

INDEX

301(K) Sample	4.4.10.1.1
301(K) Samples	4.1.4.4
702(b) Portion Collected	4.4.10.3.63
702(b) Requirement	4.3.3.2
703 Record Requests	4.4.7.2.2
	5.1.1.7.2
704(d) Sample	4.4.10.3.64

-A-

Abandonment.....	2.2.6.6
Abbreviated New Animal Drug Application (ANADA)	2.9.4.3
Abbreviated New Drug Application (ANDA)	2.9.1.4
Abnormal Containers	4.3.7.5
Access	5.2.9.2.1
Accident Insurance	1.2.1.2
Accidents	1.2.2.2
Federal Driver's Act	1.2.3.1
Federal Employee's Compensation Act	1.2.3.1
GFV	1.2.3.1
Liability.....	1.2.3.1
POV	1.2.3.1
Reports	1.5.7
Accomplishment Hours	4.4.10.3.1
Acronyms	1.10.2.8
Addendum to EIR	5.10.6
Additional (Add)	4.4.10.2.1
Additional Case History Interviews.....	8.3.4.3
Additional Information	5.10.4.3.16
Additional Personnel	2.6.4.2.7
Additional Sample	4.1.4.10
Address, Change of	3.2.15.1
Address Information Request Letter	Exhibit 3-3
Address Labels	4.5.5.8.5
Administration for Children.....	3.2.4.2
Administrative Data.....	5.10.4.3.3
Adulteration.....	4.4.6.2.2
	4.3.7

Advance of Funds

ATM.....	1.2.6
Authorization.....	1.2.6

Adverse Event Reporting/Risk Evaluation and Mitigation Strategies (REMS)

Complaints.....	8.2
FACTS Questionnaire.....	Exhibit 8-1

Advice or Rights.....	Exhibit 2-1
-----------------------	-------------

Affidavit

Import Investigation	Exhibit 6-5
In-Transit Sampling.....	4.4.7.5
	4.4.8
[FDA1664b].....	Exhibit 4-3

Informant	4.4.8.3
Dealer [FDA 1664]	4.4.8.4
	Exhibit 4-12

FDA 463a	4.4.8.5
	Exhibit 4-7
	Exhibit 4-10
	Exhibit 4-11
	Exhibit 4-13
	Exhibit 6-5

Jobber [FDA 1664a].....	4.4.8.6
	Exhibit 4-14

Parcel Post	Exhibit 4-9
Warehouse [FDA 1664]	4.4.8.4
	Exhibit 4-12

Aflatoxin Sample Schedule	Smpl Schdl 6
---------------------------------	--------------

After the Detention	2.7.2.2.2
After the fact travel order	1.2
Agency for Toxic Substances and Disease Registry	3.2.12
Agreements	3.1.2.1
Agricultural Marketing Service	3.2.1.5
Air Travel	1.2.1.1
Alcohol and Tobacco Tax & Trade Bureau (TTB)	3.2.8.1
Allergen Samples Schedule	Smpl Schdl 13
American Goods Returned.....	6.7.1
Ammonia Leaks.....	8.5.7.5
Anabolic Steroids Control Act of 1990	2.2.3.1
Analytical Assignment	4.4.10.3.2
Analyzing Data/Hypothesis Formulation.....	8.3.5
Animal Feed	6.4.7.3
Feed Sampling Chart	Smpl Schdl 11
Medicated Feed Sampling Chart.....	Smpl Schdl 12
Animal Grooming Aids.....	5.9.7
	6.4.7.4
Animal Origin Products.....	1.5.5.1
Animal Plant Health Inspection Service	3.2.1.6
Annotation of the FDA 483	5.2.3.4
Anonymity.....	5.2.9.1.3
Antibiotic.....	5.2.3.2
Anti-tampering Act.....	Exhibit 8-14
Application.....	4.5.4.2
Application for Authorization to Relabel or Perform Other Acts.....	6.2.7.3
	Exhibit 6-2
Approved Drugs	5.5.5.5
Aseptic Sample	4.3.6
Asphyxiation Hazards.....	1.5.3.4
Assistance	8.3.4.2
Assignments (Interdistrict)	1.7
Issuance Authority.....	1.7.1
Procedures.....	1.7.2
Assignments & Reporting.....	1.7.3
Creating in FACTS	Exhibit 5-9
NSD and Assignments	4.4.10.4.1
Assistance	8.3.4.2
Associate Commissioner for Regulatory Affairs	1.9.1
Association of Official Analytical Chemists (AOAC)	3.5.1
ATSDR	3.2.12
Attachments	5.10.4.3.20
Attack Rate Table	8.3.5.4
Attempted Bribery	1.6.5.2
Attire	1.6.5.1.3
Attitude	1.6.5.1.2
Audit Check Reporting	7.3.2.5
Audit/Certification	4.4.10.2.2
Audit/Certification Sample	4.1.6.1
Authority	6.1.1
Authority	4.1.1
Authority	4.4.1
Authority & Responsibility	8.8.3
Authority for Examinations and Investigations	5.1.1.12
Authority to Enter and Inspect	5.1.1
Authority to Enter and Inspect	2.2.1.1
Authority to Implement Section 702(E)(5) of FD&C Act	5.1.1.13
Auto Rental.....	1.2.1.2
Auto Safety	1.5.2

-B-

Bacteriological Problems	1.5.5.3
Banned Devices	5.6.8

Basic Premises	5.2.1.1.1
Bill of Lading	4.4.7.2.3
Biological Product	5.7.1
Biological Products	
Licensed	8.4.8.2.5
Unlicensed	8.4.8.2.6
Biologic License	2.9.3.2
Biological Samples	8.4.7.2
Biologics	6.4.7.5
Biologics	5.7
Biologics Injury/Adverse Reaction Reports	8.4.8.2.7
Biologics Injury, Reaction or Fatality	8.4.4
Biologics Inspection	5.7.2
Approach	5.7.2.5
Authority	5.7.2.1
Blood and Source Plasma Inspections	5.7.2.1.1
Brokers	5.7.6
Core Team	5.7.2
Donor Confidentiality	5.7.2.2
Guidelines	5.7.2.6
Human Tissue Inspections	5.7.2.1.2
Inspectional Objectives	5.7.2.3
Licensing	5.7.3
Listing	5.7.3
Preparation	5.7.2.4
Recommendations	5.7.2.6
Registration	5.7.3
Regulations	5.7.2.6
Responsible Person	5.7.4
Team Biologics	5.7.2
Technical Assistance	5.7.2.7
Testing Laboratories	5.7.5
Bio-research Monitoring - CBER	5.7.2.8
Bio-research Monitoring - CFSAN	5.4.1.3
Bio-research Monitoring - CVM	5.9.7
Bio-research Monitoring - CDER	5.5.1.3
Bio-research Monitoring - CDRH	5.6.1.4
Biosecurity Procedure	
Animal Grower	5.2.10
Animal Husbandry	5.2.10
Animal Producer	5.2.10
Inspection Procedure	5.2.10.2
Pre-inspection Activities	5.2.10.1
Preparation	5.2.10.1
Special Situation	5.2.10.3
Bio-terrorism	8.5.6
Bioterrorism Act	5.4.1.5
Import Requirements under the BT Act	5.1.1.14.1
Records Access	5.4.1.3
Bird Contamination	4.3.7.4.4
Collecting Exhibits and/or Subsamples	4.3.7.4.4.2
Examination/Documentation of Contamination	4.3.7.4.4.1
Summary of Sample for Evidence	4.3.7.4.4.3
Blackberry	1.5.6
Blood and Blood Products Inspection	5.7.2.1.1
Blood Values	Appendix C
Body of Report	5.4.10.2.2
Bond Action	
Application for Relief	6.2.7.11
Conditional Release	6.2.7.11
Notice of Refusal	6.2.7.11
Bonded Warehouse	6.7.2
Borrowed Samples	4.5.2.2
Brand Name	4.4.10.3.3
Break Bulk Cargo	6.7.3
Bribery	1.6.5.2
Broken Official Seals and "Temporary Seals"	4.5.4.5
Brokers	5.7.6
BSE Activities	5.9.4
Bulk Shipments	4.4.9.2
Business Cards	1.6.4
Business Premises	5.1.1.8
-C-	
Calendar (Perpetual Julian)	Appendix B
Candling	5.1.5.1
Canned & Acidified Food Sample Chart	Smpl Schdl 2
Canned Fruit Sample Chart	Smpl Schdl 7
Capital Improvements	2.6.4.2.4
Car rental	1.2.1.2
Carbadox Sample	1.5.3.7
Care & Custody of U.S. Vehicles	1.2.2.5
Carrier In-Transit Sampling	4.2.4.3
Carrier Name	4.4.10.3.4
Carriers/In-Transit Lots	4.2.5.1
Carrier's Receipt for Sample FDA 472	Exhibit 4-4
Cash Payment	1.2.1
4.2.8.3.2
Causes	8.4.5.2.1
Cautions	4.3.6.1.2
CBER Bio Research Monitoring	5.7.2.8
CDER Bio Research Monitoring	5.5.1.3
5.5.6
CDRH Bio Research Monitoring	5.6.1.4
Center for Biologics Evaluation and Research	4.5.5.3.5
2.9.3
Cell Phone	1.5.6
Center for Devices and Radiological Health (CDRH)	4.5.5.3.6
2.9.2
Center for Drug Evaluation & Research (CDER)	2.9.1
Division of Pharmaceutical Analysis (DPA)	4.5.5.3.4
Center for Food Safety & Applied Nutrition (CFSAN)	4.5.5.3.3
2.9.5
Center for Tobacco Products	4.5.5.3.8
5.8
Center for Veterinary Medicine	4.5.5.3.7
2.9.4
Centers for Disease Control & Prevention (CDC)	3.2.4.3
Certification	1.10.2.1
Certified and First Class Mail	4.5.5.9
CFSAN Bio Research Monitoring	5.4.1.6
Change of Address Information	3.2.15.1
Change of Official Station	1.2.5
Charges for Supervision FDA 790	6.2.7.9
Exhibit 6-3
Chemical	1.5.4.2.3
Chemical Contamination	4.3.7.4.5
Chemical Hazards	1.5.3.6
Chemical Spills	8.5.5.6
Chlorine Solution Pipes	5.4.5.7
Citation (Cite)	2.2.5.2
Civil Number	2.2.5.1
Claimant & Options	2.2.6.5
Claims for Reimbursement	
Documentation	1.2.7
Leave Taken In-Travel Status	1.2.7
Personal Laundry	1.2.7
Receipts	1.2.7
Reimbursable Expenses	1.2.7
Telephone Expenses	1.2.7
Travel voucher	1.2.7
Class I	2.9.2.5.1
Class I Recall	7.1.1.2.1
Class II	2.9.2.5.2
Class II Recall	7.1.1.2.2

Class III	2.9.2.5.3
Class III Recall	7.1.1.2.3
Classification of Devices	2.9.2.5
Clinical Investigators and/or Clinical Pharmacologists	5.5.5.7
Closeout Inspection	7.3.3.2
Clothing	5.1.4.1
Clothing	1.5.3.3.3
Code	7.2.8.2
Codes	3.1.2
Code of Federal Regulations (CFR)	2.2.4
Coffee, Import Exam Sample Chart	Smpl Schdl 8
Collecting the 702(B) Portion	4.3.3.3
Collecting Water Samples	4.3.6.3
Collection Date	6.5.5.1
 4.4.10.3.5
Collection of Environmental and Product Samples for Food Susceptible to Contamination with Pathogenic Microorganisms	4.3.7.7
Collection Method	4.4.10.3.6
Collection PACs	4.4.10.3.7
Collection Reason	4.4.10.3.8
Collection Records	4.4.3.1
Collection Remarks	4.4.10.3.9
Collection of Samples for Mold	4.3.7.6.1
Collection Technique	4.3
Collector	4.4.10.3.10
Collector's Id on Package/Document	4.4.10.3.11
Collector's Id on Seal	4.4.10.3.12
Color Additives	5.4.6.4
Color Additives Sample Chart	Smpl Schdl 9
Color Additives Status List	5.4.6.4
Color Certification Program	2.9.5.4
Color Slide Identification	5.3.4.2.2
Commerce (Doc)	3.2.2.1
Commercial Bill of Lading	4.5.5.8.4
Common Carrier	1.2.1
 4.5.5.8
Communication with Federal Inspector	3.1.3.2
Comprehensive Smokeless Tobacco Act	2.2.3.9
Complainant Access to Report/Results	8.2.5.4
Complainants	8.8.5.4
Complaint and Medical Device Reporting (MDR)	7.2.3.3
Complaint Files	5.4.8.3
Complaint Files	5.6.2.4
Complaint for Forfeiture	2.2.5.5
Complaint or Injury Samples	4.4.6.3
Complaint Sample	4.4.10.1.2
Complaints	5.10.4.3.11
Additional Information to Obtain	8.2.5.3
Alcoholic Beverage	8.2.3
Authorization for Medical Records Disclosure	8.2.6
Basic Information to Obtain	8.2.5.1
Categories	8.2.1
Complaint Procedure	8.2
Complainant Access to Report/ Results	8.2.5.4
Consumer Portion	8.2.7
Control Portion	8.2.7
Dietary Supplement Health and Education Act	8.4.5.2
Emergency Operations Center Guidance	8.2.4
Infant Formula and Baby Food	8.2.2
Injury/Illness Complaints	8.2.5.2
Interviews	8.2.5
Investigation Procedure	8.4.5.2.2
Medical Records	8.2.6
Sampling	8.2.7
Special Nutritional Product	8.4.5.2
Complaints, Counterfeiting/Tampering, Foodborne Disease, Injury Illness	4.3.5.1
Compliance Achievement Reporting	2.6.4.2
 Exhibit 5-15
Compliance Achievement Reporting System (CARS)	5.10.2.1
Computerized Complaint and Failure Data	5.3.8.4.1
COMSTAT	5.10.2
 Exhibit 5-14
Concurrent Administrative, Civil, and Criminal Actions	5.2.2.8
Condition	5.4.4.2
Conducting Regulatory Inspections when the Agency is Contemplating/Taking, Criminal Action	5.2.2.4
Conducting Inspections for which Fees can be Assessed	5.4.11.1
Conference for Food Protection (CFP)	3.5.5
Confidential Informants	4.4.8.3
Confidentiality	5.1.4.3
Confiscation	5.1.1.13
Consensual Electronic Surveillance	8.9.1.3
Consent Decree	2.4
Consent Decree of Injunction	2.2.8.3
Consumer Complaint Number	4.4.10.3.13
Consumer Complaints	5.2.8
 8.4.7.4
Consumer Product Safety Commission	3.2.10
Consumption Entry (CE)	6.7.4
Contacting FDA Employees	1.10.2.2
Container Freight Station (CFS)	6.7.5
Contamination	6.4.4.2
Contested Seizure	2.2.6.8
Contract Facilities	5.2.3.2
 5.6.6
Control	4.5.3.5.2
 4.5.3.6.1
Controls	4.3.6.5
Conversion Factors	Appendix D
Conveyor Belt Conditions	5.4.5.3
Cooperation with Other Agencies	8.3.1.3
Cooperative Efforts	3.1
 3.1.1
Coordination with Other Government Agencies	8.8.2
Copies	5.2.3.6.2
Compliance Achievement	2.6
Correction of FDA 483 Errors	5.2.3.1.6
Correction of GMP Deviations	2.6.4.2.5
Corrective Action	7.2.3.2
Cosmetics	6.4.3.6
 6.4.7.4
 2.9.5.3
 8.4.5.1
Cosmetic Samples	8.4.7.3
Costs Billed to District	4.2.8.3.1
Counterfeit Drug	5.1.1.13
Counterfeiting/Tampering	8.8
Authority	8.8.3
Complainant	8.8.5.4
Contact	8.8.1
Coordination	8.8.2
Distribution Facilities	8.8.5.6.2
Information Release	8.8.4
Interviews	8.8.5.2
Manufacturing Site	8.8.5.6.1
Office of Criminal Investigations	8.8.1
Office of Crisis Management	8.8.1
Purpose / Procedures	8.8.5
Records	8.8.6
Refusal	8.8.7
Responsibility	8.8.3

Responsibility	8.8.1.1
Retail Stores	8.8.5.5
Sampling.....	8.8.5.3
Security System.....	8.8.5.6.3
Standard Operating Procedures	8.8.5.1
Country of Origin.....	4.4.10.3.14
County	4.4.10.3.15
Courtroom Testimony	2.2.11
CPSC	3.2.10
Cr & Records Sent To	4.4.10.3.16
Credentials.....	5.1.1.2
.....	5.2.2
Criminal Action	5.2.2.4
Criminal Investigation	
Case Referral	8.9.1.2
Communication	8.9.1.1
Electronic Surveillance	8.9.1.3
Liaison	8.9.1.2
Office of Criminal Investigations	8.9.1
Postal Mail Cover.....	8.9.1.4
Criminal Number	2.2.5.3
Criminal Prosecution	4.4.6.2
Criteria for Consideration	5.2.1.1.2
Eligibility Criteria	5.2.1.1.2.2
Type of Inspection	5.2.1.1.2.1
Criteria for Detention	2.7.2.1
Criteria for Requesting FDA Assistance.....	3.2.5.2.4
CRX/DEA Schedule	4.4.10.3.17
Current Practices	5.4.12.2
Customs	
Division of authority	6.2.2
CVM Bio Research Monitoring.....	5.9.8
CVM Website	5.9.1

-D-

Dairy Permit Number	4.4.10.3.18
Data Elements	5.10.2.1.2
Data Integrity of Records Provided By Firm	5.3.8.4.4
Data Reporting	8.7.7
Date Collected	6.7.6
Date Collected	4.4.10.3.19
Date Issued.....	5.2.3.1.3
Date of Arrival	6.7.7
Date of Availability	6.7.8
Date Shipped	4.4.10.3.20
Dates, Import Filth Sample Chart.....	Smpl Schdl 8
DEA Approval	2.6.2.1.1
DEA Controlled Drugs.....	2.6.2.1
Dealer	4.4.10.3.26.1
Definition and Good Will	4.2.1
Identification of Lot and Records	4.2.6
Objection to Sampling Procedure	4.2.2
Relations.....	4.2
Requests Notice of Inspection	4.2.4.4
Requests Receipt	4.2.5.2
Responsible for Condition of Lot	4.2.4.1
Violation	4.4.6.2.6
Voluntarily Holding	4.4.10.1.3
Decharacterization for Non Food/Feed Purposes ..	2.8.3
Declaration for Dangerous Goods Form	Exhibit 4-18
Defense Personnel Support Center (DPSC).....	3.2.3.4
Delegated Authority	1.6.3.1
Default Decree	2.5
Reporting	2.5.2
Denaturing	2.3.1.3
.....	2.8.1
Contamination (Rodent or Bird)	2.8.2.1
Diversion.....	2.8.2

Mold	2.8.2.2
Pesticide	2.8.2.3
Department of Defense	3.2.3
Department of Health and Human Services	3.2.4
Department of Homeland Security	3.2.5
Department of Justice	3.2.6
Department of Justice	2.2.6.3
Department of Labor: OSHA	3.2.7
Department of Navy/Bureau of Medicine & Surgery	3.2.3.5
Department of Veterans Affairs Veterans Administration.....	3.2.9
Depth of Inspection	5.1.2.1
Depth of Recall.....	7.1.1.5
Designated Carriers	4.5.5.8.2
Destruction	5.2.9.2.4
.....	2.3.1.2
.....	2.4.5
.....	2.6.2
.....	8.5.7.2
Destruction by Cooperating Officials	2.6.4.2.2
Detention	2.7
Accomplishment.....	2.7.1.1.1
Authority.....	2.7.1.2
Detention Criteria	2.7.2.1
Detention Notice FDA 2289	2.7.2.3
.....	Exhibit 2-2
Detention Powers.....	2.2.10
Detention Procedure	2.7.2.2
Detention Tag FDA 2290	2.7.2.4
.....	Exhibit 2-3
Detention Tag Removal	2.7.2.5.1
Egg Products Inspection Act	2.2.10
Egg Products Inspection Act	2.7.1.2.4
Execution	2.7.2.2.1
Federal Meat Inspection Act	2.2.10
Federal Meat Inspection Act	2.7.1.2.2
Food.....	2.7.1.1.3
.....	2.7.1.3.2
.....	2.7.2.1.2
Food Drug and Cosmetic Act	2.7.1.2.1
Immediate Action	2.7.2.2
Inspection Procedure	2.7.2
Medical Device.....	2.7.1.1.2
.....	2.7.1.3.1
.....	2.7.2.1.1
Overview	2.7.1.1
Perishable Food	2.7.1.3.3
Poultry Products Inspection Act	2.2.10
Poultry Products Inspection Act	2.7.1.2.3
Procedural Steps.....	2.7.1.1.4
Sampling	2.7.3
Supervising	2.7.4
Termination of Detention	2.7.2.5
Termination Notice FDA 2291	2.7.2.5.2
.....	Exhibit 2-4
Detention	6.7.9
Detention without Physical Examination (DWPE)....	6.7.10
Determining Sample Cost.....	4.2.8.2
Device	2.7.1.3.1
Device Inspection Guides.....	1.10.3
Device Regulatory References.....	1.10.3
Device Inspections	2.2.1.3
Device Inspection	
Authority.....	5.6.1
Banned Device.....	5.6.8
Complaint Files	5.6.2.4
Contract Facilities.....	5.6.6
Device Inspection Report	5.6.9

GWQAP	5.6.5
In-Vitro Diagnostics	5.6.4
.....	5.7.2
Labeling	5.6.4
Medical Device Quality System/GMPs	5.6.2
Preparation	5.6.2.1
Quality Audit	5.6.2.2
Records	5.6.2.3
Sampling	5.6.1.2
Small Manufacturer	5.6.7
Sterile Devices	5.6.3
Substantially Equivalent	Exhibit 5-13
Technical Assistance	5.6.1.1
Types	5.6.1.3
Device Registration and Listing	2.9.2.1
Devices	6.4.7.2
Devices	5.6
Devices	2.7.2.1.3
Devices	8.4.3.4.1
Devices for Implant	8.4.3.2
Devices Injury	8.4.3
Dialysis Injury or Deaths	8.4.3.4.3
Dietary Supplements	8.4.5.2
Video Recordings	5.3.4.2.4
Digital Photos - Turbo EIR	5.3.4.4
Resize Photo	Exhibit 5-6
Insert Photo	Exhibit 5-7
Resize using MS Office Picture Manager	Exhibit 5-8
Directed Inspection	5.1.2
Disaster	2.3.2
Disaster Procedures	8.5
Disaster Types	8.5.1
Ammonia Leaks	8.5.7.5
Bio-terrorism	8.5.6
Chemical Spills	8.5.5.6
Destruction	8.5.7.2
Earthquakes	8.5.5.7
Embargoes	8.5.5.1
Explosions	8.5.5.5
FDA Responsibility	8.5.2
Field Examination	8.5.5.2
Field Operations	8.5.5
Fires	8.5.5.5
Flooding	8.5.5.3
Form FDA 2809	Exhibit 8-12
Hazardous Waste Sites	8.5.5.6
Hurricanes	8.5.5.4
Initial Information	8.5.4
Initial Procedures	8.5.4
Inspections	8.5.3
Perishable Products	8.5.7.6
Personal Safety	8.5.3
Preparation	8.5.3
Product Disposition	8.5.7
Reconditioning	8.5.7.3
Reconditioning Containers	8.5.7.7
Reconditioning Containers	8.5.7.8
Reconditioning Devices	8.5.7.10
Reconditioning Hermetically Sealed Cans	8.5.7.9
Relabeling	8.5.7.4
Riots	8.5.5.5
Samples	8.5.5.2
Segregation	8.5.7.1
Tornadoes	8.5.5.4
Types	8.5.1
Wrecks	8.5.5.6
Disclosure	5.2.9.2.3
Disclosure of Official Information	1.4
Discovery of Criminal Violation	5.2.2.5
Discussion on Duty, Power, Responsibility	5.3.6.1
Discussion with Federal Inspector	3.1.3.2
Discussion with Management	5.2.7
.....	5.10.4.3.15
Disposition of Rejects	2.4.6
Distribution	5.4.8
Distribution Facilities	8.8.5.6.2
Distribution of FDA 2289	2.7.2.3.4
Distribution of the FDA 483	5.2.3.6
Distribution Pattern	7.2.8.6
District Audit Program	7.2.8.9
District Contact	3.2.5.2.7
District Follow Up	2.2.6.9
.....	2.2.7.4
.....	2.2.8.6
District Recommendation	2.2.6.1
Diversion to Animal Feed	2.8.2
Division of Authority	6.2.2
Division of Federal-State Relations (DFSR)	1.9.2.2.4
Division of Domestic Field Investigations (DDFI)	1.9.2.2.1
Division of Field Science (DFS) (HFC-140)	1.9.2.2.3
Division of Foreign Field Investigations	1.9.2.2.2
Division of Import Operations and Policy (DIOP)	1.9.2.2.5
Documentary (Doc)	4.4.10.2.3
Documentary Samples	4.1.4.2
Documentation	4.4.9.3.1
Documentation & Cr	4.4
Documenting Interstate Shipments	4.4.7
Documenting Voluntary Destruction	2.6.4.1
Documents Obtained	4.4.10.3.21
DOD MOU's	3.2.3.1
Domestic Follow-Up of IFE Entries	6.2.3.4.2
Domestic Import (DI)	4.4.10.2.4
Domestic Import (DI) Sample	6.7.11
Domestic Import Sample	4.1.4.8
Drug Approval Status	5.5.5.2
Drug Enforcement Administration	3.2.6.2
Drug Inspection	
Adverse Event Reporting	5.5.7
Advertising	5.5.3
Approach	5.5.1.2
Authority	5.5.1
Bioresearch Monitoring	5.5.6
Dietary Supplement Status	5.5.5.4
Drug Inspection Report	5.5.8
General Elements	5.5.8
Guarantee	5.5.4
Inspection References	5.5.1.1
Labeling Agreement	5.5.4
Listing	5.5.2
Preparation	5.5.1.1
Promotion	5.5.3
Registration	5.5.2
Sampling Chart	Smpl Schdl 10
Drug Recalls	7.2.4
Drug Recall Letter	Exhibit 7-1
Drug Registration & Listing	5.5.2
Drug Status Questions	5.5.5.3
Drug/Dietary Supplement Status	5.5.5.4
Field Examination - Drugs	6.4.4
Veterinary Drugs	6.4.7.1
Drugs	5.5
Drugs Injury or Reactions	8.4.2
Dry Ice Sticker	Exhibit 4-19
Dusty Areas	4.3.6.1.4

-E-

Earthquakes 8.5.5.7

Economic Violation	4.3.8
.....	4.3.8.1
Educational And/ or Training.....	2.6.4.2.8
Egg and Egg Products	2.7.1.3.5
.....	2.7.2.1.2
Egg Products Inspection Act.....	3.2.1.3
EIR	5.10.1
Team inspections.....	5.1.2.5
Electrical Hazards	1.5.3.2
Electronic Information	5.10.5.1
Electronic Information for Official Documentation ..	5.3.8.4.5
Electronic Radiation Product Examinations and Inspections.....	2.2.1.5
Electronic Products	5.1.1.10
Embargoes.....	8.5.5.1
Emergency Operations Center Guidance	8.2.4
Emergency Permit Control	2.2.9
Emergency Requests for Confidential Information ..	3.2.4.3.4
Employee Conduct	1.6.5
Attempted Bribery	1.6.5.2
Attire	1.6.5.1.3
Attitude	1.6.5.1.2
Employee Prohibitions	1.6.5.1.4
Integrity	1.6.5.1.1
ORA Policy	1.6.5.1.5
Professional Personnel Contacts.....	1.6.5.1.6
Professional Stature	1.6.5.1
Employee Practices	5.4.7.2.2
Endorsement.....	5.10.2
English Language Requirement for FDA Documents.....	1.1
Entries	6.2.3
Entries, Formal	
Customs Entry	6.2.3.1
Electronic Entry.....	6.2.3.1
Entries, Informal.....	6.2.3.2
Entries, Other	
Mail	6.2.3.3
Personal Baggage	6.2.3.3
Personal Importation.....	6.2.3.3
Section 321 entry.....	6.2.3.3
Entries, Processing	
Affirmation of Compliance Code	6.2.3.6.2
Automated Commercial System	6.2.3.6
Notice of FDA Action	6.2.3.6.2
OASIS.....	6.2.3.6.2
Entry	6.7.12
Entry Admissibility File	6.7.13
Entry Documents (Entry Package).....	6.7.14
Entry Processing.....	6.2.3.6
Entry Sampling.....	6.2.4.3
Environmental Protection Agency	3.2.11
Environmental Sampling	4.3.7.7.1
Environmental Sampling for the Detection of Listeria Monocytogenes.....	Exhibit 4-20
Environmental Sampling for the Detection of Salmonella	Exhibit 4-21
Environmental Sampling Equipment and Instructions for Large and Small Area Environmental Surface Sampling .	4.3.7.7.2
EPA.....	3.2.11
EPA MOU's.....	3.2.11.1
Epidemic Curve.....	8.3.5.1
.....	Exhibit 8-9
Epidemiological Associations.....	8.3.4
Episode	6.5.5.2
Episode Number	4.4.10.3.22
Equipment and Utensils	5.4.5
Chlorine Solution Pipes	5.4.5.7
Conveyor Belt Conditions	5.4.5.3
Filtering Systems.....	5.4.5.1
Mercury and Glass Contamination	5.4.5.5
Sanitation of Machinery.....	5.4.5.2
Sanitation Practices	5.4.5.8
Utinsels	5.4.5.4
UV Lamps	5.4.5.6
Equipment Care, Custody, and Loss	1.6.2
Calibrations	1.6.2.1.2
Lost or Stolen Equipment.....	1.6.2.2
Maintenance of Equipment	1.6.2.1
Repair	1.6.2.1.1
Errors Discovered after Leaving Establishment.....	5.2.3.1.6.2
Errors Discovered Prior to Leaving the Establishment.....	5.2.3.1.6.1
Establish Motivation	5.2.9.1.2
Establishment Inspection Report (EIR) see Inspection Report	
Establishment Investigation.....	8.3.4.4
Estimated Value	4.4.10.3.23
European Community.....	3.4.2.1
Evidence	
Digital Photographs as Regulatory Evidence	5.3.4.3
Digital Photographs or Video Recordings	5.3.4.2.5
Digital Photos - Turbo EIR	5.3.4.4
Documentation of Responsibility	5.3.6.2
Duty.....	5.3.6.1
Evidence Development	5.3
Exhibits	5.3.3
Factory Sample	5.3.2
Guarantee	5.3.7
In-plant Photograph.....	5.3.4.1
Labeling Agreement	5.3.7.2
Photocopy	5.3.4
Photograph	5.3.4
Power	5.3.6.1
Preparation of Photographs	5.3.4.2
Providing Copies of Photographs	5.3.4.5
Recording.....	5.3.5
Responsibility	5.3.6.1
Responsible Person	5.3.6
Taping	5.3.5
Evidence Development	5.3
Complaint.....	5.3.8.4.1
Complaints	5.3.8.4
Computerized Data	5.3.8.4
.....	5.3.8.4.1
.....	5.3.8.4.2
Documentary sample	5.3.8.2
Documents	5.3.8
Electronic Data as Official Documentation	5.3.8.4.5
Electronic Records	5.3.8.3
Failure	5.3.8.4
.....	5.3.8.4.1
Film	5.3.8.3
Identification and Security of Electronic Data	5.3.8.4.3
Identification of Records	5.3.8.1
Integrity of Data	5.3.8.4.4
Managing Records Collected	5.3.8.5
Microfiche	5.3.8.3
Microfilm	5.3.8.3
Official Sample	5.3.8.2
Original Records	5.3.8.2
Patient Information	5.3.8.6
Private Information	5.3.8.6
Records	5.3.8
Sampling Request	5.3.9
Evidence Gathered in a Criminal Investigation.....	5.2.2.6
Evidence Required	4.4.6
Evidence Voluntarily Provided to the Agency	5.2.2.7

Examination	5.1.1.12
Examinations and Investigations.....	4.1.1.1
Exceptions to Fumigation.....	4.5.3.1.3
Executing the Detention.....	2.7.2.2.2
Exemption	5.4.1.5.1
Exemption Requirements.....	5.3.7.3
Exhibit Sample	4.4.10.1.4
Exhibits	4.5.2.5
	5.3.3
	5.10.5
Exhibits Collected	5.10.4.3.19
Expenses Chart	Exhibit 1-1
Explosions.....	8.5.5.5
Exportation of Merchandise Refused Admission....	6.2.7.10
External Observers	5.1.4.3
Eye Protection.....	1.5.1.1

-F-

Facilities Exempted From Registration	5.4.1.5.1
Facilities Where Electronic Products Are Used or Held	5.1.1.10
Factory Food Sample.....	4.4.10.1.5
Factory Inspection.....	1.5.4.2
Factory Samples	5.3.2
FACTS Assignment Section.....	5.3.9.1
FACTS Establishment Inspection Record (EI Record).....	5.10.3
FACTS Operations Section	5.3.9.2
FACTS Organizations Section	5.3.9.3
FACTS Personal Safety Alert.....	5.2.1.3
FACTS Reporting	
Complaints, Reporting	8.2.8
Counterfeiting / Tampering, Reporting.....	8.8.8
Criminal Investigation Reporting	8.9.1.1
Detention, Reporting.....	2.7.5
Disaster, Reporting	8.5.8
Foodborne Outbreaks Reporting	8.3.6
Investigation Reporting	8.10
Profile COMSTAT	Exhibit 5-13
Sampling Operations	4.4.10
Seizure Reporting.....	2.4.8
Voluntary Actions Reporting	2.6.4
Failure To Hold	6.1.3.2
Failure to Hold – Health Hazards – Detention without Physical Examination (DWPE)	6.1.3.4
Failure to Hold – Health Hazards – Direct FDA Evidence	6.1.3.4
Fair Packaging and Labeling Act (FPLA)	2.2.3.2
False Guaranty	4.4.6.2.5
FBI	3.2.6.3
FCE Process Filing of LACF/AF Processors.....	2.9.5.2
FDA.....	6.2.3.5.2
FDA 457 Preparation	8.6.2
FDA 457 Routing	8.6.3
FDA Commissioned State Personnel.....	3.3.1.3
FDA Directory	1.10.2.2
FDA Investigator's Responsibility.....	5.1.1.1
FDA on Disk.....	1.10.2.4
FDA Personnel with State Authority	3.3.1.1
FDA Principles	1.8.1
FDA Recall Audit Checks.....	7.3.2
FDA-USDA Agreements & MOUs.....	3.2.1.4
FDA/ORAs Manuals and Reports	1.10.2.5
FDC and INJ Numbers.....	2.2.5.4
Federal Agencies	3.1.3.1
Federal Agency Interaction	3.2
Federal Anti Tampering Act	2.2.3.3
	Exhibit 8-14

Federal Bureau of Investigation	3.2.6.3
Federal Caustic Poison Act	2.2.3.5
Federal Cigarette Labeling & Advertising Act.....	2.2.3.10
Federal Food Safety Coalition	3.2.17
Federal Food, Drug, and Cosmetic Act	2.2.1
Federal Grain Inspection Service/USDA	3.2.1.7
Federal Import Milk Act.....	2.2.3.4
Federal Meat Inspection Act.....	3.2.1.3
Federal Trade Commission (FTC).....	3.2.13
FEI Number	4.4.10.3.24
Field Exams.....	5.1.5.3
Field Examination	4.3.7.1
	4.3.8.1.2
Field Examination (Imports)	6.4
Aflatoxin	6.4.3.2
Biologics.....	6.4.6
Color Additive.....	6.4.3.3
Cosmetics	6.4.3.6
Decomposition	6.4.3.1
Device	6.4.5
Drug Contamination	6.4.4.2
Drug Labeling.....	6.4.4.1
Drug Sample	6.4.4.3
Electronic Products	6.4.8
Filth and Foreign Objects	6.4.3.1
Foods	6.4.3
Food Additive	6.4.3.3
Food Economics	6.4.3.5
Food Sanitation.....	6.4.3.1
Industrial Chemical.....	6.4.3.2
Labeling	6.4.2
Low Acid Can Food.....	6.4.3.1
Microbiological	6.4.3.1
New Drug Status	6.4.4.4
Nutrition Labeling	6.4.3.4
Pesticide	6.4.3.2
Physical Examination	6.4.1
Physical Examination	6.4.2
Radiological Health	6.4.8
Schedule	6.4.2
Standard of Acceptance	6.4.1
Tobacco Products	6.4.9
Veterinary Product	6.4.7
Field Examination & Samples.....	8.5.5.2
Field Exams.....	5.1.5.3
Field Operations	8.5.5
Field Weight Sheet	4.3.8.1.3
	Exhibit 4-6
Filer	6.7.16
Filer Evaluation.....	6.6.1
Filer Misdeclaration	6.1.3.7
Filmed or Electronic Records	5.3.8.3
Filtering Systems.....	5.4.5.1
Filth examination	4.3.9.1
Finished Product Sampling	4.3.7.7.4
Fires	8.5.5.5
Firm Locations	3.2.16
Firm Name	4.4.10.3.25
Firm Official	7.2.8.8
Firm Type	4.4.10.3.26
Firm's Recall Strategy	7.2.8.7
Firm's Training Program	5.10.4.3.8
Firms with Potential Respiratory Hazards.....	1.5.1.4.2
FIS Sample Number	4.4.10.3.27
Flag	4.4.10.1
Flooding.....	8.5.5.3
Follow Up Guidance	5.1.1.13.3
	8.3.2
Follow Up Inspections by Court Order	5.2.2.3

Food.....	5.4
Food Additives	5.4.6.3
Food Additive Nomographs.....	Exhibit 5-11
Food and Col or Additives.....	6.4.3.3
Food and Cosmetic Defense Inspectional Activities.....	5.4.1.4
Food and Cosmetic Security	5.4.1.4.1
Food Canning Establishment.....	4.4.10.3.28
Food Chemicals Codex.....	5.4.4.3
Food Drug and Cosmetic Act.....	2.7.1.2.1
Food Economics (Consumer Size Containers)	6.4.3.5
Food Establishment Inspection.....	5.4.10.1
Food Handlers Interviews	8.3.4.5
Food Illness Classification.....	Exhibit 8-6
Food Illness Report FDA 3042.....	Exhibit 8-7
Food Inspection	
Authority	5.4.1.2
Chemical Codex	5.4.4.3
Color Additives	5.4.6.4
Complaint File.....	5.4.8.3
Design	5.4.3.1
Distribution.....	5.4.8
Employees.....	5.4.2
Entry Review	5.4.1.4
Environment	5.4.3
Equipment	5.4.5
Facilities.....	5.4.3
Field Examination	5.4.1.4
Food Additives	5.4.6.3
Food Inspection Report	5.4.10.2
Food Standard Inspection.....	5.4.10.1
Food Standards	5.4.10
Food Transport Vehicle	5.4.7.3.1
Formulas.....	5.4.6.2
Grade A Dairy Plant Inspection	5.4.9.3
Ingredient Handling.....	5.4.6.1
Interstate Shipping.....	5.4.8
Management.....	5.4.2
Manufacturing Code	5.4.6.5.3
Manufacturing Process	5.4.6
Microbiological Concerns.....	5.4.7.2
Other Government Inspection.....	5.4.9
Packaging and Labeling	5.4.6.6
Personnel	5.4.2
Plant Construction	5.4.3.1
Plant Services.....	5.4.3.3
Preparation	5.4.1.1
Quality Control	5.4.6.5
Raw Material Handling.....	5.4.4.1
Raw Material Source	5.4.4
Re-Inspection User Fees	5.4.11
Recall Procedure	5.4.8.2
Receiver Vehicle.....	5.4.7.3.2
Reconciliation Examination.....	5.4.1.4.2
Routes of Contamination	5.4.7.1
Safety Precautions.....	5.4.1.4.5
Sanitation.....	5.4.7
Security Inspection Activities	5.4.1.4.1
Shipper Vehicle.....	5.4.7.3.3
Storage	5.4.7.3
Violative Inspections	5.4.10.3
Waste Disposal.....	5.4.3.2
Written Demand for Records	5.4.1.2.1
Written Request for Information.....	5.4.1.2.2
Food Inspection Report.....	5.4.10.2
Food Inspections.....	5.4.1
.....	2.2.1.2
Food Products.....	3.4.2.3
Food Recalls	7.2.2

Food Registration	5.4.1.5
Food Safety and Inspection Service.....	3.2.1.8
Food Sanitation	6.4.3.1
Food Standards	5.4.10
Food Standards Sample	4.1.5
Food Standards, (FS)	4.4.10.2.5
Food Transport Vehicles	5.4.7.3.1
Foodborne Disease	4.3.5.1
Foodborne Outbreaks	8.3
Additional Case History Interviews.....	8.3.4.3
Analysis of Data	8.3.5
Assistance.....	8.3.4.2
Attack Rate Table.....	8.3.5.4
.....	Exhibit 8-8
Classification of Illness	Exhibit 8-6
Cooperation with Other Agencies.....	8.3.1.3
Determination.....	8.3.4.1
Epidemic Curve.....	8.3.5.1
Epidemiological Investigative Technique	8.3.1
Establishment Investigation	8.3.4.4
Evaluating Epidemiological Data.....	8.3.4
Follow-Up Guidance	8.3.2
Contacting the Complainant.....	8.3.2.2.1
Information to Gather	8.3.2.2.3
Interviews.....	8.3.2.2
Medical Records	8.3.2.3
Preparation	8.3.2.1
Setting Communication Level	8.3.2.2.2
Foreign Flag Vessels	8.3.1.1
Incubation Periods	8.3.5.3
Interstate Conveyances	8.3.1.2
Interviews	8.3.4.5
Outbreaks	8.3.1
Pathogen Growth Factors	8.3.4.7
Possible Contamination Source	8.3.4.6
Pests.....	8.3.4.6.1
Poor Sanitation	8.3.4.6.3
Raw Meat.....	8.3.4.6.2
Workers	8.3.4.6.4
References.....	8.3.7
Salmonella Enteritidis (SE) in Eggs	8.3.1.4
Sample Handling.....	8.3.3.3
Sample Size	8.3.3.2
Sampling	8.3.3.1
Symptoms Determination.....	8.3.5.2
Tracebacks of Foods.....	8.3.5.5
Foods Rejected by USDA.....	3.2.1.1
Foods, Dietary Supplements & Cosmetics Injury or Reaction	8.4.5
Foreign Firms	5.1.3
Foreign Trade Zones	6.7.18
Formal Entries	6.2.3.1
Formal Entry	6.7.17
Format for Regulatory Notes	2.1.4
Forms and Other Publications	1.10.2.6
Formula/Label Correction	2.6.4.2.6
Formulas	5.4.6.2
Fourth amendment	5.2.2.4
Free Flowing Liquids	4.3.8.2.1
Freedom of Information Act	1.4.4
Complainant Access to Report/ Results	8.2.5.4
Procedures	1.4.4.1
Request for Documents	1.4.4.2
Freight Bill	4.4.7.2.4
Frequent Flyer Miles	1.2.1.1
Frozen Samples	4.5.3.5
Fumigated	4.4.10.1.6
Fumigation.....	4.5.3.1
Fumigation Safety Precautions	4.5.3.1.1

-G-

Gainsharing.....	1.2.1.4
General Considerations for All Affidavits.....	4.4.8.1
General Discussion with Management.....	5.10.4.3.15
General Inspection Procedures.....	5.2.10.2
General Investigation Reporting.....	8.10
General Procedures (aseptic sampling).....	4.3.6.1
General Procedures (investigations).....	8.8.5.1
General Procedures & Techniques	5.1.5
Glossary of Digital Terminology	5.3.4.2.6
Digital Data	5.3.4.2.6.1
Analog Data	5.3.4.2.6.2
Memory Card	5.3.4.2.6.3
Original	5.3.4.2.6.4
Original Copy	5.3.4.2.6.5
Permanent Storage Media.....	5.3.4.2.6.6
Time/Date Stamp.....	5.3.4.2.6.7
Working Copy	5.3.4.2.6.8
Glossary of Import Terms.....	6.7
Government Agency	4.2.7
Government Bill of Lading.....	4.5.5.8.3
Government-Owned Vehicles (GOVs)	1.2.2
Government Wide Quality Assurance Program	5.2.3.5
.....	5.6.5
GovTrip	1.2
Grade A Dairy Plant Inspections	5.4.9.3
Grain Elevators	1.5.3.3.2
Grand Jury	5.2.2.9
Grand Jury Proceedings	2.2.7.3
Grower	4.4.10.3.26.2
Growers	5.4.12.3
Guarantees and Labeling Agreements	5.3.7
Guarantees and Labeling Agreements	5.5.4
Guaranty	5.3.7.1
GWQAP Samples	4.1.6

-H-

Hand Ship	6.5.5.7
Handling Procedure	5.4.4.1
Hantavirus Associated Diseases.....	1.5.5.4
Harvester	4.4.10.3.26.3
Hazardous Waste Sites	8.5.5.6
Headquarters	2.2.6.2
Health Fraud	8.6.1
Health and Hygiene	1.5.1.5
Health Care Financing Administration (HCFA).....	3.2.4.4
Health Services Administration (HSA)	3.2.4.5
Hearing for Injunction	2.2.8.2
Hearing Protection	1.5.1.2
HHS MOU's	3.2.4.1
History	5.10.4.3.4
History of Menu Items	Exhibit 3-2
Home District	2.2.5.6
Hospitalized In-Travel Status	
Per Diem Coverage	1.2.4.2
Hostile and Uncooperative Interviewees	5.2.5.4
Hours	4.4.10.3.29
How Prepared	4.4.10.3.30
How to Handle the First Contact	5.2.9.1
Human Blood & Blood Products.....	2.9.3.1.1
Human Cells, Tissues, and Cellular and Tissue Based Products (HCT/Ps)	2.9.3.1.2
Donor Confidentiality	5.7.2.2
For Transplantation, Infusion, or Transfer.....	7.2.5
Inspections	5.7.2.1.2
Registration and Listing	5.7.3.1.1

Hurricanes

8.5.5.4

-I-

Identification

4.5.2

.....

4.5.2.3

Identification and Security of Electronic Storage

Media.....

5.3.8.4.3

Identification of Documentation

4.4.5

Identification of lots and records

4.2.6

Identification of Records

5.3.8.1

Identification Techniques

4.5.2.3

Identifying Lot(s) Sampled.....

4.3.2.2

Identifying Marks

4.5.2

Identifying Original Paper Records.....

5.3.8.2

IFE Entry Review.....

6.2.3.4.1

Immediate Delivery (ID) / Conditional Release.....

6.7.19

Immediate Transportation (IT)

6.7.26

Import for Export.....

5.1.1.14

Import for Export (IFE) Entries

6.2.3.4

Export Reform and Enhancement Act.....

6.2.3.4

Record-keeping requirement.....

6.2.3.4

IFE Entry Review

6.2.3.4.1

Affirmation of Compliance

6.2.3.4.1

Domestic Follow-up of IFE Entries

6.2.3.4.2

IFE Domestic Inspection Guidance

6.2.3.4.3

Import Glossary of terms

American Goods Returned.....

6.7.1

Bonded Warehouse

6.7.2

Break-bulk Cargo

6.7.3

Consumption Entry (CE)

6.7.4

Container Freight Station (CFS).....

6.7.5

Date Collected.....

6.7.6

Date of Arrival

6.7.7

Date of Availability.....

6.7.8

Detention

6.7.9

Detention without Physical Examination

.....

(DWPE)

6.7.10

Domestic Import (DI) Sample

6.7.11

Entry

6.7.12

Entry Admissibility File

6.7.13

Entry Documents (Entry Package)

6.7.14

Failure To Hold

6.1.3.2

Filer

6.7.16

Foreign Trade Zones

6.7.17

Formal Entry

6.7.18

Immediate Delivery (ID) / Conditional Release

6.7.19

Import Alerts

6.7.20

Importer of Record

6.7.21

Import Sections

6.7.22

Import Status

6.7.23

Importer Misdeclaration

6.1.3.6

Informal Entry

6.7.25

Immediate Transportation (IT)

6.7.26

Line (Line Item)

6.7.27

Lot

6.7.28

Marks

6.7.29

Port (Point) of Entry

6.7.30

Redelivery Bond (AKA Entry Bond)

6.7.31

Stripping (of Containers)

6.7.32

Substitution

6.1.3.5

Supervisory Charges

6.7.34

Warehouse entry (WE)

6.7.35

Import Investigations

6.1.2

Import Investigation Affidavit

Exhibit 6-5

Import Procedures

Import Forms Sampling

6.5.4

No Sample/No Examination

6.2.5

No Violation

6.2.6

<i>Post-hearing</i>	6.2.7.9
Cost of Supervision	Exhibit 6-3
Destruction	6.2.7.8
Exportation	6.2.7.8
Exportation	6.2.7.10
Notice of FDA Action	6.2.3.6.2
		Exhibit 6-1
Notice of Refusal of Admission	6.2.7.8
Notice of Release	6.2.7.7
<i>Violation</i>		
Application for Authorization to Relabel or Perform Other Acts	6.2.7.3
		Exhibit 6-2
Bond	6.2.7.3
Follow-Up Inspection	6.2.7.4
Importer's Certificate	6.2.7.4
Notice of Detention and Hearing	6.2.7.1
Notice of Refusal of Admission	6.2.7.5
Notice of Refusal of Admission	6.2.7.6
Notice of Release	6.2.7.5
Reconditioning	6.2.7.3
Response	6.2.7.2
Import Sample	4.1.4.9
Import Sample Charts		
Coffee & Dates	Smpl Schdl 8
Whitefish	Smpl Schdl 5
Salmonella	Smpl Schdl 1
Import Violation Patterns	6.1.3.1
In-Line Samples	4.3.7.7.3
In-Line Sampling	4.3.7.7.1
In-Plant Photographs	5.3.4.1
In-Transit Lots	4.2.5.1
In-Transit Sample	4.1.4.3
		4.3 .4
Examination without a Warrant	4.3.4.1
Examination with a Warrant	4.3.4.2
Resealing Conveyances	4.3.4.3
In-Transit Sampling	4.2.4.3
In-Transit Sampling Affidavit	4.4.7.5
In-Vitro Diagnostic Devices	8.4.3.3
In-Vitro Diagnostics	8.4.3.4.2
Inadequate Prior Notice Submission	6.2.3.5.5
Incubation Periods	8.3.5.3
Indicators	5.2.5.4.1
Individual Headings	5.2.3.1.1
Individual Narrative Headings	5.10.4.3
Individual Responsibility and Persons Interviewed	5.10.4.3.7
Induced Samples	4.1.4.5
		4.3.5.4
Ineffective Recalls	7.3.2.6
Infant Formula	2.9.5.5
Infant Formula and Baby Food	8.2.2
Informal Entries	6.2.3.3
Information Disclosure		
Requests by the public, including trade	1.4.2
Disclosure of official information Privacy Act	1.4
FOIA	1.4
Freedom of Information Act: disclosure	1.4.4
Internal FDA Documents: disclosure	1.4.5
Sharing non-public information with other Government officials	1.4.3
Subpoena	1.4.1
Information Exchange and Coordination	3.2.4.3.2
Ingredient Handling	5.4.6.1
Ingredient Supplier	4.4.10.3.26.4
Injunction	2.2.8
Consent Decree	2.2.8.3
District Follow-up	2.2.8.6
Hearing for Injunction	2.2.8.2
Permanent Injunction	2.2.8.5
Preliminary Injunction	2.2.8.5
Temporary Restraining Order	2.2.8.1
Trial	2.2.8.4
Injunction or Criminal Prosecution	4.4.6.2
Injury and Adverse Reaction		
Biologics Injury or Illness	8.4.4.2
CFSAN Regulated Products	8.4.5.3
Cosmetics Injury or Reaction	8.4.5.1
Devices for Implant	8.4.3.2
Drug Injury or Illness	8.4.2
In-Vitro Diagnostic Devices	8.4.3.3
Investigation Procedure	8.4.1
Mechanical or Electromechanical Devices	8.4.3.1
Medical Device Injury or illness	8.4.3.4
<i>Reporting</i>		8.4.8
Biologics Injury/Adverse Reaction Reports	8.4.8.2.7
Drugs	8.4.8.2.1
Foods and Cosmetics	8.4.8.2.3
Licensed Biological Products	8.4.8.2.5
Medical Device and Radiological Products	8.4.8.2.2
Reporting Forms	8.4.8.1
Routing Reports	8.4.8.2
Tobacco	8.4.8.2.8
Unlicensed Biological Products	8.4.8.2.6
Veterinary Products	8.4.8.2.4
<i>Sampling</i>	8.4.7
Biological Samples	8.4.7.2
Cosmetic Samples	8.4.7.3
Consumer Complaints	8.4.7.4
Device Samples	8.4.7.1
Vaccine Adverse Event Reporting system	8.4.4.1
Vaccine Adverse Reactions	8.4.4.1
Veterinary Products	8.4.6
Injury Illness	4.3.5.1
Injury/Illness Complaints	8.2.5.2
		8.2.1.1
Injury Samples	4.4.6.3
Insect Contamination	4.3.7.4.3
Collecting Exhibits and/or Subsamples	4.3.7.4.3.2
Examination/Documentation of Contamination	4.3.7.4.3.1
Summary of Sample for Evidence	4.3.7.4.3.3
Insects	5.4.7.1.1
		Appendix A
Inspection after Completion of Authorization to Bring Article into Compliance	6.2.7.4
IFE Domestic Inspection Guidance	6.2.3.4.3
Inspection Information	5.1
Inspection of Foreign Firms	5.1.3
Inspection of Vehicles	5.2.2.2
Inspection Procedures	5.2
Inspection Procedures	7.2.1
Inspection Refusal	5.2.5
Inspection of Vehicles	5.2.2.2
Inspection Report		
Abbreviated Inspection Report	5.10.4.3
Addendum	5.10.6
Additional Information	5.10.4.3.16
Administrative Data	5.10.4.3.3
Attachment	5.10.4.3.20
Complaint	5.10.4.3.11
Compliance Achievement Reporting System (CARS)	5.10.2.1
Discussion with Management	5.10.4.3.13.2
		5.10.4.3.15
EI Record	5.10.3
EIR	5.10.1
EIR Timeframes	5.10.4.2

Electronic information	5.10.5.1
Endorsement	5.10.2
Establishment Inspection Report	5.10.1
Exhibit.....	5.10.4.3.19
Exhibits	5.10.5
FACTS Establishment Inspection Record.....	5.10.3
Comstat Screen.....	Exhibit 5-15
Maintain Inspection Results Screens.....	Exhibit 5-16
History	5.10.4.3.4
Interstate Commerce	5.10.4.3.5
Jurisdiction.....	5.10.4.3.6
Manufacturing Code	5.10.4.3.10
Manufacturing Operation	5.10.4.3.9
Narrative Headings.....	5.10.4.3
Narrative Report	5.10.4
Non-Violative Establishments	5.10.4.1
Objectionable Conditions	5.10.4.3.13
Recall Procedures	5.10.4.3.12
Refusal	5.10.4.3.14
Responsibility	5.10.4.3.7
Samples Collected.....	5.10.4.3.17
Signature	5.10.4.3.21
Standard Narrative Report.....	5.10.4.3.1
Summary	5.10.4.3.2
Summary of Findings report	5.10.4.1
Supporting Evidence.....	5.10.4.3.13.1
Training Program	5.10.4.3.8
Turbo EIR usage.....	5.10.4
Voluntary Correction	5.10.4.3.18
Violative Establishments	5.10.4.2
Inspection System.....	5.4.6.5.1
Inspection Techniques How to Document	
Responsibility.....	5.3.6.2
Inspection walk through	5.1.2.2
Inspection Warrant.....	5.2.6
Inspectional Approach	5.1.2
.....	5.5.1.2
.....	5.7.2.5
Inspectional Authority.....	5.4.1.2
Inspectional Guidance	5.1.1.13.2
.....	5.4.1.5.3
Inspectional Observations	
Adulteration Observations	5.2.3.2.1
Annotation	5.2.3
Annotation	5.2.3.4
Correction FDA 483 Errors	5.2.3.1.6
Discussion	5.2.3
Distribution.....	5.2.3.6
FDA 483	5.2.3
.....	Exhibit 5-5
FDA 483 Statements	5.2.3.1.4
GWQAP.....	5.2.3.5
Other Observations.....	5.2.3.2.2
Non-Reportable Observations	5.2.3.3
Preparation FDA 483	5.2.3.1
Reportable Observations	5.2.3.2
Signature	5.2.3
Turbo EIR	5.2.3
Inspectional Precautions	5.1.4
Inspectional Procedure	2.7.2
Inspections.....	1.5.4
Inspections to Monitor Recall Progress.....	7.3.1
Intended Use.....	5.5.5.1
Interaction with Federal Agencies	3.2
Interagency Cooperation.....	3.2.5.2.6
Interagency Motor Pool.....	1.2.2.1
Interdistrict Assignments	1.7
Internal FDA Documents.....	1.4.5
Internal Revenue Service (IRS)	3.2.8.2
International Agreements	3.4
International Inspection	3.1.1
International	
Food Products.....	3.4.2.3
Memorandum of Understanding.....	3.4.1
MRA	3.4.2
Mutual Recognition agreement	3.4.2
Pharmaceuticals and Medical Devices.....	3.4.2.2
Internet	1.10.2.3
Interrogation: Advice of Rights	Exhibit 2-1
Interviewing Informant	5.2.9
Interviewing Persons under Arrest	2.2.11.2
Interviews.....	8.2.5
Additional Information to Obtain.....	8.2.5.3
Basic Information to Obtain.....	8.2.5.1
Complainant Access to Report/Results.....	8.2.5.4
Injury/Illness Complaints	8.2.5.2
Internet and Intranet	1.10.2.3
Interstate Commerce	5.10.4.3.5
Interstate Commerce	4.4.6.2.1
Interstate Certified Shellfish Shippers	2.9.5.6
Interstate Milk Shippers	7.2.2.1
Interstate Milk Shippers	2.9.5.7
Interstate Shellfish Sanitation Conference.....	3.5.3
Interviewing Confidential Informants	5.2.9
Interviewing Methods/Techniques	5.2.9.1.1
Interviewing Persons Under Arrest.....	2.2.11.2
Interviews	3.2.4.3.1
Interviews	8.2.5
Interviews	8.8.5.2
Introduction into Interstate Commerce	4.4.6.2.1
Inv. Samples of Filth Exhibits	4.4.10.1.7
Investigation	5.1.1.12
.....	8.8.5
Investigation, Definition	8.1
Investigation Injury & Adverse Reaction	8.4
Investigation of Foodborne Outbreaks	8.3
Investigation Requirements for Serious Adverse Events of CFSAN Regulated Products.....	8.4.5.3
Investigation/Reporting	8.4.4.2
Investigational (Inv)	4.4.10.2.6
Investigational Device Exemption (IDE) Regulation	2.9.2.2
Investigational Drugs.....	5.5.5.6
Investigational New Drug Application (IND).....	2.9.1.2
Investigational Research	
Data Reporting.....	8.7.7
Joint Research Project	8.7.2
Priority	8.7.6
Research Assignment	8.7.1
Research Project Identification Code	8.7.3
Research Project Progressive Report	8.7.4
Termination of Research Project.....	8.7.5
Investigational Samples	4.1.6
Investigations	8.1
Investigations	8.4.1
Investigations Involving the Importation Process....	6.1.3
Investigative Procedures	8.4.2.1
Investigative Procedures	8.4.3.4
Investigator Training and Certification	1.10.2.1
Invoice/Shipping Record FDA 1662	4.4.7.1
.....	Exhibit 4-8
Ionizing Radiation	1.5.4.2.4
Issuance Authority	1.7.1
Issuance of Detention Termination Notice	
FDA 2291	2.7.2.5.2
Items Not Reported In FACTS.....	2.6.4.2.9
Items Not Requiring Receipt.....	5.2.4.2
Items Requiring Receipt	5.2.4.1
Itineraries.....	1.2.9

-J-

- Joint Inspections 3.3.1.2
 Joint Research Projects 8.7.2
Jurisdiction
 Products Manufactured and/or Distributed 5.10.4.3.6
 USDA-FDA Jurisdiction Chart Exhibit 3-1

-K-**-L-**

- LACF / AF Inspections 5.1.1.7.1
 Label 4.4.9
 Label Review 4.5.3.2
 5.1.5.2
 Labeling 6.4.4.1
 5.4.6.6.2
 5.6.4
 4.3.8.3
 4.5.3.2
 Labeling Agreement 5.3.7.2
 Labels & Accompanying Labeling 4.4.9.1
 Labels and Labeling 4.4.9
 Laboratory Registration 5.7.3.1.2
 Laboratory Tests 5.4.6.5.2
 Language Requirements for FDA Documents 1.1
 Law, Regulation and Guidance 1.10.1
 Laws, Codes, Agencies 3.1.2
 Lead Investigator Qualifications 3.2.5.2.8
 Leave 1.3
 Level of Audit Checks 7.3.2.2
 Liability 1.2.2.3
 Liaison 3.2.5.2.1
 Liaison Officers 3.2.4.3.5
 Liaison with Law Enforcement / Intelligence
 Community 8.9.1.2
 Limitations 2.2.1.4
 Line (Line Item) 6.7.27
 Listing of Records 5.3.8.5
 Living Quarters 5.1.1.9
 Locating firms 3.2.16
 Lost or Stolen Credentials, Badge 1.6.3.3
 Lost or Stolen Equipment 1.6.2.2
 Lot 6.7.28
 Lot Restoration & Identification 4.3.2
 Lot Size 4.4.10.3.31
 LACF/AF Food Canning Establishment
 Registration 2.9.5.1

-M-

- Mail Entry 4.4.10.2.7
 Mail Entry Sample 4.1.4.13
 Mail or Parcel Service Shipments 4.4.7.3
 Mail/Personal Baggage 6.2.3.3
 Maintenance of Equipment 1.6.2.1
 Mammography Quality Standards Act of 1992 2.2.3.8
 Man Lifts and Ladders 1.5.4.1
 Manufacture within A Territory 4.4.6.2.4
 Manufacturer 4.4.10.3.26.5
 Manufacturer and Distribution System Follow Up 8.8.5.6
 Manufacturer's Raw Materials 2.6.4.2.3
 Manufacturing Code System 5.4.6.5.3
 Manufacturing Codes 5.10.4.3.10
 4.4.10.3.32
 Manufacturing Process 5.4.6
 Manufacturing Sites 8.8.5.6.1

- Manufacturing/Design Operations 5.10.4.3.9
 Map (ORA) Appendix E
 Marks (Imports) 6.7.29
 Mass media (Press, Radio, and TV) 1.6.1
 Meat and Poultry Products 2.7.2.1.1
 Meat Products and Poultry Products 2.7.1.3.4
 Mechanical, Electrical or Electromechanical
 Devices 8.4.3.1
 Medical Device and Radiological Products 8.4.8.2.2
 Medical Device Inspections 5.2.3.1.5
 Medical Device Notification 7.1.1.8
 Medical Device Notification Order 7.1.1.7
 Medical Device Quality System/Good
 Manufacturing Practices 5.6.2
 Medical Device Recalls 7.2.3
 Medical Device Reporting 2.9.2.7
 Medical Device Safety Alert 7.1.1.9
 Medical Device Samples 4.3.3.1
 8.4.7.1
 Medical Records 8.2.6
 8.3.2.3
 Medical Record Disclosure FDA 461 Exhibit 8-5
 Medicated Feed Mill License (FML) 2.9.4.2
 Medicated Feeds and Type A Articles 5.9.3
 MedWatch Form Exhibit 8-10
 Memorandum of Understanding 3.1.2.1
 Memo for Records Exhibit 5-17
 Mercury and Glass Contamination 5.4.5.5
 Metal Seals 4.5.4.6
 Method of Collection 4.4.10.3.33
 Method of Payment 4.2.8.3
 Method of Shipment 4.5.5.6
Microbiological Concerns 5.4.7.2
 Employee Practices 5.4.7.2.2
 Processing Equipment 5.4.7.2.1
 Microbiological Hazards 1.5.5
 Microbiological Samples 4.3.7.6
 Military Blood Banks 5.7.3.1.3
 Military Personnel & Civilian Employees' Claims 1.2.2.3.1
 Misbranding 4.3.7
 4.4.6.2.2
 Mold Contamination 4.3.7.4.6
 Moldy Food 2.8.2.2
 Monitoring Recalls 7.3
 MOU 3.1.2.1
 Multiple Date Inspections 5.2.2.1
 Multiple FDA 482 5.1.1.11
 Multiple Occupancy Inspections 5.1.1.11
 Mutual Recognition Agreements 3.4.2
 Mycotoxin Sample Chart Smpl Schdl 6

-N-

- Narcotic and Controlled Rx Drugs 4.2.5.3
 Narrative Report 5.10.4
 National Center for Drug Analysis 4.5.5.3.1
 National Center for Health Statistics 3.2.4.6
 National Conference on Interstate Milk Shipments 3.5.2
 National Drug Code 4.4.10.3.34
 National Institute of Drug Abuse 3.2.4.7
 National Institutes of Health (NIH) 3.2.4.8
 National Oceanic and Atmospheric Administration
 & National Marine Fisheries Service 3.2.2.2
National Sample Distributor (NSD) 4.4.10.4
 NSD and Assignments 4.4.10.4.1
 Overriding NSD 4.4.10.4.2
 Other Information 4.4.10.4.3
 Natural Disasters 4.3.5.3

Negative Identification.....	5.3.4.2.3
Net Weight	4.3.8.1
New Animal Drug Application (NADA)	2.9.4.4
New Drug Application (NDA).....	2.9.1.3
Nolle Prosequi (Nol Pros).....	2.2.5.7
Nolo Contendere (Nolo)	2.2.5.8
Non Government Agreements	3.5
Non Government Meetings	1.6.1.1
Non Injury/Illness Complaints.....	8.2.1.2
Non Regulatory	4.4.10.2.8
Non Regulatory Sample	4.1.7.2
Non Reportable Observations.....	5.2.3.3
Non Violative Establishments.....	5.10.4.1
Notice of Detention & Hearing.....	6.2.7.1
Notice of Inspection	5.1.1.3
.....	5.1.2.5
.....	5.2.2
.....	Exhibit 5-1
Carrier.....	4.1.1.2
Manufacturer	4.1.1.2
Request for Records FDA 482c.....	Exhibit 5-10
Sample Collection.....	Exhibit 5-4
Notice of Inspection	4.2.4
.....	4.2.4.1
Notice of Sampling.....	6.2.4.4
Notification of FBI and Us Attorney	5.2.5.4.4
Notifying Receiving Laboratories	4.5.5.5
Nutrition and Nutrition Labeling.....	6.4.3.4
Nutritional and Allergen Labeling	5.4.6.6.3

-O-

Objectionable Conditions & Management's Response.....	5.10.4.3.13
Observations.....	5.2.3.1.4
Obtaining A Voluntary Embargo.....	4.2.9.2
OCI Procedures	8.9.1
OCM / EOC Responsibility.....	8.8.1.1
Office of Criminal Investigation	8.9
.....	1.9.2.4
Office of Enforcement	1.9.2.3
Office of Regional Operations	1.9.2.2
Division of Federal-State Relations (DFSR)	1.9.2.2.3
Division of Field Investigations (HFC-130).....	1.9.2.2.1
Division of Field Science (DFS) (HFC-140)	1.9.2.2.2
Division of Import Operations Policy (DIOP).....	1.9.2.2.4
Prior Notice Center (PNC)	1.9.2.2.4.1
Office of Regulatory Affairs	1.9
ORA Map	Appendix E
Office of Resource Management	1.9.2.1
Official credentials, badge.....	1.6.3
Official Sample	
Private Individual	4.2.6.1
21 CFR 2.10	4.1.4
Official Seals	4.5.4
.....	Exhibit 4-17
Opening Sterile Sampling Containers	4.3.6.1.3
Organization, FDA	
ACRA.....	1.9.1
FDA principles	1.8.1
Office of Regulatory Affairs	1.9
ORA field organization.....	1.9.3
ORA headquarters organization	1.9.2
Organization overview	1.8
Organoleptic Examination	4.3.9
Original Cr & Records To	4.4.10.3.35
Other Acts	2.2.3
Other Government Inspections	3.1.3
.....	5.4.9

Other Inspectional Issues	5.5.5
Outbreak Determination	8.3.4.1
Outbreaks Associated with Salmonella Enteritidis in Eggs	8.3.1.4
Outbreaks Involving Interstate Conveyances	8.3.1.2
Outbreaks on Foreign Flag Vessels	8.3.1.1
Overriding NSD	4.4.10.4.2

-P-

PAC	4.4.10.3.2
PAF	4.4.10.3.2
.....	4.4.10.4
.....	4.4.10.4.3
Packaging and Labeling	5.4.6.6
Packers and Shippers	5.4.12.4
Parcel Post	4.5.5.7
Parcel Service Shipment	4.4.7.3
Partially Labeled Lot	4.4.9.3
Pathogen Growth Factors.....	8.3.4.7
Pathological Examination	4.5.3.3
Patient And/ or Consumer Identification on Records	5.3.8.6

Payment

Cost	4.2.8.2
Costs of Supervision of Relabeling other Action	6.2.7.9
Labor Cost	4.2.8.4
Method	4.2.8.3
Samples under Court Order	4.2.8.1
.....	4.2.8
Shipping Charges.....	4.5.6
Payment for Samples	6.2.4.5
Payment Method	4.4.10.3.36

Per Diem and Subsistence

Documentation	1.2.4
Foreign Travel	1.2.4
Late Charge	1.2.4
Lodging tax	1.2.4

Per Diem Rates

Commencement	1.2.4.1
Eligibility	1.2.4.1
Perishable Goods	4.2.9.1
Perishable Products	8.5.7.6
Permit Number	4.4.10.3.37
Personal Safety Plan	5.2.1.2
Personnel	5.4.2
Pesticide Contamination	2.8.2.3

Pesticide Inspection

Acreage	5.4.12.3
Application	5.4.12.3.1
Applicator	5.4.12.6
Approach	5.4.12.1
Cooperative Activities	5.4.12.2
Drift	5.4.12.3.2
Growers	5.4.12.3
Growing Dates	5.4.12.3
Misuse	5.4.12.3.2
Packer	5.4.12.4
Sampling	5.4.12.7
Shipper	5.4.12.4
Soil Contamination	5.4.12.3.2
Supplier	5.4.12.5

Pesticide Sample

.....	4.4.10.1.8
Sample Schedule Chart	Smpl Schdl 3
Pesticides	5.4.7.1.3
Pesticides, Industrial Chemicals, Aflatoxins, & Toxic Elements	6.4.3.2
Pharmaceuticals and Medical Devices	3.4.2.2

Photo Identification and Submission	5.3.4.2
Photograph Requests	5.3.4.5
Photographs.....	4.5.2.4
Photographs.....	5.3.4
PHS Recommendations Basic Sanitary Practices .	5.1.4.2
Physical Hazards	1.5.3.3
Physical Resistance/Threats/Assaults	5.2.1.2.2
Plant Construction, Design and Maintenance	5.4.3.1
Plant Services	5.4.3.3
Plants and Grounds	5.4.3
Poison Prevention Packaging Act	2.2.3.6
Policy (CR).....	4.4.3
Fed/State Cooperation	3.1.1
Consent Decree.....	2.4.1
Default Decree.....	2.5.1
Compliance Achievement	2.6.1
Port (Point) of Entry	6.7.30
Ports Covered by FDA	6.2.4.1
Ports Not Covered by FDA.....	6.2.4.2
Possible Contamination Source	8.3.4.6
Post Award (GQA)	4.4.10.2.10
Post-inspection Notification Letter.....	5.3.10
Post Seizure & Reconditioning Samples	4.2.8.1
Post Seizure (P.S.) Sample	4.1.4.7
Post Seizure (Ps).....	4.4.10.2.10
Postal Box Information	3.2.15.2
Postal Mail Cover.....	8.9.1.4
Poultry Products Inspection Act	2.7.1.2.3
.....	3.2.1.3
Pre Announcements	5.2.1.1
Pre Inspection Activities	5.2.1
.....	5.2.10.1
.....	5.6.2.1
Precautions	4.5.5.8.7
Precautions during inspections	
Aseptic Technique	5.1.4
Microbiological Contamination	5.1.4
Safety Equipment	5.1.4
Sterility.....	5.1.4
Precautions for Non Clinical Laboratory	
Inspections.....	1.5.5.2.3
Preliminary Investigation.....	8.5.4
Preliminary or Permanent Injunction	2.2.8.5
Premarket Approval	2.9.2.4
Premarket Notification Section 510(K)	2.9.2.3
Premises Used for Living Quarters	5.1.1.9
Preparation for EI	
Complaint	5.2.1
Compliance Program	5.2.1
Guidance Documents	5.2.1
Guides	5.2.1
Postponement	5.2.1.1.3
Pre-Announcement.....	5.2.1.1
Pre-Inspectional Activities.....	5.2.1
Recall follow-up	5.2.1.1.2
Preparation and References	5.4.1.1
Preparation and References	5.5.1.1
Preparation of Collection Report.....	4.4.10.3
Preparation of Detention Notice	2.7.2.3.1
Preparation of FDA 484	4.2.5.5
Preparation of Form FDA 483.....	5.2.3.1
Preparation of Page 1 (FDA 2289).....	2.7.2.3.2
Preparation of Page 2 - 5 (FDA 2289)	2.7.2.3.3
Preparing & Maintaining Digital Photographs	
Evidence	5.3.4.3
For Insertion into Turbo EIR	5.3.4.4
Prescription Drugs	4.2.5.4
Preservation Liquids	4.5.3.1.4
Prints.....	5.3.4.2.1
Prior Notice Center (PNC)	1.9.2.2.6
.....	6.2.3.5
Prior Notice of Importation of Food and Animal Feed	6.2.3.5
Prior Notice Process.....	6.2.3.5.6
Prior Notice Reception	6.2.3.5.1
Prior Notice Submission	6.2.3.5.4
Private Individuals	4.2.6.1
Privately-Owned Conveyance	4.4.7.4
Privately Owned Vehicle (POV)	
Official Business.....	1.2.3
Reimbursement for mileage	1.2.3
Procedure after Hearing "Notice of Release"	6.2.7.7
Procedure after Hearing "Refusal of Admission"	6.2.7.8
Procedure when Conditions of Authorization	
Have Been Fulfilled	6.2.7.5
Have Not Been Fulfilled	6.2.7.6
Procedure when No Violation Is Found	6.2.6
Procedure when Products Can't be Sampled/ Examined	6.2.5
Procedure When Violation Is Found.....	6.2.7
Procedures for Fumigation	4.5.3.1.2
Procedures When Threatened or Assaulted.....	5.2.5.4.3
Processing Equipment	5.4.7.2.1
Problem Area Flag (PAF)	4.4.10.3.2
Product Code	4.4.10.3.38
Product Description	4.4.10.3.39
Product Disposition	8.5.7
Product/Establishment Surveillance Report	Exhibit 8-13
Product Label	4.4.10.3.40
Product Name	4.4.10.3.41
Products Excluded From Prior Notice	6.2.3.5.3
Products Imported under Section 801(D)(3) of the FD&C Act	
.....	5.1.1.14
Inspectional Preparation	5.1.1.14.2
Requirements for Bioterrorism Act	5.1.1.14.1
Products Requiring Prior Notice	6.2.3.5.2
Products Susceptible to Contamination with Pathogenic Microorganisms	4.3.7.7
Professional Personal Contacts	1.6.5.1.6
Professional Reporting System for Vaccine	
Adverse Reactions	8.4.4.1
Professional Stature	1.6.5.1
Profile COMSTAT	Exhibit 5-13
Program Provisions	1.5.1.4.1
Promotion and Advertising	5.4.8.1
Promotion and Advertising	5.5.3
Prosecution	
District Follow-Up	2.2.7.4
Felony	2.2.7
Grand Jury Proceeding	2.2.7.3
Information	2.2.7.2
Misdemeanor	2.2.7
Section 305 Notice	2.2.7.1
Protect the Identity of the Source	5.2.9.2
Protecting the Official Seal	4.5.4.4
Protection of Privileged Information	5.2.7.1
Protective and Preventive Measures	1.5.5.2.1
Protective Clothing	1.5.1.3
Protective Equipment	1.5.1
Public Health Service Act (PHS)	2.2.3.7
Public Relations, Ethics & Conduct	1.6
Publications	1.10.2.6

-Q-

Qualifications for Credentials.....	1.6.3.2
Quality Audit	5.6.2.2
Quality Control.....	5.4.6.5

Quantity Collected.....	6.5.5.4
Quantity of Contents	5.4.6.6.1
 -R-	
Radiation Control for Health and Safety Act.....	5.1.1.10
Radiation Reporting	2.9.2.8
Radioactive Product Sampling	1.5.3.5
Rail Safety.....	1.5.3.3.1
Random Sampling	4.3.7.2
Raw Materials	5.4.4
Re-Inspection Assignment Generation	5.4.11.1.2
Re-Inspection Conducted under Section 743 of the FD&C Act	5.4.11
Re-Inspection Reporting	5.4.11.1.3
	Exhibit 5-18
 Recall Activities	
<i>Definition</i>	
Depth of Recall	7.1.1.5
Human Tissue for Transplantation	7.2.5
Level of Audit Check	7.3.2.2
Medical Device Notification	7.1.1.7
Medical Device Safety Alert	7.1.1.9
Notification	7.1.1.7
Notification Order	7.1.1.8
Recall Audit Check.....	7.3.2.1
Recall Classification.....	7.1.1.2
Recall Completed.....	7.3.3.1
Recall Number	7.1.1.6
Recall Terminated.....	7.3.3.1
Recall Type	7.1.1.3
Sub-Account Check	7.3.2.3
<i>Inspection</i>	
Market withdrawal	7.2
Procedure	7.2.1
Recall Decision Follow-Up	7.2.1.1
<i>Recall</i>	
Alert.....	7.2.7
Close-out Inspection	7.3.3.2
Conducting Audit Checks.....	7.3.2.4
Food Products.....	7.2.2
Ineffective Recall.....	7.3.2.6
Interstate Milk Shippers.....	7.2.2.1
Medical Device.....	7.2.3
Monitoring	7.3.1
Procedure	7.2.3.1
Recall Number	7.2.8
Recall Recommendation.....	7.2.8
Recalls of Human Drug Products	7.2.4.1
	Exhibit 7-1
Recommending Official.....	7.2.8.10
Reporting Audit Check.....	7.3.2.5
Sampling	7.2.6
Special Situations	7.4.1
Veterinary Drug Products.....	7.2.4.2
Recall Audit Check Report.....	Exhibit 7-2
Recall Number	4.4.10.3.43
Recall Procedure	5.4.8.2
Recall Procedures.....	5.10.4.3.12
Recall Strategy.....	7.1.1.4
Recall Terminated / Recall Completed.....	7.3.3
Recalling Firm/Manufacturer	7.2.8.3
Recalls	7.1
	4.3.5.2
Recalls of Human Drug Products.....	7.2.4.1
Recalls of Veterinary Drug Products	7.2.4.2
Reconciliation Examination Guidance Part A.....	5.4.1.4.3
Reconciliation Examination Guidance Part B.....	5.4.1.4.4
Reconciliation Examinations	5.4.1.4.2

Reconditioned	4.4.10.1.9
2.3.1.1
2.6.3
8.5.7.3
Reconditioning and Destruction.....	2.3
Reconditioning Devices	8.5.7.10
Reconditioning for Compliance.....	2.2.6.7
Reconditioning Hermetically Sealed Cans.....	8.5.7.9
Reconditioning Plastic, Paper, Cardboard, Cloth & Similar Containers.....	8.5.7.7
Reconditioning Sampling.....	4.1.4.11
Reconditioning Screw Top, Crimped Cap, & Similar Containers.....	8.5.7.8
Record Requests.....	8.8.6
 Record Review	
Electronic Filing.....	6.3.1
Entry Review	6.3.1
Regulatory Authority	6.1.1
Receipt	5.1.1.5
Receipt for Sample	4.1.1.3
4.2.5
4.2.5.2
Exhibit 4-5
Receipt in Interstate Commerce.....	4.4.6.2.3
Receipt Issued.....	4.4.10.3.44
Receipt Type	4.4.10.3.45
Receipts	5.1.1.5
Record Time Screen	6.5.5.9
Recording Complaints/Follow Ups	8.2.8
Recordings	5.3.5
Records	4.5.2.5
Records	5.6.2.3
Records Access under BT Authority.....	5.4.1.3
Records Accompanying Literature and Exhibits	4.5.2.5
Records Obtained	5.3.8
Redelivery Bond (AKA Entry Bond).....	6.7.31
Refrigerated Item.....	4.5.3.6
Refusal after Serving Warrant	5.2.5.3
Refusal of Entry	5.2.5.1
Refusal to Permit Access to or Copying of Records.....	5.2.5.2
Refusal to Permit Access to Records in Possession of Common Carriers	4.4.7.2.1
Refusal to Permit Sampling	4.2.3
Refusal to Sign the Affidavit	4.4.8.2
Refusals	5.10.4.3.14
4.2.4.2
Refusals of Requested Information	5.2.7.2
Registration and Listing	2.9.1.1
2.9.3.1
2.9.4.1
 Registration, Listing and Licensing5.7.3	
Approval of Biological Devices	5.7.3.4
Biologic License	5.7.3.3
HCT/Ps	5.7.3.1.1
Laboratories	5.7.3.1.2
Military Blood Banks.....	5.7.3.1.3
MOUs.....	5.7.3.2
Registration and Listing	5.7.3.1
Regulations	3.1.2
Regulated Industry Notification.....	5.4.11
Regulations	1.10.1
Regulations, Guidelines, Recommendations	5.7.2.6
Regulatory	4.4.10.2.11
 Regulatory	
702(a).....	2.2.1
Decharacterization	2.8.3
Definition	2.2.5
Citation	2.2.5.2

Civil Number	2.2.5.1
Complaint for Forfeiture	2.2.5.5
Criminal Number	2.2.5.3
Denaturing	2.3.1.3
Destruction	2.3.1.2
Device	2.7.1.3.1
Egg Products	2.7.1.3.5
FDC and INJ Numbers	2.2.5.4
Home District	2.2.5.6
Meat Products	2.7.1.3.4
Nolle Prosequi	2.2.5.7
Nolo Contendere	2.2.5.8
Poultry Products	2.7.1.3.5
Reconstruction	2.3.1.1
Seizing District	2.2.5.9
Subpoena Duces Tecum	2.2.5.10
Supervising District	2.2.5.11
Disasters	2.3.2
Regulatory Filing	
Abbreviated New Animal Drug Application (ANADA)	2.9.4.3
Abbreviated New Drug Application (ANDA)	2.9.1.4
Acidified Foods	2.9.5.1
Biologic License	2.9.3.2
Blood Bank Registration and Listing	2.9.3.1
Classification of Devices	2.9.2.5
Color Certification Program	2.9.5.4
Device Registration and Listing	2.9.2.1
Drug Registration and Listing	2.9.1.1
FCE Process Filing of LACF/AF Processors	2.9.5.2
Food Canning Establishment (FCE) Registration	2.9.5.1
Infant Formula	2.9.5.5
Interstate Certified Shellfish Shippers	2.9.5.6
Interstate Milk Shippers	2.9.5.7
Investigational Device Exemption (IDE) Regulation	2.9.2.2
Investigational New Drug Application (IND)	2.9.1.2
LACF	2.9.5.1
Low Acid Canned Food	2.9.5.1
Medical Device Reporting	2.9.2.7
Medicated Feed Mill License (FML)	2.9.4.2
New Animal Drug Application (NADA)	2.9.4.4
New Drug Application (NDA)	2.9.1.3
Premarket Approval	2.9.2.4
Premarket Notification - Section 510(k)	2.9.2.3
Radiation Reporting	2.9.2.8
Requests for GMP Exemption and Variances	2.9.2.6
Veterinary Medicine Registration and Listing	2.9.4.1
Voluntary Filing of Cosmetic Product Ingredient	2.9.5.3
Composition Statement Voluntary Registration of Cosmetic Product Establishment	2.9.5.3
Regulatory Notes	
Electronic Notes	2.1.2
Format for regulatory notes	2.1.4
Regulatory entries	2.1.3
Regulatory note characteristics	2.1.2
Retention of regulatory notes	2.1.5
Uses of regulatory notes	2.1.1
Regulatory References and the General Public 1.10.2.7	
Law	1.10.1
Manuals	1.10.2.5
Regulatory Submissions	2.9
Relabeling	2.4.2
Relabeling	8.5.7.4
Related Samples	4.4.10.3.46
Release of Goods	2.4.7
Release of Information	8.8.4
Removal of Detention Tags	2.7.2.5.1
Repairs	1.6.2.1.1
Repeated Filer Misdeclaration	6.1.3.7.1
Report of Analysis	
704(d) Sample	4.4.10.3.64
Reportable Observations	5.2.2.3
Adulteration Observations	5.2.2.3.2.1
Other Observations	5.2.2.3.2.2
Reporting Contacts	8.8.1
Reporting Criteria	5.10.2.1.1
Reporting Investigations Involving the Importation Process	6.1.3.8
Reporting Sample Collections	4.4.10
Reports	1.10.2.5
Reports of Criminal Activity	8.9.1.1
Reports of Observations	
5.2.3	
Representatives Invited by Firm to View Inspection	5.1.4.3
Request for Authorization to Relabel/Perform Other Acts	6.2.7.3
Request for Notice of Inspection	4.2.4.4
Request for Sample Collection	5.3.9
Requesting/Working with Computerized Complaint & Failure Data	5.3.8.4
Requesting Computerized Data	5.3.8.4.2
Requests by the Public, Including Trade	1.4.2
Requests for GMP Exemption and Variances	2.9.2.6
Requests for Records Under Section 703 of the FD&C Act	5.1.1.7.2
Resealing Conveyances	4.3.4.3
Research Assignments	8.7.1
Research Project Identification Code	8.7.3
Research Project Progress Reports	8.7.4
Reserve, 702(b)	
FACTS Documentation	4.4.10.3.63
Imports	6.5.1
Portion	4.3.3.3
Requirement	4.3.5.1
Resources for FDA Regulated Businesses	5.2.2
Respiratory Protection	1.5.1.4
Response to "Notice of Detention & Hearing"	6.2.7.2
Responsible Firm Type	4.4.10.3.47
Responsibility & Coordination	8.5.2
Responsible Individuals	5.3.6
Restoring Lot(s) Sampled	5.7.4
Retail Stores	4.3.2.1
Retention of Regulatory Notes	8.8.5.5
Retorts	2.1.5
Reverse of Tag	1.5.4.2.1
Review of Records	2.7.2.4.3
Reworking	6.3
Riots	2.4.3
Rodent Contamination	8.5.5.5
4.3.7.4.2	
Collecting Exhibits and/or Subsamples	4.3.7.4.2.2
Examination/Documentation of Contamination	4.3.7.4.2.1
Summary of Sample for Evidence	4.3.7.4.2.3
Rodent or Bird Contaminated Foods	4.3.7.4.2.1
Rodents	2.8.2.1
Routes of Contamination	5.4.7.1.2
Routine Biosecurity Procedures for Visits to Facilities	5.4.7.1.1
Housing/Transporting Domestic or Wild Animals	5.2.1.0
Routine Requests for Information	3.2.4.3.3
Routing of collection Report	4.4.10.5
Routing of FDA 484	4.2.5.6
Routing of Samples	4.5.5.2

Safety	1.5
Automobile	1.5.2
Animal Origin Products	1.5.5.1
Asphyxiation Hazards	1.5.3.4
Bacteriological Problems	1.5.5.3
Carbadox Sampling	1.5.3.7
Chemical Hazards	1.5.3.6
Electrical Hazards	1.5.3.2
Eye Protection	1.5.1.1
Factory Inspection	1.5.4.2
Hantavirus Associated Diseases	1.5.5.4
Hearing Protection	1.5.1.2
Injury Reports	1.5.7
Inspections	1.5.4
Man Lifts and Ladders	1.5.4.1
Microbiological Hazards	1.5.5
Physical Hazards	1.5.3.3
Protective Clothing	1.5.1.3
Protective Equipment	1.5.1
Radioactive Product Sampling	1.5.3.5
Respiratory Protection	1.5.1.4
Ethylene Oxide	1.5.1.4.2
Fumigation	1.5.1.4.2
Ozone	1.5.1.4.2
Respirator	1.5.1.4.1
Respiratory Protection Program	1.5.1.4.1
Medical Evaluation	1.5.1.4.1
Personal Safety	1.5
Sample Fumigation and Preservation	1.5.3.1
Sampling	1.5.3
Viral and Other Biological Products	1.5.5.2
Safety Precautions	5.2.5.4.2
Sales Records	4.4.7.1
Salmonella Sample Chart	Smpl Schdl 1
Sample	
Reserve, 702(b), Labeling, Documentary Evidence, Witness	4.1.2
702(b) Portion	4.3.3.3
702(b) Portion Collected	4.4.10.3.63
702(b) Requirement	4.3.5.1
704(d) Sample	4.4.10.3.64
Abnormal Containers	4.3.7.5
Accompanying Literature	4.5.2.5
Aseptic Sample	
Controls	4.3.6.5
Dried Powders	4.3.6.2
Handling	4.3.6.4
Procedures	4.3.6.1
Water Samples	4.3.6.3
Water Samples	4.3.6
Authority	
Examination	4.1.1.1
Investigation	4.1.1.1
Notice of Inspection	4.1.1.1
Bill of Lading	4.4.7.2.3
Borrowed Samples	4.5.2.2
Bulk Container Labeling	4.4.9.2
Complaint	4.4.6.3
Complaints	4.3.5.1
Contamination with Pathogenic Microorganisms	4.3.7.7
Definition	
301(k) Sample	4.1.4.4
Additional Sample	4.1.4.10
Audit/Certification Sample	4.1.7.1
Dealer	4.2.1
Documentary Sample	4.1.4.2
Domestic Import Sample	4.1.4.8
Food standard Sample	4.1.5
Import Sample	4.1.4.9
Induced Sample	4.1.4.5
In-Transit Sample	4.1.4.3
Investigational Sample	4.1.6
Mail Entry Sample	4.1.4.13
Non-Regulatory Sample	4.1.6.2
Official Sample	4.1.4.1
Post Seizure (P.S.) Sample	4.1.4.7
Undercover Buy	4.1.4.6
Disasters	4.3.5.3
Documentation	4.4.2
Documentation Authority	4.4.1
Documentation of Evidence	4.4.6
Documentation of Interstate Shipment	4.4.7
Documentation Policy	4.4.3
Documentation Procedure	4.4.4
Dry Ice	4.5.3.5
Sample Accountability	4.1.3
Sample Basis	4.4.10.3.48
Sample Class	4.4.10.3.49
Sample Collection	
Sample Collection	7.2.6
.....	8.2.7
.....	8.3.3.1
.....	8.4.7
Sample Collection During Inspection	5.6.1.2
Sample Collection Reports	6.5.5
Sample Collections	5.4.12.7
Sample Cost	4.4.10.3.50
Sample Criteria	4.3.7.4
Sample Delivered Date	4.4.10.3.51
Sample Delivered To	4.4.10.3.52
Sample Description	4.4.10.3.53
Sample Flags	4.4.10.3.54
Sample Fumigation and Preservation	1.5.3.1
Sample Handling	4.3.6.4
.....	4.5.3
.....	8.3.3.3
Sample Number	4.4.10.3.55
Sample Origin	4.4.10.3.56
Sample Package Identification and FDA 525	4.5.5.1
Sample Records Identification	4.4.5
Sample Schedule	4.3.3
Sample Sent To	4.4.10.3.57
National Sample Distributor (NSD)	4.4.10.4
Sample Shipment	4.5.5
Sample Shipment to Outside Agencies	4.5.5.4
Sample Size	4.3.3
Sample Size	8.3.3.2
Sample Type	4.4.10.3.58
Sampled In Transit	4.4.10.1.10
Samples	6.4.4.3
Samples Collected	5.10.4.3.17
Samples for Pathological Examination	4.5.3.3
Samples for Viral Analysis	4.3.7.8
Samples to Administration Laboratories	4.5.5.3
Sampling	
Preparation, Handling, Shipping	4.5
National Sample Distributor (NSD)	4.4.10.4
Receipt	5.2.4
.....	5.2.4.1
.....	5.2.4.2
.....	3.2.5.2.10
.....	2.7.3
.....	1.5.3
.....	8.8.5.3
Sampling District	4.4.10.3.59
Sampling Dried Powders	4.3.6.2
Bag and Poly-Liner Stitched Together Across Top Seam	4.3.6.2.1
Bag Stitched Across Top and Poly-Liner Twist	

Closed and Sealed with "Twist" Device - Wire, Plastic, Etc.....	4.3.6.2.2
Bags with Filling Spouts.....	4.3.6.2.3
Sampling from Government Agencies	4.2.7
Sampling (Imports)	
702(b) Reserve.....	6.5.1
Additional Sample.....	6.5.1
Collection Report	6.5.5
FDA Coverage	6.2.4.1
FDA Coverage.....	6.2.4.2
May Proceed Notice	6.2.4.3
Notice of FDA Action	6.2.4.4
Notice of Sampling	6.2.4.1
Official Seal	6.5.1
On-screen Review	6.2.4.3
Payment	6.5.1
Payment for Sample	6.2.4.5
Point of Destination.....	6.2.4.2
Point of Entry	6.2.4.2
Procedure	6.5.2
Technique	6.5.3
Sampling Lab or Charges	4.2.8.4
Sampling Procedures	8.3.3
Sampling Plan	
Aflatoxin	Smpl Schdl 6
Allergen Samples Schedule.....	Smpl Schdl 13
Dates and date material.....	Smpl Schdl 8
Canned and Acidified Food	Smpl Schdl 2
Canned Fruit.....	Smpl Schdl 7
Color	Smpl Schdl 9
Drug Sampling Schedules	Smpl Schdl 10
Imported White Fish.....	Smpl Schdl 5
Imports – Coffee	Smpl Schdl 8
Medicated Animal Feed	Smpl Schdl 12
Pesticides	Smpl Schdl 3
Salmonella.....	Smpl Schdl 1
Veterinary Products	Smpl Schdl 11
Wheat Carload.....	Smpl Schdl 4
Sanitary Practices	5.1.4.2
Sanitation	5.4.7
Sanitation of Machinery	5.4.5.2
Sanitation Practices	5.4.5.8
Science and Education Administration/USDA.....	3.2.1.9
Scope of Investigation.....	3.2.5.2.5
Seafood, Office of	4.5.5.3.3
Seal	
Broken Seal	4.5.4.5
FDA 415a	4.5.4
Metal Seals.....	4.5.4.6
Method.....	4.5.4.3
Non-samples	4.5.4.7
Official Seal	4.5.4
Preparation	4.5.4.1
Protection	4.5.4.4
Temporary Seal	4.5.4.5
Application	4.5.4.2
Search Warrant.....	5.1.1.13.4
Secret Service.....	3.2.5.2
Section 305 Notice	2.2.7.1
Section 322 of the Public Health Security & Bioterrorism Preparedness and response Act 2002.....	5.1.1.14
Section 702(e)(5) of the FD&C Act	5.1.1.13
Section 801(d)(3) of the FD & C Act	5.1.1.14
Security	8.8.5.6.3
Segregation.....	2.4.4
.....	8.5.7.1
Seizing District	2.2.5.9
Seizure.....	4.4.6.1
.....	5.1.1.13
Seizure.....	2.2.6
Consent Decree	2.4.1
Default Decree	2.5.1
Destruction	2.3
Destruction	2.4.5
Disposition of Rejects.....	2.4.6
First Amendment Issues	2.3
Reconditioning	2.3
Relabeling	2.4.2
Release of Goods	2.4.7
Reworking	2.4.3
Segregation.....	2.4.4
Seizure	2.2.6
Selected Amendments to the FD&C Act.....	2.2.2
Selective Sampling.....	4.3.7.3
Bird Contamination.....	4.3.7.4.4
Chemical	4.3.7.4.5
Criteria	4.3.7.4
Insect Contamination	4.3.7.4.3
Mold	4.3.7.4.6
Rodent Contamination	4.3.7.4.2
Seriously Ill Individuals	4.2.6.2
Sharing Non Public Info with Government Officials	1.4.3
Shipment	4.5.5.8.1
Shipment by Privately Owned Conveyance.....	4.4.7.4
Shipment of Hazardous or Toxic Items	4.5.5.8.6
Shipper	4.4.10.3.26.6
Shipping	4.5.5
Certified Mail	4.5.5.9
Common Carrier.....	4.5.5.8
FDA Laboratories	4.5.5.3
First Class Mail.....	4.5.5.9
Method	4.5.5.6
Notification	4.5.5.5
Overriding NSD	4.4.10.4.2
Outside agencies	4.5.5.4
Package Identification and FDA 525	4.5.5.1
Parcel Post.....	4.5.5.7
Payment.....	4.5.6
Routing.....	4.5.5.2
.....	4.5.5
Shipping Frozen Item	4.5.3.5.1
Signature	5.10.4.3.21
Signature Policy	5.2.3.1.2
Signing Non-FDA Documents	5.1.2.3
Situational Plan	5.2.1.4
Secret Service.....	3.2.5.2
Conducting a Special Investigation	3.2.5.2.9
Small Items.....	4.5.3.4
Small Business Enforcement Fairness Act	1.6.5.1
.....	5.2.3.1.1
Small Manufacturers	5.6.7
Small Sample Items	4.5.3.4
Sources of Information	1.10.2
Special Information Section	5.4.10.2.3
Special Instructions	6.4.4.4
Special Recall Situations	7.4
Special Regulatory by Product Category	1.10.3
Special Safety Precautions.....	5.4.1.4.5
Special Sampling Situations	4.3.5
Special Situation Precautions.....	5.2.10.3
Signing Non FDA Documents.....	5.1.2.3
Situational Plan	5.2.1.4
Split Sample	4.4.10.1.11
Split Samples	4.5.5.3.2
Standard Narrative Report.....	5.10.4.3.1
State Operational Authority	3.3
.....	3.3.1
.....	3.3.3

State Contacts	3.3.3
State Memoranda of Understanding	3.3.2
State's Operational Authorities.....	3.3.1
Statutory Authority	5.1.1
Statutory Authority	2.2
702(b)	2.2.1
Amendments to FD&C Act.....	2.2.2
Codes of Federal Regulations	2.2.4
Device Inspection	2.2.1.3
Drug.....	2.2.1
Enter & Inspect	2.2.1.1
Examination.....	2.2.1.4
Food Inspection	2.2.1.2
Investigation	2.2.1
Limitation	2.2.1.4
Other Acts.....	2.2.3
Record	2.2.1
Sampling.....	2.2.1
Sterile Devices	5.6.3
Sterilized Equipment	4.3.6.1.1
Storage	5.4.7.3
Storage Requirements	5.2.9.2.2
Storage Requirements	4.4.10.3.62
Stripping (Of Containers)	6.7.32
Sub Account Checks.....	7.3.2.3
Submitted To.....	6.5.5.3
Subpoena.....	1.4.1
Subpoena Duces Tecum.....	2.2.5.10
Subsamples	4.5.2.1
Substitution	6.1.3.5
Supervising District	2.2.5.11
Supervision of Reconditioning, Denaturing, or Destruction.....	2.7.4
Supervisory Charges	6.7.34
Supporting Evidence and Relevance	5.10.4.3.13.1
Surveillance.....	8.6
FDA 457 Preparation	8.6.2
FDA 457 Routing	8.6.3
Procedures	8.6.1
Survey Sample.....	4.4.10.1.12
Symptoms Determination.....	8.3.5.2

-T-

Tampering.....	4.3.5.1
Tare Determination	4.3.8.1.1
Taxi	1.2.1.3
Team Inspections.....	5.1.2.5
Team Leader Responsibilities.....	5.1.2.5.2
Team Member Responsibilities.....	5.1.2.5.1
Technical Assistance	5.1.2.4
.....	5.6.1.1
Technical Assistance	5.7.2.7
Telephone Communications	
Calling Cards	1.2.8
Calls to Residence	1.2.8
Commercial	1.2.8
Temporary Restraining Order (TRO)	2.2.8.1
Termination of Detention.....	2.7.2.5
Termination of Research Projects.....	8.7.5
Testimony	2.2.11
Interviewing Persons under Arrest.....	2.2.11.2
Miranda Warning	2.2.11.2
Preparation	2.2.11.1
Witness.....	2.2.11
Testing Laboratories	5.7.5
Tissue Residues	5.9.5
Tobacco Inspections	5.8.1

Tobacco Products	
Center of Tobacco.....	4.5.5.3.8
Injury/Adverse Reaction Reports.....	8.4.8.2.8
Inspections	5.8.1
Product Samples.....	8.4.7.6
Regulations	2.2.3.9
.....	2.2.3.10
.....	5.8.4
Technical Assistance	5.8.2
Tornadoes	8.5.5.4
Tort Claims	1.2.2.3.2
Tracebacks of Foods Implicated in Outbreaks	8.3.5.5
Transportation Records for Common Carrier	
Shipments	4.4.7.2
Travel	1.2
Transportation Records.....	4.4.7.2
Treasury Department	3.2.8
Trial for Injunction.....	2.2.8.4
Trucks.....	1.5.3.3.4
Turbo EIR	5.2.3
Type Identification	4.4.10.2
Types of Inspections	5.6.1.3

-U-

Undercover Buy.....	4.3.5.5
Unlabeled Lot	4.4.9.3
Use of GOV between Residence & Place of Employment	1.2.2.4
U.S. Attorney	3.2.6.1
U.S. Department of Agriculture (USDA)	3.2.1
U.S. Customs and Border Protection	3.2.5.1
U.S. Customs and Border Protection	6.2.3.6.1
U.S. Department of Commerce	3.2.2
U.S. District Court.....	2.2.6.4
U.S. Marshal Service	3.2.6.4
U.S. Nuclear Regulatory Commission	3.2.14
U.S. Patent and Trademark Office	3.2.2.3
U.S. Postal Service	3.2.15
Change of Address Information.....	3.2.15.1
Postal Box Information	3.2.15.2
Authority	3.2.15.3
Under State Embargo	4.4.10.1.13
Undercover Buy.....	4.1.4.6
Undercover Buy.....	4.3.5.5
United States Pharmacopoeia Convention (USP)	3.5.4
Unlabeled or Partially Labeled Lot.....	4.4.9.3
US Army Corps of Engineers	3.2.3.2
US Army Medical Research & Development Command.....	3.2.3.3
USDA Acts	3.2.1.3
USDA Complaints	3.2.1.2
USDA-FDA Jurisdiction Chart	Exhibit 3-1

Use of Evidence Gathered in the Course of a Criminal Investigation	5.2.2.6
Use of Evidence Voluntarily Provided to the Agency	5.2.2.7
Use of Tag	2.7.2.4.4
Uses of Regulatory Notes	2.1.1
Utinsels.....	5.4.5.4
UV Lamps.....	5.4.5.6

-V-

Vaccine Adverse Event Report System (VAERS)	Exhibit 8-11
Valid Sample	4.1.2
Vehicles at Receivers	5.4.7.3.2
Vehicles at Shippers	5.4.7.3.3
Veterinary Devices	5.9.6

Veterinary Drug Activities.....	5.9.2
Veterinary Medicine	5.9
Veterinary Products	8.4.8.2.4
Veterinary Products Complaints/Adverse Reactions.....	8.4.6
Vet Med Inspection	
Animal Grooming Aid.....	5.9.7
Authority	5.9.2
BSE	5.9.4
Medicated Feed.....	5.9.3
References	5.9.1
Regulatory Information	5.9.2
Tissue Residue.....	5.9.5
Type A Articles	5.9.3
Veterinary Device	5.9.6
Violative Establishments	5.10.4.2
Violative Inspections	5.4.10.3
Violative Products	2.6.4.2.1
Viral and Other Biological Products	1.5.5.2
Viral Hepatitis & Human Immunodeficiency Virus ..	1.5.5.2.2
Viscous Liquids	4.3.8.2.2
Volume Determination	4.3.8.2
Volume of Product in Commerce	7.2.8.5

Voluntary Actions

Investigator Responsibility	2.6.1
Compliance Achievement Reporting.....	2.6.4.2
DEA Controlled Drugs	2.6.2.1
Destruction	2.6.2
Disaster	2.6.1
Documenting	2.6.4.1
Reconditioning.....	2.6.3
Voluntary Corrective Action	2.6.1
Voluntary Destruction	2.6.1
Voluntary Corrections	5.10.4.3.18

Voluntary Embargo

Denaturing	4.2.9.2
Destruction	4.2.9.2
Inducing	4.2.9.2
Obtaining	4.2.9.2
Perishable Goods	4.2.9.1
State Embargo.....	4.2.9.2
.....	4.2.9

-W-

Warehouse Entry (WE)	6.7.35
Warrant for Inspection.....	5.1.1.9
Warrant Requirement.....	5.2.2.4
Waste Disposal	5.4.3.2
Way Bill.....	4.4.7.2.5
Wheat Sample Chart.....	Smpl Schdl 4
Whitefish, Import sample Chart.....	Smpl Schdl 5
Wireless Devices	1.5.6
Whole-Bag Screening	4.3.9.1
Working with A Grand Jury	5.2.2.9
Wrecks	8.5.5.6
Written Demand for Records.....	5.1.1.6
FDA 482a	Exhibit 5-2
Written Notice	5.1.1.3
Written Observations	5.1.1.4
Written Requests for Information	5.1.1.7
LACF / AF Inspections	5.1.1.7.1
Requests for Records Under Section 703 of the FD&C Act.....	5.1.1.7.2
Written Request for Information	5.4.1.2.2
FDA 482b	Exhibit 5-3
Written Request for Records.....	4.4.7.2.2

-X-

X-ray Equipment	5.1.1.10
Field Compliance Testing.....	2.6.4.2.9
Registration & Listing	2.9.2.1

-Y-

Youth and Families (ACYF).....	3.2.4.2
--------------------------------	---------

-Z-