Hodgson Russ LLP
ATTORNEYS

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LIFE SCIENCES

Life science companies face complex hurdles on route to the marketplace and may need assistance navigating agency regulations and steering clear of enforcement action. Recent regulatory changes, increased scrutiny of marketing and pricing issues, and complex intellectual property issues require realistic and effective strategies to stay competitive.

Our multidisciplinary life sciences team is experienced in regulatory compliance, unfair competition, product liability risk control, intellectual property, and enforcement. We advise on traditional and special regulatory issues and can help you participate in agency rulemaking, respond to federal and state administrative enforcement actions, and handle civil and criminal litigation.

This team works closely with other Hodgson Russ attorneys to provide core interdisciplinary counsel to our life sciences clients. We have experienced attorneys for each stage of business development, including corporate attorneys specializing in mergers and acquisitions; finance attorneys with venture capital experience; business and regulatory attorneys capable of preparing appropriate licensing, distribution arrangements, and antitrust compliance advice; cross-border attorneys with extensive experience in international tax, import and export, and international business development; and real estate practitioners who can advise on leasing or real property investment.

When challenging issues arise, Hodgson Russ provides sophisticated counseling and advice to help protect clients' operations. Our attorneys have extensive experience representing clients before the FDA Consumer Product Safety Commission (CPSC), Drug Enforcement Agency (DEA), Environmental Protection Agency (EPA), Federal Trade Commission (FTC), and the U.S. Customs Service.

Our life sciences attorneys frequently lecture and write on topics in their specific areas of concentration, including health law, FDA regulatory law, fraud and abuse, health care reimbursement, intellectual property, HIPAA, international licensing, and technology, medical device, and biotechnology transactions.

We assist life science businesses with:

Our life sciences team is multidisciplinary and experienced in regulatory compliance, unfair competition, product liability risk control, intellectual property, enforcement, and much more.

CONTACT

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- Enforcement actions, including product liability, recalls, seizures, FDA warning letters, and other notices of alleged violation
- Facilities audits and FDA inspections
- Cross-border issues, including assisting Canadian companies with bringing their products to the United States
- Cross-border and transfer tax issues
- Mergers and acquisitions
- Corporate financing
- Licensing and collaborative agreements
- Licensing, patent, or trademark protection for your product
- Regulatory and clinical research compliance
- Third-party, government, and health insurance reimbursement
- Recalls and corrective actions in conjunction with product liability
- Legislative and regulatory advocacy and policy development
- Compliance advice and white-collar criminal defense
- Compliance training and conduct audits
- Foreign Corrupt Practices Act (FCPA) compliance plans
- Analyzing permissible uses and disclosures of protected health information

Our attorneys have specific experience in medical device, drug, and biologics products and can help you navigate challenges including:

- Determining proper device classification
- Complying with cGMP (current good manufacturing practices)
- Obtaining investigational device exemptions (IDE)
- Advising on medical device reporting (MDR) strategy and compliance
- Advising on medical device pre-market applications, including 510(K) and PMAs
- Advising on drug advertising, labeling, and promotional material, including Web sites and direct-to-consumer advertising
- Addressing antitrust implications of bringing pharmaceuticals to market
- Obtaining new drug approvals, including filing veterinary applications
- Assisting in over-the-counter (OTC) drug manufacturer registration, product listing, and marketing compliance
- Food labeling
- Advising on importation of FDA-regulated products

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