



# FDA Administrative Enforcement Manual

*Florence R. Parker*

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When a problem arises with a product regulated by FDA, the Agency can take a number of actions to protect the public health. Initially, the agency works with the manufacturer to correct the problem voluntarily. If that fails, administrative enforcement and legal remedies include asking the manufacturer to recall a product and having federal marshals seize products if a voluntary recall is not done. Drugs can be seized and medical devices can be detained and imports can be stopped at the port of entry until problems are corrected. If warranted, FDA can ask the courts to issue injunctions or prosecute those that deliberately violate the law. When warranted, criminal penalties-including prison sentences-are sought.

Ensuring that your company is in compliance at all times in all departments is a never-ending task. Failure to get it right, even once, can mean excessive fines, penalties, or possible debarment. The FDA Administrative Enforcement Manual explores the control of drug research in pharmaceutical, vaccine, biologic, biotechnology, medical device, and cosmeceutical industries. Introducing basic industry techniques, the author explores every day industry problems and presents suggested methods for applying the theory to resolve them.

The book covers the ten critical Administrative Enforcement areas, including recalls, application integrity, injunctions, seizures, and more. It supplements these topics with regulations, lawsuit case studies, enforcement information, and reference materials. Offering insight into the impact of FDA enforcement on the national and international pharmaceutical industry, practitioners and industry suppliers, the book provides an understanding of drug development and manufacturing regulations in the United States and shows you what it takes to keep your company in compliance. The only complete, single source available, the FDA Administrative Enforcement Manual draws on the author's experience in the trenches of the pharmaceutical industry with administrative enforcement activities.

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