

Smart In Your World

Practical Counsel. Unique Insight.

We don't just flag problems. We offer solutions. That's how you become a trusted advisor to the world's top companies.



Cosmetics & OTC Drug Products

Arent Fox represents small and large manufacturers, distributors, and retailers of cosmetics and Over-The-Counter drug products, including many topical drug/cosmetic combination products such as sunscreens, skin protectants, skin sanitizers, and anti-acne products regulated by the FDA and Federal Trade Commission.

About Us

Founded in 1942, Arent Fox is internationally recognized in core practice areas where business and the law intersect. With more than 450 lawyers, the firm provides strategic legal counsel and multidisciplinary solutions to a global roster of corporations, governments, and trade associations.

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Regulatory Counseling

We counsel clients on regulatory compliance related to product formulations, safety testing, labeling, and advertising of cosmetics and OTC drugs. We also participate in agency rulemaking, respond to federal and state enforcement actions, and handle civil and criminal litigation. We guide these clients through interpreting and complying with the Federal Food, Drug, and Cosmetic Act, the Federal Fair Packaging and Labeling Act, and related statutes and regulations.

Advertising and Promotion

The FDA, Department of Justice (DOJ), FTC, Better Business Bureau National Advertising Division (BBB NAD), state attorneys general, and other agencies are increasingly taking pharmaceutical, medical device, and food and cosmetics companies to task for advertising and promotion practices deemed or suspected of being false, misleading or otherwise unlawful. We help our clients preemptively address these issues while offering a bench of experienced litigators should the need arise. We understand the points of view of businesses, regulators, and law-enforcement officials alike, and we draw on this knowledge to provide practical, sophisticated solutions that address competing demands and achieve strategic goals.

Proposition 65

Arent Fox represents a number of fashion, luxury goods, and personal care products companies on a wide range of regulatory and product safety issues. Specifically, we assist companies in crafting product claims to avoid unnecessary Food & Drug Administration regulation. Also, we advise clients on many issues related to product development and most marketing compliance matters, such as product defects and reporting obligations that may exist.

In addition, we have assisted clients in recalling those products in the event there is a health or safety issue. We have worked with a number of our clients on the complex and unique issues presented by Prop 65 in the state of California.

Our Work

Some of our recent cosmetics, personal care, and OTC drug product work includes:

- Advising our clients on OTC/cosmetic product formulations, color additives, manufacturing compliance, product claims, ingredient safety/nomenclature, and related regulatory issues
- Representing clients before FDA and US Customs on product detentions at US Ports of Entry
- Managing issues related to product adulteration and misbranding, recalls, corrections, stock recoveries, and market withdrawals
- Navigating the regulation of cosmetic beauty appliances, including manual and powered appliances (e.g., electrical, radio frequency, and ultrasound)
- Counseling clients on FDA facility inspections, the drafting and review of standard operating procedures (SOPs), and state disclosure laws such as the California Safe Cosmetics Act, Proposition-65, and many other issues.