FDA Fact Sheets:
Recalls

When initiated, a recall serves to protect the public health from products that present a risk of injury, gross deception or are otherwise defective. Depending on the nature of the violation and the risk to public health, a recall can include actions ranging from a simple labeling change, an in-field correction or a full or partial removal of the product from the market. Medical device recalls are typically conducted voluntarily, under 21 CFR 7, by the manufacturer or distributor. Although rarely used, FDA has the authority to issue a mandatory device recall order under 21 CFR 810 when a manufacturer or distributor has not fulfilled their responsibility by voluntarily recalling a device that poses a risk to health.

Manufacturers and distributors are required to report any correction or removal of a medical device(s) to FDA if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the *Federal Food, Drug, and Cosmetic Act* caused by the device which may present a risk to health, as outlined under 21 CFR 806.

Following the decision to recall a product, FDA typically conducts a Health Hazard Evaluation to assess the impact of the action. After the evaluation is complete, FDA assigns a recall classification of class I, class II, or class III to indicate the relative degree of health hazard posed by the product being recalled or considered for recall. A Health Hazard Evaluation designation is based upon the following classification criteria:

- **Class I recall**: There is a reasonable probability that the use of, or exposure to, the recalled product will cause serious adverse health consequences or death;
- **Class II recall**: Exposure to the product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote; and
- **Class III recall**: The use of, or exposure to, the recalled product is not likely to cause adverse health consequences.

Manufacturers and distributors that initiate a voluntary recall are required to submit a recall strategy to FDA for review. In addition, it is the responsibility of the recalling firm to promptly notify each of its affected direct accounts about the recall, typically in the form of a recall letter. FDA regulation also requires that periodic recall status reports be submitted to the appropriate FDA district office so that the progress of the recall may be monitored.

A recall may be terminated once FDA determines that the recalling firm has made all reasonable efforts to remove or correct the product in accordance with the recall

strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product, at which time FDA will issue written notification that the recall has been terminated. Public notifications of recalls are made in the weekly *FDA Enforcement Report*.