DEFINITIONS

COMPLIANCE ACHIEVEMENT: The observed repair, modification, or adjustment of a violative condition, or the repair, modification, adjustment, relabeling, or destruction of a violative product when either the product or condition does not comply with the Acts enforced by the agency.

CIVIL MONEY PENALTY: A monetary penalty for a non-criminal action that is assessed by FDA or the courts for violations of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

This part sets forth practices and procedures for hearings concerning the administrative imposition of civil money penalties by FDA. Listed below are the statutory provisions that authorize civil money penalties that are governed by these procedures.

(a) Section 303(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act (the act) authorizing civil money penalties for certain violations of the act that relate to prescription drug marketing practices.

(b) Section 303(f)(1) of the act authorizing civil money penalties for certain violations of the act that relate to medical devices and section 303(f)(2) of the act authorizing civil money penalties for certain violations of the act that relate to pesticide residues.

(c) Section 307 of the act authorizing civil money penalties for certain actions in connection with an abbreviated new drug application or certain actions in connection with a person or individual debarred under section 306 of the act.

(d) Section 539(b)(1) of the act authorizing civil money penalties for certain violations of the act that relate to electronic products.

(e) Section 351(d)(2) of the Public Health Service Act (the PHS Act) authorizing civil money penalties for violations of biologic recall orders.

(f) Section 354(h)(3) of the PHS Act, as amended by the Mammography Quality Standards Act of 1992 and the Mammography Quality Standards Act of 1998, authorizing civil money penalties for failure to obtain a certificate and failure to comply with established standards, among other things.

(g) Section 2128(b)(1) of the PHS Act authorizing civil money penalties for intentionally destroying, altering, falsifying, or concealing any record or report required to be prepared, maintained, or submitted by vaccine manufacturers under section 2128 of the PHS Act.

[60 FR 38626, July 27, 1995, as amended at 69 FR 43301, July 20, 2004]

INDICTMENT: A formal accusation by a grand jury that sets forth charges against a defendant and states when the alleged crime occurred. An indictment is not a finding of guilt. Guilt can only be determined by a judge or jury after a trial.

INJUNCTION: A civil action taken against an individual or firm seeking to stop continued
production or distribution of a violative product.

PROSECUTION: A criminal action taken against a company or individual charging violation
of the law.

RECALL AND FIELD CORRECTION: An action taken by a firm to either remove a product from the market or to conduct a field correction. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. A Class II recall is a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. A Class III recall is a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

SEIZURE: An action taken to remove a product from commerce because it is in violation of the law. FDA initiates a seizure by filing a complaint with the U.S. District Court where the product is located. A U.S. Marshal is then directed by the court to take possession of the goods until the matter is resolved.

WARNING LETTER: An informal advisory to a firm communicating the agency's position on a matter but does not commit FDA to taking enforcement action. The agency's policy

is that Warning Letters should be issued for violations which are of regulatory significance in that failure to adequately and promptly take corrections may be expected to result in enforcement action should the violation(s) continue.

For the purpose of the charts and graphs the following descriptive terms are used.

ADVERSE FINDINGS: The number of establishment inspections classified "Official Action Indicated" or "Voluntary Action Indicated" and the number of samples analyzed and classified as violative.

INDUSTRY SURVEILLANCE: The total number of establishment inspections, sample collections, field examinations and wharf examinations conducted by FDA personnel.