# INVESTIGATIONS OPERATIONS MANUAL 2015

## CONTENTS 2015

### CHAPTER 1 - ADMINISTRATION

**Pg 1**

- **SUBCHAPTER 1.1** English Language Requirement for FDA Documents
- **SUBCHAPTER 1.2** Travel
- **SUBCHAPTER 1.3** Leave
- **SUBCHAPTER 1.4** Disclosure of Official Information
- **SUBCHAPTER 1.5** Safety
- **SUBCHAPTER 1.6** Public Relations, Ethics & Conduct
- **SUBCHAPTER 1.7** Interdistrict Assignments
- **SUBCHAPTER 1.8** Organization Overview
- **SUBCHAPTER 1.9** Office of Regulatory Affairs
- **SUBCHAPTER 1.10** References

### CHAPTER 2 - REGULATORY

**Pg 37**

- **SUBCHAPTER 2.1** Regulatory Notes
- **SUBCHAPTER 2.2** Statutory Authority
- **SUBCHAPTER 2.3** Reconditioning and Destruction
- **SUBCHAPTER 2.4** Consent Decree
- **SUBCHAPTER 2.5** Default Decree
- **SUBCHAPTER 2.6** Compliance Achievement
- **SUBCHAPTER 2.7** Detention Activities
- **SUBCHAPTER 2.8** Denaturing
- **SUBCHAPTER 2.9** Regulatory Submissions

### CHAPTER 3 - FEDERAL AND STATE COOPERATION

**Pg 80**

- **SUBCHAPTER 3.1** Cooperative Efforts
- **SUBCHAPTER 3.2** Federal Agency Interaction
- **SUBCHAPTER 3.3** State Operational Authority
- **SUBCHAPTER 3.4** International Agreements
- **SUBCHAPTER 3.5** Non Government Agreements

### CHAPTER 4 - SAMPLING

**Pg 109**

- **SUBCHAPTER 4.1** General
- **SUBCHAPTER 4.2** Dealer Relations
- **SUBCHAPTER 4.3** Collection Technique
- **SUBCHAPTER 4.4** Documentation & CR
- **SUBCHAPTER 4.5** Sampling: Preparation, Handling, Shipping

### CHAPTER 5 - ESTABLISHMENT INSPECTIONS

**Pg 215**

- **SUBCHAPTER 5.1** Inspection Information
- **SUBCHAPTER 5.2** Inspection Procedures
- **SUBCHAPTER 5.3** Evidence Development
- **SUBCHAPTER 5.4** Food
- **SUBCHAPTER 5.5** Drugs
- **SUBCHAPTER 5.6** Devices
- **SUBCHAPTER 5.7** Biologics
- **SUBCHAPTER 5.8** Tobacco Products
- **SUBCHAPTER 5.9** Veterinary Medicine
- **SUBCHAPTER 5.10** Reporting

### CHAPTER 6 - IMPORTS

**Pg 336**

- **SUBCHAPTER 6.1** Imports
- **SUBCHAPTER 6.2** Import Procedures
- **SUBCHAPTER 6.3** Review of Records
- **SUBCHAPTER 6.4** Field Examination
- **SUBCHAPTER 6.5** Import Sample Collection
- **SUBCHAPTER 6.6** Filer Evaluations
- **SUBCHAPTER 6.7** Glossary of Import Terms

### CHAPTER 7 - RECALL ACTIVITIES

**Pg 368**

- **SUBCHAPTER 7.1** Recalls
- **SUBCHAPTER 7.2** Recall Notification / Inspection
- **SUBCHAPTER 7.3** Monitoring Recalls
- **SUBCHAPTER 7.4** Special Recall Situations

### CHAPTER 8 - INVESTIGATIONS

**Pg 379**

- **SUBCHAPTER 8.1** Investigations
- **SUBCHAPTER 8.2** Complaints
- **SUBCHAPTER 8.3** Investigation of Foodborne Outbreaks
- **SUBCHAPTER 8.4** Investigation - Injury & Adverse Reaction
- **SUBCHAPTER 8.5** Disaster Procedures
- **SUBCHAPTER 8.6** Surveillance
- **SUBCHAPTER 8.7** Investigational Research
- **SUBCHAPTER 8.8** Counterfeiting / Tampering
- **SUBCHAPTER 8.9** Office of Criminal Investigation (OCI)
- **SUBCHAPTER 8.10** General Investigation Reporting

### APPENDIX

**Pg 439**

### INDEX

**Pg 448**

### ORA DIRECTORY

**Pg 473**