



Food & Drug



For life sciences companies worldwide, Wiley's unique interdisciplinary team provides crucial legal and regulatory counsel to help our clients – from global corporations to innovative startups – stay ahead of the curve in an industry defined by change.

Operating at the intersection of law, policy, business, technology, and scientific innovation, Wiley is a Washington institution with a global impact, providing indispensable counsel to pharmaceutical, medical device, biotechnology, clinical research, food and dietary supplement, animal, and cosmetics companies.



As these industries face unprecedented complexities and challenges, we draw on our decades of experience – and trusted relationships with key decision-makers at all levels of government – to provide the integrated regulatory, legal, and strategic counsel our clients need to adapt and thrive.

Wiley's legal and regulatory expertise addresses virtually any challenge our clients face. We are among a small number of law firms with comprehensive practices in the food, pharmaceutical, and medical device industries, among others – all under one roof. We handle a range of complex matters before the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and related agencies – drawing on our extensive knowledge and experience working across various legal disciplines. Wiley's food practice is recognized nationwide in *Chambers USA*.

We also collaborate with our Wiley colleagues in other practice areas including Environment & Product Regulation, FTC Regulation, Intellectual Property, Telecom, Media & Technology, and White Collar Defense & Government Investigations. Whether our clients are

Capabilities



- Digital Health
- Enforcement & Recalls
- FDA and USDA Regulatory Compliance
- Food and Food Ingredients
- Food & Drug Due Diligence and Transactional Support
- Hatch-Waxman Act Litigation
- Labeling, Advertising, and Promotion
- Litigation and Administrative Advocacy
- Medical Devices
- Pharmaceuticals, Biologics, and Life Sciences
- White Collar Defense & Government Investigations

seeking to resolve an existing problem or anticipate and prevent a potential one, we can help. And with all Wiley attorneys operating out of one office, our work is coordinated, strategic, and cost-effective for clients worldwide.

This unique multidisciplinary approach is crucial as cutting-edge science and technologies drive historic changes throughout the life sciences sector, playing an ever-increasing role in the day-to-day operations of companies regulated by the FDA and the USDA. For example, genetically modified ingredients are now a material issue for consumers and regulators, and protein-based meat substitutes are a rapidly growing market segment. Artificial intelligence and machine learning are helping to expedite the discovery and development of new drugs. And mobile medical apps, wearable technology, and other digital health platforms are revolutionizing the medical device industry.

Disruptions that would have been unthinkable only a few years ago are now high-stakes issues for market participants. As groundbreaking innovations challenge well-established business models and products, large companies are seeking to evolve and compete, and smaller enterprises are pursuing a market foothold and a technological advantage. We are helping clients of all sizes capitalize on the opportunities that arise in this rapidly changing landscape, and avoid the potential risks.

We have an exceptionally broad network of working relationships inside all the key federal regulatory agencies. Our attorneys have been involved in nearly every government initiative affecting the food and pharmaceutical industries. We're familiar with the processes, the language, and the priorities of regulators, which makes us particularly effective. We help clients anticipate, maneuver, and shape the regulations that significantly impact their businesses.

We also advise clients with respect to virtually every other aspect of their business operations. Whether they're facing a potential recall, a class-action lawsuit, a complex transaction, or a Hatch-Waxman intellectual property issue, FDA- and USDA-regulated companies turn to Wiley for the coordinated legal counsel they need. For life sciences companies worldwide, ranging from innovative startups to global corporations, Wiley is their frontline partner for any legal or regulatory issues that may arise.

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