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Rebecca L. Dandeker

Partner

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Rebecca Dandeker advises clients in the life sciences and consumer health sectors on regulatory strategy, compliance, and transactional matters involving the U.S. Food and Drug Administration (FDA), Federal Trade Commission (FTC), Drug Enforcement Administration (DEA) and other federal and state agencies. Her practice spans prescription pharmaceuticals, over-the-counter (OTC) drugs, cosmetics, dietary supplements, other consumer products, and alternative therapies. She works with a wide range of clients throughout the product life cycle, from development and approval to marketing, partnerships, and post-market compliance.

Rebecca provides strategic guidance on FDA pre-approval pathways and compliance for products that do not require formal agency clearance but remain subject to extensive regulatory oversight. Her work includes advising on clinical trials, Good Manufacturing Practices (GMP), packaging and labeling requirements, distribution and retail regulations, promotional claims, market access, adverse event reporting, and emerging obligations such as those under State laws and the federal Modernization of Cosmetics Regulation Act (MoCRA). She frequently assists clients during FDA inspections and enforcement actions, including preparing responses to Form 483s, warning letters, and import alerts. She also represents clients in administrative litigation and challenges to agency decisions under the Administrative Procedure Act.

In addition to her regulatory counseling, Rebecca supports corporate and transactional matters involving FDA-regulated products, including due diligence, risk assessments, and integration planning for mergers, acquisitions, and investments. She also serves on drug promotional review committees and provides training to legal,

Practice Areas

Food & Drug
Environment & Product Regulation
Enforcement & Recalls
Labeling, Advertising, and Promotion
Product Distribution and Transactional Support

Credentials

Education
J.D., Georgetown University Law Center
B.S., *magna cum laude*, Liberty University

Bar and Court Memberships
District of Columbia Bar
Maryland Bar
U.S. District Court for the District of Maryland

regulatory, and commercial teams on FDA standards, advertising compliance, and internal policy development. Her experience further includes advising on Rx-to-OTC switches, OTC monograph reform, Hatch-Waxman and biosimilar strategies, and regulatory issues involving homeopathic and alternative products.

Representative Matters

Regulatory

- Advised global pharmaceutical and biotech companies on FDA regulatory strategy for drug and biologic development, including NDAs, 505(b)(2) applications, ANDAs, BLAs, biosimilars, and drug-device combination products.
- Provided strategic counsel on expedited approval programs such as orphan drug, fast track, breakthrough therapy, and pediatric voucher programs.
- Developed legal-scientific arguments for regulatory submissions and responses to FDA Information Requests, Complete Response Letters, and formal dispute resolution.
- Supported REMS implementation and negotiated shared system REMS agreements between brand and generic manufacturers.
- Drafted Citizen Petitions and responses involving brand/generic disputes and FDA regulatory policies.

Compliance

- Led internal teams of attorneys, regulatory scientists, and consultants in compliance investigations involving HHS OIG, False Claims Act, and corporate integrity agreements.
- Managed CAPA and remediation workstreams in collaboration with cGMP consultants following FDA inspections and enforcement actions.
- Served on Promotional Asset Review and Medical/Legal/Regulatory Committees for product launches and labeling expansions across multiple therapeutic areas.
- Developed and delivered training programs for legal, regulatory, and commercial teams on FDA rules, promotional compliance, and internal policy gap analyses.
- Conducted market withdrawal, recall, and health hazard analyses in collaboration with client quality teams.

Transactional

- Drafted and negotiated commercial agreements across the pharmaceutical supply chain, including manufacturing, distribution, pharmacovigilance, and clinical trial contracts.
- Conducted regulatory due diligence and advised on sale, purchase, royalty, and transition services agreements in biopharmaceutical M&A transactions.
- Reviewed and revised SEC disclosures and press releases related to FDA-regulated product transactions.

Litigation

- Supported litigation teams in Administrative Procedure Act lawsuits challenging FDA decisions and final agency actions.
- Acted as subject matter expert in FTC antitrust investigations involving sham petitions, reverse payments, exclusive supply agreements, and price-fixing allegations.
- Directed responses to government inquiries, including DOJ subpoenas, State Attorneys General investigations, and FTC CIDs related to drug labeling and advertising.

Professional Experience

- Private Law Practice (1995-2025)

Affiliations

- Food and Drug Law Institute (FDLI)
  - Member, Cosmetics Task Force (2025)
  - Curriculum Advisor, Intro to Drug Law & Regulation (2021, 2022)
- Federal Bar Association