



Consumer Product Safety

Our attorneys assist manufacturers, distributors, retailers, and suppliers in getting their food, drugs, medical devices, cosmetics, and consumer products to market in compliance with numerous federal and state consumer product safety laws and regulations. These product safety laws regulate thousands of consumer products across multiple industries and fall under the broad scope of agencies such as the Consumer Product Safety Commission (CPSC), the U.S. Food and Drug Administration (FDA), and the U.S. Environmental Protection Agency (EPA). These laws include the Consumer Product Safety Act (CPSA), Child Safety Protection Act, Children's Gasoline Burn Prevention Act, Federal Hazardous Substances Act (FHSA), Flammable Fabrics Act (FFA), Poison Prevention Packaging Act (PPPA), Refrigerator Safety Act, Virginia Graeme Baker Pool and Spa Safety Act (VGBA), and the Consumer Product Safety Improvement Act (CPSIA).

At Burr & Forman, our team has experience dealing with matters involving the CPSC and state issues, including the many facets of the CPSIA. We counsel clients in virtually all stages, including product development, compliance, government registration and approval, advertising, imports, labeling, reporting and recordkeeping, packaging, distribution, government inspections, internal investigations, recalls, interactions with the FDA and CPSC, and product liability litigation.

Compliance Counseling, Defense, and Proposition 65

Consumer product safety law is subject to frequent change while the CPSIA imposes considerable regulatory compliance requirements. According to the CPSIA, some companies and individuals must report to the CPSC immediately if they learn their product:

- Does not comply with a mandatory standard

PROFESSIONALS

Elizabeth B. Davis

RELATED AREAS

Insurance Litigation & Coverage

Mass Torts & Hazardous Substances

Personal Injury

Product Liability

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- Is subject to a ban under the Consumer Product Safety Act (CPSA)
- Contains a defect that could result in a substantial product hazard

We advise clients on product safety law compliance matters and on responding to customer concerns, including issues addressed publicly through SaferProducts.gov. Working alongside clients, we can design and manage product recalls, handle reporting and corrective action plans, and respond to customer complaints. Our team conducts comprehensive risk analysis and reporting by reviewing policies and procedures, disclosures, marketing material, contracts, and training material to ensure compliance with the rules of regulatory bodies. We also provide support for implementation, training, and control testing.

Our attorneys also have experience with various state product safety laws, including California's Proposition 65. Proposition 65 affects businesses nationwide by imposing strict warning notices for virtually all products sold or distributed within California that contain even very small levels of certain chemicals, and it imposes significant penalties and risks for noncompliance, as well as the risk of citizens' suits.

We assist clients in developing procedures for crisis response and accident investigation, as well as checklists to follow when immediate action is required. To decrease possible liability, we can offer employee training on how to best handle internal investigations or respond to large-scale accidents.

We also work with marketers of conventional foods and dietary supplements regarding compliance with FDA regulatory requirements and reviewing labeling for issues such as health and "natural" claims and nutrient content claims. We advise clients on current effective manufacturing processes (CGMP) and Hazard Analysis and Critical Control Points (HACCP) issues in food manufacturing agreements.

Product Stewardship and Recalls

We have experience in crisis response plans and can provide proactive guidance on risk avoidance and complaint management, as well as assistance with investigations, voluntary and involuntary product recalls, and responses to claims.

We also provide regulatory action support and defense with on-site regulatory audits, responding to civil investigative demands and regulatory inquiries as well as administrative and civil representation in associated litigation.

We work with clients on insurance claims as well as counsel consumer product manufacturers and distributors on risk-management strategies, such as auditing insurance coverage and reviewing warnings and product literature, all with the goal of reducing insurance costs. Our attorneys provide guidance on dealing with contracts with contractors, vendors, and suppliers to ensure entities are listed as additional insureds and all parties have adequate insurance coverage. Our attorneys assist clients in vendor due diligence by providing contract review, onboarding and annual due diligence audits, and vendor accountability reporting.

Our team also advises manufacturers on proper documentation of their design and safety processes, which can be crucial in a lawsuit or recall situation. We advise clients on developing procedures for monitoring and responding to customer complaints and can assist in leading training sessions on proper

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customer communication. We have handled investigations, responded to recalls and other complaints, worked with the CPSC on reporting requirements, and addressed Occupational Safety and Health Administration (OSHA) citations.

Responding to Consumer Incident Reports

Since the CPSIA launched its public online database of consumer complaints in March 2011, it has had significant business and legal implications for manufacturers, distributors, private labelers, and retailers of consumer products. The database allows consumers the capability to report product safety incidents as well as the ability to search for prior incidents and recalls of products they are considering purchasing.

The website, SaferProducts.gov, permits users to share content with social networking sites such as Facebook and Twitter. As a result, consumer complaints posted on the site can immediately be shared with millions of consumers worldwide.

We counsel clients on responding to consumer incident reports. We have experience in establishing claims processing and investigation procedures related to these reports and other consumer complaints. Our team can assist in many ways, such as developing specific guidelines and training for investigating and responding to consumer reports submitted to the SaferProducts.gov database and investigating and drafting appropriate responses to complaints.

The following is a representative sampling of our experience in this area:

- Assisting manufacturers, importers, and distributors of consumer electronics in investigations of multiple product lines regarding compliance with various statutory requirements, including the CPSA, CPSIA, Child Safety Protection Act, and Federal Hazardous Substances Act.
- Representing manufacturers and distributors in getting their drugs, medical devices, cosmetics, and consumer products to market in compliance with requirements enforced by the FDA, CPSC, and the U.S. Environmental Protection Agency (EPA).
- Counseling numerous manufacturers, importers, and retailers regarding compliance with consumer product safety requirements, including the Consumer Product Safety Improvement Act (CPSIA), the Federal Hazardous Substances Act (FHSA), the Poison Prevention Packaging Act (PPPA), and the Flammable Fabrics Act (FFA).
- Designing and managing investigations of alleged safety issues associated with a broad spectrum of medical devices and consumer products, including drug packaging, drug applicators, consumer electronics, batteries, furniture, furniture finishes, and various personal care products.
- Designing and managing national voluntary fast-track recalls for consumer products and manufacturers and importers.
- Counseling manufacturers and imports regarding regulatory requirements triggered when product safety issues arise in jurisdictions outside the U.S.
- Counseling various manufacturers regarding compliance with numerous FDA requirements including pharmaceutical and medical device approval processes, off-label drug and related issues, food safety issues and recalls, and issues associated with food additives.

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- Successfully defending allegations against international manufacturers and distributors of consumer electronics involving products liability and product safety.
- Assisting a national building products manufacturer with assessing potential nationwide product liability issues and developing strategies to avoid or minimize potential product liability claims.
- Advising clients on premarket issues and approval strategies, including marketing submissions, product classification, establishment registration, product listing, and medical device reporting.
- Advising marketers of conventional foods and dietary supplements regarding compliance with FDA regulatory requirements and reviewing labeling for issues such as health and “natural” claims and nutrient content claims. Also advising on current good manufacturing processes (GMP) and Hazard Analysis and Critical Control Points (HACCP) issues in food manufacturing agreements.
- Advising electronic cigarette manufacturers on marketing and labeling requirements, quality control manufacturing, and new product filings.
- Successfully defending product liability cases for an international heavy equipment manufacturer, a building products manufacturer, and consumer products manufacturers.
- Assisting clients in establishing or restoring working relationships with regulators.