Hogan Lovells

Combination Products

Combination products that deliver, apply, or achieve enhanced effectiveness or improve safety by combining drugs, biologics, and/or devices are rapidly emerging. Many new drugs and biologics also include innovative device components. FDA is approving new products comprised of drug, biologic, and device components in increasingly complex, integrated systems.

Our Medical Device/Technology and Pharmaceutical/Biotech practices have the combined experience to help clients minimize loss of valuable product development time due to uncertainty over regulatory classification, and to evaluate the available regulatory pathways and their likely benefits and pitfalls. Whether your product combines drugs and biologics, or either a drug or biologic with a device, and whether these components are novel, repurposed, for broad or narrow use, can have profound implications on how a product comes to market. These issues also impact the tools available to protect innovation, and the overlapping quality and manufacturing regulations for each component and the finished product throughout its lifecycle.

Representative experience

Approaching FDA with client concerns regarding the development and approval process for devices referencing drug products.

Assisted clients in drafting comments to FDA's devices referencing drugs hearing notice.

Contacts

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Practices

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Helping reverse an FDA decision that would have required new drug approval of a women's health combination product and, instead, determined that the client's product would require only 510(k) clearance as a medical device.

Preparing a request for designation letter on behalf of the sponsor of an accessory to an ophthalmic procedure, helping ensure that the accessory would be regulated by the FDA as a device rather than a drug.

Preparing a pre-RFD request designed to classify a topical dental product as a device instead of a drug.

Securing a designation of a small European biotechnology company's product as a biologic rather than a new drug, a more advantageous designation considering future would-be competitors.

Helping a client whose drug was already approved in Japan to map out the Japanese regulatory pathway for a novel implanted drug delivery system.

Counseling a client on the EU regulatory pathway and optimal business strategy for developing a novel combination product comprised of recombinant human cells encased in a device implant.

Filing numerous RFDs that have successfully persuaded the FDA to regulate our client's device-drug combination product in CDRH under the device authorities.

Our clients desired this result because they perceived regulation in CDRH under the device authorities as less onerous than the alternatives.

Assisting clients in developing and discussing with FDA novel test methods to evaluate chemical, physical, and biological modes of action for combination products and complex novel single entity products.

Assisted a client in determining the regulatory obligations applicable to its drug delivery system in the EU.

Latest thinking and events

News

State Licensing Spotlight – Prescription medical device manufacturers & distributors: Regulatory considerations applicable to medical devices versus drugs

News

FDA Finalizes Guidance for Communications About Unapproved Uses to HCPs, Clarifying Multiple Standards

News

New guidance on AI-enabled device software functions clarifies information FDA expects in marketing applications

News

Overview on the functioning of the trademark system in Europe

News

JPM2025: Regulation of artificial intelligence: Navigating a new frontier in health care

News

Framework amending the UK clinical trial regulations laid before Parliament