Mark M. Yacura

Partner

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Mark M. Yacura focuses his practice primarily on FDA legal and regulatory matters. He has practiced in this area for more than 30 years. He represents his clients before administrative agencies with a similar regulatory mission, including the Consumer Product Safety Commission (CPSC), Environmental Protection Agency (EPA), Federal Trade Commission (FTC), as well as the National Advertising Division of the Better Business Bureau ("NAD").

Mark counsels and represents domestic and foreign clients before the FDA that operate in the areas of 1) synthetic pharmaceuticals, 2) biotechnology, 3) diagnostics, 4) medical devices, 5) conventional foods, 6) dietary supplements, and 7) cosmetics. Mark assists regulated companies with the FDA approval and clearance process for drug products, diagnostics, medical devices and food ingredients. Mark also helps clients with regulatory compliance and enforcement issues involving product status issues, labeling, advertising, and current good manufacturing practice laws and regulations. This includes responding to FDA Warning Letters, adverse inspection observations, product seizures, import alerts, product detentions, recall requests, and consent decrees. Mark also counsels and represents clients with respect to advertising claims and substantiation and compliance with the Federal Trade Commission Act. He similarly represents clients before the NAD. Moreover, Mark assists clients with FDA due diligence on portfolio companies for investor groups and acquiring companies and he has expertised the FDA regulatory sections of various securities filings. Mark drafts and negotiates agreements specific to these FDA regulated industries, such as collaboration licensing, supply, and clinical trial agreements. Prior to entering private legal practice, Mark served at the FDA.

Legal Services

- Health & Life Sciences
  - FDA Regulatory Practice
  - Fraud & Abuse Compliance and Litigation

Education and Honors

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

Bar Admissions

- District of Columbia

Professional and Civic Activities

- District of Columbia Bar Association (Member)
- American Bar Association (Member)

Medical Devices and Diagnostics

- Advised diagnostic clients on various permitted "research only" uses and other device status issues, such as whether the diagnostic product will require a 510(k) or a premarket approval (PMA) or may be a combination product based on intended use and claims made.
- Assisted clients on performance testing requirements for various types of 510(k)s and advised clients on human clinical study testing requirements under an IDE for both 510(k)s and PMAs.
- Advised clients on approval/clearance strategies for medical device and diagnostic products. Prepared or aided in the preparation of 510(k) and investigational device exemptions (IDE), and reviewed labeling for submissions.
- Organized Pre-Submission meetings with CDRH, participated in Pre-Sub meetings and negotiated client's position on 510(k) filings and IDEs with CDRH.
- Counseled clients on compliance/enforcement initiatives by the FDA, including device manufacturing inspections, Form 483 responses, Warning Letter responses, border detentions, and product recalls.
- Negotiated the extent and depth of device recalls with FDA.
- Met and negotiated with the FDA regarding product clearance, labeling, and enforcement initiatives on behalf of clients.
- Advised and represented clients regarding combination products issues involving both device/drug combinations and device/biologic combinations.
- Assisted clients with Establishment Registration and Device Listing with FDA.
- Advised and assisted clients on Medical Device reporting requirements.
- Advised clients on CMS reimbursement issues.
- Represented clients on export of unapproved Medical Devices, import detentions, import alerts, and re-importation issues.
- Assisted clients with regard to highly specialized Medical Device issues including:
    - Hyaluronic acid material for knee joint injections and for wrinkle reduction
    - In vitro diagnostics
    - Combination device/drug or device/biologic products
    - Custom devices

Food and Dietary Supplements

- Reviewed labels and promotional labeling for compliance with the FDCA and its implementing regulations.
- Assisted clients with various FDA enforcement initiatives, including Current Good Manufacturing Practices (CGMP) inspection product recalls, responses to Warning Letters, border detentions, seizure actions, consent decrees, and injunctions.
- Reviewed advertising claims in print and electronic media (e.g., Internet and infomercials) regarding compliance with the Federal Trade Commission Act (FTCA). Represented clients before FTC state agencies and the National Advertising Division of the Better Business Bureau on false or misleading claims allegations.
- Advised clients on parameters for making health claims for various traditional or functional foods.
- Advised dietary supplement makers regarding proper dietary supplement claims and avoidance of drug claims identified in FDA regulations.
- Advised dietary supplement makers regarding new dietary ingredient filing requirements.
- Assisted clients in creating expert panels for evaluations as to the GRASE status of the product.
- Assisted clients in the preparation of food additive applications.
- Represented clients whose food products were contaminated with various microorganisms, such as E. Coli or Salmonella, and a client whose grain products were sprayed with unapproved pesticides.
- Advised prebiotic ingredient maker on clinical testing issues and regarding formula requirements.
- Expert witness regarding food labeling requirements for blended juices in private law suit.
- Advised various energy drink marketers on ingredient label content and Internet issues for compliance with the FDCA and the FTCA.
- Advised beer clients on various ingredient safety and adulteration issues, use of genetically modified yeasts in the manufacturing process; Bureau of Alcohol, Tobacco, Firearms, and Explosives (BATF) label warning requirements; and EPA issues regarding the use of chlorofluorocarbon (CFC) as a refrigerant.
- Advised foreign beer maker regarding contaminated agricultural ingredient and its regulatory impact.
- Advised several clients on medical food regulatory criteria and FDA enforcement.

Cosmetics and Skin Care Products

- Advised skin care clients on the line between permitted anti-aging cosmetic label and labeling claims and drug claims, as well as the

boundary between cosmetic and drug claims about reducing the appearance of scars.
- Represented clients in response to Federal Trade Commission (FTC) cease and desist letters regarding alleged unsubstantiated claims.
- Reviewed infomercials regarding various cellulite claims for their truthfulness and substantiation by clinical studies.
- Represented clients regarding border detentions and assisted the clients in relabeling the product to include permitted cosmetic claims so that products could enter U.S. commerce.
- Represented foreign sunscreen makers regarding petitioning the FDA for inclusion in the OTC monograph for sunscreens.
- Represented clients before the National Advertising Division of the Better Business Bureau regarding alleged unsubstantiated claims.
- Represented and advised client regarding the cosmetic use and medical device approval of hyaluronic acid product for wrinkle filling.

Drug and Biologic Products

- Represented and advised companies on drug approval strategies for abbreviated new drug applications, 505(b)(1) and 505(b)(2) new drug applications, and suitability petitions, as well as Orphan Drug, patent term, and new drug exclusivities and user fees matters.
- Attended FDA pre-IND, end of Phase II, pre-NDA, and other official meetings to negotiate and advocate for client's drug testing plan for approval.
- Advised clients and negotiated with the FDA to obtain Abbreviated New Drug Application (ANDA) approval for complex generics, as well as for generics mimicking an innovator drug that had been voluntarily removed from the market for reasons other than safety.
- Reviewed labels, promotional labeling websites, and advertising of prescription and over-the-counter (OTC) drug products to advise clients on compliance with the "intended use" aspects of the Food, Drug, and Cosmetic Act (FDCA) and related laws. Advised clients on "off-label" promotion issues based on scientific literature.
- Advised companies sponsoring drug companies, clinical trial service companies (CRO), institutional review boards (IRB), and clinical investigators on compliance and enforcement actions regarding good clinical practices and investigator fraud issues.
- Assisted clients on FDA and DEA inspections of their manufacturing facilities, including responses to Form 483 observations and compliance requirements.
- Represented clients in response to official FDA Warning Letters, Untitled Letters, and Consent Decrees concerning unapproved new drug, misbranding, adulteration and good manufacturing practice violation allegations. Represented clients whose products are

subject to border stops and seizure actions.

- Advised clients on product life cycle issues, including approval of new dosage forms for existing products and new uses for existing products.
- Counseled clients on various forms of exclusivities, including new drug exclusivities and Waxman/Hatch patent exclusivities, 30-month stays, and Orange Book issues.
- Assisted companies marketing metered dose inhalers and propellant issues.
- Assisted clients regarding Citizen Petitions on a variety of subjects including the status of "old" generally recognized as safe and effective (GRASE) and Drug Efficacy Study Implementation (DESI) drugs and requesting FDA to refund improper user fee assessments.
- Represented clients on Prescription Drug Marketing Act requirements regarding promotions of their prescription drugs.
- Assisted clients in obtaining monographs in the United States Pharmacopeia (USP) for their drug ingredients and drug products.
- Represented makers of homeopathic drug products regarding label claims and FDA inspections.
- Assisted clients with obtaining release of detained products at the U.S. borders.
- Counseled medical gas companies regarding drug and device claims for their combination product.
- Assisted clients regarding various DEA registration, drug shortage, rescheduling, and alleged compliance/enforcement violations.
- Advised clients regarding various drug reimbursement and rebate issues before the Center for Medicare & Medicaid Services (CMS), as well as fraud, abuse, and antitrust issues.
- Performed due diligence for banks, private equity, or venture capital groups on regulatory health of companies who were targets of a merger or acquisition, or targets for inclusion in an investor portfolio.
- Expertised the FDA regulatory sections of S-1 and various securities statements.

Presentations

07/21/16
"Hot Topics in Pharmacy Law"
Quarles & Brady Pharmacy Law Symposium