



Mark M. Yacura

Partner

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With more than three decades of experience, Mark provides strategic regulatory counsel to domestic and international clients in the pharmaceutical, medical device, food and beverage, dietary supplements and consumer products sectors. Drawing on his experience with the Food and Drug Administration (FDA), Mark advises clients navigating complex regulatory issues, clearance processes and enforcement challenges.

Mark's dynamic practice encompasses a range of distinct areas, including:

- Synthetic pharmaceuticals
- Biotechnology
- Medical devices
- Conventional foods
- Dietary supplements
- Cosmetics

Mark helps regulated companies secure clearances and approvals for drug diagnostics, medical devices and food ingredients. He also advises on compliance and enforcement issues involving product status processes, labeling and advertisement. In the area of Current Good Manufacturing Practice laws (CGMPs), Mark provides strategic assistance with FDA Warning Letters, adverse inspection observations, product seizures, import alert detentions, recall requests and consent decrees.

Clients also rely on Mark for FDA due diligence regarding portfolio companies and company acquisitions, as well as for regulatory review of securities filings. His capacities extend to drafting and negotiating agreements within the FDA industry, including licensing, supply and clinical trial agreements.

Beyond FDA matters, Mark represents companies before a number of federal administrative agencies including the Federal Trade Commission (FTC), Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC) and the National Advertising Division of the Better Business Bureau (NAD). Additionally, he assists with advertising claims, substantiation issues and compliance with the Federal Trade Commission Act.

Before Fox Rothschild

Prior to joining Fox Rothschild, Mark was a member of the FDA Regulatory Practice Group at a national law firm.

Practice Areas



- Intellectual Property
- Food & Beverage
- Medical Technology
- Cannabis Law

Bar Admissions

- District of Columbia

Education

- American University, Washington College of Law (J.D., *cum laude*, 1985)
- University of Pittsburgh (M.B.A., 1978)
- Duquesne University (B.S., 1978)

Memberships

- American Bar Association
- District of Columbia Bar Association
- Food & Drug Law Institute