CHAPTER 7 - REGULATORY

CONTENTS

SUBCHAPTER 700 - STATUTORY AUTHORITY

701 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.

701.01 - 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.

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)].

Authority to Enter and Inspect - Section 704 of the Food, Drug & Cosmetic 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 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.

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].

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.

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)].

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, 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, 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.

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.

Examinations - 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)].

Electronic Radiation Inspections - 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].

701.02 - Selected Amendments to the FD&C Act

The FDA Modernization Act of 1997 (FDAMA) - A major amendment of the FD&C Act focused on reforming the regulation of food, drugs, medical devices, and cosmetics. A few important provisions of this amendment are to streamline and speed up approval processes, to harmonize regulation of biological and drug products where feasible, to support risk-based regulation of medical devices, and to implement good guidance practices to ensure meaningful public participation in development of agency guidance documents.

Prescription Drug Amendments of 1962 - Amends the FD&C Act to require prescription drug manufacturers to prove to FDA the effectiveness of their products before marketing.

Medical Device Amendments of 1992 - Amends the FD&C Act with respect to Medical Devices.

Nutritional Labeling and Educational Act of 1990 - Amends the FD&C Act to prescribe nutrition labeling for foods.

Prescription Drug Amendments of 1992 - Amends the FD&C Act to coordinate Federal and State regulation of wholesale drug distribution.

Prescription Drug Marketing Act of 1987 - Amends the FD&C Act to ban the re-importation of drugs produced in the United States, to place restrictions on the distribution of drug samples, and to ban certain resale of drugs by hospitals and other health care entities.

Prescription Drug User Fee Act of 1992 - Amends the FD&C Act to authorize human drug application, prescription drug establishment, and prescription drug product fees.

Animal Drug Availability Act (ADAA) of 1996 - Deals with evidence of effectiveness and pre-submission conferences, limitations on residues, import tolerances, feed mill licenses and veterinary feed directives (VFDs).

Animal Medicinal Use Clarification Act (AMDUCA) of 1994 - Allows veterinarians to prescribe extra label uses of certain approved animal drugs and approved human drugs for animal use under certain conditions including existence of a valid veterinary/client/patient relationship (VCPR). The implementing regulations for AMDUCA can be found in 21 CFR Part 530.

Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988 - Addresses submission of abbreviated new animal drug applications (ANADAs) before generic animal drugs can be legally marketed. See IOM 774.03 for additional information.

Safe Medical Device Act of 1990 - Amends and provides additional authority to FDA for regulating devices. The Act provides for such things as: user reporting of deaths and serious injuries; reclassification of certain devices; provisions for mandatory reporting of recalls initiated by manufacturers and additional authority to order the recall of devices; civil penalties; incorporation of the RCHSA into the FD&C Act; and, device design validation requirements. It also contains specific time frames for writing regulations to implement provisions of the Act. The provisions to order the recall of devices, to notify users, to temporarily suspend premarket approval of a device and to impose civil penalties became effective immediately.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) authorized, in part, user fees for device premarket submissions, inspections of device manufacturers by accredited persons, the identification of the manufacturer on the actual device or attachment, electronic registration and device labeling, and premarket and labeling requirements for reprocessed single use devices.

701.03 - Other Acts

See IOM 708 and IOM 311.03 for special authorities involving detentions under the Federal Meat Inspection, Poultry Products Inspection, and Egg Products Inspection, Acts.

Anabolic Steroids Control Act of 1990 - Amends the Controlled Substances Act by adding Anabolic Steroids to Schedule III of section 202(c).

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

Federal Anti-Tampering Act - Prohibits certain tampering with consumer products (18 USC 1365). See IOM 970 for guidance on tampering investigations.

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

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

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.

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.

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.

701.04 - 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.

702 - DEFINITIONS

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

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

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).

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

FDC and INJ Numbers - The number used by the Chief Counsel's office to identify FDA cases.

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

Home District - The district in whose territory the alleged violation of the Act occurs, or in whose territory the firm or individual responsible for the alleged violation is physically located. The original point from which the article was shipped, or offered for shipment, as shown by the interstate records, is usually considered the point where 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".

Nolle Prosequi (Nol-Pros) - The prosecutor or plaintiff in a legal matter will proceed no further in prosecuting the whole suit or specified counts.

Nolo Contendere (Nolo) - A plea by a defendant in a criminal prosecution meaning "I will not contest it".

Seizing District - The district where seizure is actually accomplished. The seizing district is not necessarily the collecting district, as in the case of intransit samples.

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.

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

704 - 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.

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

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 (HFC-200) which then requests the Chief Counsel to initiate seizure action.

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.

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.

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

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.

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.

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

District Follow-up - The district monitors the progress of the seizure and forwards appropriate reports to the headquarters.

For more information on seizure actions consult Chapter 6 of the Regulatory Procedures Manual.

705 - 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.

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 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. requests, with RFDD concurrence, 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.

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

Grand Jury Proceedings - The Justice Department must proceed by indictment in all felony cases. Evidence in possession of the government is presented to the 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 511.09 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 511.04 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 511.04, 511.05, 511.06, 511.07, 511.08 and 511.09.

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.

706 - 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.

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.

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.

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.

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.

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.

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.

707 - 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.

708 - DETENTION POWERS

Sections 402 and 409(b) of the Federal Meat Inspection Act, sections 19 and 24(b) of the Poultry Products Inspection Act, sections 5(d), 19, and 23(d) of the Egg Products Inspection Act, and section 304(g) of the FD&C Act [21 U.S.C. 334 (g)] provides certain detention powers.

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 750 for inspectional procedures, which must be followed, in exercising the detention authority.

709 - 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 705).

709.01 - 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.

709.02 - 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 700-A. 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 710 - RECONDITIONING AND DESTRUCTION

710 - POLICY

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 940 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 judgement 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.

711 - DEFINITIONS

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.

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

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

712 - 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 940.

SUBCHAPTER 720 - CONSENT DECREE

720 - 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 judgement 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.

721 - 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.

722 - 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.

723 - 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.

724 - DESTRUCTION

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

725 - 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.

726 - RELEASE OF GOODS

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

729 - 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 730 - DEFAULT DECREE

730 - 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.

739 - REPORTING

Promptly submit a written report of your observations upon completion of the operation. See IOM 729.

SUBCHAPTER 740 - COMPLIANCE ACHIEVEMENT

740 - 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 Sub Chapter.

The most extensive actions in this area usually occur in disaster situations. Follow instructions in IOM Subchapter 940 - 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 should be collected of violative goods prior to voluntary destruction to support subsequent action against the responsible individuals. Take photographs where applicable. See IOM 591.01 and IOM 749.

741 - 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 749.

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.

741.01 - 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:

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.

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.

Prepare the original only and submit it to your district for transmittal to DEA.

742 - 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 741.

749 - REPORTING

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

749.01 - 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.

749.02 - 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 590-B) per district office SOP's:

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

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.

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

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.

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.

Formula/Label Correction - Based on a sample analysis, consumer complaint, etc., a product formula or label is corrected.

Additional Personnel - Employment of personnel for quality improvement or improved quality control.

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

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 750 - DETENTION ACTIVITIES

750 - OBJECTIVES

The objective of the detention is to protect the consumer by preventing the presence of or to provide for removal from commerce of meat, poultry, egg products, or devices, which are adulterated or misbranded. The various Acts described in this sub section provide certain detention powers for FDA. Pertinent sections of the Meat Inspection Act (MIA), Poultry Products Inspection Act (PPIA), Egg Products Inspection Acts (EPIA), and the Food, Drug, and Cosmetic Act (FD&C Act), and its Regulations pertaining to detentions, are printed on the reverse of page 1 of the FDA 2289, Detention Notice (IOM Exhibit 750-A).

750.01 - Federal Meat Inspection Act

See IOM 311.03 for information.

750.02 - Poultry Products Inspection Act

See IOM 311.03 for information.

750.03 - Egg Products Inspection Act

See IOM 311.03 for information.

750.04 - Food Drug and Cosmetic Act

See FD&C Act section 304(g) [21 U.S.C. 334 (g)].

Section 304(g) of the Federal Food, Drug, and Cosmetic Act provides FDA with authority to detain a device believed to be adulterated or misbranded. You should become familiar with this section and the regulations implementing it. See 21 CFR 800.55. At the present time, these regulations apply only to devices intended for human use.

750.05 - Definitions

Meat Products and Poultry Products - For FDA purposes, Meat Products & 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 & beans, etc.). Examine labels for USDA Shield or coding information to help determine if it is a USDA product.

Egg and Egg Products - The term “egg” means the shell egg of the domesticated chicken, turkey, duck, goose, or guinea.

The term “Egg Products” 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 judgement 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.

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.”

751 - INSPECTIONAL PROCEDURE

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

Placing Detention - Consider detention when so instructed by your supervisor, and only when in your judgement it appears the product will not be held voluntarily and arrangements cannot be made for local, state, or USDA authorities to take control.

751.01 - Criteria for Detention

The criteria listed are for your guidance in judging whether or not the product or products should be detained. Detention may be made when all of the requirements listed for the particular items are met.

For products subject to the Meat Inspection Act or the Poultry Products Inspection Act the requirements are:

1. The article meets the jurisdictional requirements of section 304 of the FD&C Act and is in commercial channels.
2. The article is located in an establishment which 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. The article appears to be adulterated or misbranded under the FD&C Act.

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

For products subject to the Egg Products Inspection Act the requirements are:

1. The article, whether or not in interstate commerce, is located in an establishment which 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.

For Devices the requirements 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.

751.02 - Detention Procedure

Immediate Action - After assuring yourself the criteria for detention are met, immediately advise your supervisor of the situation. The information you must furnish should consist of that requested in blocks numbered 2, 4, 5, 7, 8, 10, 11, 13, 15, 17, 18, 19, 20, 22 and 24 on the Detention Notice, FDA 2289. See IOM 751.03. For devices mark #22 and #24 N/A.

If your supervisor instructs you to detain the article, proceed as in IOM 751.03, and 751.04.

Executing The Detention - When you have been authorized by your supervisor to place a detention proceed as follows:

1. If the product is not currently stored under proper conditions to maintain its integrity, or if devices are stored in such a way as to interfere with the firm's operation, arrange for proper storage as follows:

(a) Maintain surveillance on in-transit products and detain after products are placed in storage if possible.

(b) Arrange for the custodian (dealer) to place the product in proper storage if custodian will agree.

(c) If neither (a) nor (b) is possible, place product under detention and, except for devices, remove it to proper storage facility. Notify the custodian of the place of storage (block 16 on the FDA 2289) and advise your supervisor of the necessity for including this information in the letter to the owner.

After a device is detained, it may not be moved unless specific procedures are followed. Consult your supervisor for guidance.

2. Personally inform the immediate custodian, at the highest management level, that the article is under U.S. detention, and if a device, that record keeping requirements of 21 CFR 800.55(k) are in force.
3. Prepare the "Notice of Detention, FDA-2289", as instructed in IOM 751.03 and issue page 1, the original, to the custodian named. If the product is a device, point out the appeal rights of the owner, which are listed on the back of Page 1 of the FDA-2289.
4. Affix a sufficient number of "Detention Tag, FDA-2290", to the article in a manner to assure visibility.

751.03 - Detention Notice FDA 2289

The Detention Notice, FDA 2289, is a pre-numbered five-part snap-out form, constructed and arranged to serve as a Notice of Detention and as a report of the action.

Preparation of Detention Notice - Print or type the information in the appropriate blocks. The first page blocks to be filled in are those numbered 1 through 12, 15 and 16. Once page 1 is completed, signed and issued to the custodian, it becomes an official document and the detention period begins.

You must immediately complete the additional pages of the Notice of Detention (2 through 5) and submit them to your supervisor, for processing the action. Blocks to be typed on these pages are items 13, 14 and 17 through 26. See IOM Exhibit 750-A.

Preparation of Page 1.

1. DISTRICT ADDRESS, PHONE NUMBER, NAME OF DISTRICT DIRECTOR - This may be typed in advance.
2. NAME OF CUSTODIAN - Obtain the name of the highest-ranking official of the firm at the place of detention, and issue to him. Page 1 of the FDA 2289 is to be issued to the person named in this block.
3. DETENTION NOTICE NUMBER - This is pre-stamped on each form. 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" unless devices are involved. For devices enter either "20" or "30", as instructed by your supervisor.

10. NAME OF DETAINED ARTICLE - Use the actual name of the actual product e.g., "Beef Pot Pies with mushrooms" not just "Pies". "Dr. Z's Tongue Depressors", not just "device".

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.

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.

15. REASON FOR DETENTION - Describe the apparent violation and briefly list evidence available to substantiate it. If the product is a device, always state not only the section of the FD&C Act the device 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. See Page 4 of IOM Exhibit 750-A.

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. 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)].

NAME OF FDA EMPLOYEE - Print or type.

SIGNATURE - Sign the form.

TITLE - Enter your title.

Preparation of Page 2 through 5 - 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.

17. NAME AND ADDRESS OF ARTICLE OWNER - 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.

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

19. 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.

20. NAME OF CARRIERS - List carrier or carriers involved, starting with the one who first picked up the article.

21. DATE LOT SHIPPED - Use date on a shipping document, not the invoice date.

22. 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 enter "N/A".

23. DATE LOT RECEIVED - Self-explanatory.

24. PACKING PLANT U.S.D.A. 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 devices enter "N/A".

25. DESCRIPTION OF SAMPLE - Describe sample collected in connection with the detention operations. This will be the same as on the C/R.

26. REMARKS - Elaborate on items wherever necessary. List any recommendations you made to the custodian for special storage such as refrigerated, frozen, etc.

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

Page 1, original - Give to custodian. Page 2,3,4 - Turn in to your district immediately using the fastest means possible. Page 5 - Retain in your possession.

751.04 - Detention Tag FDA 2290

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

Preparation - As soon as you have issued the Detention Notice, fill out Detention Tags, FDA 2290, following the instructions below. See IOM Exhibit 750-B.

Front of Tag.

"DETENTION DATE AND HOUR" - Copy the date and hour of detention from block #6 of the Detention Notice.

"DETENTION NOTICE NO. DN" - Copy the exact number from block #3 of the Detention Notice.

"MAXIMUM DETENTION _____ DAYS" - Copy the number of days from block #9 of the Detention Notice.

"NAME FDA EMPLOYEE" - Print or type.

"SIGNATURE" - Sign.

"TITLE" - Enter your title.

Reverse of Tag.

"NAME OF DETAINED ARTICLE" - Enter the name exactly as in Block #10 of Detention Notice.

"DETAINED ARTICLE LABELED" - Copy enough from Block #12 of Detention Notice to identify the product.

"SIZE OF DETAINED LOT" - Copy from Block #11 of Detention Notice.

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. 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, the reason for the detention and, in the case of devices, advise the custodian the lot may not be moved without written permission of the Agency. In-process devices may be completed without permission. See 21 CFR 800(h)(2) for instructions.

751.05 - 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. The article has been brought into compliance, denatured or destroyed under appropriate supervision.
2. For USDA products the USDA, state, county, or local authorities have accepted jurisdiction and control of the article.
3. For USDA products, it has been determined there is no significant violation of the FD&C Act, or of the Egg Products Inspection Act, whichever is applicable, and the USDA has been notified that FDA intends to terminate the detention.
4. Twenty consecutive days have expired (or 20 or 30 days, for devices), counting from the day and hour of detention of the product.
5. Seizure or other legal action has been accomplished.
6. The District Director or the Regional Food and Drug Director orders the termination.

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.

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 10, 12, 13,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 remaining blocks on page 2. Use 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 750-C.

752 - SAMPLING

Official samples of articles involved in this type operation are collected, prepared, and submitted, in the same manner as any other regulatory samples.

753 - 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 merchandise. Do not take any action on this 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 751.05.

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 750-C.

759 - REPORTING

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

SUBCHAPTER 760 - DENATURING

760 - OBJECTIVE

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

761 - DIVERSION TO ANIMAL FEED

Carefully consider any situation before agreeing to diversion of contaminated foods to animal feed. The indiscriminate use of contaminated food for livestock may constitute a hazard to such livestock, as well as humans.

When denaturing human foods for animal feed purposes, contact the Center for Veterinary Medicine, Division of Compliance (HFV-236) to determine if the product may be converted safely to animal feed.

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.

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. reatment 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.

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.

762 - 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 770 - REGULATORY SUBMISSIONS

Subchapter 770 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 & process filing, ANDA's, etc.).

771 - 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.

771.01 - 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 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. Briefly, registration is accomplished by submitting an FDA 2656 (Registration of Drug Establishment). The drug listing and subsequent June and December updating shall be on form FDA 2657 (Drug Product Listing). In lieu of an FDA 2657, tapes for computer inputs may be submitted, if equivalent in all elements of information specified on the FDA 2657 after initial FDA review and approval of the formats.

Registration and Listing is required whether or not interstate commerce is involved. Detailed registration instructions appear in 21 CFR 207.

An establishment shall register the first time on the form FDA 2656 - Registration of Drug Establishment. The forms may be obtained from: Food and Drug Administration, Center for Drug Evaluation and Research, Office of Management/Division of Management and Budget, Product Information Management Branch (HFD-058), 5600 Fishers Lane, Rockville, MD 20857.

General information and questions can be addressed by: Phone: (301) 594-1084 or Mail: Food and Drug Administration, Center for Drug Evaluation and Research, Office of Management/Division of Management and Budget, Product Information Management Branch (HFD-058), 5600 Fishers Lane, Rockville, MD 20857. See IOM Exhibit 540 for types for drug operations that require registration and listing.

771.02 - 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 IND's can be found in 21 CFR 312.

771.03 - 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 NDA's can be found in 21 CFR 314.

771.04 - 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 ANDA's can be found in 21 CFR 320.

772 - 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.

772.01 - 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 manufacturers and initial importers of imported 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 & 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 excempt an establishment from inspection under Section 704 of the FD & C Act [21 U.S.C. 374].

Each establishment, except initial distributors of imported 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 manufacturers must register, list and submit a United States agent notification prior to exporting to the United States. See IOM Exhibit 550 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/cdrh/reglistpage.html .
2. CDRH, Division of Small Manufacturers, International and Consumer Assistance (HFZ-220), 1350 Piccard Drive, Rockville, MD 20850, (800) 638-2041 ext. 102 or (301) 443-6597 ext. 102. 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/cdrh/reglistpage.html.
2. CDRH, Division of Small Manufacturers, International and Consumer Assistance (HFZ-220), 1350 Piccard Drive, Rockville, MD 20850, (800) 638-2041 ext. 102 or (301) 443-6597 ext. 102. 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 RLPROGRAM@cdrh.fda.gov.
2. Writing to or calling Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance/Division of Program Operations, Registration and Listing Program (HFZ-308), 9200 Corporate Blvd., Rockville, MD 20850, (301) 827-4555, press 3, then 2.

772.02 - 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.

772.03 - 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 a new device or product line for the first time, 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 550 for types of medical devices, which require 510(k) submissions. The investigator should document for CDRH review failures to submit required 510(k)s.

772.04 - 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. 885]. 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.

772.05 - Classification of Devices

All medical devices subject to the FD&C Act will be classified into one of the following:

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.

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.

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.

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.

772.06 - 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.

772.07 - 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 Assistance, 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 MDR Compliance Programs. When reviewing the manufacturer's complaint files, look for complaints, which are reportable, and have not been reported by the manufacturer.

772.08 - 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)).

773 - 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.

773.01 - Registration and Listing

See also IOM 562.

CBER provides industry with registration and listing forms, FDA 2830, Blood Establishment Registration & Product Listing, and FDA 3356, Establishment Registration & Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), are provided by CBER to industry. Instructions for completing these documents are on the reverse side of these forms along with establishment and product definitions. FDA 2830 forms are available through the district office and from the CBER, Division of Blood Applications (HFM-370) or at the PSC website or CBER's. Form 3356 is also available though CBER and the district office. Updated forms are also available at the CBER Tissue Action Plan website. Registration and listing is required whether or not interstate commerce is involved. (See IOM 562)

Human Blood & 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 - Such 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 establishment 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.

Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):

1. Who must register - Establishment registration requirements and exemptions are covered under 21 CFR 1271. 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 that manufacture HCT/Ps currently regulated under 21 CFR Part 1270 (e.g., bone, skin, corneas, and fascia) must register and list by May 4, 2001. Manufacturers of HCT/Ps not currently regulated under 21 CFR Part 1270 (e.g., reproductive cells and tissue and hematopoietic stem cells) must register when all of 21 CFR Part 1271 is finalized and effective. These manufacturers may voluntarily register before that time, but will not be subject to the regulations inspections until then. Establishments manufacturing HCT/Ps currently regulated as medical devices, drugs or biological drugs registered with FDA using forms FDA 2891 or 2656 respectively will begin to register and list with FDA using Form 3356 when all of 21 CFR Part 1271 is finalized and effective. 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 - Such 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.

773.02 - Biologic License

Licensure is a requirement for manufacturers under section 351 of the Public Health Service Act only if products are shipped interstate. Establishments apply for licensure directly to the CBER. An establishment license may cover multiple sites. For each and every product they ship in interstate commerce, firms must obtain a product license. For example, a firm may have an establishment license with product licenses for Red Blood Cells and cryoprecipitate, and also manufacture additional products not shipped interstate for which they do not obtain a license.

What is Reportable - Significant proposed changes in location, equipment, management and responsible personnel. Alterations in manufacturing methods and labeling of any product, for which a license is in effect, or for which an application for license is pending, must be reported.

When to Report - In the case of an emergency, not less than 30 days in advance of the time such changes are intended to be made (21 CFR 601.12(a).

Where to send Reports - Food and Drug Administration, Center for Biologics Evaluation and Research, Division of Blood Applications, (HFM-375), 1401 Rockville Pike, 200N, Rockville, MD 20852-1448.

774 - 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.

774.01 - 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. Registration of animal drug firms is handled by the Center for Drug Evaluation and Research (CDER). CVM maintains its own animal drug listing database.

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, within 30 days after receiving registration forms from the FDA.

How to register - An establishment registers the first time on the form FDA 2656 - Registration of Drug Establishment. The forms may be obtained from: Food and Drug Administration, Center for Drug Evaluation and Research, Office of Management/Division of Management and Budget, Product Information Management Branch (HFD-058), 5600 Fishers Lane, Rockville, MD 20857.

Where to mail completed forms - The completed FDA-2656 should be mailed to: Food and Drug Administration, Center for Drug Evaluation and Research, Office of Management/Division of Management and Budget, Product Information Management Branch (HFD-058), 5600 Fishers Lane, Rockville, MD 20857.

For information on registered firms - CVM's Registration Monitor is Lowell Fried (HFV-214), 7500 Standish Place, Rockville, MD 20855 (301) 827-0165. You may make inquiries on registration status of individual firms through Mr. Fried.

For information on animal drug listing - CVM maintains its own database for animal drug listing. You may make inquiries for information through Lowell Fried (HFV-214), (301) 827-0165.

774.02 - 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 & Questions -

Phone: (301) 827-0170.

Mail: Food & Drug Administration, Center for Veterinary Medicine (HFV-220), 7500 Standish Place, Rockville, MD 20855.

774.03 - 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 & Questions - Assistance and additional information can be obtained by writing or calling Dr. Lonnie Luther.

Phone: (301) 295-8623.

Mail: Food and Drug Administration, Center for Veterinary Medicine (HFV-102), 7500 Standish Place, Rockville, MD 20855

774.04 - 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 - NADA's 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 NADA's should be mailed to: Food and Drug Administration, Center for Veterinary Medicine (HFV-199), 7500 Standish Place, Rockville, MD 20855.

General Information & Questions - General information or questions can be answered by mail or phone by contacting Dr. Lonnie Luther.

Phone: (301) 295-8623.

Mail: Food and Drug Administration, Center for Veterinary Medicine (HFV-102), 7500 Standish Place, Rockville, MD 20855

775 - 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.

775.01 - 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 using form FDA 2541 and file scheduled process information for their products using forms FDA 2541a, "Food Process Filing for All Methods Except Low-Acid Acid Aseptic Systems".

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 - To register with FDA, processors must complete and submit the FCE Registration Form (FDA 2541) for each processing establishment location.

The pink copy of the FCE Registration form will be returned to the firm or its authorized representative upon assigning of the five-digit FCE number to the plant. For domestic plants, a yellow and blue copy of the FCE Registration Form will be forwarded to the Investigations Branch of the FDA District Office in which the plant is located. The yellow copy is to be used for notifying the LACF Registration Coordinator of the firm's assigned CFN and the blue copy is for the District's Investigations Branch records.

FCE registration information changes - Manufacturers must notify the FDA of any changes to their FCE registration information. These notifications should be for changes in firm name, ownership, street name and number when the plant does not actually change location, preferred mailing address, or authorized representative. This can be accomplished through a letter or submission of a FCE Registration Form listing "Change of Registration Information" and the type of change requested.

Where to mail completed forms - Mail completed legible forms to: LACF Registration Coordinator (HFS-618), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740-3835.

General Information and Questions -

Contacts: Nathaniel L. Murrell and Renee Duckett Green

Phone: 301 436-2411; FAX: (301) 436-2669

e-mail: LACF@cfsan.fda.gov

Mail: Center for Food Safety & Applied Nutrition, (HFS-618), 5100 Paint Branch Parkway

College Park, MD 20740-3835.

Registration changes (street number, authorized representatives, etc.) can also be sent to the above address.

775.02 - 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. That information must be submitted on forms FDA 2541a or FDA 2541c. 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 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 108.35/114),

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.

775.03 - 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, Office of Cosmetics and Colors, Division of Programs and Enforcement Policy (HFS-106), 5100 Paint Branch Parkway, College Park, MD 20740-3835, or at any FDA district office. The completed form should be mailed to the FDA Division of Programs and Enforcement Policy (HFS-106).

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 (202) 418-3414. An instruction is 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-512 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 - Within 180 days after forms are made available to the industry, the FDA 2512 should be filed for each cosmetic product being commercially distributed as of the effective date of this part. The FDA-2512 should be filed within 60 days after the beginning of commercial distribution of any product not covered within the 180-day period.

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, Office of Cosmetics and Colors, Division of Programs and Enforcement Policy (HFS-106), 5100 Paint Branch Parkway, College Park, MD 20740-3835 or at any FDA district office. The completed form should be mailed or delivered according to instructions provided with the form to: Cosmetic Product Statement, Food and Drug Administration, Division of Programs and Enforcement Policy, (HFS-106), 5100 Paint Branch Parkway, College Park, MD 20740-3835.

General information and questions -
Phone: (202) 418-3414.

775.04 - 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, Division of Programs and Enforcement Policy (HFS-106), 5100 Paint Branch Parkway, College Park, MD 20740-3835.

General information and questions -
Phone: (703) 266-4601

Contact the Food and Drug Administration, Division of Programs and Enforcement Policy (HFS-106), 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.

775.05 - 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 shall include:

(a) the quantitative formulation of the infant formula,

(b) a description of any reformulation of the formula or change in processing of the infant formula,

(c) assurances the infant formula meets regulations and, as demonstrated by the testing required under regulations, and

(d) 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 its introduction into interstate commerce. The manu-

facturer shall submit a written verification which summarizes test results and records demonstrating such formula comply 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 Nutritional Products, Labeling and Dietary Supplements, Division of Nutrition Science and Policy, HFS-831, 5100 Paint Branch Parkway, College Park, MD 20740-3835

General information and questions -

Phone: 301-436-1450.

775.06 - 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, Office of Seafood, HFS-400, 5100 Paint Branch Parkway, College Park, MD 20740

Phone: (301) 436-2300; FAX: (301) 436-2599

Persons interested in technical assistance about the National Shellfish Sanitation Program - Contact: Food and Drug Administration, Division of Cooperative Programs (HFS-628), 5100 Paint Branch Parkway, College Park, MD 20740

Phone: (301) 436-2144; FAX: (301) 436-2672

Persons interested in receiving the Interstate Certified Shellfish Shippers List (ICSSL) - Contact: Charlotte V. Epps. Mail: Food and Drug Administration, Division of Cooperative Programs (HFS-625), 5100 Paint Branch Parkway, College Park, MD 20740

Phone: (301) 436-2154; FAX: (301) 436-2672

775.07 - 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
Milk Safety Branch (HFS-626)
Division of Cooperative Programs
5100 Paint Branch Parkway
College Park, MD 20740
General Information and Questions.

Contact: Milk Safety Branch (HFS-626), Division of Cooperative Programs, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740. Phone: (301) 436-2175; FAX: (301) 436-271

General Information and Questions.

Contact: Milk Safety Branch (HFS-626), Division of Cooperative Programs, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740. Phone: (301) 436-2175; FAX: (301) 436-271

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; NOTIFICCACION 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
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DETENTION NOTICE

1. DISTRICT ADDRESS, PHONE NUMBER, NAME OF DISTRICT DIRECTOR
850 Third Ave.
Brooklyn, NY 11232
Thomas Gardine
(718) 340-7000

2. NAME OF CUSTODIAN
TO: Mr. William Jantz

3. DETENTION NOTICE NUMBER
DN 60006

4. TITLE OF CUSTODIAN
Warehouse Manager, Division II

5. TELEPHONE NO.
716- 843-7066

6. DATE AND HOUR DETAINED
1-30-99
10:45 a.m.
p.m.

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

8. ADDRESS *(Street, City, State, ZIP code)*
245 Dockage St.
Buffalo, NY 14206

9. MAXIMUM DETENTION
Twenty (20) DAYS

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, the merchandise listed below is hereby detained for the period indicated and must not be used, moved, altered or tampered with in any manner during that period (except that device may be moved and processed under 21 CFR 800.55(h)(2) pursuant to Section 304(g)(2)(B) of the latter Act) without the written permission of an authorized representative of the Secretary of the U.S. Department of Health and Human Services.

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 lbld in part "Beefy Brand Pot Pie***ingredients: Selected beef, choice green peas, carrots, selected Idaho potatoes, Mushrooms***Gravy***1 lb. 2 oz.***Packed by Burly Products Co.***Kansas City, MO EST 223" Tins in cs lbld similarly.

15. REASON FOR DETENTION
Estimated 10% of tins swelled and/or leaking.

16. DETAINED ARTICLE STORED AT *(Name, Address, ZIP code)*
Amoure Cold Storage Co., Inc.
Warehouse 3B, 321 Dockage St.
Buffalo, NY 14206

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

(Continued on the reverse of this form)

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

FORM FDA 2289 (11/89) PREVIOUS EDITION MAY BE USED **DETENTION NOTICE 1**

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."

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 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 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 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 during the period of its detention for the purpose of identifying the device as detained. Any person who would be entitled to claim a device if it were seized under Subsection (a) may appeal to the Secretary A detention of such device under this paragraph. Within five days of 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 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 -
"(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 shall be conducted as a regulatory hearing under 21 CFR Part 16, with certain exceptions Described in 21 CFR § 800.55(g)(3).

FORM FDA 2289 (11/89) (BACK)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DETENTION NOTICE

1. DISTRICT ADDRESS, PHONE NUMBER, NAME OF DISTRICT DIRECTOR
850 Third Ave.
Brooklyn, NY 11232
Thomas Gardine
(718) 340-7000

2. NAME OF CUSTODIAN
TO: Mr. William Jantz

3. DETENTION NOTICE NUMBER
DN **60006**

4. TITLE OF CUSTODIAN
Warehouse Manager, Division II

5. TELEPHONE NO.
716- 843-7066

6. DATE AND HOUR DETAINED
1-30-99 10:45 a.m. / p.m.

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

8. ADDRESS *(Street, City, State, ZIP code)*
245 Dockage St.
Buffalo, NY 14206

9. MAXIMUM DETENTION
Twenty (20) DAYS

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, the merchandise listed below is hereby detained for the period indicated and must not be used, moved, altered or tampered with in any manner during that period (except that device may be moved and processed under 21 CFR 800.55(h)(2) pursuant to Section 304(g)(2)(B) of the latter Act) without the written permission of an authorized representative of the Secretary of the U.S. Department of Health and Human Services.

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 lbld in part "Beefy Brand Pot Pie***ingredients: Selected beef, choice green peas, carrots, selected Idaho potatoes, Mushrooms***Gravy***1 lb. 2 oz.***Packed by Burly Products Co.***Kansas City, MO EST 223" Tins in cs lbld similarly.

13. APPROXIMATE VALUE OF LOT
$19,000.00

14. SAMPLE NUMBER
55566

15. REASON FOR DETENTION
Estimated 10% of tins swelled and/or leaking.

16. DETAINED ARTICLE STORED AT *(Name, Address, ZIP code)*
Amoure Cold Storage Co., Inc.
Warehouse 3B, 321 Dockage St.
Buffalo, NY 14206

17. NAME AND ADDRESS OF ARTICLE OWNER
Big Midget Food Chains
General Offices – Chicago, Illinois
Local Agent – Big Midget, Division 132
2234 Lake drive, Buffalo, NY 14238

18.NAME AND ADDRESS OF INITIAL SHIPPER OR SELLER
Burly Products Co.
1921 Packer Avenue
Kansas City, MO 64309

19. NAME AND ADDRESS OF SUBSEQUENT SHIPPERS OR SELLERS *(Continue in Remarks, if necessary)*
Big Midget Food Chains, Chicago, IL, lot shipped by Burly from KC to Chicago to Big Midget Warehouse 1st & 2nd Ave. Then shipped by Big Midget to Amoure, Buffalo.

20. NAME OF CARRIERS
KC to Chicago via Overland Transport, KC, MO
Chicago to Buffalo via IS Cartage, Chicago

21. DATE LOT SHIPPED
1-13-99 to Chicago; 1-20-99 to Buffalo

22. NAME AND ADDRESS OF PACKING PLANT
Burly Products Co., Inc.
1921 Packer Avenue
Kansas City, MO 64309

23. DATE LOT RECEIVED
1-23-99 in Buffalo

24. PACKING PLANT USDA NO.
EST 223

25. DESCRIPTION OF SAMPLE
Sample consists of 2 cs/24/1 lb. 2 oz. tins taken at rate of 2 tins from each of 24 previously unopened cases selected at random from the lot. Of the 48 tins taken, 24 were swollen to some degree and 12 of these were leaking. The other 24 were normal.

24. REMARKS *(List any recommendations made to custodian for special storage requirements, i.e., refrigeration, frozen, etc.)*
Entire lot was removed from initial location at Amoure Cold Storage Warehouse #2A, 245 Dockage St. to same firm's warehouse #3B at 321 Dockage St., Buffalo, NY, where detention was placed in effect.

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

FORM FDA 2289 (11/89) PREVIOUS EDITION MAY BE USED **DETENTION NOTICE 3**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
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 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, must not be used, moved, altered Or tampered with in any manner for the period indicated (except that devices may be moved and processed under 21 CFR 800.55(h)(2) pursuant to section 304(g)(2)(B) of the latter act) without the written permission of an authorized representative of the Secretary of the U.S. Department of Health and Human Services.

WARNING: Removal, alteration or mutilation of this Tag or Violattion 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.
1-30-2000	10:45a.m. / p.m.	**DN** 70007

MAXIMUM DETENTION
_____31____DAYS

NAME FDA EMPLOYEE *(Print or type)*
Sidney H. Rogers

SIGNATURE *(FDA Employee)*
Sidney H. Rogers

TITLE *(FDA Employee)*
Investigator

FORM FDA 2290 (4/86) Prev. Ed. May Be Used
DETENTION TAG

U.S. DETAINED.

NAME OF DETAINED ARTICLE.
Beefy brand pot pie with mushrooms

DETAINED ARTICLE LABELED

"Beefy Brand Pot Pie net wt. 1 lb. 2 oz. packed by Burly Products Co. Inc.***Kansas City, MO. EST 223"

SIZE OF DETAINED LOT

1600 cs/28/1 lb. 2oz. tins

SEE REVERSE

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	1. DISTRICT ADDRESS, PHONE NUMBER, NAME OF DISTRICT DIRECTOR 850 Third Ave. Brooklyn, NY 11232 Thomas Gardine (718) 340-7000

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 1-30-99	10:45 a.m. p.m.
6. FIRM NAME Amoure Cold Storage Co., Inc.	7. DATE AND HOUR DETENTION TERMINATED 2-6-99	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 FDA EMPLOYEE *(Print or type)*	SIGNATURE	TITLE *(FDA Employee)*
Sylvia A. Rogers	Investigator	*Sylvia A. Rogers*

FORM FDA 2291 (6/82) PREVIOUS EDITION IS OBSOLETE **DETENTION TERMINATION NOTICE 1**

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	1. DISTRICT ADDRESS, PHONE NUMBER, NAME OF DISTRICT DIRECTOR 850 Third Ave. Brooklyn, NY 11232 Thomas Gardine (718) 340-7000

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 1-30-99	10:45 a.m. p.m.
6. FIRM NAME Amoure Cold Storage Co., Inc.	7. DATE AND HOUR DETENTION TERMINATED 2-6-99	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***"

REMARKS

The Culmore County Health department assumed jurisdiction of the product at 8:35 AM on 2-6-99 when it was released form US detention. The entire 1600 case lot was hauled on 2-6-99 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 FDA EMPLOYEE *(Print or type)*	SIGNATURE	TITLE *(FDA Employee)*
Sylvia A. Rogers	Investigator	*Sylvia A. Rogers*

FORM FDA 2291 (6/82) PREVIOUS EDITION IS OBSOLETE **DETENTION TERMINATION NOTICE 2**