety of corporate clients involved in Initial Public Offerings (IPOs) and other types of financings to corporate acquisitions.

Frequently help draft and revise the regulatory sections of security disclosure documents for many of our public company clients.

Conducted U.S. due diligence on FDA, intellectual property, and antitrust issues for a major pharmaceutical client's billion dollar, multinational acquisition of a major pharmaceutical product.

Provided U.S. and EU regulatory due diligence for numerous clients, including investment firms considering investments or loans to non-client companies with novel products.

A product considered for acquisition by an animal health industry client was at high risk of never being approved or having a major delay due to the sponsor needing to conduct in-depth environmental assessments.

Evaluated a proposed purchase of a veterinary medicinal product from the standpoint of EU and United Kingdom regulatory law.