

## Enforcement & Recalls

---

We assist clients with developing strategies and responding to critical “bet the company” issues as well as routine U.S. Food and Drug Administration (FDA) enforcement matters. We also advise companies on how to comply with regulatory requirements when conducting a voluntary recall. We assist all actors in the supply chain with following best practices to remove and/or correct products to comply with laws administered by the FDA and the U.S. Department of Agriculture (USDA). We also help companies develop recall strategies, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall. We also have experience handling recalls subject to Consumer Product Safety Commission (CPSC) jurisdiction, and Wiley attorneys have represented manufacturers, distributors, and retailers of consumer products in the full range of CPSC and other product safety regulatory activities. Our experience includes the following:

- Fashioning appropriate responses to FDA Warning Letters, requests for recall, threatened seizures, or proposed consent decrees. Our experience has included a wide range of FDA-regulated activities such as current Good Manufacturing Practices (cGMP), promotion and advertising, misbranding and adulteration, validity of data submitted to the agency, adverse reaction reporting, and allegations that labeling or advertising make a food, dietary supplement, or cosmetic a “new drug.”
- Advising companies on how to respond to FDA inspections and requests for information.
- Advising companies on how to respond to new internal information that raises concerns. For example, a food, medical device, or drug company may learn that a particular lot of its product may be adulterated or that there is new adverse reaction data. We are experienced in advising companies as they consider approaching the FDA and in negotiating solutions such as a possible recall or field correction notice, if necessary. Our experience in these matters permits us to bring a degree of sophistication to handling the public relations aspects of such situations.
- Assisting management and corporate attorneys in a realistic evaluation of the company’s position and in developing data to respond to the agency’s concerns. We are experienced in developing and presenting the scientific data or considerations in a way that will be most responsive in light of the agency’s concerns and the company’s position.
- Negotiating with the FDA to favorably resolve active or threatened enforcement actions.
- Assisting with voluntary recalls of drugs, cosmetics, and both human and pet food recalls.
- Removal and corrections of medical devices and FDA mandated recalls of medical devices.

## Contact Us

Ann M. Begley

202.719.4585 | [abegley@wiley.law](mailto:abegley@wiley.law)