TABLE OF CONTENTS

CHAPTER 1 – ADMINISTRATIVE

SUBCHAPTER 1.1 - ADMINISTRATION NOTES

SUBCHAPTER 1.2 - OII TRAVEL

SUBCHAPTER 1.3 - TRAVELER' HEALTH

SUBCHAPTER 1.4 - DIVISION OF TRAVEL OPERATIONS

SUBCHAPTER 1.5 - VEHICLE ACCIDENTS

SUBCHAPTER 1.6 - TRANSPORTATION

SUBCHAPTER 1.7 - MEDIA INTERACTIONS DURING INSPECTIONS

SUBCHAPTER 1.8 - EQUIPMENT

SUBCHAPTER 1.9 - OFFICAL IDENTIFICIATION SUBCHAPTER 1.10 BUSINESS CARDS

SUBCHAPTER 1.10 - ETHICS AND INTEGRITY

SUBCHAPTER 1.12 - QUALITY MANAGEMENT

SUBCHAPTER 1.13 - OII TIME REPORTING

CHAPTER 2 – NOTES, RECORDS, AND INFORMATION

SUBCHAPTER 2.1 - REGULATORY NOTES

SUBCHAPTER 2.2 - RECORDS MANAGEMENT

SUBCHAPTER 2.3 INFORMATION DISCLOSURE

SUBCHAPTER 2.4 - ENGLISH LANGUAGE REQUIREMENT

SUBCHAPTER 2.5 - FULL NAME REQUIREMENT

CHAPTER 3 - REGULATORY

SUBCHAPTER 3.1 - PURPOSE

SUBCHAPTER 3.2 - STATUTORY AUTHORITY

SUBCHAPTER 3.3 - EVIDENCE

SUBCHAPTER 3.4 - ADVISORY ACTIONS AND OTHER NOTICES OF VIOLATIONS

SUBCHAPTER 3.5 - ADMINISTRATIVE ACTIONS

SUBCHAPTER 3.6 - PROCEDURAL STEPS FOR EXECUTION OF DETENTION AT A FIRM

SUBCHAPTER 3.7 - DENATURING

SUBCHAPTER 3.8 - JUDICIAL ACTIONS

SUBCHAPTER 3.9 - COMPLIANCE ACHIEVEMENTS FOR VOLUNTARY CORRECTIVE ACTIONS

SUBCHAPTER 3.10 - REGULATORY SUBMISSIONS

SUBCHAPTER 3.11 - REFERENCES

CHAPTER 4 - SAMPLING

SUBCHAPTER 4.1 - GENERAL

SUBCHAPTER 4.2 - DEALER RELATIONS

SUBCHAPTER 4.3 - COLLECTION TECHNIQUE

SUBCHAPTER 4.4 - DOCUMENTS COLLECTED WITH SAMPLE

SUBCHAPTER 4.5 - BIORESEARCH MONITORING SAMPLES

SUBCHAPTER 4.6 - REPORTING SAMPLE COLLECTIONS

SUBCHAPTER 4.7 - SAMPLING: PREPARATION, HANDLING, SHIPPING

CHAPTER 5 - INSPECTIONS

SUBCHAPTER 5.1 - GENERAL INSPECTION INFORMATION

SUBCHAPTER 5.2 - PRE-INSPECTION ACTIVITIES

SUBCHAPTER 5.3 - SAFETY DURING INSPECTIONS

SUBCHAPTER 5.4 - CONFIDENTIAL SOURCES

SUBCHAPTER 5.5 - INSPECTIONAL ACTIVITIES

SUBCHAPTER 5.6 - EVIDENCE DEVLOPEMENT

SUBCHAPTER 5.7 - REPORTING

SUBCHAPTER 5.8 - HUMAN AND ANIMAL FOODS

SUBCHAPTER 5.9 - COSMETICS

SUBCHAPTER 5.10 - DRUGS

SUBCHAPTER 5.11 - ANIMAL & VETERINARY

SUBCHAPTER 5.12 - MEDICAL DEVICE AND ELECTRONIC RADAIATION PRODUCT CONTROL (EPRC)

SUBCHAPTER 5.13 - BIOLOGICS

SUBCHAPTER 5.14 - BIORESEARCH MONITORING (BIMO)

SUBCHAPTER 5.15 - TOBACCO PRODUCTS

SUBCHAPTER 5.16 - COMBINATION PRODUCTS

CHAPTER 6 - IMPORTS

SUBCHAPTER 6.1 - IMPORT GENERAL

SUBCHAPTER 6.2 - ENTRY REVIEW

SUBCHAPTER 6.3 - FIELD EXAMINATION

SUBCHAPTER 6.4 - IMPORT SAMPLE COLLECTION

SUBCHAPTER 6.5 - IMPORT PROCEDURS AFTER EXAMINATION / SAMPLING

SUBCHAPTER 6.6 - IMPORT INVESTIGATIONS

SUBCHAPTER 6.7 - FILER EVALUATIONS

SUBCHAPTER 6.8 - FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP)

SUBCHAPTER 6.9 - GLOSSERY OF IMPORT TERMS

CHAPTER 7 - RECALL ACTIVITIES

SUBCHAPTER 7.1 - PURPOSE OF RECALLS

SUBCHAPTER 7.2 - RESPONSIBILITIES DURING RECALLS

SUBCHAPTER 7.3 - RECALLS AND INSPECTIONS

SUBCHAPTER 7.4 - FDA'S RECALL MONITORING ACTIVITIES

SUBCHAPTER 7.5 - RECALL COMPLETION AND TERMINATION

CHAPTER 8 - INVESTIGATIONS

SUBCHAPTER 8.1 - INVESTIGATIONS AND INSPECTIONS

SUBCHAPTER 8.2 - HUMAN AND ANIMAL FOOD INVESTIGATIONS

SUBCHAPTER 8.3 - DRUG INVESTIGATIONS

SUBCHAPTER 8.4 - DEVICE INVESTIGATIONS

SUBCHAPTER 8.5 - BIOLOGICS INVESTIGATIONS

SUBCHAPTER 8.6 - BIORESEARCH MONITORING INVESTIGATIONS

SUBCHAPTER 8.7 - TOBACCO INVESTIGATIONS

CHAPTER 9 - PUBLIC HEALTH COLLABORATION

SUBCHAPTER 9.1 - PUBLIC HEALTH COLLABORATION

SUBCHAPTER 9.2 - ROLES AND RESPONSIBILITES OF OTHER FEDERAL AGENCY

SUBCHAPTER 9.3 - STATE LOCAL, TRIBAL AND TERRITORIAL INTERACTIONS

SUBCHAPTER 9.4 - INTERNATIONAL AGREEMENTS

SUBCHAPTER 9.5 - NON-GOVERNMENT AGREEMENTS

SUBCHAPTER 9.6 - TRIBAL AFFAIRS

CHAPTER 10 – SAFETY

SUBCHAPTER 10.1 - PURPOSE

SUBCHAPTER 10.2 - UNACCEPTABLE RISK

SUBCHAPTER 10.3 - PERSONAL SAFETY

SUBHCAPTER 10.4 - EMPLOYER/EMPLOYEE SAFETY RESPONSIBILITIES

SUBCHAPTER 10.5 - FOLLOWING FIRM SAFETY REQUIREMENTS

SUBCHAPTER 10.6 - SAFETY RISK ASSESMENT FRAMEOWRKS

SUBCHAPTER 10.7 - ADDITIONAL SAFETY INFORMATION

SUBCHAPTER 10.8 - HIERARCHY OF CONTENTS

SUBCHAPTER 10.9 - PPE

SUBCHAPTER 10.10 - REGULATORY OPERATIONS SAFETY STAFF (ROSS)

SUBCHAPTER 10.11 - RESOURCES

SUBCHAPTER 10.12 - SPECIAL SAFETY SITUATIONS

SUBCHAPTER 10.13 - BIOLOGICAL HAZARDS

SUBCHAPTER 10.14 - CHEMICAL HAZARDS

SUBCHAPTER 10.15 - PHYSICAL AND RADITION HAZARDS

SUBCHAPTER 10.16 - ERGONOMIC

SUBCHAPTER 10.17 - EMPLOYEE AND TRAVELER HEALTH AND SAFETY

APPENDIX

APPENDIX A - PRINCIPAL STORED GRAIN INSECTS APPENDIX B - PERPETUAL JULIAN CALENDAR APPENDIX C - BLOOD SERUM CHEMISTRY APPENDIX D - CONVERSION TABLES

APPENDIX E - DIVISION MAPS (OBIMO, OBPO, OMDRHO, OPQO, OHAFO, OEIO, TOBACCO, ORS)

Note: Certain links in this chapter are only available to FDA employees via the FDA Intranet site and cannot be accessed by individuals outside the FDA internal network. Requests for information can be made through the Freedom of Information Act (FOIA) process described in IOM Section 8.1.3 and also at https://www.fda.gov/regulatory-information/freedom-information/how-make-foia-request.