ArentFox Schiff LLP
Attorneys

Shoshana Golden

SENIOR ASSOCIATE

Shoshana advises clients navigating regulatory compliance, government investigations, and transactional matters in the life sciences, health care, and consumer products industries.

Industries

Agriculture & AgTech
Cannabis
Health Care
Life Sciences
Longevity & Healthspan

Practices

Food, Drug, Medical Device & Cosmetic
— Cosmetics, OTC Drugs & Personal Care Products
— Drugs & Biologics
— Food & Agriculture
— Medical Devices
False Claims Act Investigations & Litigation

International

Australia
Europe

Education

Université Panthéon-Assas, LLM, European Law, 2014
American University, Washington College of Law, JD, 2013
Emory University, BA, 2010

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Shoshana provides strategic guidance to clients on a wide variety of complex regulatory, transactional, and enforcement matters that fall under the jurisdiction of the US Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), US Department of Agriculture (USDA), Federal Trade Commission (FTC), Department of Justice (DOJ), and their state counterparts.

Shoshana counsels companies of all sizes in virtually every FDA-regulated industry, with a particular focus on drugs, medical devices, and cosmetics. She additionally advises companies operating in the longevity and healthspan spaces, helping them navigate complex regulatory frameworks for numerous product types, including wearable devices, laboratory developed tests (LDTs), software as a medical device, and AI-enabled wellness tools.

In addition to providing comprehensive regulatory guidance, Shoshana frequently advises clients navigating high-stakes, regulation-driven enforcement matters, from FDA inquiries to class action lawsuits to bet-the-company litigation implicating the False Claims Act, Anti-Kickback Statute, and federal Food, Drug, and Cosmetic Act.

Shoshana provides practical, forward-thinking, and tailored guidance to meet the specific needs and goals of every client, making her a trusted advisor to companies across numerous industries.

Client Work

Regulatory Compliance

Examples of Shoshana's work include advising on:

Cosmetics

— FDA and state regulatory frameworks for cosmetics, including requirements under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA)

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Registration, listing, cGMP, and adverse event reporting requirements

- Proposed ingredients and finished product formulations
- Advertising, labeling, and promotional materials

Medical Devices

- FDA medical device classifications and applicable requirements for new and developing products
- FDA regulation of software as a medical device, particularly in the context of mobile applications, AI-enabled products, and other new and emerging technologies
- FDA regulation of general wellness products and low-risk devices
- The evolving landscape of federal and state regulatory oversight of LDTs
- Registration, listing, cGMP, and adverse event reporting requirements
- Advertising, labeling, and promotional materials

Drugs

- Compliance with FDA OTC monographs
- FDA requirements for drug volume reporting under the CARES Act
- Compliance with CMS and state drug pricing requirements
- Registration, listing, cGMP, and adverse event reporting requirements
- Advertising, labeling, and promotional materials

Conventional Foods and Dietary Supplements

- Regulatory considerations for biotechnology and agricultural technology products
- Registration and cGMP requirements
- Navigating the intersection of FDA, USDA, and EPA authority
- Proposed ingredients and finished product formulations
- Advertising, labeling, and promotional materials

Private Actions, Government Investigations, and Government Enforcement Actions

Examples of Shoshana's work include:

- Representing a pharmaceutical manufacturer in a bet-the-company DOJ investigation regarding potential liability under the False Claims Act, Anti-Kickback Statute, and Food, Drug, and Cosmetic Act
- Representing pharmaceutical manufacturers in multiple DOJ investigations involving False Claims Act allegations revolving around highly specific and complex FDA and CMS rules
- Providing guidance on and assisting with drafting responses to FDA Form 483s
- Advising on FDA-issued import alerts, Warning Letters, and Untitled Letters
- Responding to consumer and competitor challenges to product advertising and promotional claims, including cease-and-desist letters and class action lawsuits

Corporate and Transactional Matters

Examples of Shoshana's work include:

- Drafting and providing guidance on sections of SEC filings related to FDA and health care compliance
- Counseling on risk and regulatory compliance for M&A matters involving companies in the life sciences, health care, and consumer products industries
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Drafting and counseling clients on clinical trial agreements with potential study sites

- Drafting, negotiating, and advising on commercial agreements related to manufacturing and suppliers, advertising, sales and distribution, and licensing technology and products

Previous Work

Before joining ArentFox Schiff, Shoshana clerked for the Honorable Joshua P. Kolar, then a United States Magistrate Judge in the United States District Court for the Northern District of Indiana (now a Judge on the United States Court of Appeals for the Seventh Circuit). Prior to her clerkship, Shoshana was a staff attorney at the United States Department of Justice Consumer Protection Branch, where she focused on health fraud matters.

Publications, Presentations & Recognitions

Presentations

- *Exploring the Intersection of MoCRA and the OTC Drugs Industry* , ACI Advanced Legal, Regulatory and Compliance Forum on OTC Drugs (January 23, 2024)

Life Beyond the Law

Shoshana enjoys theater, traveling, and spending time with her husband and their bossy French Bulldog.

Bar Admissions

District of Columbia

Illinois

New York