ZUCKERMAN
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At the Intersection of Law, Policy, and the Market

Food and Drug Practice

ZUCKERMAN SPAEDER LLP | WASHINGTON, DC | NEW YORK | TAMPA | BALTIMORE

Zuckerman Spaeder is proud to be a longtime advocate for generic drug companies, small start-up drug, biologic, and device companies, as well as non-profits and other advocacy organizations—all with the goal of bringing affordable medical products to patients in need and contributing to the public health. Whether before FDA, Congress, other government agencies, or in court, we fight to help our clients achieve their goals.

LITIGATION

Competition in the pharmaceutical market is intense, and litigation is an essential tool for generic and other manufacturers to protect or advance their interests. Our nationally recognized litigators can help you in court when it matters most—whether that involves fighting tactics aimed at delaying approval, helping preserve or challenge Hatch-Waxman and other statutory exclusivity rights, or challenging FDA regulations and policies.

FDA COUNSELING AND COMPLIANCE

We understand the complex regulatory environment you face and can develop strategies that account for—and exploit—the scientific, policy, and legal issues at play. Our team handles all matters related to product approval, product safety, manufacturing, labeling, marketing, and FDA inspections and other post-market surveillance.

ADVOCACY ON FDA ISSUES

We have extensive experience in advocacy for our clients in front of FDA—filing comments to proposed rules and guidances, drafting and responding to FDA citizen petitions, and engaging the agency at all levels on critical regulatory and policy issues.

CONGRESSIONAL INVESTIGATIONS AND CRIMINAL DEFENSE

We understand congressional investigations and the strategic considerations vital to assisting clients subject to such investigations. For more than 40 years, Zuckerman Spaeder has represented individuals and companies in some of the most significant criminal prosecutions and investigations in the United States. When criminal charges are inevitable, our powerhouse team of litigators can aggressively defend your company or your executives in court.

> “Zuckerman Spaeder's FDA practice is among the best in the biosimilars and generics industry.”

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> If you're looking for FDA compliance or litigation advice, go nowhere else."
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EXPERIENCE WHERE IT COUNTS

No matter what issue you face, Zuckerman Spaeder can help.

Product approvals
We have extensive experience working with generic pharmaceutical manufacturers, and small start-up drug, biologic, and device companies to navigate the approval pathways for drugs and devices using ANDAs and 505(b)(2) applications, NDAs, 510(k)s (including device software functions and mobile medical apps), and PMAs. If needed, our nationally recognized litigation team can help you overcome opposition by competitors and their last-minute attempts to block your product getting to market.

Market exclusivity
For generic manufacturers, market exclusivity can be worth hundreds of millions of dollars. But companies seeking to secure or protect their 180-day Hatch-Waxman exclusivity often face hurdles like citizen petitions or lawsuits by competitors. As we have for many clients, we can help you overcome these obstacles and clear the way for an award of exclusivity.

Reimbursement issues
Once a drug or device is approved, its success on the market may depend on how it is reimbursed by the federal government, specifically CMS. We are prepared to help you strategize and work with CMS to ensure that your approved medical products are fairly and appropriately reimbursed.

Biosimilars
Biosimilars is an evolving area with unsettled legal, regulatory, and policy questions. We have been involved in biosimilars issues from their inception, participating in drafting and negotiating the legislation, litigation over the BPCIA's patent provisions and advocating for a fair, consistent approach.

GMP Compliance
Many companies face post-approval challenges. We can help develop and implement strategies for managing risk, complying with quality systems regulation, meeting good manufacturing practices (GMP) obligations, responding to FDA warning letters and "483s," and conducting internal investigations to identify potential problems. When needed, we also counsel clients on product recalls.

Tobacco regulation
The Family Smoking Prevention and Tobacco Control Act of 2009 (TCA) has given FDA regulatory authority over traditional cigarettes, electronic cigarettes, and other tobacco products. Our lawyers helped to draft and negotiate the TCA, and since its enactment, we have represented consumer and advocacy groups in addressing the major legal and policy issues that have arisen with the law's implementation and the emergence of e-cigarettes and other novel tobacco products, including premarket applications, modified risk products, and product standards.

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About Zuckerman Spaeder LLP

Zuckerman Spaeder is consistently recognized as a leading boutique law firm—and for good reason. For 40 years, the firm has attracted extraordinarily talented and experienced attorneys who are committed to each one of their clients. We help them with their most complex, high-stakes legal problems and consistently deliver positive results.

With an approach that is both aggressive and savvy, Zuckerman Spaeder seeks to resolve matters before they get to trial—often saving clients from considerable expense and unwanted attention. And when needed, the firm's focused trial lawyers know how to go toe-to-toe with government regulators, leading businesses, and the largest law firms.