

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

Representative experience

Contacts

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Washington, D.C.

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Washington, D.C.

Practices

Crisis Leadership Team

Pharmaceuticals and
Biotechnology Regulatory

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

News

Comment period ending for proposal to automatically sunset HHS/FDA/CMS regulations

News

FDA issues list of essential medicines and countermeasures required under Buy American Executive Order

News

DEA proposes revised rules for identifying and reporting suspicious orders of controlled substances

Insights

Navigating the new 'buy American' drug landscape: opportunities for some, pitfalls for others

News

FDA, CMS actions on drug importation promise much, likely deliver little

Insights

Therapeutic cannabis in France: publication of the decree authorising the experiment