Hogan Lovells

Product Approvals and Dispute Resolution

Practices

Pharmaceuticals and Biotechnology Regulatory

In the process of bringing your product to market quickly and efficiently, it's important to work with lawyers who can help you anticipate and meet FDA guidelines, avoid pitfalls, and who understand the regulatory framework.

Hogan Lovells lawyers understand the complexity of product approvals and the potential snags that could arise. With a team that includes former FDA lawyers who have seen it all, from NDAs, BLAs, combination products, and more, we routinely navigate the most complex situations including dispute resolution.

If you need help navigating product approval pathways and standards in the EU, Asia or the U.S., we can assist with the myriad of regulatory protocols – from full NDAs and 505(b)(2) applications to Biologics License Applications (BLAs) to PMAs and 510 (k)s – affecting new drugs, biotechnology, cellular and tissue products, and combination products.

In each of these areas, we can help you seek FDA approvals on establishing review "goal dates," special protocol assessments, accelerated approval and/or fast track status, and priority review pathways under the Prescription Drug User Fee Act (User Fees). Working with you, we will seek to maximize the benefits available under the law while minimizing the risks as you develop and market your products.

Working on issues regarding pending or approved Marketing Authorization Applications (MAA's), we will counsel you on the categories of variations, combination product issues where a

medicinal product is used with a medical device subject to the Medical Devices Directive, and regulating cell therapy and tissue therapy products.

Outside the traditional premarket review process, we will advise you on the FDA standards for pharmacy compounding, compliance with the FDA's OTC drug monograph standards, and on the FDA's approach to Rx-to-OTC switches.

If you reach an impasse with the FDA and must decide whether to appeal an adverse FDA decision, we'll advise on the appeal mechanisms, other forms of dispute resolution, and how to raise the issue at higher levels within the CDER, CBER, the U.S. Commissioner's Office, and regulatory bodies abroad.

Representative experience

Helped persuade the FDA to accept our client's proposed development plan after the client reached an impasse with the division on data requirements for a new dosage form.

Persuaded an FDA review division to remove a "clinical hold" placed on the study of a pharmaceutical company client's breakthrough auto-injector for use with a well-known topical analgesic drug.

Successfully appealed, through formal FDA dispute resolution mechanisms, the denial of a proposed trade name for a biotechnology company client's breakthrough biotechnology product.

Helped a biotechnology client ascertain the U.S., state, EU, and EU member state requirements for replacing the syringe for an injectable medicinal product.

Accompanied a client looking to get a product back onto the Brazilian market to the Agência Nacional de Vigilância Sanitária (ANVISA), Brazil's FDA counterpart.

Advising clients in a successful challenge of a refusal by a notified body to renew CE Certificates of Conformity for medical devices.

Advising a client in an investigation of its distribution in the EU

of incorrected labelled third party medical devices.

Advising clients securing agreements with the National Health Service (NHS) to fund their innovative and lifesaving medicines.

Assisting clients in the matters before the Polish Office for Registration of Medicinal Products, concerning the permissibility to sell medical devices after their notified body lost its notification.

Latest thinking and events

Blog Post

Will FDA be forced to implement a drug importation program?

Blog Post

FDA launches temporary "TRIP" program to help HCT/P sponsors gain regulatory clarity

News

U.S. Supreme Court rules judges must decide whether preemption applies, and clarifies when it does

Pharmaceuticals and Biotechnology Alert

Blog Post

FDA's Bendeka decision reverses approvals of Treanda generics

Hogan Lovells Publications

China drug regulator calling on international pharmaceutical companies to bring "urgently-needed" new drugs to China