has no legal authority to compel a firm to conduct a recall of a drug product; thus, drug recalls are nominally "voluntary." As a practical matter, however, firms often have no alternative but to conduct a recall of product that violates legal and regulatory requirements in some manner. The factors that support a decision to conduct a "voluntary" recall include FDA's ability to issue adverse publicity about the firm, the threat of legal action, and mitigation of product liability exposure. The FDA has issued recall "guidelines" and strongly prefers that firms conducting a recall follow the guidelines.*

Although a discussion of the conduct of a recall is beyond the scope of this book, it should be noted that every drug manufacturer should have contingency plans for conducting a recall. If properly handled, the impact of a recall can be minimized. A firm's recall plan should address assessing the health hazard associated with a product problem; contacting regulatory authorities; contacting customers; public relations; handling physician, pharmacist, and consumer inquiries; and collecting and handling returned product. Of course, in any particular situation, some of these steps may not be necessary depending on the nature of the product and a firm's operations. A firm that does not have the requisite in-house expertise should seek the assistance of qualified outside help in this area, preferably before the need arises.

Recalls are commonplace and affect all drug firms ranging from multinational innovator companies to small niche generic firms. In a typical year, approximately 500 recalls of drug products are reported by the FDA. The great majority of these recalls involve the failure of a product to comply with its specifications in some manner, such as dissolution problems or subpotency near the end of the product's shelf life. For the most part, these recalls present technical violations that present either no or minor public health issues.

"Fraud Policy"; cGMP Problems

In response to widespread problems involving the submission and review of ANDAs in the late 1980s and early 1990s, the FDA adopted its application integrity policy, commonly known as the "fraud policy," in 1991.† The fraud policy is triggered if the FDA concludes that the sponsor of an ANDA or 505(b)(2) NDA (or other premarket approval application) has committed fraud, bribery, illegal gratuities, or other unlawful acts that call into question the integrity of data supporting the sponsor's application. The policy can also be triggered by a pattern of material errors due to sloppiness and similar causes.

If the FDA notifies a firm that the fraud policy is applicable, the FDA will stop reviewing the firm's applications and supplements until the firm has rehabilitated itself. Until rehabilitation has been completed, the firm may also find itself ineligible for government contracting. Rehabilitation consists of removal of all individuals who were associated with the improper acts followed by a "validity assessment" to determine the reliability of data in the firm's applications. Validity assessments are usually conducted by independent consultants (typically former FDA employees), retained at the firm's expense, followed by FDA spot-checking of data. FDA's

* 21 CFR § 7.40–§ 7.59.

† 56 Fed. Reg. 46,191 (September 10, 1991).