FDA Fact Sheets:
Enforcement Actions

FDA can take several actions to protect public health. Enforcement actions may follow from violations uncovered by FDA during Quality System inspections, reports from competitors, and FDA monitoring of industry practices. FDA usually works with the manufacturer to achieve voluntary correction of violations.

When a manufacturer is not in compliance, an untitled letter may be issued as an unofficial action alerting the manufacturer of the need to make corrections. Alternatively, FDA may issue a warning letter, which lists the violations and possible enforcement actions that may be pursued if the problems are not voluntarily corrected. If the manufacturer does not make appropriate corrections, FDA may take legal actions including:

- Request that the manufacturer recall the product;
- Implement a seizure of the product;
- Detain product imports at the port of entry;
- Pursue an injunction;
- Pursue criminal prosecution of an individual or manufacturer;
- Pursue a consent decree with the manufacturer.

Warning letters, seizures, and consent decrees are some of the more aggressive actions that the agency may take to address regulatory noncompliance that may affect the safety of a device. In cases of criminal prosecution, prison sentences and civil money penalties may be sought. FDA also implements the Application Integrity Policy (AIP) to review the integrity of data and information submitted in applications, through which companies may be required to withdraw affected applications and FDA may defer scientific review of an application.

The agency also has utilized disgorgement and restitution to recover profits from companies with adulterated, misbranded or otherwise noncompliant products.