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Amaru J. Sánchez

Associate

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Amaru counsels domestic and global companies in matters involving products regulated by the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and relevant state agencies. As a former in-house counsel for a publicly traded company, Amaru is well-positioned to help clients navigate complex legal, regulatory, and business issues.

Representative Matters

- Prepared and submitted the New Drug Application (NDA) for a publicly traded global pharmaceutical company and assisted with ongoing communications with the FDA regarding the same.
- Served on the Medical Legal Review committee for a global pharmaceutical company.
- Advises clients on FDA requirements for expedited development and review programs such as fast track, breakthrough therapy, and priority review designations, as well as accelerated approval.
- Represents and guides clients in responding to FDA information requests as well as enforcement actions such as Warning Letters, Untitled Letters, Complete Response Letters, recalls, import detentions, and alerts.
- Counsels clients on regulations and policies involving product lifecycle, beginning with product formulation, manufacturing facilities, supply chain, labeling, compliance claims, regulatory marketing strategy, and advertising.

Practice Areas

Food & Drug
Enforcement & Recalls
Environment & Product Regulation
Environmental, Social & Governance (ESG)
FDA and USDA Regulatory Compliance
Food & Drug Due Diligence and Transactional Support
Food and Food Ingredients
Hatch-Waxman Act Litigation
Labeling, Advertising, and Promotion
Litigation and Administrative Advocacy
Pharmaceuticals, Biologics, and Life Sciences

Credentials

Education
J.D., Columbus School of Law, The Catholic University of America
M.P.H., Boston University School of Public Health
B.S., University of Florida

Bar and Court Memberships
District of Columbia Bar

Languages
Spanish

- Assists companies with due diligence involving the sale and acquisition of companies that produce FDA-regulated products, including human and animal food, as well as pharmaceutical drug companies.
- Assists food companies and trade associations in maintaining an active role in the development of domestic and global governmental regulations, policies, and industry guidance by preparing food/food ingredient related filings, organizing agency meetings, and drafting/submitting comments in response to regulatory actions.
- Experience with emerging food categories such as alternative proteins using plant, microbial, and animal cell-based technologies (also known as cultivated meat), as well as organic products and bioengineered ingredients.
- Assists clients with novel issues posed by the COVID-19 pandemic.

Professional Experience

- Executive Director, Legal/Regulatory/Compliance, CorMedix Inc. (2019-2021)
- Associate, Private law practice (2017-2019)
- Project Manager, National Quality Forum (NQF) (2011-2015)
- Health Policy Research Analyst/Advisor, Massachusetts State Legislature (2009-2011)