

Chapter 11

GLOSSARY

Acronyms and Definitions

AAFCO- Association of American Feed Control Officials

ABATE: To stop. To do away with, to nullify, to make void.

ADDITIONAL SAMPLE: A physical sample collected from a previously sampled lot bearing the same sample number as the original sample.

ADJOURNMENT: A putting off or postponing of business or of a session until another time or place, the act of a court.

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

ADMONITION: A reprimand from a judge. If the conduct is discharged, warning of the consequences of his conduct and should he be guilty of same fault, he will be punished with greater severity.

AFFIDAVIT: A written statement made voluntarily under oath. An affidavit may be made on personal knowledge or on information and belief.

ALLEGATION: An assertion or statement, made in a pleading, setting forth what its maker intends to prove.

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: A friend of the court. A person who, although not a party in a suit, is allowed to intervene to protect his interests.

AMS: See Automated Manifest System.

ANALYSIS: An examination of a sample.

ANSWER: After filing of a Claim of Ownership in a seizure, the claimant files an Answer in which he may deny any or all of the allegations of the Complaint for Forfeiture. It is any response to a Complaint.

APPEAL: The formal review by a higher court of a lower court's disposition of a lawsuit.

ARRAIGNMENT: The appearance of the defendant (in any criminal prosecution) before the court to answer the allegations made against him and to enter his plea (guilty or not guilty).

AUDIT SAMPLE: A sample collected to verify the analytical results of a private laboratory and to validate the private sector evaluation process. An audit sample is collected from the same or similar units as those tested by the private laboratory. It is also used to verify that products covered by a certification program of a foreign government comply with the requirements of that program.

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.

BILL OF PARTICULARS: Used in Criminal Cases only. A motion requesting the specifics of a charge, so that defense against the charges may be properly prepared.

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 in man.

BMP- Bioresearch Monitoring Program

BOILERPLATE LANGUAGE- Words or paragraphs of standard text used in documents or correspondence

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. If the evidence produced by the party having the burden of proof is insufficient, the court will rule against the party.

CALENDAR CALL (OR CALLING THE DOCKET): CERTIORARI means, "To be certified". A writ commanding a court to certify records to a superior Court. When the Supreme

Court grants certiorari, that means 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: The 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: A document intended to provide the foreign purchaser with a statement that the articles s/he intends to purchase comply with U.S. laws. FDA issues certificates upon request that provide a factual statement regarding FDA's knowledge of the compliance status of articles under FDA jurisdiction. See also Compliance Policy Guide 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.

CFSAN: Means the Center for Food Safety and Applied Nutrition.

CGMP- Current Good Manufacturing Practice

CHARGE SHEET: The specification of the violation attached to a Notice of Hearing. 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 HEARING):

CITEE: One who is cited. See also Hearing.

CIVIL SUIT: A lawsuit brought under the 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 seizure of a lot.

CODE OF FEDERAL REGULATIONS (CFR): The Code of Federal Regulations is a codification of the published rules in the Federal Register by the Executive Departments and Agencies of the Federal government. The CFR is divided into 51 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 1-1200. U.S. Customs regulations are found under Title 19.

COLLECTING DISTRICT: The District whose representative actually collects the sample, whether within the District territory or within the territory of an adjoining District, unless specific instructions to the contrary are issued for a particular assignment.

COMMINGLED LOTS: Merchandise arriving off the same carrier with identical markings but covered under two or more entries. A physical sample is collected under the first entry and documentary (DOC) samples from the other, marked "same action as" the first entry. 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): Published guidance for FDA personnel to assist in determining appropriate regulatory actions.

COMPLAINANT: Person registering a complaint, as a consumer complaining about an article.

COMPLAINT FOR FORFEITURE: The document furnished to the United States Attorney for filing with the Clerk of Court to initiate a seizure of a lot. (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: The individual or firm to which the imported goods have been consigned. This is not necessarily the Importer of Record.

CONSIGNEE DISTRICT: The District to which is consigned the lot sampled enroute by another District.

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.

CONTEST: To make defense to an adverse claim in a court of law; to oppose, resist, or dispute the case made by a plaintiff.

COOLER: Any insulated unit used by the CSI/CSO to hold frozen or refrigerated entries for delivery to the laboratory.

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 SUIT: A lawsuit brought under the Rules of Criminal Procedure, whereby the defendant may be punished for having violated the law, or a court order. Actions initiated under the criminal rules are prosecutions and contempt.

CUSTOMS (U.S. CUSTOMS SERVICE): "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. trade 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: Means the 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 an import sample is collected.

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

DCGM/SCAAB-The Division of contracts and Grants Management, Office of Administration, State Contracts and Assistance Agreements Branch (HFA-520)

DEA: See Drug Enforcement Agency.

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 CFR 1000.3(L).

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.

DEFAULT DECREE: A Default Decree of Condemnation is a Court Order entered when lots under seizure are not claimed or defended. The order condemns the product as being in violation and provides for 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: The party or parties named in an Information, Indictment, or Complaint for Injunction, and against whom the Government is proceeding. The article against which a seizure action is brought is also referred to as the defendant.

DE MINIMUS: Not enough to be considered.

DE MINIMUS NON CURAT LEXIS: The law will not concern itself with trifles.

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 countered 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 sworn testimony of a witness obtained outside the courtroom before trial through examination and cross-examination by the attorneys for the parties.

DETENTION: 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, or are refused entry if not brought into compliance. Device detention - see 304(g).

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

DFSR: Division of Federal-State Relations (HFC-150)

DIOP: See Division of Import Operations and Policy.

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 Rules of Criminal Procedure, and Rules 26 through 37 of the Rules of Civil Procedure.

DISMISSAL: An order of judgment disposing of an action, suit, or motion by sending it out of court. A dismissal is always in the defendant's favor.

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.

DIVISION OF IMPORT OPERATIONS AND POLICY (DIOP): A division within the Office of Regional Operations, located in FDA headquarters, Rockville, MD. DIOP issues the import alerts and provides guidance to the FDA field offices on import matters and the automated import systems.

DOCKET: A chronological listing of all pleadings and orders filed in each case. The Clerk of Court usually maintains it in the form of a "Docket Sheet".

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 405.8).

DRUG ENFORCEMENT AGENCY (DEA): A component of the Justice Department whose regulations involve controlled substances.

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 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.

EFFICACY: Worth, merit, value.

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: A restraint through formal Court order; to cease a practice or to stop further violation of the Act.

ENTRAPMENT: The act of agents of the government in inducing a person to commit a crime not contemplated by him, for the purpose of bringing criminal charges against him. Engaging in artifice and deceit to afford someone an opportunity to commit a crime is not entrapment.

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 \$1,250 or more (value subject to change).

C. Informal entry: As defined by Customs regulations, an entry whose value is currently less than \$1,250 (value subject to change) and therefore usually not imported under bond. U.S. goods returned valued at less than \$20,000 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 \$1,000, an entry document is generally not required to be filed with 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).

F. 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): An independent government agency (not associated with a Cabinet secretary). 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.

ET AL: And others. For example: samples 021-77-298 et al

EU: European Union

EXAMINING DISTRICT: The District whose laboratory examines a sample or sub-division of a sample. When Washington Laboratories examine samples they are considered the examining laboratories for the "Home" District.

EX PARTE: On one side only. These are cases in which only one side is represented or present.

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) currently 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. Section 802 describes the restrictions covering unapproved new drugs, including biological products intended for export. Also see Re-Export.

EXECUTION OF DECREE: The carrying out of the court's order for example, the destruction of goods under seizure by the Marshall 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: 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: See FDA Import Alert Retrieval System.

FIAT: A command. Order directing some legal act to be done.

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, and 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.

FISH AND WILDLIFE SERVICE: A regulatory component within the Department of Interior concerned with enforcement of laws protecting endangered and protected species; i.e., goods manufactured from an endangered species, such as aphrodisiacs from rhinoceros' horns.

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 (FREE 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 (GENERAL ACCOUNTING OFFICE): An arm of Congress that oversees Federal agencies to assure that duties, delegated by Congress, are carried out within the congressional intent.

GRAND JURY: A jury of inquiry composed of 23 citizens whose duty is to determine, in the case of proposed felony charges, if there is sufficient evidence to warrant a trial.

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 is not in violation of the FD&C Act when shipped.

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 CRITICAL CONTROL POINT (HACCP): A system by which food processors and importers evaluate the kinds of hazards that could affect their products, institute controls necessary to keep these hazards from occurring, 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. A hearing prior to consideration of criminal proceedings is provided pursuant to Section 305 of the Act. 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 DISTRICT: The District in whose territory the alleged violation of the Act occurs, or in whose territory the firm or individual responsible for the alleged violation is physically located. 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 violation occurred; and the shipper of such article, as shown by such records, is usually considered to be the alleged violator.

Where actions are based on goods which became violative after interstate shipment was made, or after reaching 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 District."

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

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 district 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 PROGRAM MANAGER (IPM): Individual designated to administer the import program requirements and other import matters in the district office, such as planning, monitoring and coordinating import activities. The IPM serves as the principal resource regarding district import matters and is the primary liaison between DIOP and the district.

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) Imported tea - see 21 CFR Part 1220; (5) 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 a 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 presented by a Grand Jury.

The United States Attorney (with witnesses deemed necessary) appears before a Grand Jury and attempts to convince this body that an offense has been committed. If the Grand Jury concurs, it approves, signs, and returns the True Bill of Indictment to the Court and the matter is then entered on the Court docket.

This procedure is utilized in second-offense cases to afford the Court the latitude of imposing the stronger penalties available for the punishment of those convicted.

INFORMAL ENTRY: See entry.

INFORMATION: The formal statement of the charges against an individual in a misdemeanor, 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 do or refrain from doing a specified act.

IN PERSONAM: Against the person.

IN REM: Against the thing.

INTERROGATORIES: Written questions propounded by one party and served on the other party in a suit, who must serve written answers thereto under oath within a given period of time.

INTERSTATE (IS): Between one state and anyplace outside of that state, or within the District of Columbia or any other territory.

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.

INVESTIGATION 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: A document 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.

IPSO FACTO: By the act itself.

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 (a_w) greater than 0.85. 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.

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

LEGAL STATUS: The legal constitution of a business enterprise as to whether it is a corporation, partnership, cooperative, or sole-ownership.

LIB-Laboratory Information Bulletin

LICENSE: Is the authorization issued by CBER to an establishment for the propagation, preparation, or manufacture of specific biological products for sale, barter, or exchange in interstate commerce.

LINE (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 entry, group of entries, or a portion of an entry of merchandise that can be clearly defined as a shipment for FDA sampling and examination purposes. An amount of a product produced during a period of time indicated by a specific code.

MAGISTRATE: A part time or full time court official authorized to try misdemeanor cases without a jury, and to 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.

MEMORANDUM OF UNDERSTANDING (MOU): This is a formal agreement with a state or local agency. The agreement does not involve a transfer of funds or a transfer of personal or real property (Agreements calling for transfer of funds, or a transfer of personal or real property are considered Interagency Agreements, see Staff Manual Guide 2810.1).

MIS- Management information system.

MITIGATION: Alleviation; abatement or diminution of a penalty or punishment imposed by law, as a result of the circumstances surrounding the crime, or the acts of the defendant (he gave the money back after robbing the bank).

MODUS OPERANDI: Manner of working.

MONITION: A formal order commanding something be done or not done. In seizure actions, a monition is a warning that goods are under the jurisdiction of a district court and nothing may be done to them save upon a court order.

MOTION: An application to a court, either written or oral, for a rule or order, such as to permit post-seizure sampling.

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.

NAI- No action indicated

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

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 representative portion of a lot of any food, drug, device, cosmetic, biologic, or radiation instrument which has been collected by an officer or employee of FDA, or an authorized cooperating official, for possible regulatory action, with records or evidence showing that the lot:

Has been introduced or delivered for introduction into interstate commerce; or is in interstate commerce; or is held for sale after interstate shipment; or is sold under guarantee (whether or not interstate commerce).

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.

PENDENTE LITE-PENDING: While litigation continues (or is pending).

PERISHABLE COMMODITY: An unprocessed product (not heat-treated, frozen, or, in any other manner, preserved) such as fresh fish or seafood and fresh produce, the quality of which may be adversely affected if held longer than 7 days under normal shipping and storage conditions.

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.

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: Whether or not a 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.

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 sufficient to support the allegations of 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.

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.

PROMULGATION: To propose and publish as an official announcement; i.e., to promulgate new regulations pursuant to the FD&C Act.

PROSECUTION: The institution of a criminal proceeding against an individual.

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.

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 Section 531 et seq.

REBUTTAL: An answer or response to a statement. To refute, oppose, or contradict that which has been stated.

RECALL: A "recall" is a firm's removal or correction of a 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.

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 reversing a court order or verdict; i.e., an appellate court may reverse a decision, rendered by a district court.

REVOCAION: 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.

REVOCAION OF PROBATION: Any person convicted of a criminal charge may be granted probation for a specified period by the District Court. If, during the period of probation, the person violates the law, his probation may be revoked and the original penalty imposed at time of sentencing can be placed in effect.

RFDD- Regional Food and Drug Director

RPM: Regulatory Procedures Manual.

SAIL-State Activity 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.

SEGREGATION: See Recondition.

SEIZING DISTRICT: The District in whose territory seizure is actually accomplished. The Seizing District is not necessarily the Collecting District - as in the case of intransit samples, or where an inspector from an adjoining District crossed the District boundary to collect a sample. The Seizing District shall be furnished with copies of the sample summary, labeling, and other documents necessary to effect the seizure.

SEIZURE: Attachment of goods through Court order by a U.S. Marshal pursuant to Section 304 of the FD&C Act.

Lot-specific seizure: seizure of all units in a specific lot or batch of a product

Open-end seizure: seizure of all units of a specific product, regardless of lot or batch

Mass seizure: seizure of all products and equipment at an establishment/facility

SELECTIVITY: U.S. Customs' entry screening mechanism. Criteria can include information concerning the importer, filer (broker), manufacturer, country, or 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, subpoena, notice, injunction, or other court order by an authorized person, to a person, 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 LIMITATION: 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 document, issued by the Clerk of the Court which, when delivered to the person named therein, requires him to appear in court, or at a deposition, or before a grand jury.

SUBPOENA DUCES TECUM: Same as above, but which also requires the person to bring with him certain records or items named in the subpoena.

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 is no genuine issues of fact that are in dispute.

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

SUMMONS: A document which 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.

SUPERVISING DISTRICT: The District that exercises supervision of reconditioned lots in connection with seizure actions.

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: Is a summary action taken by the agency and may be an intermediate step in the revocation process. Suspension provides for the immediate withdrawal of the authorization to ship a biological product for sale, barter, or exchange in interstate commerce when grounds for revocation and a danger to health exist.

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

TEMPORARY RESTRAINING ORDER: 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 district compliance officer, or other FDA personnel.

TERMINATED: Ended, adjudicated.

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.

TRP- tamper resistant packaging

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: Place of trial. If the venue is improper a court lacks jurisdiction to hear a case.

VERDICT: The decision of the trier of fact in a civil or criminal case.

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.