Hogan Lovells

Controlled Substances and DEA

Manufacturers, distributors, researchers, and pharmacies rely on our substantial experience with controlled substances regulation at the state and federal levels. We are particularly familiar with how federal and state agencies implement the complex requirements applicable to controlled substances, as well as products that are not scheduled, but have abuse potential.

We will counsel you on state and DEA regulatory compliance in a variety of circumstances, including suspicious order monitoring and reporting, scheduling, registration, recordkeeping, importation and exportation, security, theft and loss reporting, and drug disposal. We can also conduct compliance reviews of your standard operating procedures and employee training materials to assist in developing and enhancing your internal compliance procedures. And should it be necessary, we will work with you in the event of a state or federal investigation or administrative action.

Additionally, we frequently assist manufacturers with scheduling issues, whether for a new pharmaceutical product or a change in the scheduling status of an already marketed product. Combined with our extensive FDA background, our deep understanding of state and federal controlled substances laws gives us a uniquely informed perspective on, and integrated

Contacts

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Practices

Pharmaceuticals and Biotechnology
Regulatory

approach to, the range of regulatory issues you face in developing, marketing, and distributing controlled substances.

Representative experience

Advise on the interplay between FDA and DEA during the drug development process and through FDA approval and scheduling under the CSA.

Advise an OTC products distributor to assure compliance with the Comprehensive Methamphetamine Control Act.

Analyze the impact of all 50 states' controlled substances laws on launching a newly approved and scheduled new chemical entity.

Help develop SOPs to comply with security, registration, and recordkeeping requirements, and reporting and disposal obligations.

Advise manufacturers on quota issues, including increases in quota allotment to avoid drug shortages.

Help manufacturers with state and federal registration and licensing requirements during transactions to assure a seamless transfer with no business activity interruption.

Advise on the export restrictions taking into account U.S., EU, and international treaty law, so that a global pharmaceutical company could export controlled substances from the U.S. to the EU.

Advise health care providers and pharmaceutical companies on the requirements governing narcotics use for addiction treatment.

Assist clients with DEA applications to obtain exemptions for chemical preparations and mixtures.

Latest thinking and events

Insights and Analysis

Don’t sleep on trademarks! – The importance of trademark registration for pharma products in the EU

News

Publicly Traded Life Sciences Companies and Artificial Intelligence: Disclosing Risk Factors

News

Optimizing Your Future (Part II): An Update After the Supreme Court’s Landmark Decision in Purdue

News

FDA publishes long-awaited clinical trial diversity guidance

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HRSA issues 340B Program final rule modifying administrative dispute resolution process