Baker McKenzie.

FDA Practice

Our North American Life Sciences Regulatory Team has extensive experience in the complex world of products regulated by the FDA, including drugs, medical devices, food, cosmetics, and dietary supplements. The team serves as key strategic and legal advisors for innovative start-ups to global companies on matters that cover the full range of a product's life cycle.

We work with the Firm's Global Regulatory practices to assist in providing worldwide coverage of regulatory and biopharmaceutical compliance issues for a wide range of life sciences.

- Product Development
- Manufacturing and Supply
- Government Enforcement
- Transactional Due Diligence
- Compliance Investigations and Audits
- Research and Clinical Trials
- Pre-launch Planning and Commercialization
- Licensing and Collaborations

Baker McKenzie
FDA Regulatory

The complexity of the FDA-regulated products landscape requires a knowledgeable team with extensive experience navigating the regulatory ecosystem. We stay abreast of applicable laws and regulations to provide clients current and forward-thinking advice and counsel across a broad range of issues. Our deep substantive understanding of the life sciences industry and our comprehensive regulatory experience allows us to serve as strategic legal advisors. We provide critical legal advice and counsel that is aligned with the company's goals and regulatory requirements.

We advise clients on all regulatory aspects affecting the industry at a global, regional and jurisdictional level. Our industry knowledge is enhanced by our attorneys who have gained a wealth of hands-on experience from their roles served within the regulatory agencies and as senior in-house counsel for biopharmaceutical companies.

Helping Clients Navigate The Maze

Product Development

- Requirements for IND & IDEs
- Clinical holds
- Meetings with FDA
- Product Approval Strategies for prescription products, over-the-counter (OTC) products and consumer products
- Product reclassification
- Packaging and Labeling

Transactional Due Diligence

- Mergers and acquisitions
- Investments
- Divestitures
- Licensing, joint ventures and collaborations
- Cross-border transactions
- Post-acquisition integration

Compliance, Investigations & Audits

- FDA inspection preparation
- Internal audits
- Internal training
- Federal and state law compliance including Sunshine Act Monitoring
- Assist with development of policies and procedures

FDA Government Enforcement

- Formal Dispute Resolution
- Assistance with responding to 483 Observations, Warning Letter, Untitled Letters and other Agency correspondence
- Product recalls
- Import/export alerts

Pre-Launch Planning and Commercialization

- Advertising and promotion
- Promotional review
- Product labeling review
- Medical legal regulatory review
- Preparation for preapproval meetings with FDA including Advisory Committee Meeting, labeling and REMS discussions
- Assistance with development and training of medical science liaisons, sales team and managed care professionals

Litigation Support

- Assistance with Fraud and Abuse, Anti-kickback and False Claims matters related to FDA regulated products
- Assistance with product liability claims related to FDA regulated products

Manufacturing and Supply

- Manufacturing and supply agreements
- Quality agreements
- CMO audits and inspections
- Drug Quality and Security Act (DQSA) including Drug Supply Chain Security Act (DSCSA)
- Compounding

Research and Clinical Trials

- Clinical research regulation
- Clinical trial agreements
- Data coordinating center agreements
- Informed consent
- CRO agreements
- Assist with CRO engagement and management
- Steering Committee
- Part 11 Compliance
- Pharmacovigilance

Representative Experience Highlights

Biopharmaceutical

- Assisted global life sciences companies response to NMPA (China) enforcement actions and advised on premarket strategy of new drug products and drug recalls in China.
- Advised various private equity funds, investment banks and global food and pharmaceutical companies in conducting FDA and NMPA regulatory compliance due diligence reviews.
- Assisted a global biopharmaceutical client with product recall, field alerts and other related communications with the FDA.
- Provided advice and counsel to a global biopharmaceutical company on alliance management programs that involve licensing arrangements with other companies to develop and commercialize products internationally.
- Provided corporate regulatory advice and guidelines to a German pharmaceutical company relating to a project in the US that would involve the cultivation and growing of a particular type of plant that is required in the manufacture of certain pharmaceutical products.
- Advised an investment company on its CHF 20.000,000 equity-linked debt financing for a Swiss pharmaceutical company via issuance of senior secured exchangeable notes. This work involved guiding the team in negotiating and drafting the payment milestones tied to FDA regulatory filings and approvals.
- Serve on the Medical Legal Review (MLR) Team as the legal representative for a pharmaceutical company and provide advice and counsel regarding key promotional initiatives for commercializing current products and launching new campaigns.
- Assisted global companies with the development and implementation of corporate compliance programs, including various policies and procedures to support the development and commercialization of drugs and combination products.
- Provided advice and counsel to global biopharmaceutical companies on cGMP, FDA inspection preparation and response, and implementation and execution of corrective and preventative action plans.
- Assisted global pharmaceutical companies with all pre-launch planning, including the development of a compliance program, clinical trial matters and medical, legal and regulatory review of all company materials.

Shipping clinical trial products to patient homes.

Advised Thermo Fisher Scientific on the regulatory and privacy issues that would apply in 18 jurisdictions related to shipping clinical trial products and materials from clinical trial sites directly to patient homes to avoid disruptions resulting from COVID-19. In addition, Advice and counsel on legal and regulatory implications of employer initiated surveillance programs involving COVID-19 screening tests and contact tracing mechanisms.

Medical Device

- Regulatory lead counsel to multinational device and healthcare company on a number of transactions and advisory projects, including:
    - Investment with option for total acquisition of clinical stage biotech company focused on development of neurology focused medical devices
    - Supply and distribution agreement for COVID-19 test
    - Global assessment of mobile medical application classification
- Assisted a private equity company in the acquisition of major US product line.
- Lead regulatory counsel for multinational biotech company in transaction involving acquisition of digital health algorithm.
- Advise and assist with preparation of Service Agreement Template for global medical device company specializing in precision healthcare solutions.
- Assist in preparation of APA regulatory terms for purchase of technology used to develop medical device equipment for a global pharmaceutical company.
- Review development and manufacturing agreement and revise to include regulatory terms for a medical device company in the dermatologic space.
- Advise medical device company on creation of R&D program to ensure compliance with FDCA, state and federal transparency and disclosure reporting requirements.
- Provide counsel on telemedicine agreement and customer terms of use for website.

Please note: some of the matters listed on this page were handled by attorneys prior to joining Baker McKenzie.

A Premier FDA Team

The nature of the FDA regulated industry requires engagement with regulatory agencies including FDA, FTC, DOJ, HHS and regulatory authorities around the world. Our lawyers know when a matter requires such engagement. Our team understands the importance of providing practical and strategic legal advice and counsel.

LMG Life Sciences
2020 FDA Regulatory Firm to Watch

Xin Tao
Partner, Washington, DC
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Xin's practice focuses on novel food and drug applications that require FDA review and FDA Current Good Manufacturing Practices (cGMP) compliance. Xin has extensive experience advising food technology companies and investors on developing and marketing innovative products including cell-cultured meat, protein derived from microbial fermentation and bioengineering. Xin has also represented pharmaceutical companies during many FDA cGMP on-site inspections around the globe involving all aspects of cGMP regulations including sterile manufacturing and data integrity. A former research biochemist, Xin brings a deep understanding of the complex scientific issues that relate to the FDA's legal and regulatory requirements, enabling him to help clients with all phases of product development, manufacturing, and marketing. Leveraging his scientific background, he has also worked extensively on FDA enforcement actions and consumer class action litigations involving environmental contaminants in foods such as heavy metals, PFAS, and California's Proposition 65- listed chemicals

He is a recognized leader in his field:

- Rising Star, Washington, DC Food and Drug Law, Super Lawyers, 2020-2023

Genevieve Razick
Associate, Washington, DC
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@bakermckenzie.com

Genevieve practices in the area of US Food and Drug Administration and healthcare regulatory and compliance law. Genevieve focuses her practice on advising life sciences companies on a broad range of regulatory matters including advertising and promotion issues for compliance with FDA and FTC requirements, as well as conducting regulatory due diligence as it relates to the sale, acquisition and restructuring of FDA-regulated entities. Genevieve advises pharmaceutical and medical device companies on Sunshine Act reporting, PhRMA and AdvaMed Code compliance, and fraud and abuse risks for proposed arrangements involving remuneration under the Federal Anti-Kickback Statute. She also reviews formulary committee and advisory board materials for pharmaceutical companies for compliance with FDA and Anti-Kickback Statute regulatory requirements. Prior to joining Baker McKenzie, Genevieve practiced food and drug law at law firms in both DC and Atlanta.

She is a recognized leader in her field:

- Order of the Coif
- ABA/BNA Award for Excellence in the Study of Health Law, CALI Awards in Health Law Finance & Delivery
- FDA Law, Law & Social Welfare, Genetics and the Law, Corporations, Property I, Property II, Contracts II, Civil Procedure II
- Named one of the "Top Authors" for Healthcare in JD Supra Readers' Choice Awards, 2019

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