Marc C. Sanchez

Washington D.C.
In House Counsel and Consultants LLC

Email: msanchez@zuberlawler.com
Phone: +1 (212) 899-9830
Languages: English

Marc Sanchez specializes in advising foreign and domestic healthcare clients and is highly experienced in matters involving the Food, Drug, and Cosmetic Act and related laws.

Marc's clients include those from the pharmaceutical and medical device industry, as well as those from the food and beverages, and cosmetics industry. Marc is also well versed in regulatory requirements concerning Laboratory Developed Tests (LDTs), including CLIA waivers, and has advised clients navigate regulatory pathways for approval of in vitro diagnostics kits.

He provides counseling on pre-market strategies including product development, clinical investigations, orphan drug and other designations, premarket applications (e.g., NDAs, 505(b)(2)s, ANDAs, 501(k), and 513(g) submissions), controlled correspondence, dispute resolution and appeals, label negotiations, monograph reviews, GRAS petitions, marketing and classification review for human and animal products, and other pre-marketing matters.

Marc has substantial experience with Emergency Use Authorization (EUA), and has worked extensively with the FDA for the approval of COVID-19 related therapeutics.

On post-marketing strategies, Marc provides counseling on labeling, advertising and promotion, product recalls, good manufacturing practices (GMPs), and responding to agency enforcement actions.

His work also involves the United States Department of Agriculture where he handles matters encompassing drugs, biologics, and medical foods. Marc is specially well-versed in food and drug enforcement actions including OTC Drug Listings, Color Additive Certifications, and Food Contact Substance Petitions.

Education

Lewis and Clark Law School
J.D., 2010

Valparaiso University
M.S. in International Commercial Policy, 2007

University of New Mexico
B.S., 2006
Major: Finance

Bar Admission

Washington
Washington D.C.

Representative Matters

- Submitted PMTAs for over 40 companies to meet the September 2020 filing deadline (open and closed systems and e-liquid)
- Submitted PMTAs for over 20 companies to comply with the May 2022 synthetic nicotine deadline
- Regulatory submissions for moxifloxacin (application sought to add intracameral injections) and Terbinafine HCL cream and spray.
- Pre-submission and classification of an LDT used for breast cancer screening
- CLIA waiver review for Genevolve Vision Diagnostics congenital color blindness diagnostic LDT
- Classification and pre-market submission for IVD related to cranial CSF
- Application of Practice of Medicine Doctrine for Physicians 360's at-home LDTs