

# Product Regulatory & Compliance

Cozen O'Connor helps global product manufacturers, distributors and retailers achieve regulatory compliance, reduce exposure to civil litigation and government enforcement actions, and manage product withdrawals and recalls. We serve many highly regulated companies, including those in the consumer products, food & beverage, dietary supplement, drug & medical device, cosmetics, cannabis, pet, and home safety industries.

Successful companies manufacture innovative products and create bold marketing campaigns. We get that. And that is why Cozen O'Connor regulatory attorneys do not put up roadblocks to growth or product development; we put up guardrails to keep clients moving ahead at full speed.

Our attorneys have deep knowledge of all applicable federal regulations, including those enforced by the Food and Drug Administration (FDA), Consumer Product Safety Commission (CPSC), and Federal Trade Commission (FTC); model regulations of voluntary membership organizations, such as the Association of American Feed Control Officials (AAFCO); state regulations that apply to specific industries (such as cannabis) or specific geographies (such as California's Prop 65); commonly adopted industry standards, such as ASTM and ASME; and best practices issued by major trade associations.

Equally important, we know our way around the gray areas. Regulatory language is often ambiguous or incomplete, so decisions must be guided by broader knowledge of litigation trends, case law, and industry norms. Our regulatory team closely tracks all legal developments to stay abreast of shifting expectations and identify emerging "hot spots" may become the next big target for litigation.

Even with robust compliance programs, companies may face product withdrawals/recalls and legal challenges by individuals, classes, and government agencies. Cozen O'Connor partners with product manufacturers and sellers in times of crisis. We advise on the unique legal, reputational, and logistical issues stemming from product recalls and aggressively defend product liability claims when necessary.

## Cozen O'Connor has decades of experience advising companies on products regulations pertaining to:

- Advertising & Claims Made
- Labeling & Packaging
- Trademark & Copyright
- Product Safety
- Design & Manufacturing
- Product Withdrawals & Recalls
- Rebates, Gift Cards & Promotions
- Consumer Privacy
- Consumer Class Actions & Mass Torts

## Experience

Counsel a variety of manufacturers of nutritional supplements, over-the-counter drugs, beverages, and human and pet food on compliance with FDA, USDA, FTC, AAFCO, and applicable state regulations and guidelines as well as current trends in litigation affecting their respective industries.

Perform label, package, and advertising reviews for clients to ensure compliance with applicable regulations and mitigate risk of consumer protection class action lawsuits.



**Richard Fama**  
Member

rfama@cozen.com  
Phone (212) 908-1229  
Fax (866) 263-1334



**Jillian Thornton Flax**  
Member

jflax@cozen.com  
Phone (215) 665-2034  
Fax (215) 665-2013

## Related Practice Areas

- Aviation
- Cannabis
- Class Actions
- Commercial Litigation
- Food & Beverage
- Product Liability
- State Attorneys General
- Trademark & Copyright

## Industry Sectors

- Aviation
- Cannabis
- Food & Beverage

Counsel consumer product manufacturers on Consumer Product Safety Commission regulation and ASTM compliance and guide them through recalls when problems arise.

---

Advise food, beverage, cannabis, and consumer product manufacturers, distributors, and retailers on compliance with California's Proposition 65, and defend them in litigation.

---

Advise clients on country of origin claims to ensure compliance with FTC guidelines and applicable state law.

---

Won a case of first impression before the U.S. Court of Appeals for the Ninth Circuit affirming a dismissal motion approved by the district court. We represented a major food manufacturer in a putative class action alleging false advertising in its use of "Made in the USA" labels. After the initial complaint was filed, controlling state law was amended. We filed a motion to dismiss under the new law, which was granted with prejudice. That decision was appealed, and the Ninth Circuit ruled that the new law was applicable to existing claims.

---

Defeated a motion for class certification in a putative class action filed in California state court against our client, a major food manufacturer, alleging that the packaging for a specific type of dog treat misrepresented that the product was "wholesome." The plaintiffs sought approximately \$8.4 million on behalf of the putative class, plus punitive damages and attorneys' fees under California's consumer protection statutes. We defeated class certification, and plaintiffs agreed to drop all claims.

---

Won early dismissal for a major food manufacturer of a potentially sizable consumer protection class action claim that alleged false advertising of a product with annual retail sales of more than \$50 million. After winning a critical motion to bifurcate discovery, Cozen O'Connor then filed a motion to show cause, arguing that no class could be fairly defined. Plaintiffs agreed to dismiss the allegations.

---

Provide regulatory advice and counsel to a Class I medical device manufacturer.

---

Routinely assess website, labeling, and advertising materials for FDA regulatory compliance for a medical device manufacturer.

---

Developed an FDA compliant adverse event report tracking system for a medical device U.S. distributor.

---

Provide Pennsylvania regulatory advice and counsel to medical cannabis manufacturers, dispensaries, retailers, and ancillary businesses.

---

Provide New Jersey regulatory advice and counsel to medical cannabis manufacturers, dispensaries, retailers, and ancillary businesses

---

Proactively manage risk for consumer product manufacturers, component part manufacturers, distributors, and retailers by providing regulatory compliance advice concerning, among other things, relevant product testing and certification requirements, quality control process and procedure documentation as well as print and on-line advertising, packaging, and product related warnings. Additionally, review and advise on consumer complaint processes and procedures to ensure regulatory compliance and limit risk.

---

Provide ongoing regulatory advice and counsel to entities licensed, looking to become licensed or doing business with licensed cannabis businesses in Pennsylvania and New Jersey.

---

Represented a multi-state owner of cannabis licenses in connection with a joint venture to apply for a clinical registrant license.

---

Represented a medical marijuana company in an appeal regarding the company's license application.

---

Provide ongoing regulatory advice and counsel to manufacturers of CBD and THC infused beverage and food products.

---

Retained as local counsel in a California commercial litigation dispute by a Canadian diversified cannabis consumer products company that provides services and investment capital to the cannabis industry.

---

Retained as local counsel by a cannabis industry testing lab in a commercial dispute pending in Delaware.

---

Retained as local counsel by a cannabis industry testing lab in a commercial dispute pending in California.

---

Successfully prepared grower processor, dispensary, and vertical cannabis licensure applications.

---