



GARDNER

AN FDA LAW FIRM

The right partner for FDA-regulated companies.

Gardner Law provides expert counsel to FDA-regulated companies on regulatory, compliance, privacy, and litigation matters. Our industry and government experience enables us to deliver actionable advice, empowering clients to make informed decisions. We prioritize responsiveness, ensuring timely support. Our attorneys possess deep regulatory knowledge gained through experience at leading organizations.

Legal Practice Areas:

- Regulatory
- Compliance
- Privacy
- Litigation

SECTORS

Gardner Law specializes in FDA-regulated legal matters, offering expert transactional and litigation counsel across diverse industries. Our overarching mission is to positively impact lives and promote better health. This is the driving force at Gardner Law.



Medical Device



Drug



Food & Beverage



Vaccine & Biologics



Laboratory



Supplements



Veterinary



Cosmetics



Cannabis

REGULATORY THE HUMAN FACTOR.



At Gardner Law, we prioritize empathy and clear communication in our counsel to FDA-regulated companies. Our firm possesses recognized expertise in navigating complex FDA regulations, guiding clients through potential pitfalls. With specialized experience, we provide exceptional strategic guidance, ensure timely submissions, and negotiate effectively with regulators.

Representative Matters:

- Advertising and Promotion Review
- Regulatory Strategy
- FDA Pathway Assessment
- Clinical Trial Agreement Review, Drafting, and Negotiation
- Research Practices and Negotiating with FDA
- FDA Pre-Submission Meetings
- Quality System Policies and Procedures
- Recalls
- Warning Letters, Untitled Letters, Notice of Violation Letters, 483s, Import Holds, Clinical Holds
- Medical Device Submissions (IDE, 510(k), PMA, De Novo, HDE, EUA, OTC)
- Drug and Biologics Submissions (IND, NDA, ANDA, 505(b)(2), BLA, EUA, OTC)
- Food and Dietary Supplement Safety
- Labeling Negotiation with FDA
- CGMP Compliance
- Mock Inspections and Preparation
- OUS Regulatory Support



COMPLIANCE CREATIVITY IN CONTEXT.



Gardner Law provides compliance counsel with a focus on practical solutions and risk mitigation. Our attorneys possess a deep understanding of the Anti-Kickback Statute, False Claims Act, Physician Payments Sunshine Act, Stark Law, Foreign Corrupt Practices Act, among others, and are adept at developing effective strategies that translate into actionable steps for our clients. Our team is committed to finding creative and compliant ways to achieve your business objectives.

Representative Matters:

- Compliance Officer Secondments
- Design, Implement, Monitor, and Audit Compliance Programs
- Compliance Investigations
- Due Diligence for Buyers and Sellers
- Address Violative Practices
- OIG Advisory Opinions
- Sales and Marketing Program Evaluation
- Outsourced Transparency Reporting
- Risk Assessment
- Compliance Monitoring and Auditing
- Draft, Review, and Negotiate Contracts
- Reimbursement Support Services Audit
- AdvaMed, PhRMA, OIG Safe Harbor Compliance
- Seizures
- Civil Money Penalties
- Fair Market Value (FMV) Analysis
- Compliance Committee Operation
- Draft, Implement, and Train on Compliance Policies and Procedures
- Training

PRIVACY THE ART OF ARTICULATION.



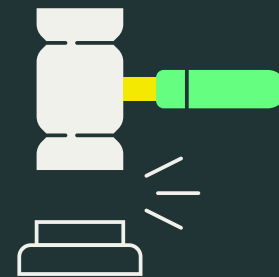
Privacy and cybersecurity law continues to change rapidly. Understanding privacy and cybersecurity requirements is paramount to any business. Our privacy-focused attorneys have the experience and know-how to help you navigate the impact of privacy laws and regulations. Complying with applicable requirements is a science, but explaining them with clarity is an art.

Representative Matters:

- Privacy Officer and DPO Secondments
- Privacy and Cybersecurity Program Audits
- Privacy and Cybersecurity Counsel
- Privacy Impact Assessments and Security Assessments
- Privacy and HIPAA Compliance Programs
- DPAs, SCCs, Transfer Impact Assessments
- Privacy Policy Drafting, Implementation, and Training
- Data Transfer Agreement, Informed Consent, and Privacy Notice Drafting
- Business Associate Agreements
- Websites and Mobile Applications
- Patient Authorization and Consent Drafting
- Privacy Compliance for FDA Complaint Handling



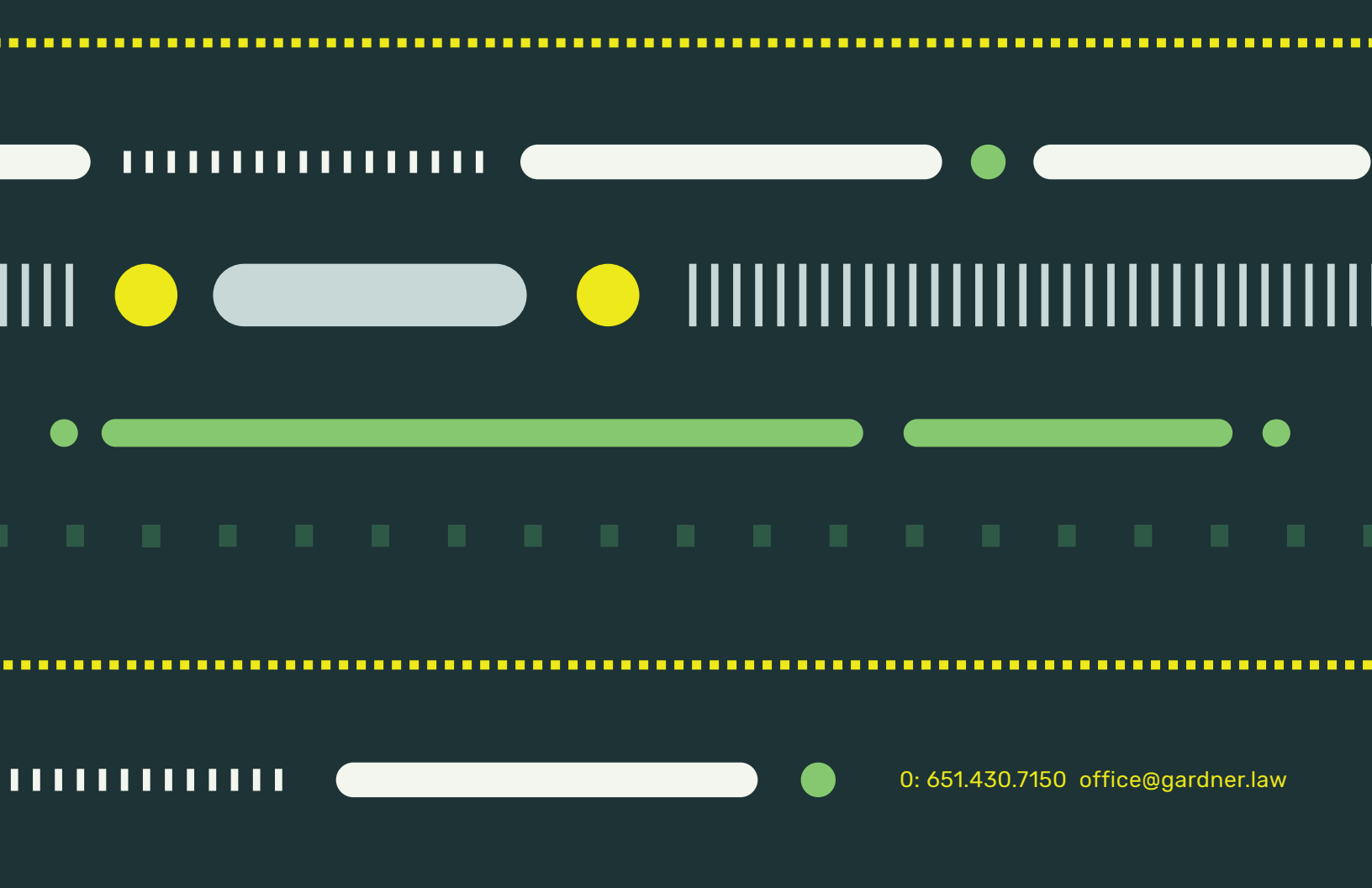
LITIGATION STRATEGIC SOLUTIONS.



We partner with our clients to resolve disputes and achieve the best possible outcomes. Our experienced attorneys understand that every dispute is unique, and we tailor our approach to protect client interests. Whether it involves disputes with competitors, regulatory enforcement actions, arbitration, or litigation, we are equipped to represent our clients in various forums and proceedings. With a deep understanding of the legal landscape and a proven track record of success, we provide strategic guidance and aggressive advocacy to help our clients achieve the best possible outcomes efficiently and effectively.

Representative Matters:

- FDA Litigation
- Consent Decrees
- Seizures
- Civil Monetary Penalties (CMPs)
- Recall Litigation
- Product Liability Litigation
- DOJ and OIG Investigations and Prosecutions
- Government Fraud Prosecutions
- False Claims Act and Anti-Kickback Statute Cases
- Civil Investigative Demands
- Search Warrants
- Injunctions
- Expert Witness Testimony
- Subpoenas
- FTC and NAD Litigation
- Labeling Class Actions
- Arbitration and Mediation



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