

Regulatory Procedures Manual

Chapter 11 – Glossary

ADDITIONAL SAMPLE: A physical sample collected from a previously sampled lot of either a domestic or imported product. Additional import samples must have the same sample number as the original sample. Additional domestic samples may have another sample number, but it must be flagged as an “ADD” Sample, with the original sample number referenced in the “Related Sample” block on the Collection Record.

ADJUDICATE (ADJUDICATION): To make a final judgment in a lawsuit, the judgment of the court.

AFFIDAVIT: For affidavits provided to FDA -A written statement from a person who has dealt with the goods sampled, knows material facts relating to the movement of the goods or to events affecting their condition, and/or or other fact relevant to the goods in question, which is obtained by an FDA employee. The affidavit is signed and sworn to (affirmed as true) by the affiant and then signed by the FDA employee. See IOM Chapter 4 and affidavit forms in that chapter.

For affidavits provided by FDA - A written statement signed in the presence of a notary public under a sworn oath that the statement is true. FDA considers such affidavits to be testimony covered by 21 CFR 20.1. See RPM Chapter 10, Requests for Testimony.

ALLEGATION: An assertion or statement, made in a pleading, setting forth what its maker intends to prove. A statement of the issues in a written document (a pleading) which a person is prepared to prove in court.

AMERICAN GOODS RETURNED: Goods produced in the United States (U.S.) which, after being exported, are subsequently returned to the U.S. Such goods are considered imports.

AMICUS CURIAE: Literally, “friend of the court.” A person who is not a party in a suit, but is allowed to file a brief to present their views on the matter before the court.

AMS: See Automated Manifest System.

ANSWER: A formal, written statement by the defendant in a lawsuit which answers each allegation contained in the complaint. In a seizure action, after filing a Claim of Ownership, the claimant files an Answer in which he may deny any or all of the allegations of the Complaint for Forfeiture.

APPEAL: The formal review by a higher court of a lower court's disposition of a lawsuit. Also, the review of an agency decision at a higher level within the agency or in a court.

BATF: See Bureau of Alcohol, Tobacco and Firearms.

BILL OF LADING B/L: The written order from a shipper to a carrier to move goods from one place to another. When available, this is the best source of shipping dates, origin, and name of shipper.

BIOLOGICAL PRODUCT: Means any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man.

BIMO: Bioresearch Monitoring Program.

BONA FIDE: Literally, "in good faith." A bona fide document is a genuine one.

BOND: A written promise to pay a certain sum of money in the event agreed upon conditions are not met. For example, section 304(d) of the FD&C Act requires a bond as a condition of the release of condemned articles for salvaging.

BOND ACTION: Action taken by Customs resulting in forfeiture of all or a portion of an entry bond when an importer fails to redeliver merchandise covered by such a bond.

BOND VIOLATION: Failure to redeliver merchandise that is in import status when demanded by Customs. Such failure may result in bond action.

BONDED WAREHOUSE: A warehouse in the U.S. where imported merchandise is stored under Customs bond prior to withdrawal for consumption entry or export.

BREAK-BULK CARGO: Term used to describe cargo that is transported in individual units, i.e., sacks, boxes, bags, or cartons which are not containerized. Also refers to loose (unbound) items such as sugar.

BROKER (CUSTOMS BROKER): Private individual or firm licensed by Customs to represent importers concerning import matters. See Filer.

BROKER'S REFERENCE NUMBER: A number assigned by brokers to identify an entry of imported merchandise. This number is not to be confused with the entry number assigned through Customs.

BUREAU OF ALCOHOL, TOBACCO AND FIREARMS: The Homeland Security Act of 2002 divided the Bureau of Alcohol, Tobacco and Firearms into two new agencies, the Bureau of Alcohol, Tobacco, Firearms, and Explosives, which has moved to the Department of Justice, and the Alcohol and Tobacco Tax and Trade Bureau (TTB),

which remained in the Department of the Treasury. This division was effective January 24, 2003. The newly created TTB will, as ATF did before it, administer and enforce the existing Federal laws and tax code provisions related to the production and taxation of alcohol and tobacco products. A memorandum of understanding (MOU) between FDA and TTB (formerly BATF) clarifies and coordinates the responsibility of each agency with respect to the identification, testing, and recall of adulterated alcoholic beverages. Further, the MOU confirms TTB (formerly BATF) policy with respect to the labeling of ingredients and substances in alcoholic beverages that pose a public health problem.

BURDEN OF PROOF: The necessity or duty of proving a fact or facts in dispute on an issue.

CERTIORARI: "To be informed of". An extraordinary writ issued by a superior court (as the Supreme Court) to call up the records of a particular case from an inferior judicial body (as a Court of Appeals). When the Supreme Court grants certiorari, it has agreed to hear the case. If it denies certiorari, it will not hear the case

CARGO CONTROL: Placement of an entry in a bonded warehouse so that movement of the goods can be controlled and traced. Cargo control may occur in those situations where an importer does not hold shipments pending a suitable release from FDA and introduces the product into domestic distribution.

CBER: Center for Biologics Evaluation and Research.

CDER: Center for Drug Evaluation and Research.

CDRH: Center for Devices and Radiological Health.

CENTRALIZED EXAMINATION STATION (CES): A privately operated facility at which imported merchandise is made available to Customs officers for physical examination. A CES may be established in any port, or any portion of a port, or any other area, under the jurisdiction of a Customs district director.

CERTIFICATE FOR EXPORT: Firms exporting products from the U.S. are often asked by foreign customers or foreign governments to supply a certificate concerning the regulatory status of a product, or the system by which a commodity is manufactured. See Compliance Policy Guide 110.100, 7150.01.

CERTIFICATION: Agreement between the U.S. government and a foreign government specifying the conditions under which FDA may accept the foreign government's certification that the product complies with the Federal Food, Drug, and Cosmetic Act and/or other pertinent Acts.

Also, a written assurance, or official representation, that some act has or has not been done, or some event occurred, or there has been compliance with some legal formality. Typically, a requester will ask that FDA certify as to the authenticity of an FDA record as a true copy. FDA processes requests or subpoenas for certification under 21 CFR 20.3.

CFSAN: Center for Food Safety and Applied Nutrition.

CGMP: Current Good Manufacturing Practice.

CHARGE SHEET: The specification of the violation attached to a Section 305 Notice. It is the proposed statement of charges that, should prosecution ensue, would become the Government's allegation in the Criminal Information.

CHECK ANALYSIS: A second examination of a sample that has been examined and found violative. Check analyses are to be conducted by other than the analyst performing the original analysis.

CITATION: See Section 305 Meeting.

CITEE: One who is cited. See also Section 305 Meeting.

CIVIL MONEY PENALTIES: Monetary penalties that are assessed by FDA for violations of the Federal Food, Drug, and Cosmetic Act (the Act) or the Public Health Service Act (see FD&C Act Section 303(f)).

CIVIL SUIT (Federal Court): A lawsuit brought under the Federal Rules of Civil Procedure. For example, seizure, injunction, and civil contempt are actions initiated under civil rules.

CLAIM: A statement of interest in seized property, affirmed by sworn oath, entered by a person in response to a seizure action.

CMP: Civil Money Penalty (see FD&C Act Section 303(f)).

CODE OF FEDERAL REGULATIONS (CFR): An annual publication which contains regulations of Executive Departments and Agencies of the Federal government. The CFR is divided into 50 titles that represent broad areas subject to Federal regulation. Each title is divided into chapters that bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas. FDA's regulations are in Title 21, Parts 1-1271. U.S. Customs regulations are found under Title 19.

COMMINGLED LOTS: Merchandise arriving off the same carrier with identical markings but covered under two or more entries. Two or more separate shipments of the same product, stored together and bearing no distinguishing marks which enable easy separation. There may be many codes in one shipment.

COMMISSION: A commission is a formal written document granting the power to perform various acts or duties

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.

COMPLIANCE POLICY GUIDES (CPG): Compliance Policy Guides explain the Food and Drug Administration (FDA) policy on regulatory issues related to FDA laws or regulations.

COMPLAINANT: Person registering a complaint, as a consumer complaining about an article. Also, the party who files the complaint in a legal action or proceeding (i.e., the plaintiff).

COMPLAINT FOR FORFEITURE: The document furnished to the United States Attorney for filing with the Clerk of Court to initiate the seizure of an article. (This document was formerly known as a Libel of Information.)

COMPLAINT SAMPLES (FLAGGED "COMPLAINT"): Samples collected from a consumer because of a complaint or injury.

CONFIDENTIALITY AGREEMENT: An agreement not to communicate certain knowledge to others.

CONSENT DECREE OF CONDEMNATION: The document entered by the court in a seizure action based on the claimant's agreement that the article seized is in violation as alleged in the Complaint for Forfeiture and the article is subject to condemnation. It is also a declaration of Claimant's intent to provide a Bond and to recondition the article under supervision of FDA and to pay costs.

CONSENT DECREE OF INJUNCTION: An injunction to which the defendant has agreed and which is filed in court.

CONSIGNEE: Person named in a bill of lading to whom or to whose order the bill promises delivery.

CONSUMER SAFETY INSPECTOR (CSI)/CONSUMER SAFETY OFFICER (CSO): FDA personnel performing inspections, investigations, sample collections, and examinations of imported articles.

CONSUMPTION ENTRY (CE): See Entry.

CONTAINER: Term used to describe a self-contained unit of various dimensions and configurations used for storage and transportation of goods.

CONTEMPT OF COURT: Any act which is calculated to embarrass, hinder, or obstruct a court in the administration of justice, or which is calculated to lessen its authority or its dignity. The willful disobedience of a judge's command or of an official court order is a contempt of court. Civil contempt consists of a failure to do something ordered by the court for the benefit or advantage of another party, and a fine is imposed. Criminal

contempt is an act done in disrespect of the court or its process or which obstructs the administration of justice, and a fine or imprisonment is imposed.

CONTEST: To dispute or challenge the case made by a plaintiff or prosecutor.

CORRECTION: "Correction" means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product or the promotional materials that cause the product to be violative, without its physical removal to some other location.

COUNT: A statement of a violation of the Act in a Criminal Information or Indictment.

COUNTERCLAIM: A claim presented by a defendant in opposition to the claim of the plaintiff, which claim could have been filed in a separate suit. If asserted in the same suit brought by plaintiff, it is called a counterclaim.

CONTRABAND: Against the law. Prohibited. Goods exported or imported into a country against its laws.

COUNTRY OF ORIGIN: The country of manufacture, production, or growth of any article of foreign origin entering the U.S. (see Customs regulation, 19 CFR Part 134).
CPG: See Compliance Policy Guides.

CREDENTIALS: Testimonials, certificates, or diploma something that gives a title to credit or confidence that a person a right to exercise official powers.

CRIMINAL CASE (Federal Court): A criminal prosecution brought under the Federal Rules of Criminal Procedure, whereby the defendant may be punished for having violated the law, or a court order.

CTP: Center for Tobacco Products

CUSTOMS (U.S. CUSTOMS SERVICE): Previously, a Bureau of the Department of the Treasury, whose primary duties included the assessment and collection of duties, taxes, and fees on imported merchandise, and the enforcement of Customs and related laws. Effective March 1, 2003, the U.S. Customs Service moved to the Department of Homeland Security and is no longer a component of the Department of the Treasury. Now referred to as Customs and Border Protection (CBP), it is the primary enforcement agency protecting the nation's borders. It continues to be responsible for regulating and facilitating international trade, collecting import duties, and enforcing U.S. laws.

CUSTOMS ENTRY NUMBER (CEN): The number assigned to an entry document and used by Customs for future references to the entry. The CEN is an 11-character entry number in the format XXX-NNNNNNN-Y. XXX represents an entry filer code assigned by Customs, NNNNNNN is a unique number, which is assigned by the broker or importer, and Y is a check digit computed from the first 10 characters based on a formula provided by Customs. Also referred to as Entry Number.

CVM: Center for Veterinary Medicine.

DALs: See Defect Action Levels.

DATE AVAILABLE: The date supplied by the importer or his/her representative as to when the shipment is available for examination by the agency. Date of availability for examination or sampling will differ based upon the mode of transport of the shipment (i.e., seaports have large facilities for containers and it may be several days before the shipment is available for examination; however, shipments delivered by trucks at the borders are usually available for examination within several hours upon arrival).

DATE COLLECTED: The date a sample is collected.

DATE OF ARRIVAL: The date a carrier transporting imported cargo arrives in the U.S.

DEA: See Drug Enforcement Administration.

DEALER: The term is agency jargon to identify the party from whom a sample was collected; this does not have to be a business concern and often is a private party. Under the Radiation Act, this term is defined slightly differently, as found in 21CFR 1000.3(f).

DEALER STATEMENT (D/S): The written statement taken from the dealer at the time a sample is collected and in which the dealer asserts that the sample obtained was taken from a lot received by him from a certain source and that those documents showing the movement of the lot were furnished for copying.

DEALER VIOLATION: A violation of Section 301(k) of the FD&C Act indicating the doing of some act after shipment in interstate commerce which resulted in the article being adulterated or misbranded.

DECLARATION: A written statement signed under the penalty of perjury. A declaration can substitute for an affidavit in federal court proceedings. 28 U.S.C. 1746. FDA considers a declaration to be testimony covered by 21 CFR 20.1.

DEFAULT DECREE: A Default Decree of Condemnation is a Court Order entered when a seized article is not claimed or defended. The order condemns the article as being in violation of the law and provides for its destruction, donation to charity, sale, or disposal as the Court may elect to decree. When signed by the Court, it signifies the final adjudicatory step in a seizure action.

DEFECT ACTION LEVELS (DALs): Established for specific commodities or products for which filth or extraneous matter is unavoidable and for which a zero tolerance would not be realistic.

DEFENDANT: In civil or criminal cases, the party or parties named in an Information, Indictment, or Complaint, and against whom the Government is proceeding. The article against which a seizure action is brought is also referred to as the defendant.

DE MINIMIS: So minor as to be disregarded; Insignificant or unimportant.

DE MINIMIS NON CURAT LEX: The principle that the law does not concern itself with minor or insignificant matters.

DENATURE: The decharacterization of an article generally through the addition of some foreign substance in sufficient quantity so as to preclude its future use for its original purpose.

DEPTH OF RECALL: "Depth of recall" means the level in the distribution chain to which the recall is to extend. This will depend on the product's degree of hazard and the extent of distribution. Levels are as follows:

1. Consumer or User Level - which may vary with product, including any intermediate wholesale or retail level. Consumer or user may include the individual consumers patients, physicians, restaurants and hospitals.
2. Retail Level - recall to the level immediately preceding the consumer or user level. It includes retail groceries, pharmacies, hospital pharmacies, dispensing physicians, institutions such as clinics and nursing homes, and any intermediate levels.
3. Wholesale level - all distribution levels between the manufacturer and the retailer. This level may not been encountered in every recall situation, i.e., the manufacturer may sell directly to the retailer.

NOTE: In some cases, the user level and the retail level may appear to refer to the same group. Certain devices, radiological products, biologics, drugs are supplied directly to physicians or hospital type environments who will, in turn, use the product in the prescribed manner on/for the consumer. This kind of special environment will be considered as the "user level."

DEPOSITION: The taking and recording of testimony of a witness under oath, in front of a court reporter prior to trial and away from the courtroom. FDA considers an employee's responses in a deposition to be testimony covered by 21 CFR 20.1. Testimony of a witness or a party taken under oath outside the courtroom, the transcript of which may become part of the court's file.

DETENTION (Imports): Administrative act where FDA requires that imported articles that appear violative under the laws FDA administers be held intact. Detained articles are released if brought into compliance with or rendered not subject to the FD&C Act (the Act), or are refused entry if not brought into compliance. (Other types of detention – section 304(g) of the Act-Administrative detention of devices; section 304(h) of the Act-Administrative detention of food.)

DEVANNING: The removal of all articles from a container for examination or sampling purposes. Also known as stripping of containers.

DIRECT ACCOUNTS: "Direct accounts" are those consignees, either domestic or foreign, who received shipments of the recalled products directly from the recalling firm or indirectly from the recalling firm's product source via drop shipment.

DISCHARGING: The unloading of imported merchandise from a carrier.

DISCOVERY: The process of obtaining information concerning the other party's case. Methods of discovery are contained in Rule 16 of the Federal Rules of Criminal Procedure, and Rules 26 through 37 of the Federal Rules of Civil Procedure.

DISMISSAL: An order or judgment that disposes of an action, suit, or motion without a trial on the issues. A legal action may be dismissed by the court for failure to introduce evidence of facts on which relief may be granted.

DIVERSION: A method used to divert products from their intended market. For example, a drug manufacturer ships a drug labeled in Spanish to an authorized distributor in Costa Rica, but the product is diverted by the distributor into the U.S. market.

DOCKET, CIVIL: A book kept by the clerk of court, in which each civil action is entered and assigned a consecutive file number. All papers filed with the clerk, all process issued and returns made thereon, all appearances, orders, verdicts, and judgments are entered chronologically in the civil docket on the folio assigned to the action and marked with its file number.

DOCKS (PIERS): Unloading facilities for vessels.

DOCUMENTARY (DOC) SAMPLE: An official sample where no actual physical product is taken. A DOC sample is collected based upon the documents accompanying the entry such as freight bills, and bills of lading, or any other record or document related to the lot or item involved. DOC samples are collected in situations where an actual physical sample is not practical or where there is little or no need for laboratory analysis. In addition to copies of transportation records, this official sample may consist of labels, photos of the product, drawings, and sketches.

DOCUMENTATION: The collection of documents to support a certain element of proof, i.e., the copying of a Bill of Lading to demonstrate that interstate commerce has been accomplished.

DOMESTIC IMPORT (DI) SAMPLE: A sample of an imported article collected after release from import status (See IOM Chapter 4).

DRUG ENFORCEMENT ADMINISTRATION (DEA): A component of the Department of Justice responsible for enforcing the controlled substances laws and regulations.

EDIFACT: See Electronic Data Interchange for Administration, Commerce, and Transportation.

EEPS: See Electronic Entry Processing System.

EFFECTIVENESS CHECKS: "Effectiveness Checks" are actions taken to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination of both. These checks are to be conducted by the recalling firm as part of its recall strategy. In the determination of which consignees should be contacted by the firm for effectiveness checks, FDA may consider as acceptable for a portion of the verification of recall effectiveness:

1. The firm's receipt and retention of response cards, e-mails, or letters from consignees in accordance with instructions issued in the recall notification.
2. Signed records or reports of actions accomplished by the firm's own representatives or signed records or reports from direct or sub-accounts.

EFFECTIVENESS CHECK LEVEL: The "Effectiveness Check Level" is an alphabetical term representing the extent to which effectiveness checks will be made within the distribution chain, including consumers or patients where appropriate.

1. Level A--100 percent of the total number of consignees to be contacted (at the specified recall depth).
2. Level B--Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees to be contacted (at the specified recall depth).
3. Level C--10 percent of the total number of consignees to be contacted (at the specified recall depth).
4. Level D--2 percent of the total number of consignees to be contacted (at the specified recall depth).
5. Level E--No checks.

ELECTRONIC DATA INTERCHANGE FOR ADMINISTRATION, COMMERCE, AND TRANSPORTATION (EDIFACT): A United Nations sponsored initiative to develop international electronic messages including electronic invoices.

ELECTRONIC ENTRY PROCESSING SYSTEM (EEPS): The link to ACS, screening portion of OASIS, and initial user interface.

ENJOIN: To require a person, through a court-ordered injunction, to perform, or to abstain or desist from performing a specified act or course of conduct. See injunction.

ENTRY: Delivery or offer for delivery of merchandise into the Customs Territory of the U.S. from an outside point.

- A. **Consumption entry (CE):** The entry documentation submitted to Customs by the importer when imported merchandise is offered for consumption.

- B. **Formal entry:** As defined by Customs regulations, an entry required to be covered by an entry bond. Currently, most entries with aggregate values of \$2,500 or more (value subject to change).
- C. **Informal entry:** As defined by Customs regulations, an entry whose value is currently less than \$2,500 (value subject to change) and therefore usually not imported under bond. U.S. goods returned (USGR) valued at \$10,000 or less are also considered informal entries. Informal entries may be converted to formal entries, pursuant to Customs regulations.
- D. **Intransit Entry (IT):** An entry document filed with Customs by the importer. It allows the merchandise to move from the port of unloading to its destination under Customs bond without the initial payment of entry fees and allows the importer 30 days to file a consumption entry. FDA usually inspects the merchandise at the destination point (port of entry).
- E. **Mail Entry:** Merchandise offered for entry through the mail. Where the value of the merchandise is less than \$2,500 (the current threshold between formal and informal entries), an entry document is generally not required to be filed with Customs. For mail entries, Customs prepares the appropriate paperwork for the entry, which is typically forwarded to the addressee by the Postal Service, who then collects the duty for Customs.
- F. **Personal Baggage Entry:** Entry of merchandise by personal baggage.
- G. **Transportation and Exportation (T&E):** An entry document (CF-7512) filed with Customs which permits merchandise to be transported through the U.S. and exported intact, without payments associated with entry, to a foreign destination. This does *not* exempt the articles from complying with the FD&C Act. See CPG Manual Section 110.700 (7153.08).
- H. **Warehouse Entry:** An entry document filed by the importer with Customs for storage of goods in a bonded warehouse without the initial payment of entry fees. (Normally, it is filed prior to manipulation or withdrawal for export).

ENTRY BOND: A bond posted by the Importer of Record with Customs, currently in the amount of three times the value of the imported product, to insure redelivery of the product for examination, reconditioning, export, or destruction.

ENTRY DOCUMENT (ENTRY PACKAGE): Documents describing the articles offered for entry which may contain a consumption entry form, commercial invoice, manifest, or other FDA notification.

ENTRY NUMBER: See Customs Entry Number.

ENVIRONMENTAL PROTECTION AGENCY (EPA): The federal government agency responsible for protecting human health and the environment. EPA enforces FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) and registers pesticides for use in the U.S. on food crops, among other duties.

ESTABLISHMENT: A place of business or residence, including all accoutrements essential to such business or resident.

- A. **Grower:** Raises livestock, raw agricultural products, or aquaculture products for sale (farms, feedlots, dairy farms, and botanicals).
- B. **Manufacturer:** Firm or individual responsible for making a product.
- C. **Packer/repacker:** Packs a product or products into different containers without making any change in the form of the product. Includes packers of raw agricultural products and medical gas repackers.
- D. **Salvage Operation:** An establishment dealing primarily in the reconditioning and resale of damaged goods.
- E. **Shipper:** Firm or individual responsible for introducing merchandise into interstate commerce by way of transport and that does not act as a manufacturer, repacker, distributor.
- F. **Warehouse:** A private or public facility for the storage of consumer products, including products reshipped from the producer or grower to the manufacturer or other customer.

EX PARTE: On one side only. These are cases in which only one side is represented or present. On behalf of only one party, without notice to any other party. For example, a request for a search warrant is an ex parte proceeding, since the person subject to the search is not notified of the proceeding and is not present at the hearing.

EXPORT: The shipment of articles from the U.S. to a foreign country. Articles that comply with the FD&C Act may be exported freely. Section 801(e)(1) contains the requirements for the export of articles that, but for intended export, would be adulterated or misbranded. Section 801(e)(2) provides additional requirements applicable to the export of unapproved medical devices; and Section 801(f)(2) addresses the export of approved drugs for unapproved uses. Section 802 provides provisions for the export of unapproved drugs, biologics, and devices. Also see Re-Export.

EXECUTION OF DECREE: The carrying out of the court's order. For example, the destruction of seized goods by the Marshal, in response to a Default Decree of Condemnation.

FACTORY FOOD SAMPLES: A sample, usually investigational in nature, obtained from an establishment where food is manufactured, processed, or packed, used to show conditions in the establishment. Such samples include in-line samples and require analysis to determine the specific conditions.

FDA ORDERED RECALL: "FDA ordered recall," means a recall initiated by a firm in response to an order for such action. Examples would be: device recalls ordered under section 518(e), Infant Formula recalls ordered under section 412(e)(1) of the act, and human tissue for transplantation ordered under 21 CFR Part 1270.

FDA RECALL AUDIT CHECK PROGRAM: The purpose of FDA audit checks is to determine the adequacy of the firm's performance in assuring that all consignees have received notification of the recall and are taking appropriate action. A FDA audit check program should be determined after evaluating the recalling firm's strategy. The audit

check levels will either be based upon the effectiveness check levels provided in 21 CFR or on other statistically valid plans. The method for conducting audit checks may be personal visits, telephone calls, or a combination thereof. Cooperating federal, state, or local officials may assist FDA in the performance of the audit checks.

FDA REQUESTED RECALL: "FDA requested recall" means a recall initiated by a firm in response to a formal request for such action by the Associate Commissioner for Regulatory Affairs, or the appropriate center director when the authority has been delegated.

FD&C Act/FDCA: The Federal Food, Drug, and Cosmetic Act.

F.D.C. OR INJ NUMBER: The F.D.C. or INJ number is the identification used by the General Counsel's Office to designate FDA cases. On all correspondence pertaining to seizure and prosecution cases, show the F.D.C. number directly under the sample number identification. On injunction cases, show the INJ number the same way.

FEDERAL IMPORT MILK ACT: An Act to regulate the importation of fluid milk and cream into the U.S. for the purpose of protecting the public health (see 21 CFR 1210).

FEDERAL TRADE COMMISSION (FTC): An independent government agency whose goal is to prevent free enterprise from being hampered by monopoly or restraints on trade or corrupted by unfair or deceptive trade practices.

FIARS: FIARS (FDA's Import Alert Retrieval System) is a computerized retrieval system for import alerts. Users navigate FIARS by searching for the import alert number, or by the problem, product, or country keyword, or by utilizing a full text search for a keyword or any other word that may be contained in the system. FDA updates FIARS nightly and the data

is accessible to FDA users via the intranet. A redacted version of the data is also available to the public via the internet.

FILER: A Customs term used to identify the individual or firm responsible for filing an entry, which is usually the broker but may be the importer.

FILTH EXHIBITS: Any material obtained to illustrate a condition. An exhibit is for court use, and is self-explanatory in nature. Usually no confirmatory analysis by the laboratory is required. Exhibits include photographs, rat and rodent pellets and mice nests.

FINAL ORDER: The last order issued by the Court in a lawsuit, which terminates the action.

FIRM INITIATED RECALL: "Firm initiated recall," means a recall that is initiated by a firm on its own volition without a formal request from FDA.

FOOD STANDARDS SAMPLES (PREFIX "F.S."): Samples collected as a direct result of an assignment in connection with food standards development.

FOR CAUSE INSPECTION: An inspection that is carried out in response to specific information that raises questions, concerns, or problems associated with an FDA regulated firm or commodity. This information could come to the attention of FDA from any source, and includes, but is not limited to, the following: the results of a sample analysis, observations made during prior inspections, recall or market withdrawal, consumer or employee complaint, adverse reaction report, or suspicion of fraud.

FOREIGN MAIL DIVISION: A designated location within a post office facility for examination of foreign mail by Customs.

FOREIGN TRADE ZONES: Areas set aside in the U.S. that allow a person to hold or otherwise manipulate goods for an unlimited period of time awaiting a favorable market in the U.S. or nearby countries without being subject to Customs duties, tax, or other charges. See CPG Manual Section 110.200 (7150.11) and Section 110.600 (7150.14).

FORFEITURE OF BOND: Literally, the loss of a bond, as a result of a failure to perform the conditions agreed upon when the bond was made.

FORMAL ENTRY: See Entry.

FP&F (FINES, PENALTIES AND FORFEITURES): Both a module of Customs ACS and a division within Customs which deals with post-entry procedures, i.e., bond actions, liquidated damages, and seizures.

FPLA (THE FAIR PACKAGING AND LABELING ACT): Applies only to retail containers of foods, drugs, cosmetics, and devices.

FREIGHT BILL (F/B): The document stating the transportation charges incurred by the carrier (a bill for the freight charges on a shipment). Next to a B/L, the freight bill is the most authentic document that supports movement of a shipment in interstate commerce.

GAO (GOVERNMENT ACCOUNTABILITY OFFICE): Was previously named the General Accounting Office. GAO, which is independent and nonpartisan, is commonly called the investigative arm of Congress. It studies how the federal government spends taxpayer dollars. GAO evaluates federal programs, audits federal expenditures, and issues legal opinions.

GRAND JURY: A jury of inquiry composed of 16-23 citizens whose duty it is to determine whether probable cause exists that a crime has been committed and whether an indictment (true bill) should be returned for such a crime. If the grand jury determines that probable cause does not exist, it returns a "no bill." The grand jury is an accusatory body; it does not determine guilt.

GREY MARKET: Generally used to describe diversion of regulated commodities purchased from foreign suppliers and introduced into the U.S. through a source other than the authorized U.S. dealer. It is also used to describe situations where a product manufactured by a foreign subsidiary of a U.S. firm is not identical to the U.S. manufactured product yet the product is shipped to the U.S. for marketing. The products may be imported by a third party from a dealer in a country other than the country of origin.

GROWER: See Establishment.

GUARANTY: A formal and signed agreement between buyers and sellers in which the latter verifies the goods he sells are not in violation of the FD&C Act when shipped. A guaranty that meets the conditions in section 303(c)(2) of the Act protects a good faith purchaser from criminal prosecution based on violations of sections 301(a) or 301(d).

HARMONIZED TARIFF SCHEDULE (HTS): Ten-digit international tariff codes that replaced TSUSA codes on January 1, 1989. This system identifies products for classification purposes. Once the classification is determined, the rates of duty, value-added tax, quota limits, and visa requirements can be obtained.

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP): A prevention-based food safety system by which food processors and importers evaluate the kinds of hazards that are reasonably likely to occur and could adversely affect the safety of their products, institute controls necessary to keep these hazards from occurring or reduce the hazard to an acceptable level, monitor the performance of these controls, and maintain records of this monitoring as a matter of routine practice.

HEALTH FRAUD: The promotion, advertisement, distribution, or sale of products, that are represented as being effective to diagnose, prevent, cure, treat, or mitigate disease or other conditions, or to provide a beneficial effect on health, but which have not been proven safe and effective. Such practices may be intended to defraud or mislead.

HEALTH HAZARD EVALUATION: A "health hazard evaluation" is an evaluation by FDA scientists of the threat to health presented by a product, including its labeling and/or

promotional materials, that is being recalled or considered for recall. It takes into account, but is not limited to, the following:

1. Deaths, diseases, injuries or other adverse reactions that have already occurred from the use of the product.
2. Existing conditions that could contribute to a clinical situation that could expose humans or animals to a health hazard.
3. Assessment of population who may be at greatest risk (age, physical condition.)
4. Assessment of degree of seriousness of the health hazard to the population at greatest risk.
5. Assessment of the likelihood of the occurrence of the health hazard.
6. Assessment of long range or immediate consequences of the hazard. See 21 CFR 7.41(a) for a full description of these factors.

HEARING: The opportunity for a party to present views. In imports, the importer may explain why his goods should not be refused entry and returned to the shipper. Many types of administrative hearings are provided for in various sections of the CFR.

HEARING RESPONDENT: Individuals who respond to the "Notice of Detention and Hearing."

HOLD OF SHIP: Portion of a vessel where cargo is stored for transportation.

HOME DIVISION: The Division in whose program the alleged violation of the Act occurs, or in whose program the firm or individual responsible for the alleged violation is included. The original point from which the article was shipped, or offered for shipment - as shown by the interstate records - is usually considered the point where the violation occurred; and the shipper of such article, as shown by such records, is usually considered to be the alleged violator.

For actions based on goods which became violative after interstate shipment was made, or after reaching their destination (such as 301(b) and 301(k) violations), the dealer in whose possession the goods are sampled is usually considered the violator and the location of this dealer determines the "Home Division."

If both the shipper and the dealer are legally responsible for the violation, and are located in different Divisions, the records and correspondence shall be processed, routed, and distributed in accordance with the needs of each Division.

IMMEDIATE DELIVERY (ID): An entry document (CF-3461) filed with Customs by the importer. An ID allows the importer to take immediate possession of the goods and allows him/her 10 days to file the Consumption Entry (CE) documentation.

IMMEDIATE DELIVERY (ID) ADVANCE NOTICE: The filing of an ID by the importer prior to the arrival of the goods at the point of entry.

IMMEDIATE EXPORT (IE) NOTICE: A document that is filed with U.S. Customs by a broker on behalf of the importer for refused merchandise prior to exportation.

IMPORTS: Products brought into the U.S. from foreign countries. Such products include American manufactured goods that are being returned to the United States. Once such products are entered (admitted by FDA and the bond is liquidated by Customs) into the United States, they are no longer considered to be in import status. Under certain limited conditions, released articles may be reverted back to import status.

IMPORT ALERTS: Information to the FDA Division offices concerning unusual or new problems affecting imports which gives background and compliance guidance information for each product and problem.

IMPORT BULLETINS: Informational bulletins that generally provide only information on a problem affecting imported products.

IMPORTER OF RECORD: The individual responsible for assuring that imported goods are in compliance with all laws affecting the importation. While the importer may authorize others to carry out certain tasks such as filing, the importer of record holds the bond and is ultimately responsible for the entry.

IMPORT RECORD DOCUMENT EXAMINATION: The examination of import records to determine if goods should be sampled and examined.

IMPORT REGULATIONS: Regulations written under the authority of specific acts administered by FDA for the regulation of imported articles: (1) foods, drugs, cosmetics, and medical devices - see 21 CFR Sections 1.83 - 1.99; (2) electronic products - see 21 CFR Part 1005; (3) Imported milk - see 21 CFR Part 1210; (4) banked human tissue for transplantation - see 21 CFR Part 1270, among others.

IMPORT SAMPLE COLLECTION: The collection of samples of articles still in import status. Sample collections may be either an actual physical collection of the product with a subsequent analysis or examination, or a documentary sample where the sample evaluation is based upon the documents accompanying the import.

IMPORT SAMPLES: Samples of commodities collected from shipments made by foreign firms into the U.S. Samples are collected by an FDA Investigator or by Customs officials for FDA.

IMPORT SECTION (801): The current section of the Federal Food, Drug, and Cosmetic Act (Chapter VIII) containing Import/Export Provisions (see 21 USC 381).

IMPORT STATUS: The status of an imported article prior to FDA admission and Customs entry. Liquidation should not occur until FDA has released the shipment for domestic distribution.

IMPORT SUPPORT AND INFORMATION SYSTEM (ISIS): The primary user interface, operational support, and reporting portion of OASIS.

IMPORTING VESSEL: Vessel used to transport articles offered for entry into the U.S.

INDICTMENT: The formal statement of the charges against an individual or entity presented by a grand jury.

The United States Attorney (with witnesses deemed necessary) appears before a grand jury and presents evidence. If at least 12 jurors concur that an offense has been committed, the grand jury returns an indictment (referred to as a "true bill") to the court and the matter is then entered on the court docket.

INFORMAL ENTRY: See entry.

INFORMATION: The formal statement of the charges against an individual for some criminal offense, issued by the U.S. Attorney, and not by a grand jury. It may always be used in misdemeanor prosecutions, and may be used in felony prosecutions only if the defendant waives his right to be indicted.

INJUNCTION: An order issued by the Court requiring a defendant to perform an act which he is obligated to perform but refuses to do, or forbidding him from doing a specified act which he is threatening or attempting to do.

IN PERSONAM: Against the person.

IN REM: Against the thing.

INTERROGATORIES: Written questions sent by one party in a lawsuit to the other party during the discovery process prior to trial. Interrogatories must be answered in writing under oath or under penalty of perjury. FDA considers the employee's response to interrogatories to be testimony covered by 21 CFR 20.1.

INTERSTATE (IS) COMMERCE: Commerce between one state or territory and anyplace outside thereof, or commerce within the District of Columbia or within any other territory. Section 201(b) of the Act.

INTRAGENCY AGREEMENTS (IAGs): Agreements between different parts of the same agency.

INTRANSIT ENTRY (IT) ADVANCE NOTICE: The filing of an IT by the importer prior to the arrival of the merchandise at the port of entry.

INTRANSIT SAMPLES (FLAGGED "IN-TRANSIT"): Samples collected from a lot after delivery for introduction in Interstate Commerce or while on the way to a consignee. Such samples may be on a manufacturer's shipping dock, in a conveyance, or in a terminal.

INTRASTATE: Within a state.

INVESTIGATIONAL SAMPLES (PREFIX "INV."): Samples collected for purposes of general information when regular sample number identification is necessary. Interstate documentation is not required at the time of collection. Should interstate documentation be possible and it is obtained at a later date (for example, after analysis shows the product is violative) such samples would then be converted to "official" samples.

INVOICE (Imports): A document that accompanies imported merchandise and contains at least the following information: (a) port of entry or merchandise destination; (b) local consignee, foreign shipper; (c) description of merchandise including any marks; (d) quantity, (e) purchase price, (f) country of origin of the merchandise.

ISIS: See Import Support and Information System.

JUDICIAL DISTRICT: Physical parameters, set by Congress, designating the counties under the jurisdiction of a United States District Court.

LABEL and LABELING: These words are defined in the FD&C Act in Sections 201(k) and 201(m).

LACF (LOW ACID CANNED FOOD): Any thermally processed foods in hermetically sealed containers, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (aw) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods. All manufacturers of low acid canned foods and acidified low acid canned foods must be registered with FDA and have a food canning establishment (FCE) number and the manufacturing process specific for the product and can size on file with FDA. See 21 CFR 108, 113, and 114.

LD-3: Airline containers used to transport imported articles.

LEGAL STATUS: The legal organization or constitution of a business enterprise; for example, as a corporation, partnership, cooperative, or sole-ownership.

LIB: Laboratory Information Bulletin

LICENSE: Means authorization issued by CBER, which is required by the PHS Act for individuals or companies who introduce or deliver for introduction into interstate commerce any biological product. Biologics license applications for human use are approved on the basis of a demonstration that the biological product is safe, pure, and potent; and that the facility in which the biological product is manufactured, processed, packed, or held meets

the standards designed to assure that the biological product continues to be safe, pure, and potent. Biological products intended for veterinary use are regulated separately.

LINE ITEM: Each portion of an entry that is listed as a separate item on an entry document. An importer may identify merchandise in an entry in multiple portions; however, an item in the entry having a different tariff description must be listed separately.

LINE RELEASE: Customs - An automated bar code system of identifying and processing "repetitive and low-risk" entries that involve a combination of the same importer, filer (broker), product, or manufacturer.

LIQUIDATED DAMAGES: A monetary claim against a person, company and surety for violations of a Customs bond.

LIQUIDATING AN ENTRY: Customs liquidates an entry when duty has been paid and the product has been determined to be admissible into the U.S.

LITIGATION: The act or process of carrying on a lawsuit.

LOT: An amount of a product produced during a period of time indicated by a specific code, or some other unique identifying characteristic. Also, an import entry, group of entries, or a portion of an entry of merchandise that can be clearly defined as appropriate for FDA sampling and examination purposes.

MAGISTRATE (U.S. Magistrates): A judicial officer of federal district courts who has some but not all of the powers of a federal district judge. They may conduct many of the preliminary or pre-trial proceedings in both civil and criminal cases; and perform certain other duties of the court, such as issuing inspection warrants.

MAIL ENTRY: See Entry.

MANDAMUS: A command that a superior court issues to a lower court or a person (including a government agency) ordering it to do its duty.

MANIFEST: An itemized listing of a vessel's cargo, with other particulars, for the facility of the customs officers. A document issued by the carrier describing the contents of merchandise being transported.

MANUFACTURER: See Establishment.

MARKET WITHDRAWAL: "Market withdrawal" means a firm's removal or correction of a distributed product which involves a minor violation for which FDA would not initiate legal action, or which involves no violation. These include normal stock rotation practices, routine equipment adjustments and repairs, and product improvement. Replacement of device components which fail or wear out after a reasonable life span will be considered a market withdrawal unless a violation of the FD&C Act has occurred and can be supported. Recovery of investigational products are normally considered a market withdrawal unless the product has been sold in domestic commercial distribution or a significant health hazard is involved necessitating classification and publication of the action as a recall.

The removal of products from the market as a result of actual or alleged tampering with individual units, and where there is no evidence of manufacturing or distribution problems will be considered a market withdrawal.

MARKS: Words or symbols, usually including the country of origin, marked on cartons, bags, and other containers of imported merchandise for identification purposes. See Customs requirements in 19 CFR Part 134.

MEDICAL DEVICE SAFETY ALERT: A medical device Safety Alert is a notification to device users that, under certain circumstances, use of or exposure ¹ to the device may pose a risk of harm.

¹ The exposure mentioned in this definition excludes electronic product radiation exposure. See 21 CFR Subchapter J.

MEMORANDUM OF UNDERSTANDING (MOU): This is a formal agreement between the Food and Drug Administration and another Government Agency (Federal, State, local) or an **informal** agreement with foreign governments or other foreign institutions. See Staff Manual Guides (SMG) 2820.1 and 2830.1. The agreement does not involve a transfer of personnel, or a transfer of funds or real property (Agreements calling for transfer of personnel, funds, or real property are considered Interagency Agreements, see SMG 2810.1).

MIS: Management information system.

MODUS OPERANDI: Manner of operating.

MOTION: A written or oral application to a court or judge, which requests a ruling or order in favor of the applicant.

MUTUAL RECOGNITION AGREEMENT (MRA): A type of memorandum of understanding that provides for the mutual assessment of the comparability of specific FDA programs or activities with those of a foreign regulatory authority. An MRA is suitable as an equivalence agreement when it can be determined that FDA's controls and the foreign regulatory authority's controls are comparable and are designed to provide the same level of protection. With respect to MRAs for good manufacturing practices (GMPs), this term means that the agency has determined that another country's regulatory system for GMPs (i.e., regulations, inspection procedures and enforcement) provides at least the same level of consumer protection as FDA's system.

NAI: No action indicated.

NCBFAA: National Customs Brokers & Forwarders Association of America, Inc.

NO-TOBACCO-SALE ORDER: An agency order that temporarily or permanently prohibits an individual retail outlet from selling tobacco products. All permanent orders shall include provisions that allow the outlet, after a specified period of time, to request that the agency compromise, modify, or terminate the order (see FD&C Act Section 303(f)).

NOTARY PUBLIC: A person authorized by the state in which they reside to administer an oath of truth to a person making an affidavit, and to apply their signature and seal or stamp to attest to the oath.

OASIS: Operational and Administrative System for Import Support.

ODNR: See Originally Detained Now Released.

OFFICIAL COMPENDIA: See FD&C Act Section 201(g)(1)(A).

OFFICIAL SAMPLES: A sample taken from a lot for which Federal jurisdiction can be established. If violative, the official sample provides a basis for administrative or legal action. Official samples generally, but not always, consist of a physical portion of the lot

sampled. See 21 CFR 2.10 for requirements regarding official samples of food, drugs, or cosmetics collected for analysis.

ORA: Office of Regulatory Affairs.

ORDER: A formal written statement from a Court, requiring action or simply stating a ruling.

ORIGINALLY DETAINED NOW RELEASED (ODNR): Notice to importer that detained merchandise has been satisfactorily shown to be in compliance with the law and is now released.

PACKER/REPACKER: See Establishment. **PACKING LIST:** Inventory of contents.

PDMA: Prescription Drug Marketing Act.

PENALTY: Damages assessed against an importer or broker, usually connected with failure to redeliver merchandise.

PENALTY CASE: See Bond Action.

PERMANENT INJUNCTION: A Decree of Permanent Injunction may be entered at any time after the complaint is filed, either following a hearing or as a result of a negotiated settlement. Defendants in an injunction proceeding may consent to a Decree of Permanent Injunction just as they consent to a Consent Decree of Condemnation in a seizure action.

Should the defendant not consent to such a decree, a trial is held in which, to prevail, the government must prove each element of its case by a preponderance of the evidence. As its name implies, a Decree of Permanent Injunction remains in effect until it is dissolved by an order of the court.

A Decree of Permanent Injunction perpetually restrains the defendants from engaging in specified violative practices and remains in force until termination.

PERSONAL BAGGAGE ENTRY: See Entry.

PLAINTIFF: The party who institutes the lawsuit; the opposite of the defendant. The government is the plaintiff in all the actions it initiates. When the Government is sued, the suing party is the plaintiff in the action.

PLANT PROTECTION AND QUARANTINE (PPQ): A division within USDA's Animal and Plant Health Inspection Service (APHIS) that prohibits or restricts the entry of foreign pests and plants, plant products, animal products and byproducts, and other materials that may harbor pests or disease. Other responsibilities include the inspection and certification of domestic commodities for export, regulation of the import and export of endangered plant species, and ensuring that imported seed is free of noxious weeds.

PLEADINGS: The papers filed in court to initiate and defend a suit, such as the Complaint, and Answer, setting forth the allegations and defense in the case. The written statements of fact and law filed by the parties to a lawsuit.

PORT (POINT) OF ENTRY: The Customs locations where the consumption entry is made. This may or may not be at the Port of Unloading.

PORT OF LOADING: The location where the final Bill of Lading is issued prior to shipment to the U.S. This may or may not be the country of origin.

PORT (POINT) OF UNLOADING OR DISCHARGING: The location where the merchandise is unloaded from the carrier. This may or may not be at the Port of Entry.

POST-SEIZURE SAMPLES (PREFIX "P.S."): A representative sample collected under court order from goods under seizure.

PPQ: See Plant Protection and Quarantine.

PRELIMINARY INJUNCTION: Court order requiring action or forbidding action until a decision can be made whether to issue a permanent injunction. Whether or not a Temporary Restraining Order (TRO) has been obtained, a Motion for Preliminary Injunction is subject to a full hearing in which (1) evidence by affidavit, and/or (2) testimony of witnesses is presented, depending on the practice of the court. Once the motion is granted, or the defendants consent to the entry of a decree, the preliminary injunction is in effect.

A preliminary injunction may stand indefinitely on the court record until the case is settled or a permanent injunction has been entered, after trial. A preliminary injunction may be dismissed, or the court, at the request of either party, may set a trial for permanent injunction at any time.

PREPONDERANCE OF EVIDENCE: The common standard of proof in civil cases. To prevail, the party bearing the burden of proof must present evidence which is more convincing than that presented by the opposing party; and which as a whole shows that the fact to be proven is more probable than not.

PRE-SENTENCE INVESTIGATION: Many courts request an investigation of convicted parties prior to the imposition of sentence. These investigations are conducted by the U.S. Probation Officer, and are governed by Rule 32(c) of the Federal Rules of Criminal Procedure.

PRE-TRIAL CONFERENCE: A meeting between the Court and the attorneys for the parties in preparation for trial. One use of a pre-trial conference is to consider ways to limit the issues for trial through admissions or agreements of counsel.

PRIMA FACIE EVIDENCE: Evidence sufficient to establish the allegations in the Complaint unless refuted by some evidence to the contrary.

PRIOR NOTICE: The FDA policy of notifying an individual or firm of a violation of the Federal FD&C Act, or other acts, when voluntary correction is an appropriate initial response to the violation. This policy is also commonly referred to as "Prior Warning."

PRIVATE LABORATORIES: Independent laboratories providing analytical services to importers, customhouse brokers, and others.

PRODUCT PROBLEM AREAS (PPAS): Also known as import targeting. This term is used to describe a program where FDA targets (samples and analyzes) specific imported products over a specific period. It can also include investigating certain import-related practices over a specified period of time.

PRO FORMA: As a matter of form. Provided or made in advance to describe items or projections. Example: a *pro forma* invoice.

PRO FORMA INVOICE: Importer's statement of value or the price paid in the form of an invoice.

PROCEDURE IN ADMIRALTY: Seizure actions taken pursuant to the FD&C Act are (per Section 304(b)) to be in conformity with the procedure in admiralty, which means the Government may initiate confiscation of articles it deems to be contraband without having to first show proof of the allegation or responsibility for the violation.

PROMULGATE: To publish; to announce officially, e.g., to promulgate new regulations pursuant to the FD&C Act.

PROSECUTION: The institution of a criminal proceeding against a person.

QUICK COLOR TEST (QCT): A field screening technique used by FDA personnel to detect lead in ceramicware.

RARE DISEASE OR CONDITION: A rare disease or condition is one that affects less than 200,000 persons in the United States or that affects more than 200,000 persons in the United States, but the drug sponsor has no reasonable expectation of recovering development costs through U.S. sales. (Section 526 of the Act.)

RCHSA: Radiation Control for Health and Safety Act covers radiation emitting electronic products and devices. These include x-ray machines, TVs, compact disc players, microwave ovens, and tanning beds. See Sections 531- 542 of the Act.

REBUTTAL: An answer or response to a statement. To refute, oppose, or contradict that which has been stated. Evidence disproving other evidence previously given or reestablishing the credibility of challenged evidence.

RECALL: A "recall" is a firm's removal or correction of marketed products, including its labeling and/or promotional materials, that FDA considers to be in violation of the laws it administers. The agency would initiate legal action for example, seizure or other

administrative or civil actions available to the agency if the product was not recalled. Recall does not include market withdrawal or a stock recovery.

RECALL CLASSIFICATION: "Recall classification" is a numerical designation, I, II, or III, that is assigned by FDA to a particular product recall that indicates the relative degree of health hazard.

1. Class I is a situation in which there is a reasonable probability (strong likelihood) that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
2. Class II is a situation in which the 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.
3. Class III is a situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

RECALL COMPLETED/RECALL TERMINATED: Recall completed is the classification status used for monitoring purposes when the recall action reaches the point at which the firm has actually retrieved and impounded all outstanding product that could reasonably be expected to be recovered, or has completed all product corrections.

Recall terminated is the monitoring classification used to indicate that FDA has determined that all reasonable efforts have been made to remove or correct the violative product in accordance with the recall strategy, and proper disposition has been made according to the degree of hazard.

RECALLING FIRM: "Recalling firm" means the firm that initiates a recall or, in the case of an FDA requested recall, the firm that has primary responsibility for the manufacture and (or) marketing of the product to be recalled.

RECALL NUMBER: A "recall number" is the number assigned to the recall of one product regardless of package size, lot numbers, or private buyers' labels, provided the labels are otherwise identical. If a manufacturer requests a wholesaler, distributor, or relabeler to extend the recall to a lower level (assuming no change of the product has occurred), the same recall number assigned to the manufacturer will be used. If the recalled product has undergone a change due to further processing or use as an ingredient or component in a new product, or has had the directions or indications for use changed, it will be considered a different product and its recall will be the responsibility of the firm responsible for the change. FDA will then assign a separate recall number.

RECALL STRATEGY: The planned course of action to be carried out by the firm in the achievement of its recall goals. The strategy will normally be developed by the recalling firm following 21 CFR, Part 7, Subpart C, Recalls. For FDA requested recalls, the agency will recommend a strategy to the recalling firm.

RECONDITION: The process of reworking a lot of goods under seizure pursuant to a Consent Decree of Condemnation, in an attempt to bring the goods into compliance with the Act.

RECONDITIONING: A process by which the importer of record, owner, or consignee may submit to FDA a written application requesting permission to bring into compliance any article, adulterated, misbranded, or in violation of Section 505 by relabeling or other action, or by rendering it other than a food, drug, device, or cosmetic.

REDELIVERY BOND: See Entry Bond.

REEFER CARGO: Refrigerated cargo.

RE-EXPORT (RE-EXPORTATION): A term used to identify goods shipped out of the U.S. after being offered for entry. This is not the same as an export of U.S. manufactured goods and is not covered by the restrictions in Section 801(e) of the FD&C Act.

RELABELING: The application of different labels to a product.

RELEASE WITH COMMENT: FDA Release Notice advising the importer the goods offered for entry are released but appear to have minor violations which the agency, in the exercise of its enforcement discretion, has refrained from enforcing at this time, and that future entries violating the Act may be detained.

RELEASED WITHOUT EXAMINATION: Form FDA-717 amended. A notice to the importer that FDA is releasing an entry for which a Notice of Sampling was issued, and the sample was collected but was not examined.

RES: Things, includes real and personal property.

RES JUDICATA: A matter finally decided on its merits by a court having competent jurisdiction and not subject to litigation again between the same parties. For example, if a product has been seized for misbranding and adjudicated by order of a Court, the same article with the same labeling containing the same misbranding may be seized subsequently and summary judgment obtained without a trial.

RESPONDENT: One who answers; as in Notice of Hearing, the response is given by the party to whom notice is given - he then is the respondent. In an appeal, the party who contends against the appeal, the appellee.

RETURN DATE: After a lot has been seized by the U.S. Marshal, the court allows a period of time so that a claimant may appear. The date this interval expires is known as the "return date". This date varies according to judicial district. If no one appears as claimant before expiration of the return date in the proceedings, the U.S. Attorney will secure a default decree of condemnation, forfeiting and disposing of the article.

RETURN OF SERVICE: The person serving the process shall make proof of service to the court.

REVERSAL: The act of a higher court in setting aside or revoking a lower court order or verdict; i.e., an appellate court may reverse a decision, rendered by a district court.

REVOCACTION: Is the cancellation of a license and the withdrawal of the authorization to ship a biological product for sale, barter, or exchange in interstate commerce either at the request of the manufacturer or when grounds exist for the agency to initiate such an action.

REVOCACTION OF PROBATION: If a person convicted of a criminal charge is placed on probation by the Court, the probation may be revoked if, during the period of probation, the person violates the law or the conditions of probation.

RFDD: Regional Food and Drug Director.

ROGATORY LETTERS: A written request from a judge in one state to a judge in another, asking that the latter take the testimony of a witness. FDA considers testimony in response to rogatory letters to be covered by 21 CFR 20.1.

RPM: Regulatory Procedures Manual.

SAIL: State Action Information Letter.

SALVAGE OPERATION: See Establishment.

SAMPLE JACKET: The file containing the investigational, analytical, and compliance or regulatory recommendation and legal documents on any civil or criminal case.

SECTION 305 MEETING: A meeting prior to consideration of criminal proceedings that is provided pursuant to Section 305 of the Act.

SEGREGATION: See Recondition.

SEIZURE: An action brought against an FDA-regulated product because it is adulterated and/or misbranded within the meaning of the FD&C Act. The purpose of such an action is to remove specific violative goods from commerce.

SELECTIVITY: U.S. Customs' entry screening mechanism. Criteria can include information concerning the importer, filer (broker), manufacturer, country, or Harmonized Tariff Schedule (HTS) code.

SENTENCE: The judgment formally pronounced by the court upon the defendant after his conviction in a criminal prosecution.

SERVICE: The delivery of a writ, summons, subpoena, or other notice to the party named in the document, thereby officially notifying him of some action or step which he is commanded to take or not to take.

SHIP-TO-SHIP COVERAGE: An import coverage approach providing for placing of FDA inspectors and analysts at a point of cargo discharge for the purpose of sampling and examination of merchandise as it is being unloaded from a carrier.

SHIPPER: See Establishment.

SPLIT SAMPLES: A sample that is divided into two or more portions for analysis by two or more laboratories.

SPONSOR: The sponsor of a work-sharing agreement is the FDA office assigned primary responsibility in the proposed agreement.

STANDARDS: The term applied to formal statements of Definitions and Standards for Foods promulgated pursuant to Section 401, FD&C Act.

STATUTE OF LIMITATIONS: This is the period in which any criminal action contemplated must be brought. In all FDC matters, the period is five (5) years; if no prosecution is filed within that time, FDA may not proceed. 18 U.S.C. 3282.

STOCK RECOVERY: "Stock recovery" means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm. The product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

STRIPPING (OF CONTAINERS): The removal of all articles from a container for examination or sampling purposes. This is also known as "devanning."

SUB-ACCOUNTS: "Sub-accounts" are consignees, either domestic or foreign, who received shipments of the recalled product from other than the recalling firm. This includes wholesalers, assemblers, and other distributors.

SUBPOENA: A court order commanding a witness to appear at a certain time and place to testify on a certain matter. For purposes of this section, a "subpoena" means a subpoena for verbal or written testimony (e.g., an affidavit). A subpoena for testimony also might include a request for records. In that case, FDA would process the subpoena under 21CFR 20.1 and 20.2.

SUBPOENA DUCES TECUM: A court order commanding a witness to produce documents at a certain time and place. FDA processes these subpoenas, which are intended for the production of records, under 21 CFR 20.2.

SUMMARY JUDGMENT: A judgment given to one party or the other without the necessity of a formal trial. This may be done when the record before the court shows there are no genuine issues of fact that are in dispute.

SUMMARY AND RECOMMENDATION (S&R): The written justification from the Division in its request for institution of a criminal prosecution.

SUMMONS: In a civil suit, a document that is served upon the defendant along with the complaint, advising him that a case has been filed against him, and requiring him to appear and answer the complaint within a specified time.

SUPERVISORY CHARGES: The charges for supervising the reconditioning and examination of articles that an importer, owner, or consignee attempts to bring into compliance after detention (See 21 CFR 1.99).

SURVEY SAMPLES: Samples obtained during a survey that is a planned operation in which the primary objective is to gather information on labeling, production, or marketing practices regarding a certain product or class of products.

Injury, poisoning, and complaint investigation samples where there is no interstate documentation available.

Samples collected in connection with Civil Defense activities.

General investigational samples collected to provide information of interest to the Administration, such as methods development and interpretation.

SUSPENSION: Means the immediate withdrawal by FDA of the authorization to introduce or deliver for introduction into interstate commerce a biological product. Suspension is a summary action taken by the agency when there is a reasonable belief that any of the grounds for revocation of a license exist and by reason thereof there is a danger to health.

TEMPORARY ABEYANCE (TA): The holding of samples in abeyance for possible future regulatory action.

TEMPORARY RESTRAINING ORDER (TRO): Temporary restraining orders are court-enforced cease and desist orders that are brought to control an emergency situation. A TRO seeks immediate, temporary relief (for a period of 10 days, which may be extended for 10 additional days) prior to the hearing for preliminary injunction.

FDA recommends a TRO when the agency believes that the violation is so serious that it must be controlled immediately. A request for a TRO also has the effect of expediting review of the underlying injunction case by the court. An inadequately documented TRO request may result in the court viewing the entire injunction action as lacking credibility.

At the court's discretion, the TRO request may be subjected to a hearing, but usually the court hears the matter *ex parte* by reviewing the documents and questioning government counsel, the FDA investigator, the Division compliance officer, or other FDA personnel.

An emergency remedy of brief duration issued by a court only in exceptional circumstances, usually when immediate or irreparable damages or loss might result before the opposition could take action.

TESTIMONY: For purposes of this section, testimony is an individual's statement given in writing (such as an affidavit or a declaration) or by appearance under oath at a proceeding. The statement might be in response to a deposition or interrogatories. Testimony is covered by 21 CFR 20.1.

TOBACCO RETAIL COMPLIANCE CHECK INSPECTIONS: Inspections of tobacco product retailers conducted by FDA or FDA-commissioned personnel to determine a retailer's compliance with the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act and its implementing regulations, with regard to tobacco products.

TRANSPORTATION AND EXPORTATION (T&E): See Entry.

TRANS-SHIPMENT: Merchandise transferred from one conveyance to another form of conveyance while enroute to the port of unloading or discharging.

USDA: U.S. Department of Agriculture.

VAI: voluntary action indicated.

VALUE OF ENTRY: The value of an entry used by Customs to determine the rate of duty and entry bond amount.

VENUE: The proper location for the trial of a case.

VERDICT: The decision of a jury after a trial.

WALK-BY EXAMINATION: A rapid inspection of imported articles conducted by FDA field personnel. Although the inspection is rapid, it should be thorough enough to determine whether a sample should be collected. The examination usually consists of a visual examination for water damage, and breakage.

WAREHOUSE: See Establishment.

WAREHOUSE ENTRY: See Entry.

WARRANT (FOR ARREST): A writ, directed to the marshal or other proper officer, requiring him to arrest the defendant or article named and bring him before the court or U.S. magistrate.

WAYBILL: This record accompanies the shipment during transit.

WHARF EXAMINATION: The examination of a product in import status, sufficient in scope to determine whether the product is in compliance with the Acts enforced by FDA.

WITNESS: A person who will appear to present evidence as testimony in any proceeding in a lawsuit. An expert witness is one who is skilled in some art, science, trade, profession, or other human activity, and may give opinions while under oath. A fact witness may not express opinions while testifying.

WORKSHEET: A document on which the analyst records his analytical work and findings.

WRIT: An order of the court.

WORK-SHARING: This term describes any arrangement between FDA and state or local agencies in which the parties agree to assume a portion of the activities necessary to fulfill common responsibilities. These arrangements are usually with state agencies having regulatory responsibilities that are essentially the same as FDA's. Ideally, these arrangements should be formalized by written memoranda.