CHAPTER 2- REGULATORY

CONTENTS

SUBCHAPTER 2.1 - REGULATORY NOTES 40
2.1.1 - USES OF REGULATORY NOTES 40
2.1.2 - REGULATORY NOTES CHARACTERISTICS 41
2.1.3 - REGULATORY ENTRIES....41
2.1.4 - FORMAT FOR REGULATORY NOTES 41
2.1.5 - RETENTION OF REGULATORY NOTES 41
SUBCHAPTER 2.2 - STATUTORY AUTHORITY 42
2.2.1 - FEDERAL FOOD, DRUG, AND COSMETIC ACT 42
2.2.1.1 - Authority to Enter and Inspect....42
2.2.1.2 - Food Inspections....42
2.2.1.3 - Device Inspections....43
2.2.1.4 - Drug Inspections....43
2.2.1.5 - Limitations....43
2.2.1.6 - Electronic Radiation Product Examinations and Inspections....43
2.2.2 - SELECTED AMENDMENTS TO THE FD&C ACT 43
2.2.3 - OTHER ACTS....44
2.2.3.1 - Anabolic Steroids Control Act of 1990 44
2.2.3.2 - Fair Packaging and Labeling Act (FPLA) 44
2.2.3.3 - Federal Anti-Tampering Act....44
2.2.3.4 - Federal Import Milk Act....44
2.2.3.5 - Federal Caustic Poison Act....44
2.2.3.6 - Poison Prevention Packaging Act....44
2.2.3.7 - Public Health Service Act (PHS)....44
2.2.3.8 - Mammography Quality Standards Act of 1992 44
2.2.3.9 - Comprehensive Smokeless Tobacco Health Education Act....44
2.2.3.10 - Federal Cigarette Labeling & Advertising Act 44
2.2.4 - CODE OF FEDERAL REGULATIONS (CFR)....44
2.2.5 - DEFINITIONS 45
2.2.5.1 - Civil Number 45
2.2.5.2 - Citation (Cite)....45
2.2.5.3 - Criminal Number....45
2.2.5.4 - FDC and INJ Numbers....45
2.2.5.5 - Complaint for Forfeiture 45
2.2.5.6 - Home District 45
2.2.5.7 - Nolle Prosequi (Nol-Pros) 45
2.2.5.8 - Nolo Contendere (Nolo)....45
2.2.5.9 - Seizing District....45
2.2.5.10 - Subpoena Duces Tecum 45
2.2.5.11 - Supervising District....45
2.2.6 - SEIZURE 45
2.2.6.1 - District Recommendation....45
2.2.6.2 - Headquarters....45
2.2.6.3 - Department of Justice....46
2.2.6.4 - U.S. District Court....46
2.2.6.5 - Claimant and Options 46
2.2.6.6 - Abandonment 46
2.2.6.7 - Reconditioning for Compliance 46
2.2.6.8 - Contested Seizure 46
2.2.6.9 - District Follow-up 46
2.2.7 - PROSECUTION 46
2.2.7.1 - Section 305 Notice....46
2.2.7.2 - Information....46
2.2.7.3 - Grand Jury Proceedings 47
2.2.7.4 - District Follow-up 47
2.2.8 - INJUNCTION 47
2.2.8.1 - Temporary Restraining Order (TRO) 47
2.2.8.2 - Hearing for Injunction....47
2.2.8.3 - Consent Decree of Injunction....47
2.2.8.4 - Trial for Injunction 47
2.2.8.5 - Preliminary or Permanent Injunction....47
2.2.8.6 - District Follow-up....47
2.2.9 - EMERGENCY PERMIT CONTROL 47
2.2.10 - DETENTION POWERS....48
2.2.11 - COURTROOM TESTIMONY 48
2.2.11.1 - Testimony Preparation 48
2.2.11.2 - Interviewing Persons under Arrest 48
SUBCHAPTER 2.3 - RECONDITIONING AND DESTRUCTION 49
2.3.1 - DEFINITIONS 49
2.3.1.1 - Reconditioning....49
2.3.1.2 - Destruction 49
2.3.1.3 - Denaturing....49
2.3.2 - DISASTERS....49
SUBCHAPTER 2.4 - CONSENT DECREE 49
2.4.1 - POLICY 49
2.4.2 - RELABELING....50
2.4.3 - REWORKING....50
2.4.4 - SEGREGATION....50
2.4.5 - DESTRUCTION 50
2.4.6 - DISPOSITION OF REJECTS....50
2.4.7 - RELEASE OF GOODS 50
2.4.8 - REPORTING....50
SUBCHAPTER 2.5 - DEFAULT DECREE....50
2.5.1 - POLICY 50
2.5.2 - REPORTING....50
SUBCHAPTER 2.6 - COMPLIANCE ACHIEVEMENT 50
2.6.1 - POLICY 50
2.6.2 - DESTRUCTION 51
2.6.2.1 - DEA Controlled Drugs....51
2.6.2.1.1 - DEA APPROVAL....51
2.6.2.1.2 - PROCEDURE 51
2.6.3 - RECONDITIONING....51
2.6.4 - REPORTING....51
2.6.4.1 - Documenting Voluntary Destruction....52
2.6.4.2 - Compliance Achievement Reporting 52
2.6.4.2.1 - VIOLATIVE PRODUCTS....52
2.6.4.2.2 - DESTRUCTION BY COOPERATING OFFICIALS...52
2.6.4.2.3 - MANUFACTURER'S RAW MATERIALS....52
2.6.4.2.4 - CAPITAL IMPROVEMENTS 52
2.6.4.2.5 - CORRECTION OF GMP DEVIATIONS 52
2.6.4.2.6 - FORMULA/LABEL CORRECTION....52
2.6.4.2.7 - ADDITIONAL PERSONNEL....52
2.6.4.2.8 - EDUCATIONAL AND/OR TRAINING....52
2.6.4.2.9 - ITEMS NOT REPORTED IN FACTS....52
SUBCHAPTER 2.7 - DETENTION ACTIVITIES....52
2.7.1 - OVERVIEW AND AUTHORITY....52
2.7.1.1 – Overview 53
2.7.1.1.1 - ACCOMPLISHING A DETENTION 53
2.7.1.1.2 - DETENTION OF DEVICES....53
2.7.1.1.3 - DETENTION OF FOODS....53
2.7.1.1.4 - DETENTION OF DRUGS....51
2.7.1.1.5 - DETENTION PROCEDURAL STEPS 53
2.7.1.2 - Authorities 53
2.7.1.2.1 - FOOD DRUG AND COSMETIC ACT....54
2.7.1.2.2 - FEDERAL MEAT INSPECTION ACT....54
2.7.1.2.3 - POULTRY PRODUCTS INSPECTION ACT 54
2.7.1.2.4 - EGG PRODUCTS INSPECTION ACT 54
2.7.1.3 - Definitions 54
2.7.1.3.1 - DEVICE....54
2.7.1.3.2 – FOOD 54
2.7.1.3.3 - PERISHABLE FOOD 54
2.7.1.3.4 - MEAT PRODUCTS AND POULTRY PRODUCTS (DUAL JURISDICTION) 55
2.7.1.3.5 - EGG AND EGG PRODUCTS (DUAL JURISDICTION) 55

2.7.1.3.6 - DRUG 54
2.7.2 - INSPECTIONAL PROCEDURE....55
2.7.2.1 - Criteria for Detention....55
2.7.2.1.1 - DEVICES....55
2.7.2.1.2 - FOOD 55
2.7.2.1.3 - MEAT AND POULTRY PRODUCTS 56
2.7.2.1.4 - EGG AND EGG PRODUCTS 56
2.7.2.1.5 - DRUGS 55
2.7.2.2 - Detention Procedure....56
2.7.2.2.1 - CONSIDERATIONS....56
2.7.2.2.2 - EXECUTING THE DETENTION 56
2.7.2.3 - Detention Order (Form FDA 2289)....57
2.7.2.3.1 - PREPARATION OF DETENTION ORDER NOTICE57
2.7.2.3.2 - PREPARATION OF PAGE 1 (FDA 2289)....57
2.7.2.3.3 - PREPARATION OF PAGE 2 THROUGH 5 (FDA-2289)....58
2.7.2.3.4 - DISTRIBUTION OF FDA-2289 59
2.7.2.4 - Detention Tag FDA 2290 59
2.7.2.4.1 - PREPARATION 59
2.7.2.4.2 - FRONT OF TAG 59
2.7.2.4.3 - REVERSE OF TAG (FDA 2290)....59
2.7.2.4.4 - USE OF TAG 59
2.7.2.5 - Termination of Detention....59
2.7.2.5.1 - REMOVAL OF DETENTION TAGS 60
2.7.2.5.2 - ISSUANCE OF DETENTION TERMINATION NOTICE FDA 2291 60
2.7.3 - SAMPLING 60
2.7.4 - SUPERVISION OF RECONDITIONING, DENATURING, OR DESTRUCTION....60
2.7.5 - REPORTING 60
SUBCHAPTER 2.8 - DENATURING....60
2.8.1 - OBJECTIVE....60
2.8.2 - DIVERSION TO ANIMAL FEED 60
2.8.2.1 - Rodent or Bird Contaminated Foods....61
2.8.2.2 - Moldy Food 61
2.8.2.3 - Pesticide Contamination 61
2.8.3 - DECHARACTERIZATION FOR NON-FOOD OR FEED PURPOSES....61
SUBCHAPTER 2.9 - REGULATORY SUBMISSIONS....61
2.9.1 - CENTER FOR DRUG EVALUATION AND RESEARCH (CDER) 61
2.9.1.1 - Registration and Listing 61
2.9.1.2 - Investigational New Drug Application (IND)....61
2.9.1.3 - New Drug Application (NDA) 61
2.9.1.4 - Abbreviated New Drug Application (ANDA)....61
2.9.2 - CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH) 62
2.9.2.1 - Device Registration and Listing 62
2.9.2.2 - Investigational Device Exemption (IDE) Regulation....63
2.9.2.3 - Premarket Notification - Section 510(k) 63
2.9.2.4 - Premarket Approval 63
2.9.2.5 - Classification of Devices....64
2.9.2.5.1 - CLASS I 64
2.9.2.5.2 - CLASS II 64
2.9.2.5.3 - CLASS III 64
2.9.2.6 - Requests for GMP Exemption and Variances....64
2.9.2.7 - Medical Device Reporting....64
2.9.2.8 - Radiation Reporting 65
2.9.3 - CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)....65
2.9.3.1 - Registration and Listing 65
2.9.3.1.1 - HUMAN BLOOD AND BLOOD PRODUCTS 65
2.9.3.1.2 - HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) 66
2.9.3.2 - Biologic License....66
2.9.4 - CENTER FOR VETERINARY MEDICINE (CVM)....66
2.9.4.1 - Registration and Listing 66
2.9.4.2 - Medicated Feed Mill License (FML)....67
2.9.4.3 - Abbreviated New Animal Drug Application (ANADA) ..67
2.9.4.4 - New Animal Drug Application (NADA)....67
2.9.5 - CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN) 68
2.9.5.1 - Low Acid Canned Food (LACF) / Acidified Foods (AF) Food Canning Establishment (FCE) Registration....68
2.9.5.2 - FCE Process Filing of LACF/AF Processors 68
2.9.5.3 - Cosmetics 69
VOLUNTARY REGISTRATION OF COSMETIC PRODUCT ESTABLISHMENTS (21 CFR 710) 69
VOLUNTARY FILING OF COSMETIC PRODUCT INGREDIENT COMPOSITION STATEMENT (21 CFR 720)....69
2.9.5.4 - Color Certification Program 69
2.9.5.5 - Infant Formula 70
2.9.5.6 - Interstate Certified Shellfish (Fresh and Frozen Oysters, Clams, and Mussels) Shippers....70
2.9.5.7 - Interstate Milk Shippers (IMS) 70
2.9.6 –CENTER FOR TOBACCO PRODUCTS 71

CHAPTER 2 EXHIBITS
2-1 INTERROGATION: ADVICE OF RIGHTS....72
2-2 FORM FDA 2289 74
2-3 DETENTION TAG 79
2-4 FORM FDA 2291 80

SUBCHAPTER 2.1 - REGULATORY NOTES

Regulatory notes are the contemporaneous, sequential record of your daily investigatory efforts. They record your observations relevant to violations and active cases. They are the vital link between your findings and your subsequent testimony in court. Because of the data, which regulatory notes contain, such as information pertaining to open investigatory files, trade secrets, and personal information protected under the Privacy Act, they are confidential. Regulatory notes are government property. The notes cannot be released to anyone outside the Agency, except with the express permission of your management and after following FDA's procedures. (See IOM Subchapter 1.4)

See IOM 1.2.4 for guidance on administrative notes.

2.1.1 - USES OF REGULATORY NOTES

Accurate regulatory notes are to refresh your memory when reporting certain important details of a sample collection, inspection, and investigation. Notes also support the principle of "presumption of regularity", i.e., in the absence of clear evidence to the contrary, courts presume public officers properly discharge their official duties. Regulatory notes are useful as a means to refute assertions by defendants, witnesses or others. Regulatory notes also aid in defending lawsuits against FDA agents. This has been an issue of significance in a number of regulatory cases in the Federal Sector.

2.1.2 - REGULATORY NOTES CHARACTERISTICS

See IOM 1.1 for English language requirement. Regulatory notes should be accurate, objective, factual, and free of personal feelings or conclusions. Regulatory notes should be made at the time of the event they represent. Regulatory notes are original contemporaneous, sequential recordings of an activity, and may be handwritten (in ink) or electronic. Do not erase, edit or rewrite original notes. Do not leave excessive space between diary entries. Whether handwritten or electronic, any additions, deletions, or corrections to regulatory notes should be identified by strike through (~~strike through~~ font for electronic notes) for deletions, brackets [ ] for additions and by initialing and dating your changes.

Electronic Regulatory notes: you should be able to identify and attest the electronic notes were taken by you to ensure document integrity. You should exercise good judgment when deciding if a change is contemporaneous or if change should be initialed and dated. For example, changes or backspacing to correct information ordinarily would not need initialing and dating as long as the changes were made contemporaneously with the activity being documented. Otherwise, you should initial and date the change. Adhere to agency directives and procedures to safeguard and file electronic notes. Regulatory notes can be printed, and each page initialed (handwritten initials) and dated by the investigator. If this procedure is used, the original disk or Compact Disk-Recordable (CD-R) can be identified with the firm name, dates, and investigator's initials; placed in a FDA-525 envelope or equivalent; and then sealed with an Official Seal, FDA-415a. NOTE: See IOM 5.3.3 - Exhibits, for guidance on the identification and storage of electronic data obtained from inspected firms, and used as exhibits for the EIR.

2.1.3 - REGULATORY ENTRIES

Regulatory notes should contain sufficient detail to refresh an investigator's memory regarding inspections, investigations and sample collections. They should include objectionable conditions, pertinent information about your activities during an operation, details of a sample collection, etc. If a checklist is used during an inspection, don't repeat that information in your regulatory notes and attach it to your EIR. The checklist should be handled as part of the notes. See also 5.10.1. Likewise, when relevant information is contained on an FDA form, or in an exhibit collected during an inspection, that information need not be repeated in your notes.

Regulatory notes should contain the substance of all significant discussions with people contacted during the activity; e.g., discussions of individual responsibility and refusals. When entering a direct quote in your regulatory notes, such as a statement against self-interest, it is important the exact words be used to preserve the original intent of the individual and subject. Every quote of significance appearing in the final report should be in your regulatory notes since they are part of the source documents, which will support any regulatory or administrative action.

Regulatory notes should not contain purely administrative information. See IOM 1.2.4 for guidance on administrative notes.

2.1.4 - FORMAT FOR REGULATORY NOTES

Keep your handwritten regulatory notes in a bound notebook. Bound notebooks provide continuity and integrity and also prevent lost or misplaced pages. Loose-leaf and spiral bindings allow easy removal of pages, an invitation to vigorous and heated cross-examination on the witness stand.

Regulatory notes in electronic format are a valuable tool to expediting the conduct of an inspection. They may be stored on computer disk or CD-R, but should be preserved in a manner that ensures data integrity.

Regulatory notes whether written or electronic are subject to audit at any time; must be available for review; and must, on demand, be surrendered to your supervisors or other authorized personnel. The bound notebook in which your regulatory notes are kept should be identified with your name, telephone number, and address to facilitate their return if lost. To assist in the return of lost regulatory notes, include the following information in the bound notebook's inside cover or as a placard affixed to the back cover:

> This book is the property of the U.S. Government.
> If found, drop in mail box.
> POSTMASTER: Postage guaranteed
> Please return to: [Enter the appropriate district (or resident post's) mailing address here, including the zip code]

Advancing technology may increase the preservation options available. District policy should be followed regarding the preservation of all regulatory notes.

2.1.5 - RETENTION OF REGULATORY NOTES

Identify your regulatory notes with your name and the inclusive dates they cover before they are turned over for storage. Follow your District's policy regarding the maintenance of regulatory notes.

Based on your district's policy, regulatory notes (including computer disks or CD-Rs) may be kept by you, filed with the final report, or kept by the district in a separate, designated file. At a minimum, retain regulatory notes for the same period of time as the inspection report, collection report or other investigational report, or until all court actions, including appeals, have been adjudicated.

If you leave FDA, or are transferred from your district, identify any regulatory notes in your possession and turn them in to the district you are leaving. Districts are to retain regulatory notes as official records as outlined in the FDA Staff Manual Guide.

Regulatory notes prepared by headquarters' personnel during a field inspection/investigation are official records. Headquarters personnel are to follow their Center's policy regarding the retention of regulatory notes. In general, all regulatory notes should be maintained in the District or Center where the original report is filed.

SUBCHAPTER 2.2 - STATUTORY AUTHORITY

Various acts specify the authority conferred on the Secretary of DHHS. This authority is delegated by regulations to the Commissioner of Food and Drugs, and certain authorities are delegated further by him.

2.2.1 - FEDERAL FOOD, DRUG, AND COSMETIC ACT

This Act, as amended, and its regulations provide the basic authority for most operations.

Examinations, Investigations, and Samples - Collecting samples is an important and critical part of FDA's regulatory activities. While inspections and investigations may precede sample collection, a case under the law does not normally begin until a sample has been obtained. Proper sample collection is the keystone of effective enforcement action.

The basic authority for FDA to take samples falls under the statutory provisions of section 702(a) of the FD&C Act [21 USC 372(a)], which authorizes examinations and investigations for the purposes of this Act.

For tobacco products, section 702(a)(1)(B) of the FD&C Act directs FDA to contract with states to inspect retailers within that state in connection with the enforcement of the Act when feasible.

Section 702(b) of the FD&C Act [21 USC 372(b)] requires FDA to furnish, upon request, a portion of an official sample for examination or analysis to any person named on the label of an article, the owner thereof, or his attorney or agent. In a precedent case, "United States v. 75 Cases, More or Less, Each Containing 24 Jars of Peanut Butter, the U.S. Circuit Court of Appeals for the Fourth Circuit held the taking of samples is authorized under section 702(b) of the FD&C Act [21 U.S.C. 372(b)], since this section "clearly contemplates the taking of samples." See Kleinfeld and Dunn 1938-1949 at 126. The FD&C Act also refers to samples in sections 704(c) and 704(d) [21 USC 374(c) and 374(d)].

2.2.1.1 - Authority to Enter and Inspect

Authority to Enter and Inspect - Section 704 of the FD&C Act [21 U.S.C. 374] provides the basic authority for establishment inspections. This authorizes you to enter, and to inspect at reasonable times, within reasonable limits, and in a reasonable manner, establishments or vehicles being used to process, hold or transport food, drugs, devices, tobacco products, or cosmetics. The statute does not define, in specific terms, the meaning of "reasonable". FDA's establishment inspection procedures maintain this authority extends to what is reasonably necessary to achieve the objective of the inspection.

2.2.1.2 - Food Inspections

Authority to inspect food plants resides in the general inspectional authority of section 704 of the FD&C Act [21 U.S.C. 374]. Section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act") (PL 107-188), signed into law on June 12, 2002, created a new section 414, "Maintenance and Inspection of Records," in the FD&C Act. Under this new authority, the Secretary of Health and Human Services (the Secretary) may by regulation establish requirements for persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain food records. These records identify the immediate previous sources and the immediate subsequent recipients of food. In addition, section 414(a), "Records Inspection," and section 704(a), "Factory Inspection" authorize the Secretary to access and copy all records related to an article of food if: (1) the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, and (2) the records are necessary to assist the Secretary in making such a determination. FDA plans to carry out its authority to inspect all records and other information described in section 414 in a similar manner as FDA's authority to perform inspections of facilities (i.e., upon presentation of appropriate credentials and a written notice at reasonable times, within reasonable limits, and a reasonable manner.) FDA employees will not invoke this authority during inspections unless the requirements for record access under the Bioterrorism Act are satisfied. Further guidance is available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm292745.htm .

The Infant Formula Act of 1980 added new authority to the FD&C Act. Section 412 of the FD&C Act [21 U.S.C. 350a] extends the definition of adulteration to include specific nutritional, quality and good manufacturing control requirements. It also mandates a firm make available batch records, quality control records, nutrient test data and methodology, and similar documents for examination and copying. Section 704(a)(3) of the FD&C Act [21

U.S.C. 374(a)(3)] gives investigators the right to examine and copy these records.

2.2.1.3 - Device Inspections

Section 704(a) of the FD&C Act [21 U.S.C. 374(a)] provides the general inspectional authority to inspect medical device manufacturers. The Medical Device Amendments of 1976 provided additional authority to inspect records, files, papers, processes, controls, and facilities to determine whether restricted devices are adulterated or misbranded. The Amendments also provide FDA authority, under section 704(e) [21 U.S.C. 374(e)], to inspect and copy records required under Section 519 or 520(g) of the FD&C Act [21 U.S.C. 360i or 360j(g)].

2.2.1.4 - Drug Inspections

In the case of drug inspections, FDA has explicit authority to address the delay, denial, limiting, or refusal of an inspection, under Section 707 of the Food and Drug Administration Safety and Innovation Act (FDASIA), which created new Section 501(j) of the FD&C Act [21 U.S.C. 351(j)]. Section 501(j) deems adulterated any drug that is manufactured in an establishment that delays, limits, denies or refuses to permit entry or inspection. FDA issued draft guidance with examples of the types of conduct that FDA considers to be in violation of Section 501(j) of the FD&C Act. This guidance also specified that under certain circumstances delaying, denying, limiting or refusing a request for records in advance or in lieu of an inspection under Section 706 may also result in a manufacturer's drugs being adulterated under the FD&C Act.

2.2.1.5 - Limitations

Section 704 of the FD&C Act [21 U.S.C. 374] provides authority for FDA to conduct inspections of factories, warehouses, establishments, and vehicles, and all pertinent equipment, finished and unfinished materials, containers, and labeling therein where food, drugs, devices, tobacco products, or cosmetics are manufactured or held. This section does not include a provision to inspect records within those facilities, except for inspections of prescription drugs, nonprescription drugs intended for human use, and restricted devices, or tobacco products as stipulated in 704(a)(1)(B) [21 U.S.C. 374(a)(1)(B)], or inspections of infant formula described in 704(a)(3) of the FD&C Act [21 U.S.C. 374(a)(3)].

Keep in mind that several other sections of the Act or of regulations also include provision for inspection and copying of required records. For example, 505(k) provides authority to access and copy records required for new drug applications and abbreviated new drug applications, 512(k)(2) and 512(m)(5) of the FD&C Act [21 U.S.C. 360b(k)(2) and 360b(m)(5)] provide access and copying of records regarding new animal drug and medicated feed permits, HACCP regulations in 21 CFR 123 for fish and fishery products provide for access and copying of required records, and 920(c) provides access, with written notice, to records in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products.

Some firms will allow access to files and other materials for which the FD&C Act does not give mandatory access, but retain the right to later refuse. Management may propose the following alternatives:

1. That inspections to obtain data from these files be made without issuing an FDA-482, Notice of Inspection. You cannot agree to this because the act requires the notice be issued before the inspection.
2. That when data is provided, you are advised in writing it is being given voluntarily. In this instance accept the written or oral statement, and include it as part of the EIR.

Management may insist answers to specific questions be provided by the firm's legal department or other administrative officers. In some instances, management may request questions be submitted in writing. In these cases, try to obtain answers necessary to complete the inspection. Do not submit lists of questions unless specifically instructed to do so by your supervisor.

2.2.1.6 - Electronic Radiation Product Examinations and Inspections

The authority for obtaining samples of radiation-emitting electronic products for testing is provided in Section 532(b)(4) of the FD&C Act [21 U.S.C. 360ii(b)(4)].

The authority to inspect factories, warehouses, and establishments where electronic products are manufactured or held is provided in Section 537(a) of the FD&C Act [21 U.S.C. 360nn(a)]. This authority is limited; FDA must find "good cause" that methods, tests, or programs related to radiation safety (such as noncompliance with a standard) may be inadequate or unreliable. If there is no finding of "good cause," inspections must be voluntary unless another authority, such as Section 704(a) of the FD&C Act [21 U.S.C. 374(a)] for medical devices, exists. The authority to inspect books, papers, records, and documents relevant to determining compliance with radiation standards is provided in Section 537(b) of the FD&C Act [21 U.S.C. 360nn(b)]. The Electronic Product Radiation Control prohibited acts and enforcement authorities are specified in Sections 538 and 539 of the FD&C Act [21 U.S.C. 360oo and 360pp].

2.2.2 - SELECTED AMENDMENTS TO THE FD&C ACT

The amendments to the FD&C Act are summarized in Regulatory Procedures Manual (RPM) chapter 2-2.

2.2.3 - OTHER ACTS

See IOM 2.2.10 and IOM 3.2.1.3 for special authorities involving detentions under the Federal Meat Inspection, Poultry Products Inspection, and Egg Products Inspection, Acts.

2.2.3.1 - Anabolic Steroids Control Act of 1990

The Anabolic Steroids Control Act amends the Controlled Substances Act by adding Anabolic Steroids to Schedule III of section 202(c).

2.2.3.2 - Fair Packaging and Labeling Act (FPLA)

Fair Packaging and Labeling Act (FPLA) is an Act to prevent the use of unfair or deceptive methods of packaging or labeling of certain consumer commodities.

2.2.3.3 - Federal Anti-Tampering Act

Federal Anti-Tampering Act prohibits certain tampering with consumer products (18 USC 1365). See IOM 8.8 for guidance on tampering investigations.

2.2.3.4 - Federal Import Milk Act

Federal Import Milk Act regulates the importation of raw and pasteurized bovine milk and cream from foreign producers.

2.2.3.5 - Federal Caustic Poison Act

Primarily a labeling Act specifying warnings and precautionary statements on labeling of certain household caustic preparations.

2.2.3.6 - Poison Prevention Packaging Act

Provides for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances.

2.2.3.7 - Public Health Service Act (PHS)

Public Health Service Act (PHS) - Sampling: For biological products, which are also drugs under the FD&C Act, the sampling authority of both Acts exists.

Section 351(c) of Part F, Title III of the Public Health Service (PHS) Act [42 USC 262(c)] authorizes inspections of biological establishments (vaccines, serum, and blood). Authority to collect samples and records is found in 21 CFR 600.22. Section 361(a) of Part G of the PHS Act [42 USC 264] authorizes inspection and other activities for the enforcement of 21 CFR 1270, Human Tissue Intended for Transplantation, and 21 CFR 1240, Interstate Quarantine Regulations. Part 1240 covers the mandatory pasteurization for all milk in final package form intended for direct human consumption; the safety of molluscan shellfish; the sanitation of food service; and food, water, and sanitary facilities for interstate travelers on common carriers.

2.2.3.8 - Mammography Quality Standards Act of 1992

Mammography Quality Standards Act of 1992 amends the Public Health Service Act to establish the authority for the regulation of mammography services and radiological equipment.

2.2.3.9 - Comprehensive Smokeless Tobacco Health Education Act

Comprehensive Smokeless Tobacco Health Education Act mandates a program to inform the public of any dangers to human health resulting from the use of smokeless tobacco products and includes specific requirements for smokeless tobacco products' labeling and advertising.

2.2.3.10 - Federal Cigarette Labeling & Advertising Act

Federal Cigarette Labeling & Advertising Act requires a comprehensive federal program to deal with cigarette labeling and advertising to adequately inform the public of health risks and create a uniform regulatory structure across the United States. The Act includes specific requirements for cigarette for cigarette labeling and advertising.

2.2.4 - CODE OF FEDERAL REGULATIONS (CFR)

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas. For example, the specific regulation covering drug GMPs appears as "21 CFR 211", that is, Title 21, Part 211. Regulations enforced by FDA are found in volumes 1-8 of Title 21, parts 1-1299. They are updated as of April 1 of each year. The Federal Register and the CFR must be used together to determine the latest version of a given rule.

2.2.5 - DEFINITIONS

The following terms are used in assignments, correspondence, and various procedures described in this manual and used throughout FDA.

2.2.5.1 - Civil Number

A docket number used by US district courts to identify civil cases (seizure and injunction).

2.2.5.2 - Citation (Cite)

The section 305 Notice is a statutory requirement of the FD&C Act. It provides a respondent with an opportunity to show cause why he should not be prosecuted for an alleged violation. Response to the notice may be by letter, personal appearance, or an attorney(s).

2.2.5.3 - Criminal Number

A docket number used by the US district courts to identify criminal cases (prosecutions).

2.2.5.4 - FDC and INJ Numbers

The number used by the Chief Counsel's office to identify FDA cases.

2.2.5.5 - Complaint for Forfeiture

A document furnished to the U.S. attorney for filing with the clerk of the court to initiate a seizure.

2.2.5.6 - Home District

The Home District is 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 the violation occurred; and the shipper of such article, as shown by such records, may be considered to be the alleged violator.

Where actions against a firm are based on goods which became violative after interstate shipment was made, or after reaching its destination (such as 301(k) violations), the dealer in whose possession the goods are sampled may be considered the violator, and the location of this dealer determines the "Home District".

2.2.5.7 - Nolle Prosequi (Nol-Pros)

The prosecutor or plaintiff in a legal matter will proceed no further in prosecuting the whole suit or specified counts.

2.2.5.8 - Nolo Contendere (Nolo)

A plea by a defendant in a criminal prosecution meaning "I will not contest it".

2.2.5.9 - Seizing District

The district where seizure is actually accomplished. The seizing district is not necessarily the collecting district, as in the case of in transit samples.

2.2.5.10 - Subpoena Duces Tecum

A writ commanding a person to appear in court bringing with him certain designated documents or things pertinent to the issues of a pending controversy.

2.2.5.11 - Supervising District

The district which exercises supervision over reconditioning lots in connection with seizure actions.

2.2.6 - SEIZURE

Seizure is a judicial civil action directed against specific offending goods, in which goods are "arrested." Originally designed to remove violative goods from consumer channels, it was intended primarily as a remedial step; however, the sanction often has a punitive and deterrent effect.

For more information on seizure actions consult RPM Chapter 6-1 “Seizures.”

2.2.6.1 - District Recommendation

The district considers all evidence, including any establishment inspection, sample collection, and analytical results. If indicated, seizure is recommended to headquarters.

2.2.6.2 - Headquarters

Except for certain direct seizure authority, district seizure recommendations are referred to the appropriate center for approval. If approved, the case is referred to the Office of Enforcement and Import Operations (HFC-200) which then requests the Chief Counsel to initiate seizure action.

2.2.6.3 - Department of Justice

The Food and Drug Division of the Department's Office of Chief Counsel reviews and forwards the seizure action to the U.S. attorney in whose judicial district the violative goods are located, through the seizing district. The U.S. attorney files a Complaint for Forfeiture addressed to the U.S. district court, setting forth the facts of the case and calling for the "arrest" of the goods. This Complaint is filed with the appropriate district court.

2.2.6.4 - U.S. District Court

The court orders the arrest of the goods by issuing a motion and warrant to the U.S. marshal, directing seizure of the goods.

The marshal seizes the goods, which then become the property of the court. You may be asked to assist the marshal in the seizure. If so, submit a memorandum to your district office covering this activity.

2.2.6.5 - Claimant and Options

Any person who has an interest in the goods may appear as claimant or to intervene, and claim the goods.

2.2.6.6 - Abandonment

If no claimant appears within a specified time, (return date), then the U.S. attorney requests a Default Decree of Condemnation and Forfeiture, in which the court condemns the goods and directs the U.S. marshal to destroy or otherwise dispose of the goods. Usually, the District assists the marshal in determining the method of disposal, and you may be asked to help in the actual disposition. Any disposition must be in accordance with the National Environmental Policy Act of 1969 (NEPA); 42 U.S.C. 4321-4347.

2.2.6.7 - Reconditioning for Compliance

A claimant may appear and propose the goods be reconditioned to bring them into compliance. After the FDA agrees to the method of reconditioning, the court issues a Decree of Condemnation permitting reconditioning under the supervision of the FDA, after a bond is posted. Salvage operations may include:

1. Cleaning, reworking, or other processing,
2. Relabeling, or
3. Denaturing.

2.2.6.8 - Contested Seizure

A claimant may file an answer to the complaint and deny the allegations. The issues then go to trial.

2.2.6.9 - District Follow-up

The district seizure recommendations are concurrently reviewed by the Center, OEIO and the OCC.

2.2.7 - PROSECUTION

Prosecution is a criminal sanction directed against a firm and/or responsible individuals. They can be pursued at two levels: misdemeanor or felony. A prosecution is punitive, with the view of punishing past behavior and obtaining future compliance.

2.2.7.1 - Section 305 Notice

The section 305 Notice is a statutory requirement of the Act. It provides a respondent with an opportunity to explain why he should not be prosecuted for the alleged violation. Response to the notice may be by letter, personal appearance or attorney.

Under certain circumstances, the Agency will refer prosecution (or for further investigation) without first providing the opportunity for presentation of views in accordance with section 305 [See 21 CFR 7.84(a)(2) and (3)].

The facts developed at the hearing are reviewed, along with other evidence, and the district prepares a recommendation that the case be:

1. Placed in permanent abeyance, with no further action, or
2. Placed in temporary abeyance, in which case the decision is delayed pending additional evidence, or for other reasons, or
3. Considered, with RFDD concurrence, for an ad hoc meeting when there is an indication of potential felony charges or the case is especially unusual, or
4. Forwarded to the Justice Department for prosecution.

The district recommendation is reviewed by Headquarters units in the light of current policy and procedure. If prosecution is indicated, the case is forwarded to the Office of Chief Counsel (OCC) for review. If the Chief Counsel agrees, the matter is forwarded to the Department of Justice (DOJ) where it is reviewed again. If DOJ concurs, the case is forwarded to the appropriate U. S. Attorney. Non-concurrence results in return of the case to FDA.

2.2.7.2 - Information

An Information is a legal document filed in misdemeanor actions identifying the defendants and setting forth the charges. The Information is forwarded to the appropriate U.S. Attorney, who then files the legal instruments. A trial date is set by the court. Ideally, trial preparation is

collaboration between representatives of the U. S. Attorney's office, OCC, the District and the involved Center.

2.2.7.3 - Grand Jury Proceedings

The Justice Department must proceed by indictment in all felony cases. Evidence in possession of the government is presented to a grand jury which decides if it is sufficient to warrant prosecution. If the grand jury returns a "True Bill", and the defendant pleads not guilty at the arraignment, preparation for trial begins.

The deliberations of a federal grand jury are secret, and only those whom the court has placed under Rule 6(e) of the Federal Rules of Criminal Procedure may be privy to the grand juries activities. Consequently, if you have been designated under the Rule, you may not divulge your knowledge of grand jury affairs to anyone, including colleagues or supervisors, unless they, too, have been placed under the Rule. Strict adherence to the rule of grand jury secrecy protects not only the integrity of the government's investigation, and the validity of any indictment the grand jury might return, but the rights of the person accused. See IOM 5.2.2.9 Working with a Grand Jury.

When you are assigned to work with, or for, a grand jury and are instructed as part of that assignment to conduct an inspection or an investigation, do not issue a Notice of Inspection (FDA-482) (See IOM 5.2.2.4 Conducting Regulatory Inspections When the Agency is Contemplating Taking, or is Taking, Criminal Action). Check with district management and the Assistant U.S. Attorney or Chief Counsel Attorney involved, prior to initiating this type of assignment. Also, refer to IOM 5.2.2.4, 5.2.2.5, 5.2.2.6, 5.2.2.7, 5.2.2.8 and 5.2.2.9.

2.2.7.4 - District Follow-up

Appropriate reports are made to the Administration when the case terminates. Follow-up may involve inspections either of a routine nature or as directed by the court.

2.2.8 - INJUNCTION

An injunction is a civil restraint issued by the court to prohibit violations of the Act. Injunction is designed to stem the flow of violative products in interstate commerce, and to correct the conditions in the establishment.

Injunction actions must be processed in strict time frames. Therefore, you may be requested to conduct an inspection to determine the current condition of a firm and to obtain specific information required for the injunction.

2.2.8.1 - Temporary Restraining Order (TRO)

Upon presentation of evidence, the U.S. district court may issue an order restraining defendant from certain acts, for a specific length of time. This period may be extended by order of the court.

2.2.8.2 - Hearing for Injunction

Prior to the expiration of the TRO, if one is involved, the U.S. Attorney, assisted by the district, presents evidence to support an injunction.

2.2.8.3 - Consent Decree of Injunction

The defendants may, following conferences with the U.S. Attorney, consent to a decree of preliminary or permanent injunction. If not, the issue goes to trial.

2.2.8.4 - Trial for Injunction

A preponderance of evidence is required to support an injunction. This differs from a prosecution, which requires evidence establishing guilt "beyond a reasonable doubt". Trial is before the district court. There is no trial by jury, unless demanded by the defendant. In violations of injunction (contempt), the action is brought under the Rules of Criminal Procedure.

2.2.8.5 - Preliminary or Permanent Injunction

A preliminary or permanent injunction enjoins a firm or individuals from continuing a specific violation(s). The terms of the injunction specify the steps to be taken to correct the violations at issue.

2.2.8.6 - District Follow-up

Generally, the district will police an injunction to assure the terms of the decree are met. This may include routine inspections or actual supervision of compliance activities dictated by the terms of the injunction.

2.2.9 - EMERGENCY PERMIT CONTROL

Section 404 of the FD&C Act [21 U.S.C. 344] provides for the issuance of temporary permits prescribing the conditions governing the manufacture, processing or packing of certain classes of foods. It applies to foods subject to contamination by injurious microorganisms, where such contamination cannot be adequately determined after such articles have entered interstate commerce.

2.2.10 - DETENTION POWERS

FDA has administrative detention authority for food under section 304(h) of the FD&C Act [21 U.S.C. 334(h)], and for devices and drugs under section 304(g) of the FD&C Act [21 U.S.C. 334 (g)], when FDA has a reason to believe that the article is adulterated or misbranded.

FDA also has detention authority for certain products regulated by USDA under sections 402 and 409(b) of the Federal Meat Inspection Act, sections 19 and 24(b) of the Poultry Products Inspection Act, and sections 5(d), 19, and 23(d) of the Egg Products Inspection Act. See IOM 2.7.1.2 for information on these authorities.

In essence, articles subject to the Federal Meat Inspection Act or the Poultry Products Inspection Act that are believed to be adulterated or misbranded under the FD&C Act may be detained. FDA representatives may detain articles subject to the Egg Products Inspection Act, which are suspected to be in violation of that statute.

Devices may be detained under the FD&C Act for a maximum of thirty days when there is reason to believe they are adulterated or misbranded under the FD&C Act.

See IOM 2.7.2 for inspectional procedures, which must be followed, in exercising the detention authority.

2.2.11 - COURTROOM TESTIMONY

Effective testimony, whether it be in court before a judge or jury, grand jury or opposing counsel at a deposition, is a result of quality investigative skills; the ability to prepare factual and informative investigative reports; and thorough preparation for being a fact witness.

As a witness, you are required to testify from memory, but you are allowed to refer to diary notes, reports and memoranda, when necessary to refresh your recollection. For this reason, and the fact they are available to opposing counsel, the Agency insists your notes, reports and the like always be accurate, organized and complete.

There is little difference in giving testimony in court, in a deposition or before a grand jury. In a deposition, testimony is given upon interrogation by opposing counsel, under oath, before a court reporter. Be guided by your (the Government's) attorney in preparing for a deposition. Once completed, the deposition is available to all persons interested in the case, and is available for use at trial.

In a grand jury, testimony is given under oath to a group of jurors who determine whether sufficient evidence exists to charge someone with a felony (See IOM 2.2.7.3).

2.2.11.1 - Testimony Preparation

The following suggestions may be helpful in preparing to provide testimony in court, before a grand jury or at a deposition:

1. Carefully and thoroughly reviewing your diary notes, inspection reports and all samples collected.
2. Be neat in your personal appearance; dress conservatively in business attire, and be well groomed.
3. When you take the witness stand, get comfortable, sit erectly and carefully look around to familiarize yourself with the court surroundings.
4. Tell the truth. If asked, do not hesitate to admit you have discussed your testimony in advance with the U.S. Attorney's office.
5. Be sure you understand the question before you answer. If you don't understand the question, request clarification. Take your time. Give each question such thought as required to understand and formulate your answer. Do not answer questions too quickly. Give your attorney time to raise an objection in case it is a question you should not answer. Answer questions clearly and loudly enough so everyone can hear you. Look at the jury and address your remarks to it so all jury members will be able to hear and understand you. Speak directly and authoritatively, and do not use ambiguous phrases such as, "I guess so", "I believe," etc. Do not be afraid to say, "I don't know".
6. Be polite and serious at all times. Give an audible answer to all questions. Do not nod your head yes or no.
7. Do not lose your temper, even if baited by an attorney. Do not spar with examining attorneys; answer questions frankly, factually and confidently, then stop. Do not answer questions, which have been objected to until the court rules on the objection. Do not volunteer information.
8. If you make a mistake answering a question, correct it immediately. If a question can't be truthfully answered with a yes or no, you have the right to explain your answer. If you are asked questions about distances, time or speed, and your answer is only an estimate, be sure you make that clear.
9. If a recess is declared while you are on the stand, keep to yourself. Do not discuss your testimony with anyone except on special instructions from the U.S. Attorney or his/her assistant.
10. Be natural, be yourself. Do not be intimidated by personalities.

2.2.11.2 - Interviewing Persons under Arrest

Miranda Warning - In the Agency's normal course of operation, it is not necessary to read a person their rights, (i.e.: Miranda warnings) because the Agency does not routinely interview individuals who are in custody (under arrest). Miranda warnings are not necessary, during discussions with management when conducting inspections, during investigational interviews, or during a section 305 of the FD&C Act [21 U.S.C. 335] meeting

because the individuals being interviewed are not in custody, and are free to leave at any time.

In certain situations, however, FDA personnel may interview someone who is already in custody. In this case, the individual must be given their Miranda rights.

When this situation is encountered, copy page 1 of IOM Exhibit 2-1. If the subject cannot speak/read English, you must arrange for a form in the appropriate language. Read this material to the individual, preferably in the presence of another person, and then have them sign and date the waiver statement. Submit the signed statement with your report. If the individual refuses to sign the statement, indicate this on the unsigned statement, and identify the witness on the document. Submit the unsigned statement with your report.

SUBCHAPTER 2.3 - RECONDITIONING AND DESTRUCTION

Sections 304 and 801 of the FD&C Act [21 U.S.C. 334 and 381] provide the legal basis for reconditioning or destruction of goods under domestic seizure or import detention.

Reconditioning and destruction are the means whereby goods are brought into compliance with the law, or permanently disassociated from their intended use. Manpower may not be expended on supervision of reconditioning and destruction of goods except under administrative controls, detention, or emergency and disaster operations. See IOM 8.5 for operations in disasters.

FDA does not seek or condone the destruction of books or other publications. FDA policy and practice tries to be sensitive to the potential First Amendment issues associated with the regulation of books and other printed materials that function as labeling of a product. See Compliance Policy Guide 140.100. In the context of judicial enforcement, disposition of any labeling subject to the court's jurisdiction is determined by the court. In a voluntary compliance situation, the disposition is the prerogative of the manufacturer, distributor, wholesaler, or retailer. Agency policy does not authorize field employees to direct or limit the options for disposition of violative labeling or other printed materials in such circumstances. Good judgment should always be exercised in such matters.

Section 536(b) of the FD&C Act [21 U.S.C. 360ll (b)] provides authority for electronic products to be reworked if FDA determines they can be brought into compliance with radiation performance standards. Therefore, reconditioning of radiation-emitting products must be approved by CDRH, Office of Compliance, prior to implementation to assure compliance with performance standards. If a foreign manufacturer conducts the reconditioning, the district should notify both the importer/consignee and the foreign manufacturer's agent of all FDA actions.

2.3.1 - DEFINITIONS

2.3.1.1 - Reconditioning

The reworking, relabeling, segregation, or other manipulation which brings a product into compliance with the law, whether or not for its original intended use.

2.3.1.2 - Destruction

The procedures involved in rendering a product unsalvageable. Destruction may be accomplished by burning, burial, etc.

2.3.1.3 - Denaturing

Decharacterization of a product, whereby it is made unusable for its originally intended purpose.

2.3.2 - DISASTERS

Reconditioning and destruction of contaminated merchandise in times of disasters can assume national proportions and is handled differently than normal operations.

Instructions for operations pertaining to reconditioning and destruction during non-attack type disasters is covered in IOM 8.5.

SUBCHAPTER 2.4 - CONSENT DECREE

2.4.1 - POLICY

Seized goods may be released under bond, by court order to be destroyed or brought into compliance. The order normally provides for supervision of the operation by FDA. Release of the bond depends upon your certification the court order has been satisfactorily executed.

Do not undertake reconditioning until you are certain a court order has been entered, bond posted, and goods released by the marshal. Be certain the identity and amount of goods corresponds with that seized. Be sure you are familiar with the terms of the court order.

Reconditioning or destruction may, at times, be permitted without continuous supervision. However, the lot must be checked before operations start, rechecked intermittently and upon completion. Supervision must be sufficient to assure none of the lot was diverted. All of the goods involved in the action, including reconditioned goods as well as discarded material such as screenings, old labels,

etc., must be accounted for. If organoleptic examination will not permit a judgment regarding the degree of compliance, collect suitable samples for laboratory examination. If the reconditioning process does not appear to comply with the order, immediately advise the claimant and your supervisor.

2.4.2 - RELABELING

Before permitting any relabeling operation, be sure FDA has approved the proposed new label. Provide an accounting of disposition of the old labels. Submit three (3) copies of the new label and three (3) copies of the old label with your report of the operation.

2.4.3 - REWORKING

Before permitting any manipulation, determine the proposed process has been approved by your district. This includes ensuring the facilities and equipment to be used are sanitary and effective for the proposed process. Report the yield of the reworked product.

2.4.4 - SEGREGATION

Thoroughly examine goods set aside as legal, and submit samples for laboratory examination, if indicated. Follow up on disposition of reject material to prevent illegal diversion. Describe the method of destruction of unfit material resulting from the segregation process.

2.4.5 - DESTRUCTION

Supervise and describe the method of destruction of goods, labels, labeling, etc. and report the amount destroyed.

2.4.6 - DISPOSITION OF REJECTS

Arrange for reject materials to be destroyed in an approved manner, under your supervision. The method of disposition will have already been approved by the District, and in some cases set out in the Consent Decree.

2.4.7 - RELEASE OF GOODS

Do not authorize release of reconditioned goods, unless specifically directed by your supervisor. Formal release is normally handled by district headquarters.

2.4.8 - REPORTING

Promptly submit a detailed report upon conclusion of the operation. Where the operation is prolonged, submit interim progress reports. Include the following information in your report of the operation:

1. Identification of the case (sample number, court number, FDA number, product and claimant).
2. Description of the method of reconditioning or destruction.
3. Disposition of rejects; explanation for unaccounted goods.
4. Findings of field examinations.
5. Exhibits and samples collected. Do not pay for samples collected during reconditioning operations conducted under a Consent Decree.
6. Expenses, including time spent in supervision and travel, mileage, per diem, and incidental expenses.

SUBCHAPTER 2.5 - DEFAULT DECREE

2.5.1 - POLICY

When no claimant appears in a seizure case, the court issues a Default Decree of Condemnation condemning the goods. It may or may not specify the manner of disposal. Disposition, whether by destruction, distribution to charitable institutions or sale by salvage must be approved and monitored by the Government.

Primary responsibility for disposition of seized lots following a default decree lies with the U.S. Marshal's Office.

FDA inspectional personnel frequently accompany the marshal to witness the operation. Although you are there in an advisory capacity, assist the marshal in every way to assure compliance with the court order.

2.5.2 - REPORTING

Promptly submit a written report of your observations upon completion of the operation. See IOM 2.4.8.

SUBCHAPTER 2.6 - COMPLIANCE ACHIEVEMENT

2.6.1 - POLICY

FDA uses a blend of industry voluntary correction and regulatory actions to help achieve industry compliance.

A voluntary corrective action is defined as the observed voluntary repair, modification, or adjustment of a violative condition, or product. For purposes of this definition, violative means the product or condition does not comply with the Acts or associated regulations enforced by the Agency.

Voluntary destruction in lieu of seizure of small lots of violative goods shall be encouraged, where the proposed method is adequate. Supervision of voluntary segregation and denaturing of violative goods shall not be provided, except where it can be accomplished with dispatch, minimal inspectional resources, and in a manner consistent with procedures outlined in this Subchapter.

The most extensive actions in this area usually occur in disaster situations. Follow instructions in IOM Subchapter 8.5 - Disaster Procedures.

Do not engage in actual destruction, reconditioning, repair, modification, etc. of goods. This is the responsibility of the owner or dealer. You are in the capacity of witness only. Samples of violative goods should be collected prior to voluntary destruction to support subsequent action against the responsible individuals. Take photographs where applicable. See IOM 5.10.2.1 and IOM 2.6.4, 2.6.4.1/2 or reporting requirements.

2.6.2 - DESTRUCTION

Before you supervise destruction, be sure management is aware the action is voluntary and that you are acting only as a witness. See IOM 2.6.4.

Witness all destructions personally, making certain destroyed goods are rendered totally unsalvageable for food, drug, device, etc. use. Keep in mind personal and public safety. Exercise proper precautions in dealing with potentially dangerous substances and situations. Comply with local ordinances regarding the disposition of garbage and trash.

Note certain products should not be disposed of in a conventional manner (e.g.: sanitary landfill, flushing down the drain, etc.). In particular, certain products which have been banned in the past (chloroform, methapyrilene, hexachlorophene, PCB, etc.), are classified by EPA as hazardous and toxic substances and may require a special method of disposal by a licensed hazardous disposal facility. Any possible hazardous or toxic substance (carcinogen, mutagen, etc.) should not be disposed of without prior consultation by the firm with the U.S. Environmental Protection Agency and/or the regulating state authority. Refer to 21 CFR 25 and the National Environmental Protection Act for guidance regarding the environmental impact of voluntary destructions.

2.6.2.1 - DEA Controlled Drugs

FDA and DEA have a written policy to permit FDA representatives, in certain situations, to witness the destruction of DEA controlled drugs. The procedures and instructions to follow when these drugs are destroyed are:

2.6.2.1.1 - DEA APPROVAL

FDA and the Drug Enforcement Administration (DEA) have a mutual, written policy concerning witnessing the destruction of drugs under the distribution control of DEA. This provides for FDA, upon receiving a request to witness such destruction, to advise the DEA regional office and obtain approval for the action. If approval is requested by telephone and verbally approved, the approval should be reduced to writing for the record.

2.6.2.1.2 - PROCEDURE

The necessity for FDA personnel to witness destruction of DEA controlled drugs will normally happen only when FDA is already present in the firm, encounters DEA controlled drugs, and is requested to witness destruction, or when DEA controlled drugs are to be destroyed at the same time FDA is witnessing destruction of drugs not under DEA control.

If you are in a firm either making an inspection or to witness destruction of drugs under FDA's distribution control, and the firm requests you also witness destruction of DEA controlled drugs, do not commit yourself. Telephone your supervisor for instructions. You will be advised whether or not to proceed after your district communicates with DEA. In all other situations refer the requester to DEA.

If the request to witness the destruction is approved, observe the destruction, and prepare DEA Form DEA 41 as follows:

1. List each dosage form of each drug on a separate line. Calculate amounts for columns 6 and 7.
2. Line out the inappropriate sentences in the paragraph following line 32.
3. Date and sign the form.
4. Type or print your name, title, and district under your signature.

Submit the form to your district for transmittal to DEA.

2.6.3 - RECONDITIONING

The supervision of voluntary segregation of violative goods without the regulatory safeguards of seizure should be avoided. Voluntary segregation and destruction of violative lots should be encouraged; but under no circumstances should you supervise the voluntary segregation and salvage of unfit goods, regardless of the nature of the violation or the size of the lot. Be sure management is aware the segregation is its responsibility. Collect samples where indicated, and/or advise the dealer or owner of his responsibilities under the law. If the dealer decides to voluntarily destroy any lot, refer him to the National Environmental Protection Act (NEPA). See IOM 2.6.2.

2.6.4 - REPORTING

Report any voluntary correction of a problem unrelated to a district recommendation for regulatory action.

2.6.4.1 - Documenting Voluntary Destruction

Prior to supervising voluntary destruction, prepare a statement on the firm's letterhead or on an FDA 463a, Affidavit, providing the following information.

1. Voluntary nature of the action, with you as a witness.
2. Name of the product, including applicable code marks.
3. Condition of the lot.
4. Amount.
5. Method of destruction.
6. Signature of responsible individual.

2.6.4.2 - Compliance Achievement Reporting

The following are examples of compliance actions to be described in the report, EI Record, and reported into the Compliance Achievement Reporting System in FACTS (Exhibit 5-15) per district office SOP's:

2.6.4.2.1 - VIOLATIVE PRODUCTS

Voluntary destruction by the person in possession of any violative product.

2.6.4.2.2 - DESTRUCTION BY COOPERATING OFFICIALS

Destruction of violative products by a cooperating food or health official, where such product was discovered by and reported to such official by FDA when those officials were doing work for FDA under contract. Do not report formal condemnation by cooperating officials in the usual course of their independent work.

2.6.4.2.3 - MANUFACTURER'S RAW MATERIALS

Voluntary destruction of manufacturer's raw materials during the course of an inspection. For example, decomposed cream or filthy milk.

2.6.4.2.4 - CAPITAL IMPROVEMENTS

Significant improvements correcting a violative condition such as new equipment, rodent-proofing, etc. These should be reported at follow-up inspections where actual improvement has been accomplished or committed, and the improvement is the result of a previous FDA observation or suggestion and not as a result of a seizure, injunction or prosecution.

2.6.4.2.5 - CORRECTION OF GMP DEVIATIONS

During an inspection the investigator observes GMP deficiencies have been corrected since the previous EI. These corrections are based on the previous FDA 483.

2.6.4.2.6 - FORMULA/LABEL CORRECTION

Based on a sample analysis, consumer complaint, etc., a product formula or label is corrected.

2.6.4.2.7 - ADDITIONAL PERSONNEL

Employment of personnel for quality improvement or improved quality control.

2.6.4.2.8 - EDUCATIONAL AND/OR TRAINING

Initiation of an educational and/or training program among employees or producers, or other general industry movement to improve conditions.

2.6.4.2.9 - ITEMS NOT REPORTED IN FACTS

Do not report:

1. Recalls, although voluntary, because they are already recorded elsewhere (FACTS).
2. Corrections which are not directly attributable to the efforts of FDA, or states under contract to FDA.
3. Corrections as a result of a seizure, injunction or prosecution.

For products involving the field compliance testing of diagnostic X-Ray equipment, use form FDA 2473a to report these actions, as directed by the Compliance Program. Submit the completed form to your district. Your district will submit a copy to the CDRH, Office of Compliance and maintain a copy for the district files.

SUBCHAPTER 2.7 - DETENTION ACTIVITIES

2.7.1 - OVERVIEW AND AUTHORITY

Detention protects the public by preventing movement in interstate or intrastate commerce of a food, device, or drug that an authorized FDA representative has reason to believe is adulterated or misbranded, while FDA institutes appropriate action. Administrative detention is implemented to gain immediate control over products when there is reason to believe the products are adulterated or misbranded. Such actions are designed for swift and immediate action to ensure that adulterated or misbranded products do not enter commerce or, if they are already in commerce, to stop them from reaching consumers. FDA may initiate seizure against detained foods, devices, and drugs, and/or injunction under sections 304(a) and 302 of the FD&C Act, respectively. In addition, FDA may consider instituting other action against detained foods, such as mandatory recall under section 423 of the FD&C Act, suspension of a food facility's registration under section 415(b) of the FD&C Act, or emergency permit control under section 404 of the FD&C Act

The specific statutory authorities, as well as specific set of guidelines that apply to a food, device, or drug are outlined in this section of the IOM[1]. The detention of a food, device, or drug will depend on the product involved; the situation and evidence observed or collected; and the statutory authority for the detention.

2.7.1.1 – Overview

Detention is an administrative action, as opposed to a civil judicial action, such as seizure or injunction, which is accomplished by a court order (See IOM 2.2.6[2] and 2.2.8[3]).

A food, device, or drug in "domestic import" as well as "import status" could be detained as described in this subchapter provided they meet the criteria listed below. Generally, however, we will use our import detention authority to detain foods, devices, and drugs in import status. Import detention is covered separately in IOM Chapter 6 - Imports.

2.7.1.1.1 - ACCOMPLISHING A DETENTION

Accomplishing a Detention can take one or more paths depending on the product involved and the statute that applies. The applicable statutes and implementing regulations are explained in the "Authorities" section of this subchapter. The FD&C Act provides the authority for administrative detention of foods in section 304(h) and devices and drugs in section 304(g) of the FD&C Act.

Other statutes, such as the Federal Meat Inspection Act[18] (FMIA) (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act[19] (PPIA) (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act[20] (EPIA) (21 U.S.C. 1031 et seq.), provide the authority for detention of foods processed in a facility under dual jurisdiction of FDA and the U.S. Department of Agriculture (USDA).

2.7.1.1.2 - DETENTION OF DEVICES

Detention of devices that an authorized FDA representative has reason to believe are adulterated or misbranded can only be accomplished under one statutory path: FD&C 304(g) of the FD&C Act with implementing regulations set forth in 21 CFR 800.55.

2.7.1.1.3 - DETENTION OF FOODS

Detention of food (human or animal) except for food exclusively regulated by USDA, that FDA has reason to believe is adulterated or misbranded can be accomplished under one statutory path: section 304(h) of the FD&C Act with implementing regulations set forth in 21 CFR part 1, subpart K[17]. FDA's administrative detention authority applies to both foods offered for import and food in domestic commerce. FDA's authority to administratively detain food under section 304(h) is separate and distinct from FDA's authority to refuse admission of imported food under section 801[8](a). Import detention applies to food offered for import into the U.S. which may be subject to refusal of admission.

Detention of foods that USDA regulates (i.e., meat, poultry, or processed egg products) at a dual-jurisdiction facility that meets the jurisdictional requirements of section 304 of the FD&C Act and for which there is reason to believe that such food is adulterated or misbranded can be accomplished under one of the following three statutory paths: sections 402 and 409(b) of the FMIA [21 U.S.C. 672], section 19 of the PPIA [21 U.S.C. 467], or sections 19 and 23(d) of the EPIA[21 U.S.C. 1048], respectively. Alternatively to detaining food that USDA regulates within a dual-jurisdiction facility, detention of foods that USDA regulates (meat, poultry, and processed egg products) CANNOT be accomplished when those products are inside a USDA-inspected facility. FDA does not have authority to administratively detain food that is within the exclusive jurisdiction of the USDA

2.7.1.1.4 - DETENTION OF DRUGS

Detention of drugs that an authorized FDA representative has reason to believe are adulterated or misbranded can only be accomplished under one statutory path: FD&C 304(g) of the FD&C Act with implementing regulations set forth in 21CFR 1.980.

2.7.1.1.5 - DETENTION PROCEDURAL STEPS

The procedures to be followed in both ordering and terminating a detention differ depending on the applicable authority. You must consult with your supervisor before detaining any food from a dual jurisdiction facility under section 304 of the FD&C Act or under the detention authorities in FMIA, PPIA, and EPIA. Furthermore, you must have the approval of the District Director in whose district the article of food is located or an official senior to the District Director prior to detaining any food under section 304(h) of the FD&C Act. You must have the approval of the FDA District Director before detaining any device or drug under section 304(g).

2.7.1.2 - Authorities

This subsection provides information on FDA's detention authorities. Pertinent sections of the FMIA, PPIA, EPIA, and FD&C Act, and FDA regulations pertaining to detention of devices, drugs, and foods, are printed on the reverse of page 1 of Form FDA 2289, Detention Order (IOM Exhibit 2-2[14]).

2.7.1.2.1 - FOOD DRUG AND COSMETIC ACT

Section 304(g) of the FD&C Act provides FDA with authority to detain a device or drug believed to be adulterated or misbranded. You should become familiar with this section and the regulations implementing this authority. See 21 CFR 800.55 and 21 CFR 1.980. At the present time, the device regulations apply only to devices intended for human use. See FD&C Act section 304(g) [21 U.S.C. 334 (g)].

Section 304(h) of the FD&C Act provides FDA with the authority to order the detention of any article of food that is found during an inspection, examination, or investigation under the FD&C Act, if FDA has reason to believe that such article is adulterated or misbranded. You should become familiar with this section of the FD&C Act and the implementing regulations in 21 CFR Part 1, Subpart K.

2.7.1.2.2 - FEDERAL MEAT INSPECTION ACT

Federal Meat Inspection Act (FMIA) - Sections 402 and 409(b) provide the FDA with the authority to detain meat products subject to the FMIA, found outside an USDA inspected plant, if the FDA has reason to believe the products are adulterated or misbranded under the FD&C Act. The detention may not exceed twenty (20) days and the items detained shall not be moved by any person from the place of detention until released by the FDA representative.

2.7.1.2.3 - POULTRY PRODUCTS INSPECTION ACT

Poultry Products Inspection Act (PPIA) -Sections 19 and 24(b) provide the FDA with the authority to detain poultry products subject to the PPIA found outside an USDA inspected plant, if the FDA has reason to believe the products are adulterated or misbranded under the FD&C Act. Detention may not exceed twenty (20) days and the items detained shall not be moved from the place of detention until released by the FDA representative.

2.7.1.2.4 - EGG PRODUCTS INSPECTION ACT

Egg Products Inspection Act (EPIA) - Sections 19 and 23(d) provide the FDA with the authority to detain egg products subject to the EPIA, found outside an USDA inspected plant, if the FDA has reason to believe the products are in violation of the EPIA Act. Detention may not exceed twenty (20) days and the items detained shall not be moved from the place of detention until released by the FDA representative.

2.7.1.3 - Definitions

2.7.1.3.1 - DEVICE

Section 201(h) of the FD&C Act [21 U.S.C. 321 (h)] defines a device as follows: "The term "device" *** means an instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

1. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any primary intended purposes."

2.7.1.3.2 – FOOD

The term food as used in section 304(h) of the FD&C Act, is defined in section 201(f) of the FD&C Act[22], as follows: “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” In addition, a dietary supplement, as defined in section 201(ff) of the FD&C Act, is deemed a food within the meaning of the FD&C Act.

Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients, infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

2.7.1.3.3 - PERISHABLE FOOD

For the purpose of detention of food under section 304(h)(2) of the FD&C Act, the term “perishable food” means food that is not heat-treated; not frozen; and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 calendar days under normal shipping and storage conditions. See 21 CFR 1.377[24].

2.7.1.3.4 - MEAT PRODUCTS AND POULTRY PRODUCTS (DUAL JURISDICTION)

For FDA purposes, meat products and poultry products are defined as the carcasses of cattle, sheep, swine, goats, horses, mules, other equines, or domesticated birds, parts of such carcasses, and products made wholly or in part from such carcasses, except products exempted by U.S.D.A. because they contain a relatively small amount of meat or poultry products (e.g.; meat flavored sauces, pork and beans, etc.). Examine labels for USDA Shield or coding information to help determine if it is a USDA product.

2.7.1.3.5 - EGG AND EGG PRODUCTS (DUAL JURISDICTION)

The term "egg" means the shell egg of the domesticated chicken, turkey, duck, goose, or guinea.

The term "egg product" means any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as he may prescribe to assure the egg ingredients are not adulterated and such products are not represented as egg products. This would be done on a case by case basis by USDA.

2.7.2.3.6 - DRUG

Section 201(g)(1) of the FD&C Act [21 U.S.C. 321(g)(1)] defines a drug as follows: The term “drug” means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the Unites States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such statement.

2.7.2 - INSPECTIONAL PROCEDURE

Direct attention to meat, poultry, or egg products only when found during your regular operations; instructed to do so in a Compliance Program Guidance Manual; following up on complaints; or, on other assignments as directed by your supervisor.

Administrative detention of food under section 304(h) of the FD&C Act should be considered only when FDA has reason to believe that the article of food is adulterated or misbranded. The detention order must be approved by the FDA District Director of the district in which the food is detained or an FDA official senior to such Director (21 CFR 1.391).

In evaluating whether FDA has reason to believe that the article of food is adulterated or misbranded for purposes of detention of food, consider a number of factors, including, but not limited to, the reliability and reasonableness of the evidence or information and the totality of the specific facts and circumstances involved..

2.7.2.1 - Criteria for Detention

The criteria listed below are for your guidance in judging whether or not the product or products should be detained. Detention should be considered when all of the requirements listed for the particular detention authority are met.

2.7.2.1.1 - DEVICES

For detention of devices under section 304(g) of the FD&C Act[25], the primary criteria are:

1. You have reason to believe the device is adulterated or misbranded.
2. There is no reasonable assurance the device will not be used, moved, altered, or tampered with in any manner before the FDA can take appropriate legal action.
3. The device is intended for human use.

2.7.2.1.2 - FOOD

For detention of food under section 304(h) of the FD&C Act, the primary criteria are:

1. The article meets the definition of food in section 201(f) of the FD&C Act.
2. You have reason to believe that the article of food is adulterated or misbranded (if you believe that the food may also present a threat of serious adverse health consequences, immediately advise your supervisor of the situation so that the District can promptly notify CFSAN, CVM, and/or FDA’s Emergency Operations Center, as appropriate, for assessment of hazard(s)).
3. The article of food is not a meat, poultry, or egg product inside a USDA-inspected facility. If the article of food is a meat, poultry, or egg product outside a USDA-inspected facility, consult with your supervisor.

If all of the above conditions are met, contact your supervisor and consider administrative detention.

2.7.2.1.3 - MEAT AND POULTRY PRODUCTS

For detention of food subject to the Federal Meat Inspection Act[28] or the Poultry Products Inspection Act[29] the requirements are:

1. The article meets the jurisdictional requirements of section 304 of the FD&C Act[30] and is in commercial channels.
2. The article is located in a facility that does not have USDA meat or poultry inspection service.
3. The article is intended for human food channels or could be readily diverted into such channels.
4. FDA has reason to believe the article is adulterated or misbranded under the FD&C Act.

NOTE: For any contemplated detentions of meat and poultry based on adulteration under section 402(b) of the FD&C Act[31] [21 U.S.C. 342 (b)], check with your supervisor. These detentions should be cleared with the Center for Food Safety and Applied Nutrition.

2.7.2.1.4 - EGG AND EGG PRODUCTS

For detention of products subject to the Egg Products Inspection Act[32] the requirements are:

1. The article, whether or not in interstate commerce, is located in a facility that does not have USDA Egg Products Inspection Service.
2. The article is intended for human food channels or could be readily diverted into such channels.
3. There is reason to believe the article is in violation of the Egg Products Inspection Act.

2.7.2.1.5 – DRUGS

For detention of drugs under section 304(g) of the FD&C Act, the primary criteria are:

1. The article(s) meets the definition of drug in section 201(g)(1) of the FD&C Act.
2. You have reason to believe the drug(s) are adulterated or misbranded.

2.7.2.2 - Detention Procedure

After assuring that the criteria for detention are met, immediately advise your supervisor of the situation. The information you furnish should consist of that requested in blocks numbered 2, 4, 5, 7, 8, 10, 11, 13, 15, 19, 20, 21, 22, 24 and 26 on the Detention Order, FDA 2289. See IOM 2.7.2.3[33].

For detention of l devices and drugs under section 304(g) the District director in whose District the device or drugs involved are located must approve the detention order in writing. For articles of food under section 304(h) of the FD&C Act, the District Director in whose District the article of food involved is located, or an FDA official senior to such director, must approve the detention order in writing. If prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible.

2.7.2.2.1 - CONSIDERATIONS

If the article of food to be detained is in-transit aboard a conveyance, e.g., railcar, truck, or ship, be aware that that detention of food aboard a conveyance may impact other activities of commerce that are dependent upon the ongoing operation of the conveyance.

FDA may allow the detained food to be removed from the conveyance to a storage facility. However, consult with your supervisor on this matter because the determination of whether the food can be moved from the conveyance to another location should be made based on considerations about the nature of the contaminant, security, preservation of the food, and accessibility to the food during the period of detention.

For all detentions, follow the guidance in IOM section 4.3.4 to determine when FDA may examine a package that is in the possession, control or custody of a common carrier. Guidance on resealing a conveyance is also found in IOM section 4.3.4.3.

If your supervisor instructs you to detain the article, proceed as in IOM 2.7.2.3[34], and 2.7.2.4[35].

2.7.2.2.2 - EXECUTING THE DETENTION

When you have been authorized to place a detention proceed as follows:

1. If the article is a food indicate the conditions that are to be maintained while the article is detained by checking the appropriate method in Block 28 on the Detention Order (Form FDA 2289). After a device, drug, or food is detained, it may not be moved unless specific procedures are followed. Consult your supervisor for guidance.

   a. For detention of food under section 304(h), determine the storage conditions required, e.g., refrigeration, and whether movement to another facility is necessary to either provide the storage conditions required or for security purposes. Consult your supervisor for guidance. Indicate conditions that are to be maintained while the article of food is detained in the “Remarks” section of the detention notice (block #26). If applicable, also indicate that the movement of the food to another facility during detention has been authorized in writing by an authorized FDA representative, pursuant to 21 CFR 1.380 and 1.381.

   b. Maintain surveillance on detained products, including the in-transit products, during their transfer and after the products are placed in storage if possible.

c. Ensure the custodian (i.e., the person in possession of the article when detained) places or maintains the detained product under the proper storage conditions.
d. If neither (a) nor (b) is possible, place product under detention and remove it to a proper storage facility. Notify the custodian of the place of storage (use block 16 on the FDA-2289) and advise your supervisor of the necessity for including this information in the letter to the custodian and/or owner of the article.

2. Personally inform the immediate custodian, at the highest management level, that the article is under FDA detention. If the article is a device, inform the custodian that the record keeping requirements of 21 CFR 800.55(k)[40] are in effect. If the article is a drug, inform the custodian that the record keeping requirements of 21CFR 1.980(k) are in affect..

3. Prepare the Form FDA-2289, as instructed in IOM 2.7.2.3.1, and issue page 1, the original, to the custodian named. If the product is a device, a drug, or an article of food detained under section 304(h) of the FD&C Act, point out the appeal rights of the owner, of the article, which are listed on the back of Page 1 of the FDA-2289, and include the right to appeal with or without requesting an informal hearing.

4. Affix Detention Tags, FDA-2290 to the article in a manner to assure visibility. If necessary, a label other than the Detention Tag may be used to identify an article(s) of food that has been detained, provided the label includes all the information listed on the current FDA-2290.

2.7.2.3 - Detention Order (Form FDA 2289)

The Detention Order,(Form FDA 2289), is a pre-numbered five-part snap-out form, constructed and arranged to serve as the detention order as a report of the action and as a notice to the custodian of an opportunity for an informal hearing.

2.7.2.3.1 - PREPARATION OF DETENTION ORDER NOTICE

Print or type the information in the appropriate blocks of the Form FDA 2289. The first page blocks which must be filled for detentions of foods in accordance with 21 CFR 1.382[41] are those numbered 1, 3, 6, 9, 10, 11, 12, 15, 16, 017, and 18. Indicate the name and title of the person who approved the detention order and the manner in which the approval was obtained in blocks #17 and 18. For devices or drugs, mark #24 and #26 as N/A. For meat, poultry or egg products not being detained under the authority of section 304(h) of the FD&C Act[42], mark #17 and 18 as N/A. Block 2 should also be completed. Once page 1 is completed, signed, and issued to the custodian of the product, it becomes an official document and the detention period begins.

You should immediately complete the additional pages of the Form FDA 2289 (Pages 2 through 5) and submit them to your supervisor, for processing the action. Blocks to be filled in on these pages are items 13, 14 and 19 through 28. These blocks should be completed as appropriate (e.g. if samples were collected) or according to the product being detained (e.g. device, drug, or food) if the pertinent information can be readily determined. See IOM Exhibit 2-2.

2.7.2.3.2 - PREPARATION OF PAGE 1 (FDA 2289)

Preparation of Page 1:

1. DISTRICT ADDRESS, PHONE NUMBER, FAX NUMBER, NAME OF DISTRICT and the DISTRICT DIRECTOR'S E-MAIL ADDRESS – This may be typed in advance. For detention of articles of food, the FDA District Director's email address and fax number must also be included in this block. For detentions under the FMIA, PPIA, and EPIA, this information should also be included.

2. NAME OF CUSTODIAN - Obtain the name of the highest-ranking official of the firm at the place of detention and issue to the official. Page 1 of the Form FDA 2289 is to be issued to the person named in this block.
3. DETENTION ORDER NUMBER - This is normally pre-stamped on each form. In the event that an electronic version of the form is used in the field, the detention number from a pre-printed detention form must be entered and the original pre-printed form bearing that number destroyed. Any correspondence or subsequent actions should reference this number.
4. TITLE OF CUSTODIAN - Insert proper official title such as president, warehouse manager, etc. Do not use courtesy titles.
5. TELEPHONE NO. - Insert the office telephone number, including area code.
6. DATE AND HOUR DETAINED - Insert actual date and time you hand the original to the custodian. The period of detention begins when you issue the original to that person.
7. FIRM NAME - Enter the legal name of the custodial firm.
8. ADDRESS - Use complete street name, city, state and Zip Code of custodial firm.
9. MAXIMUM DETENTION _____ DAYS - Enter "20" for detention of meat, poultry or egg products. Enter either "20" or "30", as instructed by your supervisor, for detention of devices under section 304(g) of the FD&C Act, for the detention of drugs under section 304(g) of

the FD&C Act, or detention of articles of food under section 304(h) of the FD&C Act.

10. NAME OF DETAINED ARTICLE – Provide a complete list of the detained articles. Use the complete name of the product as labeled, e.g., "Beef Pot Pies with mushrooms", not just "Pies"; "Dr. Z's Tongue Depressors", not just "device". If there is insufficient space to list all the detained articles, attach Administrative Detention Continuation Form FDA 2289c to provide a complete list of all detained articles, and indicate in Block 10 that this list is attached. Be sure to record the Administrative Detention Order number from the original FDA 2289 on the FDA 2289c to link the two forms.
11. SIZE OF DETAINED LOT - Indicate number of cases or other type container or article and subordinate containers, e.g., 2000 cases/24/#2 cans, 250 half sides pork carcasses, 500/fore quarters veal, 95 crates/50 lbs. whole fryers, 25/30 lb. cans frozen eggs, etc.
12. DETAINED ARTICLE LABELED - Quote enough labeling so the article can be positively identified. Include product numbers, lot numbers, serial numbers, control codes, grade marks, etc. Follow the instructions in #10 above about using the FDA 2289c if there is insufficient space for a complete list of the labels..

15. REASON FOR DETENTION - Give a brief, general statement of the reasons for detention, i.e., describe the apparent violation and briefly list evidence available to substantiate it. In the case of detention of food under section 304(h) of the FD&C Act, include information supporting the Agency's reason to believe the food is adulterated or, misbranded. If there are multiple reasons for the Agency's belief, list all the reasons and indicate if any reasons apply to a specific article or articles. If needed, use Form 2289c, the Administrative Detention Continuation Form, and note that the reasons are provided in the attached continuation form, and state at the top of the text block on 2289c that "The articles identified below from Box 10 were detained for the following reasons:"

Keep in mind that any classified information supporting the detention of food must be protected from unauthorized disclosure in the interest of national security. Consult with your supervisor for the requirement to protect classified information according to Executive Order 12958. If the product is a device or drug, always state not only the section of the FD&C Act the device or drug is believed to violate, but the particulars of the violation as well. Discuss the reasons for detention with your supervisor when you obtain the permission to detain a device or drug. See page 3 of IOM Exhibit 2-2.

16. DETAINED ARTICLE STORED AT - In most instances this will be the same as the custodial firm indicated in blocks 7 and 8. However, if the product has been moved to another location, enter the name and address of the firm and location where it finally comes to rest and will stay until the detention is terminated. Include any applicable conditions of transportation to the final storage locale. Once the product is detained, it is unlawful to move it without direct authority from FDA, except that devices may be moved and processed under 21 CFR 800.55(h)(2) pursuant to section 304(g)(2)(B) of the FD&C Act [21 U.S.C. 334 (g)(2)(B)] and drugs may be moved and processed under 21CFR1.980(h)(2) pursuant to section 304(g)(2)(B) of the FD&C Act [21 U.S.C. 334 (g)(2)(B)]. Articles of food detained under section 304(h) of the FD&C Act may only be moved if FDA approves a request to modify a detention order under 21 CFR 1.381(c).

17. Name and title of person who approved the detention order.

18. Indicate whether approval of the detention order was written or oral. If oral, you must obtain written confirmation of the approval as soon as possible. For detentions other than detention of food under section 304(h) of the FD&C Act, enter "N/A."

NAME OF FDA EMPLOYEE - Print or type.
SIGNATURE - Sign the form.
TITLE - Enter your title.

28. STORAGE OF DETAINED ARTICLES – Identify the appropriate storage conditions for the detained articles by checking the box marked either N/A, frozen, refrigerated or ambient, and, if conditions other than those which are temperate related are necessary, mark "other" and provide explanation.

2.7.2.3.3 - PREPARATION OF PAGE 2 THROUGH 5 (FDA-2289)

The blocks on pages 2 through 5 are identical and completion of these constitutes your report on the detention, unless directed otherwise by your supervisor.

13. APPROXIMATE VALUE OF LOT - This is the wholesale or invoice value of the merchandise. Estimate if there is no documentary reference you can quote.
14. SAMPLE NUMBER(S) - List numbers of any samples taken in connection with the detention.

19. NAME AND ADDRESS OF THE ARTICLE(S) OWNDER – This will probably be the same as the custodian's. However they may differ in the case of public warehouses or consigned goods. Enter the name and address, including zip code, of the actual owner. In the case of detention of food, if the owner of the article can be readily determined, you must issue a copy of the detention order to the owner as well as the custodian listed in block #2.

20. NAME AND ADDRESS OF INITIAL SHIPPER OR SELLER - Enter name and address of person or firm who first shipped or sold the product.

21. NAME AND ADDRESS OF SUBSEQUENT SHIPPERS OR SELLERS - If products have passed through more than one firm prior to coming to your

attention, list these firms and indicate transit points under their control.
22. NAME OF CARRIERS - List carrier or carriers involved, starting with the one who first picked up the article and indicate transit points under their control.
23. DATE LOT SHIPPED - Use date on a shipping document, not the invoice date.
24. NAME AND ADDRESS OF PACKING PLANT - Enter firm name and address of the plant where products were actually packed, processed, manufactured or assembled. For devices, drugs, or articles of food other than meat, poultry, and egg products, enter "N/A".
25. DATE LOT RECEIVED - Date the article was received by the firm at the location where currently detained.
26. PACKING PLANT USDA NO. - All plants under U.S. Department of Agriculture inspections are numbered. This number is placed on products packed or processed in that particular plant. Enter the complete number. For a device, drug or article of food other than meat, poultry, and egg products, enter "N/A".
27. DESCRIPTION OF SAMPLE - Describe sample(s) collected in connection with the detention operations. This will be the same as on the C/R.

REMARKS -Use FDA Form 2289c to elaborate on items wherever necessary. List any recommendations you made to the custodian for special storage such as refrigerated, frozen, etc.

2.7.2.3.4 - DISTRIBUTION OF FDA-2289

Distribution of FDA-2289 - The five-part snap-out is distributed as follows:

1. Page 1, original - Give to custodian and, if applicable, give a copy of page 1 to the owner of the article. Give the two-sided text page listing statutory references to the owner of the article.
2. Page 2, 3, 4 - Turn in to your district immediately using the fastest means possible.
3. Page 5 - Retain in your possession.

2.7.2.4 - Detention Tag FDA 2290

This tag is a warning and identification device intended to be affixed to the detained products.

2.7.2.4.1 - PREPARATION

As soon as you have issued the Detention Notice, fill out Detention Tags, FDA 2290, following the instructions below. See IOM Exhibit 2-3.

2.7.2.4.2 - FRONT OF TAG

- "DETENTION DATE AND HOUR" - Copy the date and hour of detention from block #6 of the Detention Order (
  FDA Form 2289).
- "DETENTION Order NO. DO" - Copy the exact number from block #3 of the Detention Order.
- "MAXIMUM DETENTION _____ DAYS" - Copy the number of days from block #9 of the Detention Order.
- "NAME FDA EMPLOYEE WHO ISSUED DETENTION Order" - Print or type.
- "SIGNATURE" - Sign.
- "TITLE" - Enter your title.
- "NAME OF THE EMPLOYEE AFIXING TAG (if different from issuing employee)"
- "SIGNATURE OF EMPLOYEE AFIXING TAG (if different from issuing employee)"
- "TITLE OF EMPLOYEE AFIXING TAG (if different from issuing employee)"

2.7.2.4.3 - REVERSE OF TAG (FDA 2290)

- "NAME OF DETAINED ARTICLE" - Enter the name exactly as in Block #10 of Detention Order.
- "DETAINED ARTICLE LABELED" - Copy enough from Block #12 of Detention Order to identify the product.
- "SIZE OF DETAINED LOT" - Copy from Block #11 of Detention Order.

2.7.2.4.4 - USE OF TAG

Complete and affix tags so they are visible on several sides of the lot detained. Use sufficient tags to give adequate warning the lot is under U.S FDA Detention and must not be used, moved, or tampered with, in any manner.

Each tag has a self-locking pin, the point of which should be firmly inserted in an appropriate seam, border, flap, or other area of the container or product, and pulled sharply downward to engage the top curve of the pin. Do not just lay tags on the articles. Secure them to the containers or products. If locking pin cannot be used, tape or tie the tag firmly onto the container or item.

Advise the custodian that Detention Tags have been affixed, and of the reason for the detention. Also advise the custodian that the merchandise may not be moved without written permission of the Agency. In-process devices may be completed without permission. For devices, see 21 CFR 800.55(h)(2)[53] for instructions. For drugs, see 21CFR 1.980(h)(2) for instructions. For detention of foods, see 21 CFR 1.381(c)[54].

2.7.2.5 - Termination of Detention

When final action has been taken on the detention, you will be authorized to terminate the detention. This will occur when one of the following conditions has been met.

1. For articles of food under detention, the article of food has been destroyed under appropriate supervision.
2. For drugs or devices, the product has been brought into compliance or destroyed under appropriate supervision. For meat, poultry, or egg products detained under authority of the FMIA[55], PPIA[56], or EPIA[57]the product has been brought into compliance, denatured or destroyed under appropriate supervision.

3. For meat, poultry, and egg products detained under authority of the FMIA, PPIA, or EPIA, the USDA, state, county, or local authorities have accepted jurisdiction and control of the article.
4. For meat, poultry, and egg products detained under authority of the FMIA, PPIA, or EPIA, it has been determined there is no significant violation of the FD&C Act, or of the EPIA, whichever is applicable, and the USDA has been notified that FDA intends to terminate the detention.
5. Twenty calendar days have expired (or, if an additional ten calendar day detention period has been ordered, thirty calendar days have expired), counting from the day and hour of detention of the product. In this circumstance, no action is necessary on the part of the District.
6. A seizure action under section 304(a) of the FD&C Act has been instituted in court and the goods have been seized by the U.S. Marshals pursuant to a court issued warrant, or injunction action under section 302 of the FD&C Act has been instituted in Court.
7. The district director or the Regional Food and Drug Director order the termination.

2.7.2.5.1 - REMOVAL OF DETENTION TAGS

As soon as you are authorized to terminate the detention, proceed to where the detained material is stored, personally remove and completely destroy all detention tags. Do not merely throw them in the trash.

2.7.2.5.2 - ISSUANCE OF DETENTION TERMINATION NOTICE FDA 2291

Issuance of Detention Termination Notice FDA 2291 - As soon as you have removed all detention tags, tell the custodian the article is no longer under detention. Immediately prepare a Detention Termination Notice by filling out blocks 1 through 12, and the bottom of the form to include name, title, and signature. Give the original (page 1) to the custodian. This terminates the detention.

Complete the "Remarks" section to elaborate on pertinent information such as supervision, reconditioning, destruction accomplished, etc. The Detention Termination Notice, FDA 2291, together with Detention Notice, FDA 2289, will, unless instructed otherwise, constitute the complete report on the detention. See IOM Exhibit 2-4.

2.7.3 - SAMPLING

Official samples of articles involved in this type of operation are collected, prepared, and submitted in the same manner as any other regulatory samples. In the case of food detained under Section 304(h) of the FD&C Act[59], consult with your supervisor to determine whether the suspected contaminant in articles of food that have been detained makes it necessary to follow sampling procedures that may be different from those followed for routine regulatory samples.

2.7.4 - SUPERVISION OF RECONDITIONING, DENATURING, OR DESTRUCTION

Methods and procedures for reconditioning, denaturing, or destruction, will be proposed to the district by the owner of the devices, drugs, or meat, poultry, or egg products. For food detained under Section 304(h) of the FD&C Act[60], destruction will likely be the only option, and it can only be done after FDA approves in writing a request to modify the detention order. For all detentions, do not take any action on reconditioning, denaturing, or destruction unless you are authorized by your supervisor. The district officials will determine the adequacy of the proposed method. If satisfactory, you will be advised of the procedure and authorized to monitor the action.

When the operation is satisfactorily completed, and when authorized, terminate the detention as indicated in IOM 2.7.2.5.2[61].

The results of the reconditioning, denaturing, or destruction may be described in the "Remarks" section on the Detention Termination Notice, FDA 2291, if desired. See IOM Exhibit 2-4[62].

2.7.5 - REPORTING

Except in unusual situations, or unless instructed otherwise by your supervisor, the Detention Order, Form FDA 2289, the Detention Order Termination, Form FDA 2291, and the FACTS Collection Record are designed to provide all information required to report the action from detention to termination.

SUBCHAPTER 2.8 - DENATURING

2.8.1 - OBJECTIVE

The basic purpose of denaturing is to prevent salvage or diversion of violative materials for human consumption.

2.8.2 - DIVERSION TO ANIMAL FEED

The indiscriminate use of contaminated food for livestock may constitute a hazard to such livestock, as well as humans. Due to this concern, all diversion request of this nature should be forwarded to District Compliance for review and consultation with Center for Veterinary Medicine, Division of Compliance to determine if the product may be converted to animal feed.

2.8.2.1 - Rodent or Bird Contaminated Foods

Diversion of rodent or bird contaminated foods for animal feed is authorized only when the contaminated product is treated by heat to destroy Salmonella organisms. In the case of wheat and other grains containing rodent excreta, a suitable heat process may be used or the product is examined bacteriologically and shown not to contain Salmonella.

2.8.2.2 - Moldy Food

If processors insist on salvage of moldy grain or foods for animal feed use, it must be done under proper supervision, and provide for:

1. Treatment by dry heating to destroy viable spoilage microorganisms (generally, this will result in grain having a toasted color and odor), and
2. Evidence it does not contain mycotoxins, and
3. Evidence, by animal feeding studies, the product is safe for animal use.

2.8.2.3 - Pesticide Contamination

Foods contaminated by pesticides residues should not be diverted to animal food use unless a determination is made which assures illegal residues will not result in the food animal or their food products, e.g., meat, milk, eggs.

2.8.3 - DECHARACTERIZATION FOR NON-FOOD OR FEED PURPOSES

The choice of methods, should be made by considering the type of the denaturant, the physical properties of the diverted material, and the ultimate use of the article.

SUBCHAPTER 2.9 - REGULATORY SUBMISSIONS

Subchapter 2.9 provides information on the procedures for obtaining information and filing applications with the agency. These will be covered by Center. The filing and registration requirements are directed by the FD&C Act and its implementing regulations. They are filed, in most cases, by industry (e.g.: drug registration, LACF registration and process filing, ANDA's, etc.).

2.9.1 - CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

The FD&C Act and its regulations require the filing of certain forms by firms which produce human drugs and drug related products. The requirements and procedures for these are described below.

2.9.1.1 - Registration and Listing

Owners or operators of all drug establishments not exempt under Section 510(g) of the FD&C Act21 U.S.C. 360 (g)] or 21 CFR 207.10, that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs, including blood products, and biologicals, are required to register each such establishment and to submit a list of every drug in commercial distribution, whether or not the output of such establishment or any particular drug so listed enters interstate commerce. Changes in the Act, resulting from the FDA Amendments Act of 2007 (PL 110-85) require drug establishment registration and drug listing information be submitted electronically unless a waiver is granted, effective June 1, 2009.

Registration and Listing are required whether or not interstate commerce is involved.

The guidance document on electronic submissions for drug establishments' registration and drug product listing is available at:

http://www.fds.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/guidances/ucm072339.pdf.

General information and questions can be addressed by: Phone: 301-210-2840 or e-mail: eDRLS@fda.hhs.gov. See IOM Exhibit 5-12 for types for drug operations that require registration and listing.

2.9.1.2 - Investigational New Drug Application (IND)

An application which a drug sponsor must submit to FDA before beginning tests of a new drug on humans. The IND contains the plan for the study and is supposed to give a complete picture of the drug, including its structural formula, animal test results, and manufacturing information. Detailed instructions for the submission of INDs can be found in 21 CFR 312.

2.9.1.3 - New Drug Application (NDA)

A New Drug Application is an application requesting FDA approval to market interstate commerce a new drug for human use. The application must contain among other things, data from clinical studies needed for FDA review from specific technical viewpoints, including chemistry, pharmacology, biopharmaceutics, statistics, and anti-infectives, microbiology. Detailed instructions for the submission of NDAs can be found in 21 CFR 314.

2.9.1.4 - Abbreviated New Drug Application (ANDA)

A simplified submission permitted for a duplicate of an already approved drug. ANDAs are for products with the same or very closely related active ingredients, dose form, strength, administration route, use, and labeling as a

product already shown to be safe and effective. An ANDA includes all the information on chemistry and manufacturing controls found in a new drug application (NDA), but does not have to include data from studies in animals and humans. It must, however, contain evidence the duplicate drug is bioequivalent to the previously approved drug. Information concerning the submission of ANDAs can be found in 21 CFR 320.

2.9.2 - CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

The FD&C Act, its amendments, and the regulations promulgated under the Act, require the filing of certain forms and submission of certain data by those involved in the production (and in some cases the use) of medical devices and radiological products. Within the CDRH, the Division of Small Manufacturers, International and Consumer Assistance (HFZ-220) has been charged with responsibility for providing information and assistance to industry in complying with these requirements. The general requirements are discussed below, as are several issues unique to CDRH submissions.

2.9.2.1 - Device Registration and Listing

Section 510 of the FD&C Act [21 U.S.C. 360] and 21 CFR 807 describe the establishment registration, device listing, and premarket notification requirements and specify conditions under which establishments are exempt from these requirements.

Manufacturers of finished devices (including device specification developers, reprocessors of single use devices), repackers and relabelers, foreign exporters and initial importers of medical devices, are required to register their establishments by submitting a form FDA 2891. After initial submission, annual registration is accomplished by use of the Center for Devices and Radiological Health (CDRH) computer generated FDA 2891(a). Component manufacturers are not required to register if the components are sold to registered device establishments for assembly into finished devices. Registration and listing is required, however, if the component is labeled for a health care purpose and sold to medical or clinical users. Optical laboratories, clinical laboratories, dental laboratories, orthotic and prosthetic appliance assemblers, hearing aid dispensers and others who, using previously manufactured devices, perform a service function for physicians, dentists, other licensed practitioners or their patients, are exempt from establishment registration if they are located in the United States. X-ray assemblers are exempt from establishment registration. An exemption from registration does not exempt an establishment from inspection under Section 704 of the FD&C Act [21 U.S.C. 374].

Each establishment, except initial importers of medical devices, required to register must list their devices. Device listing is accomplished using a form FDA-2892; the same form is used to update listing information.

All foreign manufacturers are required to notify FDA of the name, address, telephone and fax numbers, and e-mail address of their United States agent. The United States agent must reside or have a physical place of business in the United States. Post office boxes, answering services and machines are not allowed.

Establishments are required to register and list, even if interstate commerce is not involved. Foreign establishments must register, list and submit a United States agent notification prior to exporting to the United States. See IOM Exhibit 5-13 for types of medical device operations, which require registration and listing.

An establishment must initially register on the form FDA 2891, and list on form FDA 2892 which may be obtained from:

1. FDA Internet site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm .
2. CDRH, Division of Small Manufacturers, International and Consumer Assistance (HFZ-220), 1350 Piccard Drive, Rockville, MD 20850, 800-638-2041. Please note this is an automated publications' request line. Caller must leave name, address, phone number and publications needed.

A sample United States agent notification letter may be obtained from:

1. FDA Internet site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm.
2. CDRH, Division of Small Manufacturers, International and Consumer Assistance (HFZ-220), 1350 Piccard Drive, Rockville, MD 20850, 800-638-2041. Please note this is an automated publications' request line. Caller must leave name, address, phone number and publications needed.

General information and policy questions can be addressed by:

1. Sending an e-mail message to device.reg@fda.hhs.gov.
2. Writing to or calling Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance/Division of Risk Management Operations, Regulatory Policy and Systems Branch, 10903 New Hampshire Ave, Bldg 66, Silver Spring, MD 20993, 301-796-7400.

2.9.2.2 - Investigational Device Exemption (IDE) Regulation

The IDE regulation in 21 CFR 812 contains requirements for sponsors, Institutional Review Boards (IRBs) and Clinical Investigators. Additional requirements are found in 21 CFR 50, Informed Consent, and 21 CFR 56, IRB's. All Sponsors of device clinical investigations must have an approved IDE, unless specifically exempted by the regulation. Sponsors who have an approved IDE are exempt from requirements on labeling, registration and listing, premarket notification, performance standards, premarket approval, GMPs except the design control provisions, banning of devices, restricted devices, and color additives.

Provisions for obtaining an IDE, and the sections of the regulations, with which sponsors, investigators, and IRBs must comply, differ according to the risks posed by the device. Sponsors of nonsignificant risk devices must obtain IRB approval, and are subject to a limited number of provisions; sponsors of significant risk (See 21 CFR 812.3(m)) investigations are subject to the entire regulation.

There are investigations, described in 21 CFR 812.2(c) that are exempt from the IDE regulation. Exempted investigations apply to devices and diagnostics, which meet the criteria in the regulation. These devices are, however, still subject to other regulatory requirements of the Act, such as labeling, premarket approval of Class III devices, and GMPs (as stated in the preamble to the IDE regulation).

A Sponsor who knows a new device is not "substantially equivalent" to a preamendment device, or who is not sure if a device is "substantially equivalent" without conducting a clinical investigation, must obtain an approved IDE to conduct the clinical investigation. After collecting clinical data, a sponsor who desires to market a device must either submit a premarket notification (510k) or premarket approval application to FDA. A premarket notification may be submitted if the sponsor believes the data supports a finding of substantial equivalence.

Certain radiation-emitting electronic devices that are investigational are also subject to radiological health regulations, 21 CFR 1000 through 1050.

Transitional devices must have an approved IDE in order to be investigated.

Sponsors, Monitors, IRBs, Investigators, and Non-Clinical Toxicological Laboratories will be covered under the Bioresearch Monitoring Program. FDA has the authority to inspect and copy records relating to investigations. Records identifying patients by name will be copied only if there is reason to believe adequate informed consent was not obtained, or investigator records are incomplete, false, or misleading.

2.9.2.3 - Premarket Notification - Section 510(k)

The Medical Device Amendments of 1976 require device manufacturers to notify the CDRH at least 90 days before commercially distributing a device. This is known as a "Premarket Notification" or a "510(k)" submission. "Commercial distribution", for practical purposes, means the device is held for sale. These 510(k) requirements do not apply to Class I devices unless the device is intended for a use which is of substantial importance in preventing impairment of human health, or to any Class I device that presents a potential unreasonable risk of illness or injury. See section 510(l) of the FD&C Act [21 U.S.C. 360(l)]

A manufacturer must submit a Premarket Notification to FDA in any of the following situations:

1. Introducing a device into commercial distribution for the first time.
2. Introducing for the first time, a new device or product line which may already be marketed by another firm.
3. Introducing or reintroducing a device with significant changes or modifications affecting the safety or effectiveness of the device. Such changes or modifications could relate to design, material, chemical composition, energy source, manufacturing method, or intended use.

These requirements do not apply to "custom devices." A "custom device" is a device made exclusively for, and to meet the special needs of, an individual physician or health professional, or for use by an individual patient named in the order of a physician or dentist (such as specially designed orthopedic footwear). A "custom device" is not generally available in finished form for purchase; and is not offered through labeling or advertising for commercial distribution.

Refer to IOM Exhibit 5-13 for types of medical devices, which require 510(k) submissions. The investigator should document for CDRH review failures to submit required 510(k)s.

2.9.2.4 - Premarket Approval

Class III devices are required to undergo premarket approval in accordance with the provisions of Section 515 of the FD & C Act [21 U.S.C. 360e]. Premarket approval for a device is initiated with the submission of an application to FDA. Prior to approval of a premarket approval application (PMA), or a supplemental PMA, FDA has the authority to inspect the applicant's facilities and those records pertinent to the PMA.

Compliance Program Guidance Manual 7383.001 contains specific guidance on performing PMA pre-approval and post-approval inspections.

Inspections of manufacturing facilities are usually required prior to approval of a Premarket Approval Application. A full GMP inspection may not be necessary if there has been a recent satisfactory inspection covering a device similar to the PMA device.

Requests for PMA inspections issue from HFZ-306. The assignments will request the firm be inspected for compliance with the GMP regulations, and with their commitments in the PMA.

2.9.2.5 - Classification of Devices

All medical devices subject to the FD&C Act will be classified as either Class I, Class II, or Class III medical devices.

Manufacturers who have questions regarding the classification of a device can write CDRH under Section 513(g) of the FD&C Act [21 U.S.C. 360c (g)] and request an opinion as to the status of the device.

2.9.2.5.1 - CLASS I

Class I - General - Devices for which general controls (i.e., the controls in Section 501, 502, 510, 516, 518, 519 and 520 of the FD&C Act [21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j]) provide reasonable assurance of safety and effectiveness.

2.9.2.5.2 - CLASS II

Class II - Special Controls - Devices for which the general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness of the device, and for which there is sufficient information to promulgate special controls, necessary to provide such assurance.

2.9.2.5.3 - CLASS III

Class III - Premarket Approval - Devices which:

1. Cannot be placed into Class I or II because insufficient information exists to provide assurance of safety and effectiveness, and cannot be placed into Class II because too little data exists to support the promulgation of special controls, and
2. Are purported or represented to be for use in supporting or sustaining human life, or for a use which is of substantial importance in preventing impairment of human health, or
3. Presents a potentially unreasonable risk of illness or injury.

Unless they are determined substantially equivalent to devices distributed prior to the 1976 Medical Device Amendments, devices proposed for marketing after May 28, 1976, fall automatically into Class III. Class III medical devices marketed before May 28, 1976, and the substantially equivalent devices marketed after that date, remain subject to the premarket notification requirements until required to have an approved PMA. Petitioners can request to have such devices reclassified into Class I or II. Transitional devices, those regulated as new drugs before May 28, 1976, are automatically assigned to Class III.

2.9.2.6 - Requests for GMP Exemption and Variances

Section 520f(2)(A) of the FD&C Act [21 U.S.C. 360j (f)(2)(A)] allows manufacturers, trade organizations, or other interested persons to petition for exemption or variance from all or part of the GMP. Filing a petition does not defer compliance with the GMP requirements, and petitions will not be processed while an investigation is ongoing, or while regulatory action is pending.

Some Class I devices have been exempted from the GMP through the classification process. Each classification panel was required to consider the Class I devices reviewed by that panel and recommend if they should be exempt from the GMP. Devices exempted from the GMP by the classification process are published in classification regulations in the Federal Register.

Devices labeled or otherwise represented as sterile are not eligible for exemption from the GMP regulation. A sterile device is subject to all GMP requirements pertinent to sterility and sterilization processes.

No exemptions will be granted from 21 CFR 820.198 - Complaint Files, which requires the device manufacturer to have an adequate system for complaint investigation and follow-up. This Policy extends to 820.180 - General Requirements, which gives authorized FDA employees access to complaint files, device related injury reports, and failure analysis records for review and copying. When FDA has granted a manufacturer an exemption from one or more GMP requirements, the manufacturer still has the responsibility to implement appropriate quality control measures to assure the finished device has the quality it purports to possess, as stated in Section 501(c) of the FD&C Act [21 U.S.C. 351 (c)]. A manufacturer who has been granted a GMP exemption is still subject to inspection under Section 704(a) of the FD&C Act [21 U.S.C. 374 (a)], and may be subject to regulatory action if devices are adulterated or misbranded.

2.9.2.7 - Medical Device Reporting

The Medical Device Reporting (MDR) regulation and the changes mandated by the Safe Medical Devices Act of 1990 (SMDA) is a mandatory information reporting

system. It requires manufacturers, importers, and users of medical devices to report to FDA certain adverse experiences caused or contributed to by their devices. This program is administered by the Center's Office of Surveillance and Biometrics. The regulation requires a report be submitted to FDA whenever a manufacturer or an importer becomes aware of information that its device:

1. May have caused or contributed to a death or serious injury, or
2. Has malfunctioned and, if the malfunction recurs, is likely to cause or contribute to a death or serious injury.

Under the Safe Medical Devices Act of 1990, user facilities must report device-related deaths to FDA and to the manufacturer, if known. User facilities must also report device-related serious illnesses and injuries to the manufacturer, or to FDA if the manufacturer is unknown. In addition, SMDA also requires user facilities to submit to FDA, on an annual basis, a summary of all reports submitted.

The CDRH Division of Small Manufacturers International and Consumer Assistance and the Office of Surveillance and Biometrics should be contacted for further guidance about the MDR regulation. Inspections for compliance with the MDR regulation are conducted following the guidance contained in the Compliance Program 7382.845 - Inspection of Medical Device Manufacturers. When reviewing the manufacturer's complaint files, look for complaints, which are reportable, and have not been reported by the manufacturer.

2.9.2.8 - Radiation Reporting

Prior to introduction of products into commerce, manufacturers of radiation-emitting electronic products must submit radiation safety Product Reports if the product is listed and marked in Table 1 of 21 CFR 1002.1. (Non-medical radiation products have NO registration and listing requirements, but the same type of information is included in these reports.) These are premarket documents but there is no timeframe for review and manufacturers do not have to wait for clearance. However, these documents must be processed by CDRH, Office of Compliance to provide rapid import entry of electronic products. Radiation Product Reports provide technical specifications, how products comply with standards, and radiation testing and quality control programs to support the firm's (self)-certification of compliance of each product.

In addition, manufacturers must file annual reports (if specified in Table 1), defect or noncompliance reports when appropriate (similar to recall notices), and accidental radiation occurrence reports when appropriate (similar to, and sometimes replaced by, Medical Device Reports (MDRs)).

2.9.3 - CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

The requirements for the registration and licensing of biological products fall under both the Public Health Service Act (PHS) and the FD&C Act.

2.9.3.1 - Registration and Listing

See also IOM 5.7.3.

CBER provides industry with registration and listing forms, FDA 2830, Blood Establishment Registration and Product Listing, and FDA 3356, Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). Instructions for completing these documents are on the reverse side of these forms along with establishment and product definitions. Registration forms are available through the district office and through CBER's Office of Communication, Training and Manufactures Assistance, and from the CBER website. Registration and listing is required whether or not interstate commerce is involved. (See IOM 5.7.3)

2.9.3.1.1 - HUMAN BLOOD AND BLOOD PRODUCTS

Human Blood and Blood Products:

1. Who must register - Section 510 of the FD&C Act and 21 CFR 607 delineate the requirements and exemptions relating to the registration of establishments engaged in the collection, manufacturing, preparation, or processing of human blood or blood products. Registration and listing are required whether or not interstate commerce is involved. Fixed blood collection sites that have supplies or equipment requiring quality control or have an expiration date, e.g., copper sulfate, centrifuges, etc., or are used to store donor records, must register. Temporary collection sites, to which all blood collection supplies are brought on the day of collection and are completely removed from the site at the end of the collecting period (except beds, tables, and chairs) and blood mobiles, are not required to register. All Military blood bank establishments are required to register. (MOU with Department of Defense [Federal Cooperative Agreements Manual] Regarding Licensure of Military Blood Banks.) Brokers, who take physical possession of blood products, such as in storage, pooling, labeling, or distribution, are required to register. Blood establishments located outside of the United States that import or offer for import blood products into the U.S. are required to register with FDA. They must also provide the name of the United States agent, the name of each importer, and each person who imports or offers for import these blood products.
2. When to register - Establishments must register within five days after beginning operations and must submit a

list of blood products they distribute commercially. They must register annually thereafter.
3. How to register - Owners or operators of blood establishments register using the Form FDA 2830. Refer to Compliance Policy Guide (CPG) 230.110 for additional information on registration. These persons may complete and submit Form FDA 2830 on the Internet or may submit a paper form.
4. Where to mail completed paper forms - Mail completed legible forms to: Food and Drug Administration, Center for Biologics Evaluation and Research, Division of Blood Applications (HFM-370), 1401 Rockville Pike, 200N, Rockville, MD 20852-1448.
5. General Information and Questions:
   Phone: 301-827-3546
   Email: bloodregis@cber.fda.gov
   Mail: Food and Drug Administration, Center for Biologics Evaluation and Research, Division of Blood Applications, (HFM-370), 1401 Rockville Pike, 200N, Rockville, MD 20852-1448.

2.9.3.1.2 - HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)

Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):
1. Who must register - Establishment that manufacture HCT/Ps that are regulated solely under the authority of section 361 of the Public Health Service Act (42USC264) (the PHS Act) must register and list with CBER whether or not the HCT/P enters into interstate commerce (21 CFR 1271.1). Establishments that manufacture HCT/Ps that are regulated as drugs, devices and/or biological products under section 351 of the PHS Act and/or the Federal Food, Drug and Cosmetic Act, must register and list with CBER following procedures in subpart B, 21 CFR 1271.21 thru 1271.37. Registration and listing are required if the establishment recovers, processes, stores, labels, packages, or distributes any human cell or tissue, or screens or tests the cell or tissue donor. Establishments exempted from registration are listed in 21 CFR 1271.15. Establishments that only have HCT/Ps under premarket review (IND/IDE/BLA/PMA) do not have to register and list until the HCT/P has been licensed, approved or cleared by FDA.
2. When to register - Establishments must register within five days after beginning operations and must submit a list of each HCT/P manufactured.
3. How to register - To register a Form FDA 3356 must be completed.
4. Where to mail completed forms - Mail completed legible forms to: Food and Drug Administration, Center for Biologics Evaluation and Research, (HFM-775), 1401 Rockville Pike, 200N, Rockville, MD 20852-1448, Attention: Tissue Establishment Registration Coordinator. Or it may be submitted by FAX according to form instructions. Alternatively, establishments may now submit the information electronically via the Electronic Human Cell and Tissue Establishment Registration (eHCTERs) page.
5. General Information and Questions:
   Phone: 301-827-6176 (Tissue Establishment Registration Coordinator)
   Email: tissuereg@cber.fda.gov
   Mail: Food and Drug Administration, Center for Biologics Evaluation and Research, HFM-775, 1401 Rockville Pike, 200N, Rockville, MD 20852-1448.

2.9.3.2 - Biologic License

Section 351 of the Public Health Service Act requires individuals or companies who manufacture biological products for introduction into interstate commerce to hold a license for the products. Biologics licenses are issued by CBER and CDER (21 CFR 601.4).

What changes to an approved biologics license application are reportable - Applicants must inform the FDA about each change in the product, production process, quality controls, equipment, facilities, responsible personnel, or labeling established in the approved license application (21 CFR 601.12).

When to Report - Major changes require supplement submission and approval prior to distribution of products made using the change (21 CFR 601.12(b)). Certain changes require supplement submissions at least 30 days prior to distribution of the product made using the change, and other minor changes need only be described in an annual report (21 CFR 601.12(c) and (d)).

Where to send Reports - For licensed biological products regulated by CBER: Document Control Center (HFM-99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, 200N, Rockville, MD 20852-1448. For licensed biological products regulated by CDER: Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs (Specify OND Review Division) 5901-B Ammendale Road, Beltsville, MD 20705-1266. (21 CFR 600.2)

2.9.4 - CENTER FOR VETERINARY MEDICINE (CVM)

Requirements for registration and filing of various applications by firms which manufacture animal drugs, feeds, and other veterinary products are required by the FD&C Act.

2.9.4.1 - Registration and Listing

Owners or operators of all drug establishments, not exempt under section 510(g) of the FD&C Act [21 U.S.C. 360 (g)] or subpart D of 21 CFR 207, who engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs are required to register.

Also, they must submit a list of every drug in commercial distribution, except that listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment, and there exists joint ownership and control among all the establishments.

Who must register - Owners and operators of establishments engaged in manufacture or processing of drug products must register and list their products.

When to register - The owner or operator of an establishment must register within 5 days after beginning of the operation and submit a list of every drug in commercial distribution at that time. Owners or operators of all establishments engaged in drug activities described in 21 CFR 207.3(a)(8) shall register annually.

The Guidance document on electronic submissions for drug establishment registration and drug product listing is available at:
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072339.pdf.

For information on registered animal drug firms - CVM's Registration Monitor is Charise Kasser (HFV-212), 7519 Standish Place, Rockville, MD 20855 240-276-9069. You may make inquiries on registration status of individual firms through Ms. Kasser.

For information on animal drug listing - CVM maintains its own database for animal drug listing. You may make inquiries for information to 240-276-9300.

2.9.4.2 - Medicated Feed Mill License (FML)

Who must register - The manufacture of a Type B or Type C medicated feed containing a Category II drug, from a Type A medicated article, must hold an approved license (FDA 3448). The mill must be registered with the Food and Drug Administration, Information Management Team, HFD-095, to obtain an FDA Registration Number and be operating in compliance with Good Manufacturing Practices as described in 21 CFR 225 by passing an inspection conducted by FDA or a designated party.

How to obtain a license application - Form FDA 3448 is available on the Center for Veterinary Medicine's web page or from the Food and Drug Administration, Center for Veterinary Medicine, Division of Animal Feeds (HFV-220), 7500 Standish Place, Rockville, MD 20855. Where to mail completed forms - Mail completed legible form to the Division of Animal Feeds at the address above. Supplemental applications also go to the above address.

General Information and Questions:
Phone: 240-276-9300.
Mail: Food and Drug Administration, Center for Veterinary Medicine (HFV-220), 7500 Standish Place, Rockville, MD 20855.

2.9.4.3 - Abbreviated New Animal Drug Application (ANADA)

The Generic Animal Drug and Patent Term Restoration Act amended the FD&C Act to provide for the approval of generic copies of previously approved animal drug products. The generic product may be approved by providing evidence it contains the same active ingredients, in the same concentration, as the approved article, and is bioequivalent. The information is submitted to the FDA in the form of an Abbreviated New Animal Drug Application or ANADA.

How to file - An ANADA must be submitted to FDA on the form FDA 356V. The format and content of the application must be in accordance with the policies and procedures established by FDA's Center for Veterinary Medicine. The application must be filled out completely in triplicate and submitted to the address below.

Where to obtain forms - ANADA's also use the form FDA 356 which can be obtained from: Food and Drug Administration, Center for Veterinary Medicine (HFV-12), 7500 Standish Place, Rockville, MD 20855.

Where to mail completed forms - Completed legible applications should be mailed to: Food and Drug Administration, Center for Veterinary Medicine (HFV-199), 7500 Standish Place, Rockville, MD 20855.

General Information and Questions - Assistance and additional information can be obtained by calling 240-276-9300.

2.9.4.4 - New Animal Drug Application (NADA)

A new animal drug is any drug intended for use in animals other than man. Manufacturers of new animal drugs must complete a New Animal Drug Application (NADA), and receive approval prior to distribution.

How to file - Applications must be submitted on a form FDA 356. The applications must be signed by the applicant or by an authorized attorney, agent, or official. The application must be filled out completely, in triplicate, and submitted to the address below.

Where to obtain forms - NADAs use form FDA 356 which can be obtained from: Food and Drug Administration, Center for Veterinary Medicine (HFV-12), 7500 Standish Place, Rockville, MD 20855.

Where to mail completed forms - Completed NADAs should be mailed to: Food and Drug Administration, Center for Veterinary Medicine (HFV-199), 7500 Standish Place, Rockville, MD 20855.

General Information and Questions - General information or questions can be answered by calling 240-276-9300.

2.9.5 - CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

The FDA issued 21 CFR 1, an interim final regulation in FR Vol. 68 No. 197 pgs. 58893-58974 on October 10, 2003 that requires affected domestic and foreign facilities that manufacture/process, pack or hold food for human or animal consumption in the United States to register with the FDA by December 12, 2003. The interim final rule implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). For more information see the FDA/CFSAN website on food firm registration.

The FD&C Act and its regulations require certain firms to register and to file scheduled processes, while other firms are requested to do this voluntarily. CFSAN provides guidance and assistance as described below.

2.9.5.1 - Low Acid Canned Food (LACF) / Acidified Foods (AF) Food Canning Establishment (FCE) Registration

Food Canning Establishments (FCE) (foreign and domestic) engaged in the manufacture of Low Acid Canned Food/Acidified Foods (LACF/AF) offering their products for interstate commerce within the United States are required by 21 CFR Parts 108, 113, and 114 to register their facility with the FDA as indicated below.

Who must register - All commercial processors of LACF and AF products located in the US, and all processors in other countries who export their LACF or AF into the US must register their processing plants with the FDA. Wholesalers, importers, distributors, brokers, shippers, etc. are not required to register and file scheduled process information. However, they must ensure the processing firms they represent comply with all registration and process filing requirements.

When to register - Commercial LACF and AF processors in the US must register with FDA not later than 10 days after first engaging in the manufacture, processing, or packing of AF or LACF. Processors in other countries must register before offering any such products for import into the US.

How to register - Processors must submit Form FDA 2541 for each physical processing plant location electronically or on paper . The form includes information identifying a "facility contact person" (FCP) for each plant being registered. The FCP should be an authorized, responsible official of the commercial processor.

For electronic submissions, the processor will immediately receive the FCE number, however, for paper submissions, a copy of the FCE Registration form will be returned to the firm's preferred mailing address, when applicable, upon FDA assigning the five-digit FCE number to the plant. For domestic plants, whether submitted electronically or on paper, a copy of the FCE Registration Form will be forwarded to the OEI Coordinator email inbox in the FDA District Office in which the plant is located. The OEI Coordinator sends a response notifying the LACF Registration Coordinator of the firm's assigned FEI and the LACF Coordinator will manually add the FEI to the LACF system. For foreign plants, whether submitted electronically or on paper, a copy of the FCE Registration Form will be forwarded to the DIOP FEI Merge Request Inbox. An email response is sent notifying the LACF Registration Coordinator notifying the firm's assigned FEI and the LACF Coordinator will manually add the FEI to the LACF system.

FCE registration information changes - Manufacturers must notify the FDA of any changes to their FCE registration information. These notifications should be made using form FDA 2541 for changes in firm name, ownership, street name and number, or preferred mailing address. It would be marked as a "Change of Registration Information" and the type of change requested. Where to mail completed forms - Mail completed legible forms to: LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740-3835.

General Information and Questions:
E-mail: LACF@fda.hhs.gov

2.9.5.2 - FCE Process Filing of LACF/AF Processors

In addition to processors registering their establishments with the FDA, processors must also submit and file scheduled process information for their LACF/AF products with the FDA. Processors may submit electronically or by paper using one or more of the follow forms depending on the products' processing method: Form FDA 2541d, FDA 2541e, FDA 2541f, or FDA 2541g. FDA encourages processors to submit electronically. Processes must be filed no later than 60 days after registration and prior to packing a new product or, in the case of firms in other countries, before importing their products into the United States.

It is the responsibility of the manufacturer and/or its authorized representative to ensure the design process used is safe from a standpoint of public health significance

and will destroy or inhibit the growth of microorganisms. This is accomplished through the consultation of and recommendations by a process authority. Documentation that scheduled processes are delivered should be maintained through appropriate and accurate record keeping. Forms and documentation must be presented in English.

Process filing information consists of the following:
1. FCE number to the processing plant,
2. Submission Identifier (SID) number to identify a specific form submitted by the manufacturer,
3. Governing regulation (LACF - 21 CFR 108.35/113 or AF - 21 CFR 108.25/114),
4. Food name or description, which includes form or style of the product (whole, sliced, diced, etc.) and packing medium (in water, in brine, in tomato sauce, etc.),
5. Container type,
6. Process Establishment Source, and
7. Container dimensions in inches and/or capacity.
8. Scheduled process, and
9. Other critical factors if applicable

2.9.5.3 - Cosmetics

VOLUNTARY REGISTRATION OF COSMETIC PRODUCT ESTABLISHMENTS (21 CFR 710)

Who should register - The owner or operator of a cosmetic product establishment, which is not exempt under 21 CFR 710.9, and engages in the manufacture or packaging of a cosmetic product, is asked to register each such establishment, whether or not the product enters interstate commerce. This request extends to any foreign cosmetic product establishment whose products are exported for sale in any State as defined in section 201(a)(1) of the FD&C Act [21 U.S.C. 321 (a)(1)]. No registration fee is required.

Time for registration - The owner or operator of an establishment entering into the manufacture or packaging of a cosmetic product should register the establishment within 30 days after the operation begins.

How and where to register - The FDA 2511 - Registration of Cosmetic Product Establishment is available from the FDA, CPK-2, Office of Cosmetics and Colors, Cosmetics Staff (HFS-125), 5100 Paint Branch Parkway, College Park, MD 20740-3835, or at any FDA district office. The completed form should be mailed to HFS-125. The form is also available online at VCRP Online Forms. Establishments can also be registered online at VCRP Online Registrations.

Information requested - The FDA 2511 requests information on the name and address of the cosmetic product establishment, including post office ZIP code; all business trading names used by the establishment; and the type of business (manufacturer and/or packer). The information requested should be given separately for each establishment.

General information and questions - Call 240-402-1345, or e-mail at https://www.accessdata.fda.gov/scripts/ocacapp/client/vcrp/contact/. Instructions are sent with the forms.

VOLUNTARY FILING OF COSMETIC PRODUCT INGREDIENT COMPOSITION STATEMENT (21 CFR 720)

Who should file - Either the manufacturer, packer, or distributor of a cosmetic product is requested to file a FDA-2512 Cosmetic Product Ingredient Statement, whether or not the product enters interstate commerce. The request extends to any foreign manufacturer, packer, or distributor of a cosmetic product exported for sale in any State as defined in section 201(a)(1) of the FD&C Act [21 U.S.C. 321 (a)(1)]. No filing fee is required.

Times for filing - The FDA 2512 should be filed for each cosmetic product being commercially distributed. The FDA-2512 should be filed within 60 days after the beginning of commercial distribution of any product.

How and where to file - The FDA 2512 and FDA 2514 - Discontinuance of Commercial Distribution of Cosmetic Product Formulation are obtainable on request from the FDA, CPK-2, Office of Cosmetics and Colors, Cosmetics Staff (HFS-125), 5100 Paint Branch Parkway, College Park, MD 20740-3835 or at any FDA district office. The forms are also available online at VCRP Online Forms. The completed form should be mailed or delivered according to instructions provided with the form to HFS-125. The FDA-2512 Cosmetic Product Ingredient Statement can also be filed online at VCRP Online Registrations.

General information and questions - Phone: 240-402-1345, or e-mail at https://www.accessdata.fda.gov/scripts/ocacapp/client/vcrp/contact/.

2.9.5.4 - Color Certification Program

Request for Certification - A request for certification of a batch of color additive (straight, repack, lake) should be submitted in duplicate. Formats for these requests are found in 21 CFR 80.21. The fee prescribed in 21 CFR 80.10 should accompany the request, unless the firm has established with the FDA an advanced deposit to be used for prepayment of such fees.

A sample accompanying a request for certification must be submitted under separate cover, and should be addressed to the Food and Drug Administration, Color Certification Branch (HFS-107), 5100 Paint Branch Parkway, College Park, MD 20740-3835.

Where to mail request - Mail or deliver the request to the Food and Drug Administration, Color Certification Branch (HFS-107), 5100 Paint Branch Parkway, College Park, MD 20740-3835.

General information and questions - Phone: 240-402-1136, or e-mail at Naomi.Richfield-Fratz@cfsan.fda.gov.

Contact the Food and Drug Administration, Color Certification Branch (HFS-107), 5100 Paint Branch Parkway, College Park, MD 20740-3835.

Costs - There is a fee for services provided (analytical work) which will vary based on type (straight, repack, lake), weight, number of batches, etc. See 21 CFR 80.10.

2.9.5.5 - Infant Formula

Who should register - There are three types of notifications:

1. First Notification - All manufacturers of infant formula sold in the US, and any manufacturer of a "new infant formula", must register with FDA no less than 90 days before it is introduced into interstate commerce. The first notification must include:
   a. The name and description of the physical form of the infant formula,
   b. The explanation of why the formula is a new infant formula,
   c. The quantitative formulation of the infant formula,
   d. A description of any reformulation of the formula or change in processing of the infant formula, when applicable,
   e. Assurances the infant formula meets the requirements for quality factors and nutrient content requirements,
   f. Assurances the infant formula meets regulations and, as demonstrated by the testing required under regulations, and
   g. Assurances the processing of the infant formula complies with regulations.
2. Second notification - This notification is given to FDA after the first production of an infant formula, and before it is introduced into interstate commerce. The manufacturer must submit a written verification that summarizes test results and records' demonstrating such formula complies with regulations.
3. Third notification - This notification must be sent to FDA if the manufacturer determines a change in the formulation or processing of the formula may adversely affect the article.

Where to mail notifications - Notifications should be sent to: Food and Drug Administration, Office of Nutrition, Labeling and Dietary Supplements, Infant Formula and Medical Foods Staff, HFS-850, 5100 Paint Branch Parkway, College Park, MD 20740-3835.

General information and questions phone: 240-402-2373.

2.9.5.6 - Interstate Certified Shellfish (Fresh and Frozen Oysters, Clams, and Mussels) Shippers

Persons interested in receiving general information about the National Shellfish Sanitation Program - Contact: Food and Drug Administration, Division of Seafood Safety, HFS-325, 5100 Paint Branch Parkway, College Park, MD 20740. Phone: 240-402-2300; FAX: 301-436-2601

Persons interested in technical assistance about the National Shellfish Sanitation Program - Contact: Food and Drug Administration, Retail Food & Cooperative Programs Coordination Staff (HFS-320), 5100 Paint Branch Parkway, College Park, MD 20740. Phone: 240-402-2149; FAX: 301-436-2672

Persons interested in receiving the Interstate Certified Shellfish Shippers List (ICSSL) - Contact: Charlotte V. Epps. Mail: Food and Drug Administration, Retail Food & Cooperative Programs Coordination Staff (HFS-320), 5100 Paint Branch Parkway, College Park, MD 20740. Phone: 240-402-2154; FAX: 301-436-2672

2.9.5.7 - Interstate Milk Shippers (IMS)

Rules for inclusion in the IMS List - All Grade A milk shippers certified by State Milk Sanitation Rating authorities as having attained an acceptable sanitation compliance and enforcement rating are include in the IMS list. These ratings are based on compliance with the requirements of the "USPHS/FDA Grade A Pasteurized Milk Ordinance (PMO) and/or the Grade A Condensed and Dry Milk Products and Condensed and Dry Whey Ordinance (DMO)" and are made in accordance with the procedures set forth in "Methods of Making Sanitation Rating of Milk Shippers" and the "Procedures Governing the Cooperative State-Public Health Service/ Food and Drug Administration Program of the National Conference on Interstate Milk Shippers". The IMS List is published semi-annually and updated monthly on the FDA website.

To obtain a free copy of the IMS List contact:

Food and Drug Administration
Dairy and Egg Branch (HFS-316)
Division of Plant and Diary Food Safety
5100 Paint Branch Parkway
College Park, MD 20740

General Information and Questions.

Contact: Dairy and Egg Branch (HFS-316), Division of Plant and Diary Food Safety, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740. Phone: 240-402-1700

2.9.6 –CENTER FOR TOBACCO PRODUCTS

The FD&C Act and its amendment under the Family Smoking Prevention and Tobacco Control Act require manufacturers or importers to submit certain information to the FDA including: Tobacco Health Document Submission, Establishment Registration and Product Listing, and Listing of Ingredients in Tobacco Products.

General information regarding industry submissions or the process can be found at:
http://www.fda.govlTobaccoProducts/ResourcesforYou/ForManufacturers/default.htm

INTERROGATION: ADVICE OF RIGHTS

YOUR RIGHTS

Place _____
Date _____
Time _____

Before we ask you any questions, you must understand your rights.

You have the right to remain silent.

Anything you say can be used against you in court.

You have the right to talk to a lawyer for advice before we ask you any questions and to have him with you during questioning.

If you cannot afford a lawyer, one will be appointed for you before any questioning if you wish.

If you decide to answer questions now without a lawyer present, you will still have the right to stop answering at any time. You also have the right to stop answering at any time until you talk to a lawyer.

WAIVER OF RIGHTS

I have had read to me this statement of my rights and I understand what my rights are. I am willing to make a statement and answer questions. I do not want a lawyer at this time. I understand and know what I am doing. No promises or threats have been made to me and no pressure or coercion of any kind has been used against me.

Signed _____

Witness: _____

Witness: _____

Time: _____

INTERROGATORIO: NOTIFICACION DE LOS DERECHOS

SUS DERECHOS

Lugar _____
Fecha _____
Hora _____

Antes de hacerle pregunta alguna, Ud. debe entender lo que son sus derechos.

Ud. tiene el derecho de mantener silencio.

Culquier cosa que diga Ud. puede ser usada en su contra en un tribunal.

Ud. tiene el derecho de consultar con un abogado para que éste le aconseje antes de que le hagamos las preguntas y también tiene derecho a la presencia del abogado durante el interragatorio.

Si Ud. no puede pagar los gastos de un abogado, se le asignara uno antes de iniciarse el interragotorio, si así lo desea Ud.

Si Ud. se decide a contestar las preguntas ahora sin la presencia del abogado, Ud. tiene todavía el derecho de negarse a contestar en cualquier momento. Ud. tiene también el derecho de interrumpir las contestaciones en cualquier momento hasta que haya consultado con un abogado.

RENUNCIA A LOS DERECHOS

Me han leído esta declaración de mis derechos y entiendo lo que son. Estoy despuesto a hacer una declaración y a contestar las preguntas. No quiero que esté presente un abogado en este momento. Tengo conciencia de lo que hago. No se me han hecho ni promesas ni amenazas y no se has ejercido presión alguna en mi contra.

Firmado _____

Testigo: _____

Testigo: _____

Hora:_____

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DETENTION ORDER

1a. DISTRICT ADDRESS

1b. PHONE NUMBER

1c. NAME OF DISTRICT DIRECTOR

1d. EMAIL ADDRESS

1e. FAX NUMBER

2. NAME OF CUSTODIAN
TO:

3. DETENTION ORDER NUMBER
DO

4. TITLE OF CUSTODIAN

5. TELEPHONE NUMBER

6. DATE AND HOUR DETAINED
a.m.
p.m.

7. FIRM NAME

8. ADDRESS *(Street, City, State, ZIP Code)*

9. MAXIMUM DETENTION
_____ DAYS

Pursuant to *(Check applicable Section(s))* ☐ Section 304(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act), ☐ Section 304(g) of the FD&C Act, ☐ Sections 402 and 409b of the Federal Meat Inspection Act, ☐ Sections 19 and 24(b) of the Federal Poultry Inspection Act, and/or ☐ Sections 19 and 23(d) of the Federal Egg Products Inspection Act, the article(s) listed in blocks 10 - 12 below on this form must not be used, moved, altered or tampered with in any manner during the detention period without the written permission of an authorized representative of the Secretary of the U.S. Department of Health and Human Services, except that, pursuant to Section 304(g)(2)(B) of the FD&C Act, 1) a device may be moved and processed under 21 CFR 800.55(h)(2), and 2) a drug may be moved and processed under 21 CFR 1.980(h)(2). An article of food detained pursuant to Section 304(h) of the FD&C Act shall not be consumed, moved, altered or tampered with in any manner during the detention period, unless the detention order is first modified under 21 CFR 1.381(c).

10. NAME OF DETAINED ARTICLE(S)

11. SIZE OF DETAINED LOT

12. DETAINED ARTICLE(S) LABELED *(Include Master Carton Label)*

15. REASON FOR DETENTION

16. DETAINED ARTICLE(S) STORED AT *(Name, Address, ZIP Code)*

17. NAME AND TITLE OF PERSON WHO APPROVED THE DETENTION ORDER

18. APPROVAL OF DETENTION ORDER
☐ Written ☐ Verbal

28. STORAGE OF DETAINED ARTICLES *(Select appropriate – Per 21 CFR1.303(b)(7), the detained articles must be stored by only these methods.)*
☐ N/A ☐ Frozen ☐ Other *(For non-temperature related storage conditions; specify)*: _____
☐ Refrigerated at _____ °F ☐ Ambient

NAME OF FDA EMPLOYEE *(Type or print)*

TITLE *(FDA Employee)*

SIGNATURE *(FDA Employee)*

FORM FDA 2289 (9/14) PREVIOUS EDITION IS OBSOLETE DETENTION ORDER 1

See instructions following page 5 in this electronic form version.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DETENTION ORDER

1a. DISTRICT ADDRESS

1b. PHONE NUMBER

1c. NAME OF DISTRICT DIRECTOR

1d. EMAIL ADDRESS

1e. FAX NUMBER

2. NAME OF CUSTODIAN
TO:

3. DETENTION ORDER NUMBER
DO

4. TITLE OF CUSTODIAN

5. TELEPHONE NUMBER

6. DATE AND HOUR DETAINED
a.m.
p.m.

7. FIRM NAME

8. ADDRESS *(Street, City, State, ZIP Code)*

9. MAXIMUM DETENTION
_____ DAYS

Pursuant to *(Check applicable Section(s))* ☐ Section 304(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act), ☐ Section 304(g) of the FD&C Act, ☐ Sections 402 and 409b of the Federal Meat Inspection Act, ☐ Sections 19 and 24(b) of the Federal Poultry Inspection Act, and/or ☐ Sections 19 and 23(d) of the Federal Egg Products Inspection Act, the article(s) listed in blocks 10 - 12 below on this form must not be used, moved, altered or tampered with in any manner during the detention period without the written permission of an authorized representative of the Secretary of the U.S. Department of Health and Human Services, except that, pursuant to Section 304(g)(2)(B) of the FD&C Act, 1) a device may be moved and processed under 21 CFR 800.55(h)(2), and 2) a drug may be moved and processed under 21 CFR 1.980(h)(2). An article of food detained pursuant to Section 304(h) of the FD&C Act shall not be consumed, moved, altered or tampered with in any manner during the detention period, unless the detention order is first modified under 21 CFR 1.381(c).

10. NAME OF DETAINED ARTICLE(S)

11. SIZE OF DETAINED LOT

12. DETAINED ARTICLE(S) LABELED *(Include Master Carton Label)*

13. APPROXIMATE VALUE OF LOT

14. SAMPLE NUMBER

15. REASON FOR DETENTION

16. DETAINED ARTICLE(S) STORED AT *(Name, Address, ZIP Code)*

17. NAME AND TITLE OF PERSON WHO APPROVED THE DETENTION ORDER

18. APPROVAL OF DETENTION ORDER
☐ Written ☐ Verbal

19. NAME AND ADDRESS OF ARTICLE(S) OWNER

20. NAME AND ADDRESS OF INITIAL SHIPPER OR SELLER

21. NAME AND ADDRESS OF SUBSEQUENT SHIPPERS OR SELLERS *(Continue in Remarks, if necessary)*

22. NAME OF CARRIERS

23. DATE LOT SHIPPED

24. NAME AND ADDRESS OF PACKING PLANT

25. DATE LOT RECEIVED

26. PACKING PLANT USDA NUMBER

27. DESCRIPTION OF SAMPLE

28. STORAGE OF DETAINED ARTICLES *(Select appropriate – Per 21 CFR1.393(b)(7), the detained articles must be stored by only these methods.)*
☐ N/A ☐ Frozen ☐ Other *(For non-temperature related storage conditions; specify)*: _____
☐ Refrigerated at _____ ° F ☐ Ambient

NAME OF FDA EMPLOYEE *(Type or print)*

TITLE *(FDA Employee)*

SIGNATURE *(FDA Employee)*

FORM FDA 2289 (9/14) PREVIOUS EDITION IS OBSOLETE DETENTION ORDER 2

Section 304(h) of the Food, Drug and Cosmetic Act is quoted below:

"(h) Administrative Detention of Foods.
(1)Detention Authority.
(A) In general. An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has reason to believe that such article is adulterated or misbranded.

(B) Secretary's approval. An article of food may be ordered detained under subparagraph (A) only if the Secretary or an official designated by the secretary approves the order. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

(2) Period of detention. An article of food may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable the Secretary to institute an action under subsection (a) or section 302. The Secretary shall by regulation provide for procedures for instituting such action on an expedited basis with respect to perishable foods.

(3) Security of detained article. An order under paragraph (1) with respect to an article of food may require that such article be labeled or marked as detained, and shall require that the article be removed to a secure facility, as appropriate. An article subject to such an order shall not be transferred by any person from the place at which the article is ordered detained, or from the place to which the article is so removed, as the case may be, until released by the Secretary or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the article pursuant to the execution of a bond while the article is subject to the order, and section 801(b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is subject to the order.

(4) Appeal of detention order.
(A) In general. With respect to an article of food ordered detained under paragraph (1), any person who would be entitled to be a claimant for such article if the article were seized under subsection (a) may appeal the order to the Secretary. Within five days after such an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Secretary shall be considered a final agency action for purposes of section 702 of title 5, United States Code. If during such five-day period the Secretary fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

(B) Effect of instituting court action. The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Secretary institutes an action under subsection (a) or section 302 regarding the article of food involved."

Please see 21 CFR 1.402 (copied here) for the requirements for submitting an appeal for administrative detention of foods. If you decide to appeal the detention order, you may also request a hearing as part of the appeal by filing a timely notice of intent to request a hearing and then noting your request for a hearing as part of your appeal. Pursuant to 21 CFR 16.26, a request for a hearing may be denied, in whole or in part, if the Presiding Officer determines that no genuine and substantial issue of fact has been raised by the material submitted. A hearing will not be granted on issues of policy or law. If you request a hearing as part of your appeal, you should submit with your appeal and request for a hearing the materials, data, and information that you believe shows there is a genuine and substantial issue of fact regarding the propriety of the detention and any other information you would like the presiding officer to consider when deciding your appeal and request for a hearing. If your appeal is denied, written notice of a determination of summary judgment will be provided, explaining the reasons for denial. If you do not request a hearing as part of your appeal, you should submit with your appeal all of the materials, data and information that you would like the Presiding Office to consider when deciding your appeal.

Section 1.401 and 1.402 of Title 21, Code of federal Regulations, are quoted below as notice of opportunity for appeal and a regulatory hearing for administrative detention of foods:

"Section 1.401 Who is entitled to appeal?
Any person who would be entitled to be a claimant for the article of food, if seized under section 304(a) of the FD&C Act, may appeal a detention order as specified in section 1.402. Procedures for establishing entitlement to be a claimant for purposes of section 304(a) of the FD&C Act are governed by Supplemental Rule C to the "Federal Rules of Civil Procedure."

Sec. 1.402 What are the requirements for submitting an appeal?
"(a) If you want to appeal a detention order, you must submit your appeal in writing to the FDA District Director, in whose district the detained article of food is located, at the mailing address, e-mail address, or fax number identified in the detention order according to the following applicable timeframes:

(1) Perishable food: If the detained article is a perishable food, as defined in section 1.377, you must file an appeal within 2 calendar days of receipt of the detention order.
(2) Nonperishable food: If the detained article is not a perishable food, as defined in section 1.377, you must file a notice of an intent to request a hearing within 4 calendar days of receipt of the detention order. If the notice of intent is not filed within 4 calendar days, you will not be granted a hearing. If you have not filed a timely notice of intent to request a hearing, you may file an appeal without a hearing request. Whether or not it includes a request for hearing, your appeal must be filed within 10 calendar days of receipt of the detention order. (b) Your request for appeal must include a verified statement identifying your ownership or proprietary interest in the detained article of food, in accordance with Supplemental Rule C to the Federal Rules of Civil Procedure.

(c) The process for the appeal of a detention order under this section terminates if FDA institutes either a seizure action under section 304(a) of the FD&C Act or an injunction under section 302 of the FD&C Act (21 U.S.C. 276) regarding the article of food involved in the detention order.

(d) As part of the appeals process, you may request an informal hearing. Your request for a hearing must be in writing and must be included in your request for an appeal specified in paragraph (a) of this section. If you request an informal hearing, and FDA grants your request, the hearing will be held within 2 calendar days after the date the appeal is filed."

Any informal hearing of a detention order for food must be conducted as a regulatory hearing under 21 CFR Part 16 as modified by section 1.403.

For more information, please see 21 CFR Part 1, subpart K and 21 CFR Part 16.

Section 304(g) of the Food, Drug and Cosmetic Act is quoted below:

(g)(1) If during an inspection conducted under section 704 of a facility or a vehicle, a device, drug, or tobacco product which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device, drug, or tobacco product detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under subsection (a) or section 302, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device, drug, or tobacco product may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device, drug, or tobacco product during the period of its

(Continued on the reverse of this page)

detention for the purpose of identifying the device, drug, or tobacco product as detained. Any person who would be entitled to claim a device, drug, or tobacco product if it were seized under subsection (a) may appeal to the Secretary a detention of such device, drug, or tobacco product under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

"(2)(A) Except as authorized by subparagraph (B), a device, drug, or tobacco product subject to a detention order issued under paragraph

(1) shall not be moved by any person from the place at which it is ordered detained until -

"(I) released by the Secretary, or

"(II) the expiration of the detention period applicable to such order, whichever occurs first.

"(B) A device subject to a detention order under paragraph (1) may be moved -

(1) may be moved -

"(I) in accordance with regulations prescribed by the Secretary, and

"(II) if not in final form for shipment, at the discretion of the manufacturer of the device for the purpose of completing the work required to put it in such form."

Section 800.55(g)(1)-(2) of Title 21, Code of Federal Regulations, is quoted below as notice of opportunity for appeal and a regulatory hearing:

"(g) Appeal of a detention order.

(1) A person who would be entitled to claim the devices, if seized, may appeal a detention order. Any appeal shall be submitted in writing to FDA District Director in whose district the devices are located within 5 working days of receipt of a detention order. If the appeal includes a request for an informal hearing, as defined in Section 201(y) of the Act, the appellant shall request either that a hearing be held within 5 working days after the appeal is filed or that the hearing be held at a later date, which shall not be later than 20 calendar days after receipt of the detention order.

(2) The appellant of a detention order shall state the ownership or proprietary interest the appellant has in the detained devices. If the detained devices are located at a place other than an establishment owned or operated by the appellant, the appellant shall include documents showing that the appellant would have legitimate authority to claim the devices if seized."

Any informal hearing on an appeal of a detention order for devices shall be conducted as a regulatory hearing under 21 CFR Part 16, with certain exceptions Described in 21 CFR § 800.55(g)(3).

Sections 402 and 409(b) of the Federal Meat Inspection Act is quoted below:

"Sec. 402. Whenever any carcass, part of a carcass, meat or meat food product of cattle, sheep, swine, goats, horses, mules, or other equines or any product exempted from the definition of a meat food product, or any dead, dying, disabled, or diseased cattle, sheep, swine, goat, or equine is found by any authorized representative of the Secretary upon any premises where it is held for purposes of, or during or after distribution in, commerce or otherwise subject to Title I or II of this Act, and there is reason to believe that any such article is adulterated or misbranded and is capable of use as human food, or that it has not been inspected, in violation of the provisions of Title I of this Act or of any other Federal law or the laws of any State or Territory or the District of Columbia, or that such article or animal has been or is intended to be, distributed in violation of any such provisions, it may be detained by such representative for a period not to exceed twenty days, pending action under Section 403 of this Act or notification of any Federal, State, or other governmental authorities having jurisdiction over such article or animal, and shall not be moved by any person, firm, or corporation from the place at which it is located when so detained, until release by such representative. All official marks may be required by such representative to be removed from such article or animal before it is released unless it appears to the satisfaction of the Secretary that the article or animal is eligible to retain such marks. (21 U.S.C. 672.)

Sec. 409.

(b) The detainer authority conferred by Section 402 of this Act shall apply to any authorized representative of the Secretary of Health and Human Services for purposes of the enforcement of the Federal, Food, Drug, and Cosmetic Act with respect to any carcass, part thereof, meat, or meat food product of cattle, sheep, swine, goats, or equines that is outside any premises at which inspection is being maintained under this Act, and for such purposes the first reference to the Secretary in Section 402 shall be deemed to refer to the Secretary of Health and Human Services. (21 U.S.C. 679)"

Sections 19 and 24(b) of the Poultry Products Inspection Act is quoted below:

"Sec. 19. Whenever any poultry product, or any product exempted from the definition of a poultry product, or any dead, dying, disabled, or diseased poultry is found by an authorized representative of the Secretary upon any premises where it is held for purposes of, or during or after distribution in, commerce or otherwise subject to this Act, and there is reason to believe that any such article is adulterated or misbranded and is capable of use as human food, or that it has not been inspected, in violation of the provisions of this Act or of any other Federal law or the Laws of any State or Territory, or the District of Columbia, or that it has been or is intended to be, distributed in violation of any such provisions, it may be detained by such representative for a period not to exceed twenty days, pending action under Section 20 of this Act or notification of Any Federal, State, or other governmental authorities having jurisdiction over such article or poultry, and shall not be moved by any person, from the place at which it is located when so detained, until released by such representative. All official marks may be required by such representative to be removed from such article or poultry before it is released unless it appears to the satisfaction of the Secretary that the article or poultry is eligible to retain such marks."

Sec. 24.

"(b) The detainer authority conferred by Section 19 of this Act shall apply to any authorized representative of the Secretary of Health and Human Services for purposes of the enforcement of the Federal Food, Drug and Cosmetic Act with respect to any poultry carcass, or part or product thereof, that is outside any official establishment, and for such purposes for first reference to the Secretary in Section 19 shall be deemed to refer to the Secretary of Health and Human Services."

Sections 19 and 23(d) of the Egg Products Inspection Act is quoted below:

"Sec. 19. Whenever any eggs or egg products subject to the Act, are found by any authorized representative of the Secretary upon any premises and there is reason to believe that they are or have been processed, brought, sold, possessed, used, transported, or offered or received for sale or transportation in violation of this Act or that they are in any other way in violation of this Act, or whenever any restricted eggs capable of use as human food are found by such a representative in the possession of any person not authorized to acquire such eggs under the regulations of the Secretary, such articles may be detained by such representative for a reasonable period but not to exceed twenty days, pending action under Section 20 of this Act or notification of any Federal, State, or other governmental authorities having jurisdiction over such articles and shall not be moved by any person from the place at which they are located when so detained until released by such representative. All official marks may be required by such representative to be removed from such articles before they are released unless it appears to the satisfaction of the Secretary that the articles are eligible to retain such marks."

"Sec. 23(d). The detainer authority conferred on representatives of the Secretary of Agriculture by Section 19 of this Act shall apply to any authorized representative of the Secretary of Health and Human Services for the purposes of paragraph (d) of Section 5 of this Act, with respect to any eggs or egg products that are outside any plant processing egg products."

(Continued on next page)

Section 1.980(g)(1)-(2) of Title 21, Code of Federal Regulations, is quoted below as notice of opportunity for appeal and a regulatory hearing for administrative detention of drugs"

"(g) Appeal of a detention order. (1) A person who would be entitled to claim the drugs, if seized, may appeal a detention order. Any appeal must be submitted in writing to the FDA District Director in whose district the drugs are located within 5 working days of receipt of a detention order. If the appeal includes a request for an informal hearing, as defined in section 201(x) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(x)), the appellant must request either that a hearing be held within 5 working days after the appeal is filed or that the hearing be held at a later date, which must not be later than 20 calendar days after receipt of a detention order.

(2) The appellant of a detention order must state the ownership or proprietary interest the appellant has in the detained drugs. If the detained drugs are located at a place other than an establishment owned or operated by the appellant, the appellant must include documents showing that the appellant would have legitimate authority to claim the drugs if seized."

Any informal hearing on an appeal of a detention order for drugs shall be conducted as a regulatory hearing under 21 CFR Part 16, with certain exceptions Described in 21 CFR § 1.980(g)(3)."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

U.S. DETAINED

The Lot of goods to which this tag is affixed is

DETAINED BY THE UNITED STATES GOVERNMENT

In accordance with the provisions of Section 304(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); Section 304(g) of the FD&C Act; Sections 402 and 409(b) of the Federal Meat Inspection Act; Sections 19 and 24(b) of the Poultry Products Inspection Act; or Sections 19 and 23 (d) of the Egg Products Inspection Act, the merchandise listed below is hereby detained for the period indicated. The merchandise must not be used, moved, altered or tampered with in any manner during that period without the written permission of an authorized representative of the Secretary of the U.S. Department of Health and Human Services, except that, pursuant to section 304(g)(2)(B) of the FD&C Act, a device may be moved and processed under 21 CFR 800.55(h)(2) and a drug may be moved and processed under 21 CFR 1.980(h)(2). An article of food detained pursuant to Section 304(h) of the FD&C Act shall not be consumed, moved, altered or tampered with in any manner during the detention period, unless the detention order is first modified under 21 CFR 1.381(c).

WARNING: Removal, alteration or mutilation of this Tag or Violation of any of the above conditions is punishable by fine or imprisonment or both.

SEE REVERSE OF THIS TAG FOR DESCRIPTION OF DETAINED MERCHANDISE

DETENTION DATE &	HOUR	DETENTION NOTICE NO.
	a.m.	**DN**
	p.m.	

MAXIMUM DETENTION _____ DAYS

NAME FDA EMPLOYEE ISSUING DETENTION NOTICE *(Print or type)*

SIGNATURE FDA EMPLOYEE ISSUING DETENTION NOTICE

TITLE FDA EMPLOYEE ISSUING DETENTION NOTICE

NAME FDA EMPLOYEE AFFIXING TAG *(If different from issuing employee)*

SIGNATURE FDA EMPLOYEE AFFIXING TAG

TITLE FDA EMPLOYEE AFFIXING TAG

FORM FDA 2290 (9/14) Prev. Ed. May NOT Be Used
DETENTION TAG

U.S. DETAINED

NAME OF DETAINED ARTICLE

DETAINED ARTICLE LABELED

SIZE OF DETAINED LOT

SEE REVERSE

FORM FDA 2290 (9/14)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DETENTION TERMINATION NOTICE

1a. DISTRICT ADDRESS
850 Third Ave.
Brooklyn, NY 11232

1b. PHONE NUMBER
718-340-7000

1c. NAME OF DISTRICT DIRECTOR
Thomas Gardine

[redacted]

TO:

2. NAME OF CUSTODIAN
Mr. William Jantz

3. DETENTION NOTICE NUMBER
DN 60006

4. TITLE OF CUSTODIAN
Warehouse Manager, Division II

5. DATE AND HOUR DETAINED
12-29-05
10:45 a.m. / p.m

6. FIRM NAME
Amoure Cold Storage Co., Inc.

7. DATE AND HOUR DETNTION TERMINATED
1-6-06
8:35 a.m. / p.m

8. ADDRESS *(Street, City, and State)*
245 Dockage St.
Buffalo, NY

9. ZIP CODE
14206

The merchandise listed below which, pursuant to Sections 402 and 409(b) of the Federal Meat Inspection Act; Sections 19 and 24(b) of the Poultry Products Inspection Act; Sections 19 and 23(d) of the Egg Products Inspection Act; or Section 304(g) of the Federal Food, Drug, and Cosmetic Act, was detained on the above date and bears the above detention number, is hereby released and the detention is terminated.

10. NAME OF DETAINED ARTICLE
Beefy Brand Beef Pot Pie with Mushrooms

11. SIZE OF DETAINED LOT
1600cs/24 – 1 lb. 2 oz tins

12. DETAINED ARTICLE LABELED *(Include Master Carton Label)*
Tins labeled in part with paper labels: “Beefy Brand Pot Pie***ingredients: Selected beef, choice green peas, carrots, selected Idaho potatoes, Mushrooms***Gravy composed of: Water, beef stock, and flour***Net Wt. 1 lb. 2 oz.***Packed by Burly Products Co.***General Offices Kansas City, MO EST 223” Tins in cases labeled in part: “***24/ 1 lb 2 oz tins Beefy Pot Pies***EST 223***”

NAME OF FDA EMPLOYEE *(Type or Print)*	SIGNATURE *(FDA Employee)*	TITLE *(FDA Employee)*
Sylvia A. Rogers	*Sylvia A. Rogers*	Investigator

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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REMARKS
The Culmore County Health department assumed jurisdiction of the product at 8:35 AM on 1-6-06 when it was released from US detention. The entire 1600 case lot was hauled on 1-6-06 by the ACE Trucking Co., 2993 Longway Place, Buffalo, NY, from Amoure Cold Storage Co., Warehouse #3B, 321 Dockage St., Buffalo, NY, to the county landfill at Port Road and Culmore County Road #8 where the lot was dumped, crushed by bulldozers, buried in a ditch, and covered with approximately five feet of earth.
The entire operation was supervised by Culmore County Health Department Inspectors Robert J. Sandi and Henry D. Larky and FDA Investigator Sylvia A. Rogers.
FDA supervision time and expenses:
Inspectional time – 6 hours
Mileage – 22 miles in US Gov't car G11-396

Sylvia A. Rogers
Sylvia A. Rogers
Investigator

NAME OF FDA EMPLOYEE *(Type or Print)*	SIGNATURE *(FDA Employee)*	TITLE *(FDA Employee)*
Sylvia A. Rogers	*Sylvia A. Rogers*	Investigator