

INDEX

301(K) Sample	4.4.10.1.1	Aflatoxin Sample Schedule.....	Smpl Schdl 6
301(K) Samples	4.1.4.4	After the Detention	2.7.2.2.2
702(b) Portion Collected	4.4.10.3.63	After the fact travel order	1.2
702(b) Requirement	4.3.3.2	Agency for Toxic Substances and Disease Registry	3.2.12
703 Record Requests	4.4.7.2.2	Agreements	3.1.2.1
.....	5.1.1.7.2	Agricultural Marketing Service	3.2.1.5
704(d) Sample.....	4.4.10.3.64	Air Travel.....	1.2.1.1
		Alcohol and Tobacco Tax & Trade Bureau (TTB).....	3.2.8.1
		Allergen Samples.....	8.4.7.5
		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	5.11.4.3.20
		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.....	4.1.4.12
		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

-A-

-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
 Biologicals 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 5.5.6
 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
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

-C-

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
 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 5.5.6
 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	Complaints, Counterfeiting/Tampering, Foodborne Disease, Injury Illness	4.3.5.1
Class III	2.9.2.5.3	Compliance Achievement Reporting	2.6.4.2
Class III Recall	7.1.1.2.3	Exhibit 5-15
Classification of Devices	2.9.2.5	Compliance Achievement Reporting System (CARS)	5.11.2.1
Clinical Investigators and/ or Clinical Pharmacologists.....	5.5.5.7	Computerized Complaint and Failure Data.....	5.3.8.4.1
Closeout Inspection.....	7.3.3.2	COMSTAT	5.11.2
Clothing.....	5.1.4.1	Exhibit 5-14
Clothing	1.5.3.3.3	Concurrent Administrative, Civil, and Criminal Actions.....	5.2.2.8
Code	7.2.8.2	Condition	5.4.4.2
Codes	3.1.2	Conducting Regulatory Inspections when the 4.1.4.6	
Code of Federal Regulations (CFR)	2.2.4	Agency is Contemplating/Taking, Criminal Action ..	5.2.2.4
Coffee, Import Exam Sample Chart	Smpl Schdl 8	Conducting Inspections for which Fees can be Assessed	5.4.11.1
Collecting the 702(B) Portion	4.3.3.3	Conference for Food Protection (CFP).....	3.5.5
Collecting Water Samples.....	4.3.6.3	Confidential Informants.....	4.4.8.3
Collection Date	6.5.5.1	Confidentiality	5.1.4.3
.....	4.4.10.3.5	Confiscation	5.1.1.13
Collection of Environmental and Product Samples for Food Susceptible to Contamination with Pathogenic Microorganisms	4.3.7.7	Consensual Electronic Surveillance	8.9.1.3
Collection Method	4.4.10.3.6	Consent Decree	2.4
Collection PACs	4.4.10.3.7	Consent Decree of Injunction	2.2.8.3
Collection Reason	4.4.10.3.8	Consumer Complaint Number	4.4.10.3.13
Collection Records	4.4.3.1	Consumer Complaints	5.2.8
Collection Remarks.....	4.4.10.3.9	8.4.7.4
Collection of Samples for Mold	4.3.7.6.1	Consumer Product Safety Commission.....	3.2.10
Collection Technique.....	4.3	Consumption Entry (CE).....	6.7.4
Collector.....	4.4.10.3.10	Contacting FDA Employees.....	1.10.2.2
Collector's Id on Package/Document.....	4.4.10.3.11	Container Freight Station (CFS)	6.7.5
Collector's Id on Seal	4.4.10.3.12	Contamination.....	6.4.4.2
Color Additives	5.4.6.4	Contested Seizure	2.2.6.8
Color Additives Sample Chart.....	Smpl Schdl 9	Contract Facilities	5.2.3.2
Color Additives Status List	5.4.6.4	5.6.6
Color Certification Program.....	2.9.5.4	Control.....	4.5.3.5.2
Color Slide Identification	5.3.4.2.2	4.5.3.6.1
Commerce (Doc).....	3.2.2.1	Controls.....	4.3.6.5
Commercial Bill of Lading	4.5.5.8.4	Conversion Factors	Appendix D
Common Carrier	1.2.1	Conveyor Belt Conditions	5.4.5.3
.....	4.5.5.8	Cooperation with Other Agencies	8.3.1.3
Communication with Federal Inspector.....	3.1.3.2	Cooperative Efforts	3.1
Comprehensive Smokeless Tobacco Act	2.2.3.9	3.1.1
Complainant Access to Report/Results	8.2.5.4	Coordination with Other Government Agencies	8.8.2
Complainants	8.8.5.4	Copies	5.2.3.6.2
Complaint and Medical Device Reporting (MDR).....	7.2.3.3	Compliance Achievement	2.6
Complaint Files.....	5.4.8.3	Correction of FDA 483 Errors	5.2.3.1.6
Complaint Files.....	5.6.2.4	Correction of GMP Deviations	2.6.4.2.5
Complaint for Forfeiture	2.2.5.5	Corrective Action.....	7.2.3.2
Complaint or Injury Samples	4.4.6.3	Cosmetics	6.4.3.6
Complaint Sample	4.4.10.1.2	6.4.7.4
Complaints.....	5.11.4.3.11	2.9.5.3
Additional Information to Obtain	8.2.5.3	8.4.5.1
Alcoholic Beverage	8.2.3	Cosmetic Samples	8.4.7.3
Authorization for Medical Records Disclosure ...	8.2.6	Costs Billed to District.....	4.2.8.3.1
Basic Information to Obtain	8.2.5.1	Counterfeit Drug.....	5.1.1.13
Categories	8.2.1	Counterfeiting/Tampering.....	8.8
Complaint Procedure.....	8.2	Authority	8.8.3
Complainant Access to Report/ Results	8.2.5.4	Complainant	8.8.5.4
Consumer Portion.....	8.2.7	Contact.....	8.8.1
Control Portion.....	8.2.7	Coordination	8.8.2
Dietary Supplement Health and Education Act..	8.4.5.2	Distribution Facilities.....	8.8.5.6.2
Emergency Operations Center Guidance.....	8.2.4	Information Release	8.8.4
Infant Formula and Baby Food	8.2.2	Interviews	8.8.5.2
Injury/Illness Complaints.....	8.2.5.2	Manufacturing Site.....	8.8.5.6.1
Interviews.....	8.2.5	Office of Criminal Investigations.....	8.8.1
Investigation Procedure	8.4.5.2.2	Office of Crisis Management.....	8.8.1
Medical Records	8.2.6	Purpose / Procedures.....	8.8.5
Sampling.....	8.2.7		
Special Nutritional Product	8.4.5.2		

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 5.11.2.1.2
 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
 Procedure 2.6.2.2
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
Definitions 5.3.8.3.1
 Delegated Authority 1.6.3.1
Default Decree 2.5

Reporting 2.5.2
Delaying, Denying, Limiting or Refusing Drug Inspections 5.5.5.8
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

INDEX

INVESTIGATIONS OPERATIONS MANUAL 2018

Device Inspections	2.2.1.3	Relabeling.....	8.5.7.4
Device Inspection		Riots.....	8.5.5.5
Authority.....	5.6.1	Samples.....	8.5.5.2
Banned Device	5.6.8	Segregation	8.5.7.1
Complaint Files	5.6.2.4	Tornadoes	8.5.5.4
Contract Facilities	5.6.6	Types	8.5.1
Device Inspection Report	5.6.11	Wrecks.....	8.5.5.6
GWQAP.....	5.6.5	Disclosure	5.2.9.2.3
In-Vitro Diagnostics.....	5.6.4	Disclosure of Official Information	1.4
.....	5.7.2	Discovery of Criminal Violation	5.2.2.5
Labeling	5.6.4	Discussion on Duty, Power, Responsibility	5.3.6.1
Medical Device Quality System/GMPs	5.6.2	Discussion with Federal Inspector.....	3.1.3.2
Preparation	5.6.2.1	Discussion with Management	5.2.7
Quality Audit.....	5.6.2.2	5.11.4.3.15
Records.....	5.6.2.3	Disposition of Rejects	2.4.6
Reports of Corrections and Removals.....	5.6.9	Distribution	5.4.8
Sampling.....	5.6.1.2	Distribution Facilities	8.8.5.6.2
Small Manufacturer.....	5.6.7	Distribution of FDA 2289.....	2.7.2.3.4
Sterile Devices.....	5.6.3	Distribution of the FDA 483.....	5.2.3.6
Substantially Equivalent.....	Exhibit 5-13	Distribution Pattern	7.2.8.6
Technical Assistance.....	5.6.1.1	District Audit Program.....	7.2.8.9
Tracked Medical Devices	5.6.10	District Contact.....	3.2.5.2.7
Types	5.6.1.3	District Follow Up	2.2.6.9
Device Registration and Listing	2.9.2.1	2.2.7.4
Devices.....	6.4.7.2	2.2.8.6
Devices.....	5.6	District Recommendation.....	2.2.6.1
Devices.....	2.7.2.1.3	Diversion to Animal Feed.....	2.8.2
Devices.....	8.4.3.4.1	Division of Authority	6.2.2
Devices for Implant	8.4.3.2	Division of Federal-State Relations (DFSR)	1.9.2.2.4
Devices Injury.....	8.4.3	Division of Domestic Field Investigations (DDFI)	1.9.2.2.1
Dialysis Injury or Deaths	8.4.3.4.3	Division of Field Science (DFS) (HFC-140).....	1.9.2.2.3
Dietary Supplements.....	8.4.5.2	Division of Foreign Field Investigations	1.9.2.2.2
Video Recordings.....	5.3.4.2.4	Division of Import Operations and Policy (DIOP)	1.9.2.2.5
Digital Photos - Turbo EIR	5.3.4.4	Documentary (Doc).....	4.4.10.2.3
Resize Photo	Exhibit 5-6	Documentary Samples	4.1.4.2
Insert Photo	Exhibit 5-7	Documentation.....	4.4.9.3.1
Resize using MS Office Picture Manager	Exhibit 5-8	Documentation & Cr.....	4.4
Directed Inspection	5.1.2	Documenting Interstate Shipments.....	4.4.7
Disaster	2.3.2	Documenting Voluntary Destruction	2.6.4.1
Disaster Procedures.....	8.5	Documents Obtained.....	4.4.10.3.21
Disaster Types	8.5.1	DOD MOU's.....	3.2.3.1
Ammonia Leaks	8.5.7.5	Domestic Follow-Up of IFE Entries.....	6.2.3.4.2
Bio-terrorism	8.5.6	Domestic Import (DI).....	4.4.10.2.4
Chemical Spills	8.5.5.6	Domestic Import (DI) Sample	6.7.11
Destruction.....	8.5.7.2	Domestic Import Sample	4.1.4.8
Earthquakes.....	8.5.5.7	Drug Approval Status.....	5.5.5.2
Embargoes.....	8.5.5.1	Drug Enforcement Administration.....	3.2.6.2
Explosions.....	8.5.5.5	Drug Inspection	
FDA Responsibility	8.5.2	Adverse Event Reporting	5.5.7
Field Examination	8.5.5.2	Advertising.....	5.5.3
Field Operations	8.5.5	Approach	5.5.1.2
Fires.....	8.5.5.5	Authority.....	5.5.1
Flooding	8.5.5.3	Bioresearch Monitoring.....	5.5.6
Form FDA 2809	Exhibit 8-12	Dietary Supplement Status.....	5.5.5.4
Hazardous Waste Sites	8.5.5.6	Drug Inspection Report.....	5.5.8
Hurricanes.....	8.5.5.4	General Elements.....	5.5.8
Initial Information	8.5.4	Guarantee.....	5.5.4
Initial Procedures	8.5.4	Inspection References.....	5.5.1.1
Inspections.....	8.5.3	Labeling Agreement	5.5.4
Perishable Products.....	8.5.7.6	Listing	5.5.2
Personal Safety	8.5.3	Preparation	5.5.1.1
Preparation	8.5.3	Promotion	5.5.3
Product Disposition	8.5.7	Registration	5.5.2
Reconditioning.....	8.5.7.3	Sampling Chart	Smpl Schdl 10
Reconditioning Containers.....	8.5.7.7	Drug Recalls	7.2.4
Reconditioning Containers.....	8.5.7.8	Drug Recall Letter	Exhibit 7-1
Reconditioning Devices	8.5.7.10	Drug Registration & Listing	5.5.2
Reconditioning Hermetically Sealed Cans	8.5.7.9	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..... 5.11.1
 Team inspections..... 5.1.2.5
 Electrical Hazards 1.5.3.2
 Electronic Databases and Queries..... 5.3.8.3.2
 Electronic Information 5.11.5.1
 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..... 5.11.2
 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
 Utensils 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	FDA Directory	1.10.2.2
Microfiche	5.3.8.3	FDA Investigator's Responsibility	5.1.1.1
Microfilm	5.3.8.3	FDA on Disk.....	1.10.2.4
Official Sample.....	5.3.8.2	FDA Personnel with State Authority	3.3.1.1
Original Records.....	5.3.8.2	FDA Principles	1.8.1
Patient Information.....	5.3.8.6	FDA Recall Audit Checks.....	7.3.2
Private Information.....	5.3.8.6	FDA-USDA Agreements & MOUs	3.2.1.4
Records	5.3.8	FDA/ORA Manuals and Reports	1.10.2.5
Sampling Request	5.3.9	FDC and INJ Numbers	2.2.5.4
Evidence Gathered in a Criminal Investigation.....	5.2.2.6	Federal Agencies	3.1.3.1
Evidence Required	4.4.6	Federal Agency Interaction	3.2
Evidence Voluntarily Provided to the Agency.....	5.2.2.7	Federal Anti Tampering Act.....	2.2.3.3
Examination	5.1.1.12	Exhibit 8-14
Examinations and Investigations	4.1.1.1	Federal Bureau of Investigation.....	3.2.6.3
Exceptions to Fumigation.....	4.5.3.1.3	Federal Caustic Poison Act	2.2.3.5
Executing the Detention.....	2.7.2.2.2	Federal Cigarette Labeling & Advertising Act.....	2.2.3.10
Exemption	5.4.1.5.1	Federal Food Safety Coalition	3.2.17
Exemption Requirements.....	5.3.7.3	Federal Food, Drug, and Cosmetic Act	2.2.1
Exhibit Sample	4.4.10.1.4	Federal Grain Inspection Service/USDA	3.2.1.7
Exhibits.....	4.5.2.5	Federal Import Milk Act.....	2.2.3.4
.....	5.3.3	Federal Meat Inspection Act.....	3.2.1.3
.....	5.11.5	Federal Trade Commission (FTC).....	3.2.13
Exhibits Collected.....	5.11.4.3.19	FEI Number.....	4.4.10.3.24
Expenses Chart	Exhibit 1-1	Field Exams	5.1.5.3
Explosions.....	8.5.5.5	Field Examination	4.3.7.1
Exportation of Merchandise Refused Admission.....	6.2.7.10	4.3.8.1.2
External Observers	5.1.4.3	Field Examination (Imports)	6.4
Eye Protection.....	1.5.1.1	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

-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).....	5.11.3
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 5-14
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

Fires.....	8.5.5.5	Safety Precautions	5.4.1.4.5
Firm Locations.....	3.2.16	Sanitation.....	5.4.7
Firm Name	4.4.10.3.25	Security Inspection Activities	5.4.1.4.1
Firm Official.....	7.2.8.8	Shipper Vehicle.....	5.4.7.3.3
Firm Type.....	4.4.10.3.26	Storage.....	5.4.7.3
Firm's Recall Strategy.....	7.2.8.7	Violative Inspections.....	5.4.10.3
Firm's Training Program	5.11.4.3.8	Waste Disposal	5.4.3.2
Firms with Potential Respiratory Hazards.....	1.5.1.4.2	Written Demand for Records.....	5.4.1.2.1
FIS Sample Number	4.4.10.3.27	Written Request for Information	5.4.1.2.2
Flag.....	4.4.10.1	Food Inspection Report	5.4.10.2
Flooding	8.5.5.3	Food Inspections.....	5.4.1
Follow Up Guidance.....	5.1.1.13.3	2.2.1.2
.....	8.3.2	Food Products	3.4.2.3
Follow Up Inspections by Court Order.....	5.2.2.3	Food Recalls	7.2.2
Food.....	5.4	Food Registration	5.4.1.5
Food Additives	5.4.6.3	Food Safety and Inspection Service.....	3.2.1.8
Food Additive Nomographs.....	Exhibit 5-11	Food Sanitation.....	6.4.3.1
Food and Col or Additives	6.4.3.3	Food Standards	5.4.10
Food and Cosmetic Defense Inspectional Activities	5.4.1.4	Food Standards Sample	4.1.5
Food and Cosmetic Security.....	5.4.1.4.1	Food Standards, (FS)	4.4.10.2.5
Food Canning Establishment.....	4.4.10.3.28	Food Transport Vehicles.....	5.4.7.3.1
Food Chemicals Codex.....	5.4.4.3	Foodborne Disease	4.3.5.1
Food Drug and Cosmetic Act.....	2.7.1.2.1	Foodborne Outbreaks	8.3
Food Economics (Consumer Size Containers).....	6.4.3.5	Additional Case History Interviews.....	8.3.4.3
Food Establishment Inspection.....	5.4.10.1	Analysis of Data.....	8.3.5
Food Handlers Interviews	8.3.4.5	Assistance.....	8.3.4.2
Food Illness Classification.....	Exhibit 8-6	Attack Rate Table.....	8.3.5.4
Food Illness Report FDA 3042.....	Exhibit 8-7	Exhibit 8-8
Food Inspection		Classification of Illness.....	Exhibit 8-6
Authority.....	5.4.1.2	Cooperation with Other Agencies.....	8.3.1.3
Chemical Codex	5.4.4.3	Determination	8.3.4.1
Color Additives.....	5.4.6.4	Epidemic Curve	8.3.5.1
Complaint File.....	5.4.8.3	Epidemiological Investigative Technique	8.3.1
Design.....	5.4.3.1	Establishment Investigation.....	8.3.4.4
Distribution.....	5.4.8	Evaluating Epidemiological Data	8.3.4
Employees	5.4.2	<i>Follow-Up Guidance</i>	8.3.2
Entry Review.....	5.4.1.4	Contacting the Complainant.....	8.3.2.2.1
Environment.....	5.4.3	Information to Gather	8.3.2.2.3
Equipment.....	5.4.5	Interviews	8.3.2.2
Facilities	5.4.3	Medical Records	8.3.2.3
Field Examination	5.4.1.4	Preparation.....	8.3.2.1
Food Additives.....	5.4.6.3	Setting Communication Level	8.3.2.2.2
Food Inspection Report	5.4.10.2	Foreign Flag Vessels.....	8.3.1.1
Food Standard Inspection	5.4.10.1	Incubation Periods.....	8.3.5.3
Food Standards	5.4.10	Interstate Conveyances.....	8.3.1.2
Food Transport Vehicle	5.4.7.3.1	Interviews	8.3.4.5
Formulas.....	5.4.6.2	Outbreaks	8.3.1
Grade A Dairy Plant Inspection	5.4.9.3	Pathogen Growth Factors	8.3.4.7
Ingredient Handling.....	5.4.6.1	<i>Possible Contamination Source</i>	8.3.4.6
Interstate Shipping.....	5.4.8	Pests.....	8.3.4.6.1
Management.....	5.4.2	Poor Sanitation.....	8.3.4.6.3
Manufacturing Code	5.4.6.5.3	Raw Meat	8.3.4.6.2
Manufacturing Process	5.4.6	Workers	8.3.4.6.4
Microbiological Concerns	5.4.7.2	References	8.3.7
Other Government Inspection	5.4.9	Salmonella Enteritidis (SE) in Eggs.....	8.3.1.4
Packaging and Labeling	5.4.6.6	Sample Handling	8.3.3.3
Personnel.....	5.4.2	Sample Size	8.3.3.2
Plant Construction	5.4.3.1	Sampling.....	8.3.3.1
Plant Services.....	5.4.3.3	Symptoms Determination	8.3.5.2
Preparation	5.4.1.1	Tracebacks of Foods.....	8.3.5.5
Quality Control.....	5.4.6.5	Foods Rejected by USDA.....	3.2.1.1
Raw Material Handling	5.4.4.1	Foods, Dietary Supplements & Cosmetics Injury or Reaction.....	8.4.5
Raw Material Source	5.4.4	Foreign Firms.....	5.1.3
Re-Inspection User Fees.....	5.4.11	Foreign Trade Zones	6.7.18
Recall Procedure.....	5.4.8.2	Formal Entries.....	6.2.3.1
Receiver Vehicle.....	5.4.7.3.2	Formal Entry.....	6.7.17
Reconciliation Examination.....	5.4.1.4.2	Format for Regulatory Notes	2.1.4
Routes of Contamination.....	5.4.7.1	Forms and Other Publications	1.10.2.6

INDEX

Formula/Label Correction.....2.6.4.2.6
 Formulas5.4.6.2
 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
 Procedures1.4.4.1
 Request for Documents.....1.4.4.2
 Freight Bill.....4.4.7.2.4
 Frequent Flyer Miles1.2.1.1
 Frozen Samples.....4.5.3.5
 Fumigated4.4.10.1.6
 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 Management5.11.4.3.15
 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 Data5.3.4.2.6.1
 Analog Data5.3.4.2.6.2
 Memory Card.....5.3.4.2.6.3
 Original5.3.4.2.6.4
 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 Terms6.7
 Government Agency4.2.7
 Government Bill of Lading.....4.5.5.8.3
 Government-Owned Vehicles (GOVs).....1.2.2
 Government Wide Quality Assurance Program5.2.3.5
 5.6.5
 GovTrip.....1.2
 Grade A Dairy Plant Inspections.....5.4.9.3
Grain Elevators.....1.5.3.3.2
 Grand Jury5.2.2.9
 Grand Jury Proceedings2.2.7.3
 Grower4.4.10.3.26.2
 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 Samples4.1.6

-H-

Hand Ship6.5.5.7
 Handling Procedure5.4.4.1
 Hantavirus Associated Diseases.....1.5.5.4
 Harvester.....4.4.10.3.26.3
 Hazardous Waste Sites.....8.5.5.6
 Headquarters2.2.6.2
 Health Fraud8.6.1
 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 Injunction2.2.8.2
 Hearing Protection1.5.1.2
 HHS MOU's.....3.2.4.1
 History.....5.11.4.3.4

INVESTIGATIONS OPERATIONS MANUAL 2018

History of Menu Items.....Exhibit 3-2
 Home District2.2.5.6
Hospitalized In-Travel Status
 Per Diem Coverage1.2.4.2
 Hostile and Uncooperative Interviewees5.2.5.4
 Hours.....4.4.10.3.29
 How Prepared4.4.10.3.30
 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 Confidentiality5.7.2.2
 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-

Identification4.5.2
 4.5.2.3
 Identification and Security of Electronic Storage
 Media5.3.8.4.3
Identification of Documentation.....4.4.5
 Identification of lots and records.....4.2.6
Identification of Records.....5.3.8.1
 Identification Techniques4.5.2.3
 Identifying Lot(s) Sampled4.3.2.2
 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 Compliance6.2.3.4.1
 Domestic Follow-up of IFE Entries6.2.3.4.2
 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
 Entry6.7.12
 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 Alerts6.7.20
 Importer of Record.....6.7.21
 Import Sections.....6.7.22
 Import Status6.7.23
 Importer Misdeclaration.....6.1.3.6
 Informal Entry6.7.25

Inspection of Vehicles	5.2.2.2	Other Observations	5.2.3.2.2
Inspection Report		Non-Reportable Observations	5.2.3.3
Abbreviated Inspection Report	5.11.4.3	Preparation FDA 483	5.2.3.1
Addendum	5.11.6	Reportable Observations	5.2.3.2
Additional Information	5.11.4.3.16	Signature	5.2.3
Administrative Data	5.11.4.3.3	Turbo EIR	5.2.3
Attachment	5.11.4.3.20	Inspectional Precautions	5.1.4
Complaint	5.11.4.3.11	Inspectional Procedure	2.7.2
Compliance Achievement Reporting System (CARS)		Inspections	1.5.4
.....		Inspections to Monitor Recall Progress	7.3.1
5.11.2.1		Intended Use	5.5.5.1
Discussion with Management	5.11.4.3.13.2	Interaction with Federal Agencies	3.2
.....	5.11.4.3.15	Interagency Cooperation	3.2.5.2.6
EI Record	5.11.3	Interagency Motor Pool	1.2.2.1
EIR	5.11.1	Interdistrict Assignments	1.7
EIR Timeframes	5.11.4.2	Internal FDA Documents	1.4.5
Electronic information	5.11.5.1	Internal Revenue Service (IRS)	3.2.8.2
Endorsement	5.11.2	International Agreements	3.4
Establishment Inspection Report	5.11.1	International Inspection	3.1.1
Exhibit	5.11.4.3.19	International	
Exhibits	5.11.5	Food Products	3.4.2.3
FACTS Establishment Inspection Record	5.11.3	Memorandum of Understanding	3.4.1
Comstat Screen	Exhibit 5-14	MRA	3.4.2
Inspectional Basis	5.11.3.1	Mutual Recognition agreement	3.4.2
Maintain Inspection Results Screens	Exhibit 5-16	Pharmaceuticals and Medical Devices	3.4.2.2
History	5.11.4.3.4	Internet	1.10.2.3
Interstate Commerce	5.11.4.3.5	Interrogation: Advice of Rights	Exhibit 2-1
Jurisdiction	5.11.4.3.6	Interviewing Informant	5.2.9
Manufacturing Code	5.11.4.3.10	Interviewing Persons under Arrest	2.2.11.2
Manufacturing Operation	5.11.4.3.9	Interviews	8.2.5
Narrative Headings	5.11.4.3	Additional Information to Obtain	8.2.5.3
Narrative Report	5.11.4	Basic Information to Obtain	8.2.5.1
Non-Violative Establishments	5.11.4.1	Complainant Access to Report/Results	8.2.5.4
Objectionable Conditions	5.11.4.3.13	Injury/Illness Complaints	8.2.5.2
Recall Procedures	5.11.4.3.12	Internet and Intranet	1.10.2.3
Refusal	5.11.4.3.14	Interstate Commerce	5.11.4.3.5
Responsibility	5.11.4.3.7	Interstate Commerce	4.4.6.2.1
Samples Collected	5.11.4.3.17	Interstate Certified Shellfish Shippers	2.9.5.6
Signature	5.11.4.3.21	Interstate Milk Shippers	7.2.2.1
Standard Narrative Report	5.11.4.3.1	Interstate Milk Shippers	2.9.5.7
Summary	5.11.4.3.2	Interstate Shellfish Sanitation Conference	3.5.3
Summary of Findings report	5.11.4.1	Interviewing Confidential Informants	5.2.9
Supporting Evidence	5.11.4.3.13.1	Interviewing Methods/Techniques	5.2.9.1.1
Training Program	5.11.4.3.8	Interviewing Persons Under Arrest	2.2.11.2
Turbo EIR usage	5.11.4	Interviews	3.2.4.3.1
Voluntary Correction	5.11.4.3.18	Interviews	8.2.5
Violative Establishments	5.11.4.2	Interviews	8.8.5.2
Inspection System	5.4.6.5.1	Introduction into Interstate Commerce	4.4.6.2.1
Inspection Techniques How to Document		Inv. Samples of Filth Exhibits	4.4.10.1.7
Responsibility	5.3.6.2	Investigation	5.1.1.12
Inspection walk through	5.1.2.2	8.8.5
Inspection Warrant	5.2.6	Investigation, Definition	8.1
Inspectional Approach	5.1.2	Investigation Injury & Adverse Reaction	8.4
.....	5.5.1.2	Investigation of Foodborne Outbreaks	8.3
.....	5.7.2.5	Investigation Requirements for Serious Adverse	
Inspectional Authority	5.4.1.2	Events of CFSAN Regulated Products	8.4.5.3
Inspectional Guidance	5.1.1.13.2	Investigation/Reporting	8.4.4.2
.....	5.4.1.5.3	Investigational (Inv)	4.4.10.2.6
Inspectional Observations		Investigational Device Exemption (IDE) Regulation	2.9.2.2
Adulteration Observations	5.2.3.2.1	Investigational Drugs	5.5.5.6
Annotation	5.2.3	Investigational New Drug Application (IND)	2.9.1.2
Annotation	5.2.3.4	Investigational Research	
Correction FDA 483 Errors	5.2.3.1.6	Data Reporting	8.7.7
Discussion	5.2.3	Joint Research Project	8.7.2
Distribution	5.2.3.6	Priority	8.7.6
FDA 483	5.2.3	Research Assignment	8.7.1
.....	Exhibit 5-5	Research Project Identification Code	8.7.3
FDA 483 Statements	5.2.3.1.4	Research Project Progressive Report	8.7.4
GWQAP	5.2.3.5		

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 5.11.4.3.6
 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 5.11.4.3.10
 4.4.10.3.32
 Manufacturing Process 5.4.6
 Manufacturing Sites 8.8.5.6.1
 Manufacturing/Design Operations 5.11.4.3.9
 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.....	5.11.4
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.....	5.11.4.1
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
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.....	5.11.4.3.13
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 Copy.....	5.3.8.3.1.3
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.....	5.4.12

Acreage.....	5.4.12.3	Compliance Program.....	5.2.1
Application.....	5.4.12.3.1	Guidance Documents.....	5.2.1
Applicator.....	5.4.12.6	Guides.....	5.2.1
Approach.....	5.4.12.1	Postponement.....	5.2.1.1.3
Cooperative Activities.....	5.4.12.2	Pre-Announcement.....	5.2.1.1
Drift.....	5.4.12.3.2	Pre-Inspectional Activities.....	5.2.1
Growers.....	5.4.12.3	Recall follow-up.....	5.2.1.1.2
Growing Dates.....	5.4.12.3	Preparation and References.....	5.4.1.1
Misuse.....	5.4.12.3.2	Preparation and References.....	5.5.1.1
Packer.....	5.4.12.4	Preparation of Collection Report.....	4.4.10.3
Sampling.....	5.4.12.7	Preparation of Detention Notice.....	2.7.2.3.1
Shipper.....	5.4.12.4	Preparation of FDA 484.....	4.2.5.5
Soil Contamination.....	5.4.12.3.2	Preparation of Form FDA 483.....	5.2.3.1
Supplier.....	5.4.12.5	Preparation of Page 1 (FDA 2289).....	2.7.2.3.2
Pesticide Sample	4.4.10.1.8	Preparation of Page 2 - 5 (FDA 2289).....	2.7.2.3.3
Sample Schedule Chart.....	Smpl Schdl 3	Preparing & Maintaining Digital Photographs	
Pesticides.....	5.4.7.1.3	Evidence	5.3.4.3
Pesticides, Industrial Chemicals, Aflatoxins, & Toxic Elements.....	6.4.3.2	For Insertion into Turbo EIR.....	5.3.4.4
Pharmaceuticals and Medical Devices.....	3.4.2.2	Prescription Drugs.....	4.2.5.4
Photo Identification and Submission.....	5.3.4.2	Preservation Liquids.....	4.5.3.1.4
Photograph Requests.....	5.3.4.5	Prints.....	5.3.4.2.1
Photographs.....	4.5.2.4	Prior Notice Center (PNC).....	1.9.2.2.6
Photographs.....	5.3.4	6.2.3.5
PHS Recommendations Basic Sanitary Practices.....	5.1.4.2	Prior Notice of Importation of Food and Animal Feed.....	6.2.3.5
Physical Hazards.....	1.5.3.3	Prior Notice Process.....	6.2.3.5.6
Physical Resistance/Threats/Assaults.....	5.2.1.2.2	Prior Notice Reception.....	6.2.3.5.1
Plant Construction, Design and Maintenance.....	5.4.3.1	Prior Notice Submission.....	6.2.3.5.4
Plant Services.....	5.4.3.3	Private Individuals.....	4.2.6.1
Plants and Grounds.....	5.4.3	Privately-Owned Conveyance.....	4.4.7.4
Poison Prevention Packaging Act.....	2.2.3.6	Privately Owned Vehicle (POV)	
Policy (CR)	4.4.3	Official Business.....	1.2.3
Fed/State Cooperation.....	3.1.1	Reimbursement for mileage.....	1.2.3
Consent Decree.....	2.4.1	Procedure after Hearing "Notice of Release".....	6.2.7.7
Default Decree.....	2.5.1	Procedure after Hearing "Refusal of Admission".....	6.2.7.8
Compliance Achievement.....	2.6.1	Procedure when Conditions of Authorization	
Port (Point) of Entry.....	6.7.30	Have Been Fulfilled.....	6.2.7.5
Ports Covered by FDA.....	6.2.4.1	Have Not Been Fulfilled.....	6.2.7.6
Ports Not Covered by FDA.....	6.2.4.2	Procedure when No Violation Is Found.....	6.2.6
Possible Contamination Source.....	8.3.4.6	Procedure when Products Can't be Sampled/ Examined.....	6.2.5
Post Award (GQA).....	4.4.10.2.10	Procedure When Violation Is Found.....	6.2.7
Post Inspectional Contacts	5.1.2.6	Procedures for Fumigation.....	4.5.3.1.2
Post-inspection Notification Letter.....	5.3.10	Procedures When Threatened or Assaulted.....	5.2.5.4.3
Post Seizure & Reconditioning Samples.....	4.2.8.1	Processing Equipment.....	5.4.7.2.1
Post Seizure (P.S.) Sample.....	4.1.4.7	Problem Area Flag (PAF).....	4.4.10.3.2
Post Seizure (Ps).....	4.4.10.2.10	Product Code.....	4.4.10.3.38
Postal Box Information.....	3.2.15.2	Product Description.....	4.4.10.3.39
Postal Mail Cover.....	8.9.1.4	Product Disposition.....	8.5.7
Poultry Products Inspection Act.....	2.7.1.2.3	Product/Establishment Surveillance Report.....	Exhibit 8-13
.....	3.2.1.3	Product Label.....	4.4.10.3.40
Pre Announcements.....	5.2.1.1	Product Name.....	4.4.10.3.41
Pre Inspection Activities.....	5.2.1	Products Excluded From Prior Notice.....	6.2.3.5.3
.....	5.2.10.1	Products Imported under Section 801(D)(3) of the	
.....	5.6.2.1	FD&C Act	5.1.1.14
Precautions.....	4.5.5.8.7	Inspectional Preparation.....	5.1.1.14.2
Precautions during inspections		Requirements for Bioterrorism Act.....	5.1.1.14.1
Aseptic Technique.....	5.1.4	Products Requiring Prior Notice.....	6.2.3.5.2
Microbiological Contamination.....	5.1.4	Products Susceptible to Contamination with Pathogenic Microorganisms.....	4.3.7.7
Safety Equipment.....	5.1.4	Professional Personal Contacts.....	1.6.5.1.6
Sterility.....	5.1.4	Professional Reporting System for Vaccine Adverse Reactions.....	8.4.4.1
Precautions for Non Clinical Laboratory Inspections 1.5.5.2.3		Professional Stature.....	1.6.5.1
Preliminary Investigation.....	8.5.4	Profile COMSTAT.....	Exhibit 5-13
Preliminary or Permanent Injunction.....	2.2.8.5	Program Provisions.....	1.5.1.4.1
Premarket Approval.....	2.9.2.4	Promotion and Advertising.....	5.4.8.1
Premarket Notification Section 510(K).....	2.9.2.3	Promotion and Advertising.....	5.5.3
Premises Used for Living Quarters.....	5.1.1.9	Prosecution	
Preparation for EI			
Complaint.....	5.2.1		

INDEX

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

Definition

Account..... 7.1.1.12
 Consignee..... 7.1.1.11
 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-Recall..... 7.1.1.10
 Sub-Account Check..... 7.3.2.3

Inspection

Market withdrawal..... 7.2
 Procedure..... 7.2.1
 Recall Decision Follow-Up..... 7.2.1.1

Recall

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

INVESTIGATIONS OPERATIONS MANUAL 2018

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
 Sample Collections..... 7.2.7
 Special Situations..... 7.4.1
 Tobacco Product Recalls..... 7.2.6
 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..... 5.11.4.3.12
 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 Sections 414 and 704
 of the FD&C Act..... 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	Medicated Feed Mill License (FML).....	2.9.4.2
Refusal to Permit Sampling	4.2.3	New Animal Drug Application (NADA).....	2.9.4.4
Refusal to Sign the Affidavit.....	4.4.8.2	New Drug Application (NDA).....	2.9.1.3
Refusals	5.11.4.3.14	Premarket Approval.....	2.9.2.4
.....	4.2.4.2	Premarket Notification - Section 510(k).....	2.9.2.3
Refusals of Requested Information.....	5.2.7.2	Radiation Reporting.....	2.9.2.8
Registration and Listing	2.9.1.1	Requests for GMP Exemption and Variances.....	2.9.2.6
.....	2.9.3.1	Veterinary Medicine Registration and Listing.....	2.9.4.1
.....	2.9.4.1	Voluntary Filing of Cosmetic Product Ingredient	2.9.5.3
Registration, Listing and Licensing	5.7.3	Composition Statement Voluntary Registration	
Approval of Biological Devices	5.7.3.4	of Cosmetic Product Establishment.....	2.9.5.3
Biologic License	5.7.3.3	Regulatory Notes	2.1
HCT/Ps	5.7.3.1.1	Electronic Notes	2.1.2
Laboratories	5.7.3.1.2	Format for regulatory notes	2.1.4
Military Blood Banks	5.7.3.1.3	Regulatory entries	2.1.3
MOUs.....	5.7.3.2	Regulatory note characteristics	2.1.2
Registration and Listing	5.7.3.1	Retention of regulatory notes	2.1.5
Regulations.....	3.1.2	Uses of regulatory notes	2.1.1
Regulated Industry Notification	5.4.11	Regulatory References and the General Public.	1.10.2.7
Regulations	1.10.1	Law	1.10.1
Regulations, Guidelines, Recommendations	5.7.2.6	Manuals	1.10.2.5
Regulatory.....	4.4.10.2.11	Regulatory Submissions	2.9
Regulatory		Reinspection Compliance Branch Actions.....	5.4.11.1.5
702(a)	2.2.1	Relabeling	2.4.2
Decharacterization	2.8.3	Relabeling	8.5.7.4
Definition	2.2.5	Related Samples.....	4.4.10.3.46
Citation	2.2.5.2	Release of Goods	2.4.7
Civil Number	2.2.5.1	Release of Information.....	8.8.4
Complaint for Forfeiture	2.2.5.5	Removal of Detention Tags	2.7.2.5.1
Criminal Number.....	2.2.5.3	Repairs.....	1.6.2.1.1
Denaturing	2.3.1.3	Repeated Filer Misdeclaration	6.1.3.7.1
Destruction.....	2.3.1.2	Report of Analysis	4.1.1.4
Device	2.7.1.3.1	704(d) Sample	4.4.10.3.64
Egg Products	2.7.1.3.5	Reportable Observations	5.2.3.2
FDC and INJ Numbers	2.2.5.4	Adulteration Observations	5.2.3.2.1
Home District	2.2.5.6	Other Observations	5.2.3.2.2
Meat Products.....	2.7.1.3.4	Reporting Contacts	8.8.1
Nolle Prosequi.....	2.2.5.7	Reporting Criteria.....	5.11.2.1.1
Nolo Contendere.....	2.2.5.8	Reporting Investigations Involving the Importation Process	
Poultry Products	2.7.1.3.5	6.1.3.8
Reconstruction	2.3.1.1	Reporting Sample Collections	4.4.10
Seizing District.....	2.2.5.9	Reports.....	1.10.2.5
Subpoena Duces Tecum	2.2.5.10	Reports of Criminal Activity.....	8.9.1.1
Supervising District	2.2.5.11	Reports of Observations	5.2.3
Disasters	2.3.2	Representatives Invited by Firm to View	
Regulatory Filing		Inspection.....	5.1.4.3
Abbreviated New Animal Drug Application (ANADA)	2.9.4.3	Request for Authorization to Relabel/Perform	
Abbreviated New Drug Application (ANDA)	2.9.1.4	Other Acts	6.2.7.3
Acidified Foods	2.9.5.1	Request for Notice of Inspection	4.2.4.4
Biologic License	2.9.3.2	Request for Sample Collection	5.3.9
Blood Bank Registration and Listing.....	2.9.3.1	Requesting/Working with Computerized	
Classification of Devices.....	2.9.2.5	Complaint & Failure Data	5.3.8.4
Color Certification Program	2.9.5.4	Requesting Computerized Data	5.3.8.4.2
Device Registration and Listing	2.9.2.1	Requests by the Public, Including Trade	1.4.2
Drug Registration and Listing	2.9.1.1	Requests for GMP Exemption and Variances	2.9.2.6
FCE Process Filing of LACF/AF Processors	2.9.5.2	Requests for Records Under Section 703 of the	
Food Canning Establishment (FCE)		FD&C Act	5.1.1.7.2
Registration.....	2.9.5.1	Resealing Conveyances	4.3.4.3
Infant Formula.....	2.9.5.5	Research Assignments	8.7.1
Interstate Certified Shellfish Shippers.....	2.9.5.6	Research Project Identification Code.....	8.7.3
Interstate Milk Shippers	2.9.5.7	Research Project Progress Reports	8.7.4
Investigational Device Exemption (IDE)		Reserve, 702(b)	4.1.2
Regulation.....	2.9.2.2	FACTS Documentation.....	4.4.10.3.63
Investigational New Drug Application (IND).....	2.9.1.2	Imports	6.5.1
LACF	2.9.5.1	Portion	4.3.3.3
Low Acid Canned Food	2.9.5.1	Requirement	4.3.5.1
Medical Device Reporting.....	2.9.2.7	Resources for FDA Regulated Businesses	5.2.2
		Respiratory Protection	1.5.1.4
		Response to "Notice of Detention & Hearing"	6.2.7.2

INDEX

Responsible Firm Type 4.4.10.3.47
 Responsibility & Coordination 8.5.2
 Responsible Individuals 5.3.6
 5.7.4
 Restoring Lot(s) Sampled 4.3.2.1
 Retail Stores 8.8.5.5
 Retention of Regulatory Notes 2.1.5
 Retorts 1.5.4.2.1
 Reverse of Tag 2.7.2.4.3
 Review of Records 6.3
 Reworking 2.4.3
 Riots 8.5.5.5
Rodent Contamination 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 2.8.2.1
 Rodents 5.4.7.1.2
 Routes of Contamination 5.4.7.1
 Routine Biosecurity Procedures for Visits to Facilities
 Housing/Transporting Domestic or Wild Animals ... 5.2.10
 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

-S-

Safety 4.3.5
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

INVESTIGATIONS OPERATIONS MANUAL 2018

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
 Allergen Samples 8.4.7.5
 Allergen Samples Schedule Smpl Schdl 13
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
Collecting Surveillance Samples on Farms 4.3.5.6
Collecting Feed Samples for BSE Analysis 4.3.5.7
 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 4.1.4.12
 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
 Responsibility 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 7.2.7
 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	Imported White Fish	Smpl Schdl 5
.....	8.3.3.3	Imports – Coffee.....	Smpl Schdl 8
Sample Number	4.4.10.3.55	Medicated Animal Feed	Smpl Schdl 12
Sample Origin	4.4.10.3.56	Pesticides.....	Smpl Schdl 3
Sample Package Identification and FDA 525	4.5.5.1	Salmonella	Smpl Schdl 1
Sample Records Identification	4.4.5	Veterinary Products.....	Smpl Schdl 11
Sample Schedule	4.3.3	Wheat Carload	Smpl Schdl 4
Sample Sent To	4.4.10.3.57	Sanitary Practices	5.1.4.2
National Sample Distributor (NSD).....	4.4.10.4	Sanitation	5.4.7
Sample Shipment.....	4.5.5	Sanitation of Machinery	5.4.5.2
Sample Shipment to Outside Agencies	4.5.5.4	Sanitation Practices	5.4.5.8
Sample Size	4.3.3	Science and Education Administration/USDA	3.2.1.9
Sample Size	8.3.3.2	Scope of Investigation	3.2.5.2.5
Sample Type	4.4.10.3.58	Seafood, Office of	4.5.5.3.3
Sampled In Transit	4.4.10.1.10	Seal	
Samples	6.4.4.3	Broken Seal	4.5.4.5
Samples Collected	5.11.4.3.17	FDA 415a	4.5.4
Samples for Pathological Examination	4.5.3.3	Metal Seals	4.5.4.6
Samples for Viral Analysis	4.3.7.8	Method	4.5.4.3
Samples to Administration Laboratories	4.5.5.3	Non-samples.....	4.5.4.7
Sampling		Official Seal	4.5.4
Limiting or Preventing Collection of Samples of a Drug	4.2.3.1	Preparation	4.5.4.1
Preparation, Handling, Shipping	4.5	Protection.....	4.5.4.4
Objective.....	4.5.1	Temporary Seal	4.5.4.5
National Sample Distributor (NSD).....	4.4.10.4	Application	4.5.4.2
Receipt.....	5.2.4	Search Warrant	5.1.1.13.4
.....	5.2.4.1	Secret Service	3.2.5.2
.....	5.2.4.2	Section 305 Notice.....	2.2.7.1
.....	3.2.5.2.10	Section 322 of the Public Health Security & Bioterrorism	
.....	2.7.3	Preparedness and response Act 2002	5.1.1.14
.....	1.5.3	Section 702(e)(5) of the FD&C Act	5.1.1.13
.....	8.8.5.3	Section 801(d)(3) of the FD & C Act	5.1.1.14
Sampling District	4.4.10.3.59	Security	8.8.5.6.3
Sampling Dried Powders	4.3.6.2	Segregation	2.4.4
Bag and Poly-Liner Stitched Together Across		8.5.7.1
Top Seam	4.3.6.2.1	Seizing District	2.2.5.9
Bag Stitched Across Top and Poly-Liner Twist-		Seizure	4.4.6.1
Closed and Sealed with "Twist" Device - Wire,		5.1.1.13
Plastic, Etc.	4.3.6.2.2	Seizure	2.2.6
Bags with Filling Spouts.....	4.3.6.2.3	Consent Decree.....	2.4.1
Sampling from Government Agencies	4.2.7	Default Decree.....	2.5.1
Sampling (Imports)		Destruction.....	2.3
702(b) Reserve	6.5.1	Destruction	2.4.5
Additional Sample	6.5.1	Disposition of Rejects	2.4.6
Collection Report	6.5.5	First Amendment Issues.....	2.3
FDA Coverage	6.2.4.1	Reconditioning	2.3
FDA Coverage	6.2.4.2	Relabeling.....	2.4.2
May Proceed Notice	6.2.4.3	Release of Goods.....	2.4.7
Notice of FDA Action	6.2.4.4	Reworking.....	2.4.3
Notice of Sampling	6.2.4.1	Segregation	2.4.4
Official Seal.....	6.5.1	Seizure	2.2.6
On-screen Review	6.2.4.3	Selected Amendments to the FD&C Act	2.2.2
Payment.....	6.5.1	Selective Sampling	4.3.7.3
Payment for Sample	6.2.4.5	Bird Contamination	4.3.7.4.4
Point of Destination.....	6.2.4.2	Chemical.....	4.3.7.4.5
Point of Entry	6.2.4.2	Criteria	4.3.7.4
Procedure	6.5.2	Insect Contamination.....	4.3.7.4.3
Technique	6.5.3	Mold	4.3.7.4.6
Sampling Lab or Charges	4.2.8.4	Rodent Contamination.....	4.3.7.4.2
Sampling Procedures	8.3.3	Seriously Ill Individuals.....	4.2.6.2
Sampling Plan		Sharing Non Public Info with Government Officials	1.4.3
Aflatoxin.....	Smpl Schdl 6	Shipment	4.5.5.8.1
Allergen Samples Schedule.....	Smpl Schdl 13	Shipment by Privately Owned Conveyance	4.4.7.4
Dates and date material.....	Smpl Schdl 8	Shipment of Hazardous or Toxic Items	4.5.5.8.6
Canned and Acidified Food	Smpl Schdl 2	Shipper	4.4.10.3.26.6
Canned Fruit.....	Smpl Schdl 7	Shipping	4.5.5
Color.....	Smpl Schdl 9	Certified Mail.....	4.5.5.9
Drug Sampling Schedules	Smpl Schdl 10	Common Carrier	4.5.5.8
		FDA Laboratories	4.5.5.3

INDEX

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 5.11.4.3.21
 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
 Source 5.3.8.3.1.2
 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 4.5.3.2
 Standard Narrative Report 5.11.4.3.1
 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

INVESTIGATIONS OPERATIONS MANUAL 2018

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 5.11.4.3.13.1
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 for Tobacco Products 2.9.6
 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
 Technical Assistance 5.8.4
 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
 Undercover Buy 4.1.4.6

Intentionally Left in Blank