

5





**REGULATORY
PROCEDURES MANUAL**
August 1997

Department of Health and Human Services
U.S. Food & Drug Administration
Office of Regulatory Affairs
Office of Enforcement
Division of Compliance Policy



CONTENTS

INTRODUCTION	vii	CHAPTER 8 - INFORMATION DISCLOSURE	
CHAPTER 1 - REGULATORY ORGANIZATION		Expert Witness	341
Office of Regulatory Affairs	2	Testimony	342
Center for Biologics and Research	4	FOIA	345
Center for Drug Evaluation and Research	6	Sharing Non-Public Information with Federal Government Officials	355
Center for Devices and Radiological Health	8	Sharing Non-Public Information with State and Local Government Officials	358
Center for Food Safety and Applied Nutrition	9	Sharing Non-Public Information with Foreign Government Officials	360
Center for Veterinary Medicine	12	CHAPTER 9 - IMPORT OPERATIONS/ACTIONS	
Enforcement Policy Directory	14	Import Procedures	403
CHAPTER 2 - FDA AUTHORITY		Coverage of Personal Importations	408
Selected Amendments to the Federal Food, Drug, and Cosmetic Act	31	Importation of Biological Products	410
Other Laws	38	FDA National Import Procedure Regarding Warehouse Entries	414
CHAPTER 3 - OTHER REGULATORY AGENCIES		Release Notices	415
Commissioning State and Local Officials	43	Automatic Detention	417
Work Sharing Agreements	52	Notice of Detention and Hearing	424
CHAPTER 4 - ADVISORY ACTIONS		Response to Notice of Detention and Hearing	426
Warning Letters	77	Notice of Refusal of Admission	429
Untitled Letters	93	Reconditioning	430
CHAPTER 5 - ADMINISTRATIVE ACTIONS		Supervisory Charges	434
Citations	139	Bond Actions	435
Detentions	134	Import Information Directives	438
Administrative Detentions of Devices	136	Priority Enforcement Strategy for Problem Importers	440
License Revocation and Suspension	143	Import For Export	444
Section 305 Meeting	148	CHAPTER 10 - OTHER PROCEDURES	
Order for Retention, Recall, and/or Destruction of Human Tissue	154	Prior Notice	475
CHAPTER 6 - JUDICIAL ACTIONS		EIR Conclusions and Decisions	476
Seizure	185	ITS and Support Facilities- Classifications and Administrative Actions	479
Injunctions	202	Reporting and Monitoring	480
Inspection Warrants	214	Ad Hoc Committee	482
Search Warrants	217	Appeal Process	484
Prosecutions	219	CHAPTER 11 - GLOSSARY	
CHAPTER 7 - RECALL AND EMERGENCY PROCEDURES		General Terms and Definitions	485
Recall Procedures	285		
Emergency Procedures	310		

CHAPTER 11

GLOSSARY

GENERAL TERMS AND DEFINITIONS

ABATE: To put an end to; demolish; to do away with, to nullify, to make void.

ABI: See Automated Broker Interface.

ACS: See Automated Commercial System.

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 to a person accused, on being 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 (a) on personal knowledge, or (b) 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. 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. Also used to verify that products covered by a certification program of a foreign government comply with the requirements of that program.

AUTOMATED BROKERS INTERFACE (ABI): A module of the ACS that permits qualified participants (brokers, importers, carriers, port authorities, etc.) to interface directly with the U.S. Customs Service data center in order to transmit data pertaining to merchandise being imported into the United States.

AUTOMATED COMMERCIAL SYSTEM (ACS): The comprehensive tracking, controlling, and processing system of the U.S. Customs Service.

AUTOMATED MANIFEST SYSTEM (AMS): A module of the ACS that is designed to control imported merchandise from the time a carrier's cargo manifest is electronically transmitted to Customs until control is relinquished to another segment of ACS.

AUTOMATIC DETENTION: An administrative act of detaining an entry without physical examination solely on the basis of information regarding past violative history and/or other information which indicates the appearance of a violation.

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.

BONA FIDE: Literally 'in good faith'. A bona fide

testimony indicating why the material should not be refused entry or to discuss how the product will be brought into compliance with the law. See 21 CFR 1.94. (This form will generally be replaced by electronic processing and computer generated forms as districts become automated).

NOTICE OF REFUSAL OF ADMISSION (NORA) (FORM FDA-772): Form issued to importer indicating that an entry of merchandise appears violative and that it is refused admission into the U.S. This occurs after the importer has been provided an opportunity to present testimony concerning the violation. The shipment must be exported or destroyed under Customs' supervision in 90 days. (This form will generally be replaced by electronic processing and computer generated forms as districts become automated).

NOTICE OF SAMPLING (FORM FDA-712): Notifies importer that a sample will be or has been collected and informs the importer to hold the entry intact pending further notice (see 21 CFR 1.90). (This form will generally be replaced by electronic processing and computer generated forms as districts become automated).

NUNC PRO TUNC: Now for then - a phrase applied to acts allowed to be done after the time when they should have been done, with a retroactive effect.

NUTRITIONAL LABELING AND EDUCATION ACT (NLEA): Requires that essentially all food have full nutrition information and defines the conditions under which health and ingredient claims may be made. Also provides for exemption of certain products and businesses.

OASIS: See 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 (NO PREFIX): 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).

OPERATIONAL AND ADMINISTRATIVE SYSTEM FOR IMPORT SUPPORT (OASIS): Composed of EEPS and ISIS.

ORA: Means the 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.

PENALTY: Damages assessed against an importer/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