

# Anne D. Spiggle

OF COUNSEL  
she / her / hers

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By working with clients to navigate the complex world of federal regulation by the U.S. Food and Drug Administration, Anne Spiggle helps clients focus on their business objectives. Anne believes she can best enable clients to achieve their goals by taking a multi-faceted, “think-out-of-the-box” approach that considers the client’s needs from regulatory and public policy angles. She has developed a broad range of regulatory experience, representing clients in connection with the development, promotion and sale of:

- Foods
- Dietary supplements
- Prescription and over-the-counter drugs
- Cosmetics
- Medical devices
- Animal feed
- Consumer products

Anne’s representation of clients includes significant experience on a wide range of regulatory and public policy matters involving the Food and Drug Administration (FDA), the Federal Trade Commission (FTC), the Consumer Product Safety Commission (CPSC) and other federal and state health and safety regulatory agencies. This experience includes:

- Counseling clients on regulatory requirements
- Assisting clients in responding to regulatory enforcement actions
- Helping clients engage in the regulatory process through preparation of regulatory submissions (such as Citizen Petitions, New Dietary Ingredient submissions and comments on agency rulemakings)
- Advising clients on product labeling, advertising, and promotion and claims substantiation, and helping clients respond to challenges to their labeling, advertising, and promotion

Anne also counsels clients on reporting adverse events and carrying out product recalls. She assists clients in conducting regulatory due diligence on corporate transactions and private equity investments. Drawing on her years of experience engaging with regulators,

## Capabilities

- Food, Drug & Device
- Consumer Products & Luxury Goods
- Medical Devices
- Life Sciences
- Pharmacy
- Advertising & Digital Media

lawmakers, and industry, Anne can think creatively to provide clients with practical advice and fresh perspective.

## Education

- Georgetown University Law Center (J.D., *cum laude*, 2002)
- Cornell University (B.A., *magna cum laude*, 1996)

## Bar Admissions

- District of Columbia, 2003
- Maryland, 2002

## Memberships

- District of Columbia Bar
- Maryland State Bar Association

# Matters

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## FDA

- Counseled clients on bringing products to market under FDA's COVID-19-related Emergency Use Authorization framework and enforcement discretion policies.
- Counseled multiple clients on FDA and state requirements related to the inclusion of CBD in regulated products.
- Assisted client in preparation and submission of comments addressing FDA implementation of the Food Safety Modernization Act.
- Assisted multiple clients in assessing "new dietary ingredient" status of dietary supplement ingredients.
- Counseled client in preparation for FDA inspection of manufacturing facilities.
- Counseled client in handling cosmetic product customs detention.
- Submitted trade complaint regarding marketing of unapproved new drugs.
- Routinely provide comprehensive label review and regulatory compliance analysis.
- Represented drug company in submission of extensive comments addressing reimportation of prescription drugs.

## FTC/NAD

- Successfully defended clients facing an FTC inquiry regarding advertising and promotional claims for antimicrobial products.
- Counsel clients on compliance issues related to advertising and promotion in mainstream media, online, and in social media.
- Successfully defended dietary supplement company's advertising claims before the National Advertising Division (NAD) of the Better Business Bureau.

## CPSC

- Routinely submit 15(b) filings with the CPSC and coordinate product recalls on behalf of consumer product companies and retailers.
- Successfully defended company against CPSC challenge regarding appropriate age-

grading of consumer products.

- Advise multiple companies on compliance with the Consumer Product Safety Improvement Act of 2008 (CPSIA).

#### **Transactional Work**

- Represented numerous private equity funds in conducting regulatory due diligence on corporate transactions.
- Routinely conduct due diligence on FDA-regulated companies.

## Publications

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March 31, 2026

#### **In-House Influence Podcast**

*Co-Host, In-House Influence Podcast, Washington, D.C.*

February 27, 2024

#### **FDA 2023-24: A Look Back & A Peek Forward**

*A Curated FDA Review*