# Mark Yacura

Of Counsel
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Mark Yacura provides strategic regulatory counsel to domestic and international clients in the pharmaceutical, medical device, food and beverage, dietary supplements and consumer products sectors.

A member of the Firm's Intellectual Property group, Mr. Yacura offers clients more than 30 years of strategic regulatory counsel to domestic and international clients in the pharmaceutical, biologics, medical device, conventional food and beverage, dietary supplements, cannabis/CBD products as well as OTC drug, cosmetics and other consumer products sectors.

Based upon his previous experience at the Food and Drug Administration (FDA), Mr. Yacura advises clients navigating complex regulatory issues, premarket approval/clearance processes as well as compliance and enforcement challenges. He represents clients in a variety of areas, including synthetic pharmaceuticals, biotechnology, medical devices, cannabis, conventional foods, dietary supplements and cosmetics.

Mr. Yacura helps regulated companies secure clearances and approvals for drugs, diagnostics, food ingredients, and medical devices, including those involving electromagnetic compatibility. He also advises on FDA and FTC compliance and enforcement labeling and advertising requirements and claims. He represents clients before the FDA regarding product regulatory status, Current Good Manufacturing Practices (cGMP) compliance/enforcement matters as well as adulteration and misbranding issues. Mr. Yacura provides strategic assistance with FDA Warning Letters, adverse inspection observations, product seizures, import alerts and detentions, recall requests and consent decrees.

Clients also rely on Mr. Yacura 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 master services, consulting, licensing, supply and clinical trial agreements.

Beyond FDA matters, Mr. Yacura 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.

## Representative Matters

- Represented medical device and diagnostic manufacturers before the FDA regarding EUA's and Premarket Submissions involving devices incorporating artificial intelligence and machine learning technologies.
- Represented maker of cord blood products manufacturer regarding an FDA safety review of its chosen trade name for a biological treatment use.
- Served as U.S. Agent for a European contract manufacturer regarding drug establishment registration and drug product listing and related reporting requirements under the Cares Act.
- Represented dietary supplement manufacturers regarding website labeling compliance following receipt of a Warning Letter from the FDA.

- Assisted in responding to Center for Medicare and Medicaid Services (CMS) concerning a negative reimbursement decision regarding the homologous use of a minimally manipulated tissue-based product.
- Aided a European pharmaceutical company regarding FDA regulatory issues involving importation and launch of an Orphan Drug Product.
- Aided a Mexican flour manufacturer with the navigation of importation and labeling requirements to market the product in the United States.
- Assisted a plant-based food maker and marketer with the product label and product name to assure FDA compliance.
- Drafted an FDA Regulatory section of securities filing for a pharmaceutical product manufacturer.
- Represented a pharmaceutical consultant in the review and revision of a Master Services Agreement with a major medical device manufacturer.

## Professional Honors & Activities

- Member – American Bar Association
- Member – District of Columbia Bar Association
- Member – Food & Drug Law Institute
- Member – Baker Donelson's Food and Beverage Incident Response Team

## Publications

- "How Food Manufacturers Should Prepare for Impact of MAHA Strategy Report" (September 2025)
- "What Food and Beverage Manufacturers Should Be Considering With HHS Secretary Kennedy at the Reins," republished on April 18, 2025, in *Corporate Compliance insights* (March 2025)

## Education

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

## Admissions

- District of Columbia, 1986