HUSCH BLACKWELL



Tracey Gonzalez

SENIOR COUNSEL

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OVERVIEW

Tracey helps food, beverage, cosmetic, and drug manufacturers, distributors, and importers ensure that their products reach the market.

Tracey divides her practice between assisting domestic clients with Food & Drug Administration (FDA) registrations, regulations, and approvals and working with organizations overseas to ensure that their imports meet both FDA and Customs & Border Protection (CBP) requirements. She regularly reviews labels, packaging, and marketing materials; handles FDA registrations and import alerts; conducts FDA-related due diligence for corporate transactions; and advises on facility inspections, enforcement actions, and product market withdrawals and recalls. After more than 15 years in the practice area, Tracey knows the FDA's requirements backwards and forwards, and she is equally knowledgeable about Federal Trade Commission (FTC), Environmental Protection Agency (EPA), and U.S. Department of Agriculture (USDA) standards and regulations as well.

Early in her career, Tracey handled a seafood import matter and soon became the go-to attorney at her boutique firm for FDA and CBP questions. She quickly found herself assisting with products from makeup to medical devices, and she realized she was especially passionate about working with foods, beverages, and other everyday items that consumers use on a regular basis. Today, Tracey supports a wide variety of clients, from food and beverage startups to a medical spa to luxury goods providers.

A people person who values getting to know clients personally, Tracey regards her chief responsibility as simply providing the answers clients need. She's always

Industry

Financial Services & Capital Markets

Services

Customs
Food Safety & Regulation
Functional Foods & Beverages
Hemp Food & Beverage
International Trade & Supply Chain
Product Safety

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on hand to advise on a new regulation, answer a classification question, review a label, or weigh a potential drug claim. As a business-minded attorney, Tracey intuitively understands the essential nature of FDA and CBP compliance: getting these regulatory matters right ensures market access for the products that drive clients' businesses.

Experience

- Reviewed packaging, labeling, marketing/advertising materials, websites, and other materials for FDA, USDA, CBP, and other regulatory agency compliance.
- Advised clients on FDA health, allergen, and other claims; USDA organic claims; and FTC advertising claims.
- Provided advice on product market withdrawals and recalls.
- Assisted clients with GRAS notifications, Prop 65 issues, ingredient lists, and claim substantiation.
- Handled FDA registrations, import alerts, detentions/refusals, 766 reconditioning requests, and other compliance issues.
- Assisted with facility inspections and drafting responses to 483s, warning letters, and other enforcement actions.
- Conducted FDA-related due diligence for mergers and acquisitions.
- Drafted and reviewed contracts with suppliers, distributors, brand partners, and others.
- Assisted with litigation issues, trademark and copyright registrations, state and local licensing, and other regulatory issues.
- Ensured importer compliance with FDA, CPSC, USDA, EPA, and other federal regulations.
- Assisted clients with protests, seizures, penalty mitigation, prior disclosures, binding rulings, tariff classification, 301 duties, country of origin/marking, ADD/CVD, forced labor, and other issues.
- Determined client eligibility for duty savings through free trade agreements, tariff engineering, supply chain restructuring, and first-sale programs.

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Education

- J.D., Benjamin N. Cardozo School of Law
    - *Cardozo Arts and Entertainment Law Journal*, Editor-in-Chief
- B.A., Pennsylvania State University

Admissions

- New York

Tracey is associated with the Washington, DC office for telephone and mail purposes only. She is not admitted to practice in District of Columbia.

Clerkships

- Honorable Richard K. Eaton, U.S. Court of International Trade

Community Leadership

Tracey has recently begun volunteering with Holiday House, a local Sarasota/Tampa Bay program that provides a free holiday shopping and gifting experience for students at Title 1 schools.

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*Tracey works remotely. Contact Tracey via email or telephone for in-person/virtual meetings. Use the Washington, DC office address for mail/deliveries only.

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