

PRESS RELEASE

Experienced Regulatory IP Attorney Mark Yacura Joins Baker Donelson

May 31, 2022

Mark Yacura, an intellectual property attorney with more than 30 years of experience providing strategic regulatory counsel to domestic and international clients, has joined Baker Donelson as of counsel in the Firm's Washington, D.C. office.

With 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, **Mr. Yacura** utilizes his experience at the Food and Drug Administration (FDA) to advise on complex regulatory issues, premarket approval/clearance processes, and compliance and enforcement challenges. He helps regulated companies secure clearances and approvals for drugs, diagnostics, medical devices and food ingredients.

Mr. Yacura also advises on FDA and Federal Trade Commission (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. He provides strategic assistance with FDA Warning Letters, adverse inspection observations, product seizures, import alerts and detentions, recall requests and consent decrees. He also conducts FDA due diligence regarding portfolio companies and company acquisitions, as well as regulatory review of securities filings.

Beyond FDA matters, Mr. Yacura represents companies before a number of federal administrative agencies including the 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.