

## TABLE OF CONTENTS

### Volume One

#### How to Use The Service

#### Newsletters

#### Tab 100: Overview of FDA Enforcement

<b>Executive Summary</b> .....	¶ 100
FDA's Enforcement Universe .....	¶ 101
FDA's Enforcement Objective .....	¶ 102
Appropriate Response to FDA Enforcement .....	¶ 103
<b>Administrative Enforcement Powers</b> .....	¶ 110
<b>Judicial Enforcement Powers</b> .....	¶ 120
Civil Enforcement Litigation .....	¶ 121
Criminal Enforcement Litigation.....	¶ 122
Relationship Between Criminal and Civil/ Administrative Sanctions .....	¶ 123
Relationship Between FDA Enforcement Litigation and Private Litigation.....	¶ 124
<b>FDA's Enforcement Policy</b> .....	¶ 130
Prior Notice.....	¶ 131
<b>Why FDA Decides to Pursue Enforcement</b>	
<b>Action</b> .....	¶ 140
Recent Enforcement Trends.....	¶ 141
<b>FDA Regulation of Products in Interstate Commerce</b> .....	¶ 150
<b>How FDA Rulemaking Affects Law Enforcement</b> .....	¶ 160
FDA's Use of Unofficial Regulations .....	¶ 161
How Courts Interpret FDA Rulemaking.....	¶ 162
FDA and Public Participation .....	¶ 163
<b>FDA and Other Federal Agencies</b> .....	¶ 170
FDA and Congress .....	¶ 171
<b>FDA and State and Local Agencies</b> .....	¶ 180
State Embargoes .....	¶ 181
FDA Cooperation with States .....	¶ 182
Preemption.....	¶ 183
FDA and Bioterrorism .....	¶ 184
State Enforcement of Tobacco Product Restrictions .....	¶ 185
<b>FDA and International Collaboration</b> .....	¶ 190
FDA's MRA With the European Union .....	¶ 191

#### Tab 200: FDA's Enforcement Organization:

##### Who Does What

<b>Executive Summary</b> .....	¶ 200
<b>FDA as Part of Executive Branch of Government</b> .....	¶ 210
FDA Budget: Implications for Enforcement .....	¶ 211
<b>FDA Field Offices: Their Operations and Role in Enforcement</b> .....	¶ 220
Regional Offices .....	¶ 221
District Offices .....	¶ 222
Resident Posts .....	¶ 223

Inspections Branch .....	¶ 224
Laboratory Branch .....	¶ 225
Compliance Branch .....	¶ 226
FDA Office Locations and Information.....	¶ 227
International Offices and Posts.....	¶ 228

#### **FDA Centers: Their Operations and Role in**

<b>Enforcement</b> .....	¶ 230
Center for Drug Evaluation and Research (CDER) .....	¶ 231
Center for Devices and Radiological Health (CDRH).....	¶ 232
Center for Food Safety and Applied Nutrition (CFSAN).....	¶ 233
Center for Biologics Evaluation and Research (CBER).. ¶ 234	¶ 234
Center for Veterinary Medicine (CVM).....	¶ 235
Center for Tobacco Products (CTP) .....	¶ 236

#### **FDA's Office of Regulatory Affairs: Supervising**

<b>Enforcement Actions</b> .....	¶ 240
Office of Enforcement and Import Operations .....	¶ 241
Other Operational Offices .....	¶ 242
Office of Criminal Investigations.....	¶ 243
<b>Office of the Commissioner</b> .....	¶ 250
<b>Office of the Chief Counsel</b> .....	¶ 260
<b>U.S. Department of Justice</b> .....	¶ 270
U.S. Attorney's Office.....	¶ 271
Office of Consumer Protection Litigation, Civil Division.....	¶ 272

#### **Sources of Information About FDA**

<b>Enforcement</b> .....	¶ 280
FDA Manuals and Other Materials .....	¶ 281
Freedom of Information Act (FOIA) .....	¶ 282
Trade Press and Other Information Sources.....	¶ 283
FDA Internet Sites.....	¶ 284
Sources of Additional Information .....	¶ 285
<b>Dispute Resolution</b> .....	¶ 290

#### Tab 300: Inspections

<b>Executive Summary</b> .....	¶ 300
FDA Annual Inspection Statistics .....	¶ 301
General Characteristics of FDA Inspections .....	¶ 302
<b>FDA's Authorities During Inspections</b> .....	¶ 310
FDA's Authority To Obtain Product Records .....	¶ 311
FDA's Authority To Inspect Carriers .....	¶ 312
Inspections Without Warrants .....	¶ 313
Consent .....	¶ 314
<b>FDA's Reasons for Inspecting Companies</b> .....	¶ 320
Company Circumstances That Trigger Inspections.....	¶ 321
FDA's Expert Investigators.....	¶ 322
<b>The FDA Inspection</b> .....	¶ 330
How Investigators Prepare for Inspections.....	¶ 331
Investigators' Credentials and Notices of Inspection.....	¶ 332
Entry and Observation .....	¶ 333
Investigators' Access to Documents .....	¶ 334

## Table of Contents

### Tab 300 (cont'd)

Sampling.....	¶ 335
Interviews.....	¶ 336
Affidavits.....	¶ 337
Photographs and Tape Recordings.....	¶ 338
Issuance of 483 (Inspectional Observations).....	¶ 339
<b>Company Responses to Inspections.....</b>	<b>¶ 340</b>
Preparing a Company Inspection Plan.....	¶ 341
Receiving the Notice of Inspection.....	¶ 342
Accompanying the Investigator.....	¶ 343
Providing Access to Documents.....	¶ 344
Company Response to Sampling.....	¶ 345
Company Response to Requests to Interview	
Employees.....	¶ 346
Company Response to Affidavits.....	¶ 347
Permitting Photographs or Tape Recordings.....	¶ 348
Responding to the 483.....	¶ 349
<b>Refusals of Inspection.....</b>	<b>¶ 350</b>
Actions FDA May Consider As Refusals.....	¶ 351
FDA Response to a Refusal.....	¶ 352
Administrative Warrants.....	¶ 353
<b>FDA Information About Completed</b>	
<b>Inspections.....</b>	<b>¶ 360</b>

### Tab 400: Warning Letters

<b>Executive Summary.....</b>	<b>¶ 400</b>
Purposes of the Warning Letter.....	¶ 401
Background of the Warning Letter.....	¶ 402
Trends in Issuing Warning Letters.....	¶ 403
<b>Authority To Issue Warning Letters.....</b>	<b>¶ 410</b>
Center Concurrence for Warning Letters.....	¶ 411
<b>Criteria for Warning Letters.....</b>	<b>¶ 420</b>
<b>Procedures for Issuing Warning Letters.....</b>	<b>¶ 430</b>
Recipients of Warning Letters.....	¶ 431
Situations When Warning Letters Are Not	
Sent.....	¶ 432
<b>Responding to Warning Letters.....</b>	<b>¶ 440</b>
Who Should Respond.....	¶ 441
What Should Be Said.....	¶ 442
How the FDA May React.....	¶ 443
Warning Letter Close-out Letter Program.....	¶ 444
<b>Public Availability of Warning Letters.....</b>	<b>¶ 450</b>
<b>Other FDA Regulatory Correspondence.....</b>	<b>¶ 460</b>

### Tab 500: Adverse Publicity Disseminated by FDA

<b>Executive Summary.....</b>	<b>¶ 500</b>
<b>FDA's Authority To Issue Publicity.....</b>	<b>¶ 510</b>
FDA's Written Policy.....	¶ 511
Advance Notice of FDA Publicity.....	¶ 512
<b>Types of FDA Publicity.....</b>	<b>¶ 520</b>
Who Prepares FDA Publicity.....	¶ 521
Media Dissemination of FDA Activity.....	¶ 522
<b>Ways Adverse Publicity Can Affect</b>	
<b>Companies.....</b>	<b>¶ 530</b>
<b>Responding to Adverse Publicity.....</b>	<b>¶ 540</b>
Action Plan for Response to Enforcement	
Crisis.....	¶ 541

### Tab 600: Recalls and Administrative Injunction

<b>Executive Summary.....</b>	<b>¶ 600</b>
Voluntary vs. Mandatory Recalls.....	¶ 601
Company Recall Plans.....	¶ 602
<b>Definition of a Recall.....</b>	<b>¶ 610</b>
Market Withdrawals and Stock Recoveries.....	¶ 611
Notifying the FDA.....	¶ 612
Information Required by the FDA.....	¶ 613
Classification Criteria for Recalls.....	¶ 614
FDA Guidelines for Recalls.....	¶ 615
Reporting Corrections and Removals.....	¶ 616
<b>Company-initiated Recalls.....</b>	<b>¶ 620</b>
<b>FDA-requested Recalls.....</b>	<b>¶ 630</b>
<b>Recall Strategy.....</b>	<b>¶ 640</b>
Depth of Recall.....	¶ 641
Public Warning.....	¶ 642
Effectiveness Checks.....	¶ 643
FDA Requirements for Company	
Communications.....	¶ 644
Implementing a Recall Plan.....	¶ 645
<b>Consequences of a Recall.....</b>	<b>¶ 650</b>
Need to Protect Information.....	¶ 651
Need to Prepare for Inspection.....	¶ 652
<b>FDA-ordered Recalls.....</b>	<b>¶ 660</b>
Medical Devices.....	¶ 661
Infant Formula.....	¶ 662
Biological Products.....	¶ 663
Foods.....	¶ 664
Tobacco Products.....	¶ 665

### Tab 700: Product Approvals

<b>Executive Summary.....</b>	<b>¶ 700</b>
Suspensions and Withdrawals.....	¶ 701
Deferral, Delay and Denial of Approval.....	¶ 702
The "Debarment" Law.....	¶ 703
<b>Approvals Subject to Suspension.....</b>	<b>¶ 710</b>
New Human or Animal Drugs.....	¶ 711
Biological Products.....	¶ 712
Low-acid Canned Foods.....	¶ 713
Medical Devices.....	¶ 714
<b>Withdrawal of Product Approvals.....</b>	<b>¶ 720</b>
Grounds for Withdrawal.....	¶ 721
Inspection Evidence.....	¶ 722
Process for Withdrawal of Product License.....	¶ 723
Summary Judgement for Withdrawing	
Approvals.....	¶ 724
Withdrawal of ANDA Approvals.....	¶ 725
Exports.....	¶ 726
<b>When FDA Finds Fraud in Product</b>	
<b>Applications.....</b>	<b>¶ 730</b>
Temporary Denial of ANDA Approvals.....	¶ 731
Temporary Suspension of Distribution of	
Generic Human Drugs.....	¶ 732
The Application Integrity Policy.....	¶ 733
Application Integrity Policy and Corrective	
Action.....	¶ 734
Validity Assessment Under the Application	
Integrity Policy.....	¶ 735

*Tab 700 (cont'd)*

Application Integrity Policy Decisions Are Not Final .....	¶736
Relationship Between the Application Integrity Policy and the “Debarment” Law .....	¶737
Fraud in Approved Applications .....	¶738
AIP List.....	¶739
<b>Debarment .....</b>	<b>¶740</b>
What Debarment Means .....	¶741
Debarment of Companies .....	¶742
Debarment of Individuals .....	¶743
Implementation of Debarment Authority.....	¶744
Debarment Status Chart .....	¶745
<b>Additional Actions Affecting Product Approvals .....</b>	<b>¶750</b>
FDA Refusal To File.....	¶751
Preapproval Inspections.....	¶752
Compliance Tracking Systems .....	¶753
Downgrading Therapeutic Equivalence Evaluations of Drugs .....	¶754

**Tab 800: Government Contracts**

<b>Executive Summary .....</b>	<b>¶800</b>
<b>FDA’s Government-wide Quality Assurance Program (GWQAP) .....</b>	<b>¶810</b>
Procurement Duties .....	¶811
Pre-award Evaluation Process .....	¶812
Consequences of Unacceptable Determinations .....	¶813
FDA’s Compliance Status Information System (COMSTAT).....	¶814
<b>Criminal Fraud and Debarment in Government Procurement Activities .....</b>	<b>¶820</b>

**Tab 900: Imports**

<b>Executive Summary .....</b>	<b>¶900</b>
Trends in Import Enforcement.....	¶901
<b>Statutory Authority Over Imports .....</b>	<b>¶910</b>
U.S. Bureau of Customs and Border Protection .....	¶911
FDA’s Operational and Administrative System for Import Support (OASIS).....	¶912
FDA’s Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) System .....	¶913
FDA’s Permissive Debarment Authority for Food Importers.....	¶914
<b>Import Alerts and Detention .....</b>	<b>¶920</b>
Detention .....	¶921
Automatic Detention.....	¶922
The Question of Detentions as Rulemakings.....	¶923
Responding to Detention .....	¶924
Import Hearings.....	¶925
<b>The Import Process.....</b>	<b>¶930</b>
Reconditioning and Relabeling .....	¶931
Redelivery Bond.....	¶932
Sampling of Perishable Goods .....	¶933
Reimportation and Import-for-Export .....	¶934

Special Procedures for Problem Importers .....	¶935
Schematic Diagram of FDA’s Import Procedures .....	¶936
<b>Exportation .....</b>	<b>¶940</b>
Exports of Unapproved Products .....	¶941
Exports of Investigational and Unfinished Products.....	¶942
Labeling of Exports .....	¶943
Export of Condemned Articles .....	¶944
Export Certificates.....	¶945

**Volume Two****Tab 1000: Civil Money Penalties**

<b>Executive Summary .....</b>	<b>¶1000</b>
<b>Penalties Involving Medical Devices .....</b>	<b>¶1010</b>
<b>Penalties Involving Radiation-emitting Products .....</b>	<b>¶1020</b>
<b>Penalties Involving Prescription Drugs.....</b>	<b>¶1030</b>
<b>Penalties Involving Biological and Other Public Health Products .....</b>	<b>¶1040</b>
Biological Products .....	¶1041
Other Public Health Penalties.....	¶1042
<b>Penalties Involving Generic Human Drugs .....</b>	<b>¶1050</b>
<b>Penalties Involving Food .....</b>	<b>¶1055</b>
<b>Penalties Involving Clinical Trial Registry and Results Data Bank Requirements.....</b>	<b>¶1060</b>
<b>Penalties Involving Tobacco Products.....</b>	<b>¶1065</b>
<b>How FDA Imposes Civil Money Penalties.....</b>	<b>¶1070</b>
Initiation of Civil Money Penalty Proceedings.....	¶1071
Evidence and Subpoena Authority.....	¶1072
Hearing Procedures .....	¶1073
Appeals .....	¶1074
<b>Relationship Between Civil Money Penalties and Criminal Penalties: The <i>Halper</i> Case.....</b>	<b>¶1080</b>

**Tab 1100: Seizures**

<b>Executive Summary .....</b>	<b>¶1100</b>
<b>Avoiding Seizure.....</b>	<b>¶1110</b>
State Embargoes .....	¶1111
Medical Devices .....	¶1112
Counterfeit Drugs .....	¶1113
Foods .....	¶1114
Tobacco Products.....	¶1115
<b>The Seizure Process .....</b>	<b>¶1120</b>
Judicial Procedure .....	¶1121
Simple Seizures .....	¶1122
Mass Seizures .....	¶1123
Test Case Seizures .....	¶1124
Court Decisions on Seizures.....	¶1125
<b>How a Seizure Begins .....</b>	<b>¶1130</b>
<b>How Products Are Seized.....</b>	<b>¶1140</b>
<b>Claiming Seized Products .....</b>	<b>¶1150</b>
Challenging a Seizure.....	¶1151
<b>Disposition of Seized Products .....</b>	<b>¶1160</b>
Contesting FDA Seizures .....	¶1161
Default and Destruction.....	¶1162
Consent and Destruction.....	¶1163

## Table of Contents

Consent and Reconditioning.....	¶ 1164
The Consent Decree .....	¶ 1165
Typical Decree Proposed by the FDA .....	¶ 1166
Typical Responses to Proposed Decrees.....	¶ 1167
Disposition of Seized Imports .....	¶ 1168
<b>Multiple Seizures .....</b>	<b>¶ 1170</b>
Seizures and Injunctions.....	¶ 1171
Seizure of Labeling.....	¶ 1172

### Tab 1200: Injunctions

<b>Executive Summary.....</b>	<b>¶ 1200</b>
Purpose of Injunctions.....	¶ 1201
Injunction Trends .....	¶ 1202
<b>Actions that Prompt FDA To Seek</b>	
<b>Injunctions .....</b>	<b>¶ 1210</b>
<b>Kinds of Injunctions.....</b>	<b>¶ 1220</b>
Permanent Injunctions .....	¶ 1221
Preliminary Injunctions .....	¶ 1222
Temporary Restraining Orders .....	¶ 1223
Contempt.....	¶ 1224
<b>Procedures for Processing Injunctions.....</b>	<b>¶ 1230</b>
FDA District Office Decisions About	
Injunctions .....	¶ 1231
Headquarters' Decisions About Injunctions .....	¶ 1232
Review of Injunctions by FDA's Office of	
General Counsel .....	¶ 1233
<b>Avoiding FDA Injunctions .....</b>	<b>¶ 1240</b>
<b>Legal Standards of FDA Injunctions .....</b>	<b>¶ 1250</b>
Irreparable Harm.....	¶ 1251
Likelihood of Recurrence.....	¶ 1252
Who May Be Enjoined .....	¶ 1253
<b>Defenses Against Injunctions.....</b>	<b>¶ 1260</b>
<b>Terms of Settlement for Injunctions .....</b>	<b>¶ 1270</b>
Typical Consent Decree .....	¶ 1271
New "Standard" Terms of Injunctions.....	¶ 1272

### Tab 1300: Criminal Liability

<b>Executive Summary.....</b>	<b>¶ 1300</b>
Who Files Charges?.....	¶ 1301
Availability of Defenses.....	¶ 1302
<b>Statutory Authority for Criminal</b>	
<b>Enforcement .....</b>	<b>¶ 1310</b>
Acts That Are Misdemeanors .....	¶ 1311
Acts That Are Felonies.....	¶ 1312
<b>Strict Individual Liability:</b>	
<b>The Park Doctrine .....</b>	<b>¶ 1320</b>
The Dotterweich Case .....	¶ 1321
The Park Case.....	¶ 1322
Potential Conflicts of Interest.....	¶ 1323
<b>Vicarious Corporate Liability.....</b>	<b>¶ 1330</b>
<b>Defenses .....</b>	<b>¶ 1340</b>
Objective Impossibility .....	¶ 1341
Responsible Relationship .....	¶ 1342
Guaranty .....	¶ 1343
<b>When Will the FDA Recommend</b>	
<b>Prosecution?.....</b>	<b>¶ 1350</b>
When Will the Justice Department	
Proceed?.....	¶ 1351

<b>Opportunity to Present Views .....</b>	<b>¶ 1360</b>
When No 305 Meeting Is Offered.....	¶ 1361
When a 305 Meeting Is Offered.....	¶ 1362
Responding to a Notice for a 305 Meeting .....	¶ 1363
The 305 Meeting.....	¶ 1364
<b>Violations With Knowledge or Intent.....</b>	<b>¶ 1370</b>
<b>Federal Crimes Involving the FDA.....</b>	<b>¶ 1380</b>
Counterfeiting.....	¶ 1381

### Tab 1400: Criminal Case Development

<b>Executive Summary.....</b>	<b>¶ 1400</b>
<b>How the FDA Investigates Criminal Cases.....</b>	<b>¶ 1410</b>
Investigation Coordination.....	¶ 1411
Information Sought During Criminal	
Investigations .....	¶ 1412
Documents Sought in Criminal	
Investigations.....	¶ 1413
Investigating Responsibility and Intent.....	¶ 1414
The Office of Criminal Investigations (OCI).....	¶ 1415
<b>How the FDA Processes Criminal Cases .....</b>	<b>¶ 1420</b>
Prosecution Process When There Is a	
Section 305 Notice .....	¶ 1421
Prosecution Process Without a Section	
305 Notice .....	¶ 1422
FDA Referrals for Criminal Investigation .....	¶ 1423
Contempt of Court and Violations of	
Probation .....	¶ 1424
<b>Role of the Department of Justice.....</b>	<b>¶ 1430</b>
How the Department of Justice Processes	
FDA Referrals .....	¶ 1431
Furthering the Investigation .....	¶ 1432
The Grand Jury.....	¶ 1433
Search Warrants .....	¶ 1434
Resolution of the Investigation .....	¶ 1435
<b>Roles of Other Federal Organizations in FDA</b>	
<b>Investigations.....</b>	<b>¶ 1440</b>

### Tab 1500: Sentencing

<b>Executive Summary.....</b>	<b>¶ 1500</b>
Importance of Corporate Compliance and	
Ethics Programs .....	¶ 1501
<b>Federal Sentencing Laws.....</b>	<b>¶ 1510</b>
Fines .....	¶ 1511
Restitution .....	¶ 1512
Forfeiture .....	¶ 1513
Probation .....	¶ 1514
Imprisonment.....	¶ 1515
Statutory Criteria for Sentencing .....	¶ 1516
<b>The Sentencing Guidelines .....</b>	<b>¶ 1520</b>
Sentencing for Violations of the Federal Food,	
Drug and Cosmetic Act .....	¶ 1521
<b>Sentencing Individuals Under the</b>	
<b>Guidelines .....</b>	<b>¶ 1530</b>
The Total Offense Level .....	¶ 1531
How Prison Terms Are Calculated .....	¶ 1532

Tab 1500 (cont'd)

How Individuals' Fines Are Calculated..... ¶1533  
 Departures That Affect Calculations ..... ¶1534

**Sentencing Organizations Under the Guidelines ..... ¶1540**  
 Restitution by Corporations ..... ¶1541  
 Fines for Corporations..... ¶1542  
 Probation for Corporations..... ¶1543  
 Guidelines Application to FDA-regulated  
 Companies..... ¶1544  
 Effective Compliance and Ethics Programs ..... ¶1545  
 Reporting Crimes ..... ¶1546  
 Ultimate Benefits of Compliance and Ethics  
 Programs ..... ¶1547  
 Office of Inspector General Voluntary  
 Compliance Guidance for Pharmaceutical  
 Companies..... ¶1548

**Tab 1600: Current Good Manufacturing Practices**

**Executive Summary ..... ¶1600**  
**The Basis of Current Good Manufacturing Practice ..... ¶1610**  
**The Regulation of CGMPs ..... ¶1620**  
 CGMP Requirements ..... ¶1621  
 CGMP Guidance ..... ¶1622  
 Judicial Enforcement..... ¶1623  
 Warning Letters ..... ¶1624  
 Delay in Product Approval..... ¶1625  
 Other Consequences of CGMP  
 Noncompliance ..... ¶1626  
 Costs of Compliance ..... ¶1627

**The Drug CGMPs ..... ¶1630**  
 Scope and Application..... ¶1631  
 Requirements..... ¶1632  
 Revisions to the Drug CGMP..... ¶1633

**The Device Quality System Regulations ..... ¶1640**  
 Scope and Application..... ¶1641  
 Requirements..... ¶1642  
 Compliance Issues..... ¶1643

**The Food Sanitation Regulations ..... ¶1650**  
 Requirements..... ¶1651  
 HACCP..... ¶1652  
 Dietary Supplements ..... ¶1653  
 Other Food Processing CGMP Regulations ..... ¶1654

**Other FDA CGMP Requirements ..... ¶1660**  
 Biological Products ..... ¶1661  
 Medicated Animal Feeds..... ¶1662  
 Cosmetics ..... ¶1663  
 Tobacco Products ..... ¶1664  
 Combination Products ..... ¶1665

**CGMP Inspections ..... ¶1670**  
 FDA Inspection Authority ..... ¶1671  
 CGMP Inspection Issues ..... ¶1672  
 Responding to a CGMP Inspection ..... ¶1673  
 How FDA Assesses CGMP Noncompliance..... ¶1674

**Appendix I**

**U.S. Criminal Code**

**Selected Sections**

False, Fictitious or Fraudulent Claims ..... §287  
 Conspiracy to Commit Offense or to Defraud  
 United States ..... §371  
 Power of Court ..... §401  
 Smuggling Goods into the United States ..... §545  
 Statements or Entries Generally ..... §1001  
 Frauds and Swindles..... §1341  
 Fraud by Wire, Radio, or Television ..... §1343  
 Injunctions against Fraud ..... §1345  
 Tampering with Consumer Products ..... §1365  
 Influencing or Injuring Officer or Juror  
 Generally..... §1503  
 Obstruction of Proceeding before  
 Departments, Agencies, and Committees ..... §1505  
 Prohibited Activities ..... §1962  
 Imposition of a Sentence ..... §3553  
 Sentence of Fine ..... §3571  
 Imposition of a Sentence of Fine and  
 Related Matters ..... §3572

**Federal Food, Drug and Cosmetic Act, as Amended (21 U.S.C. §301 et seq.)**

**Selected Sections**

**Chapter II — Definitions**

Definitions; Generally [§321]..... Sec. 201

**Chapter III — Prohibited Acts**

Prohibited Acts [§331] ..... Sec. 301  
 Injunction Proceedings [§332] ..... Sec. 302  
 Penalties [§333]..... Sec. 303  
 Seizure [§334] ..... Sec. 304  
 Hearing Before Report of Criminal  
 Violation [§335]..... Sec. 305  
 Debarment, Temporary Denial of Approval,  
 and Suspension [§335a] ..... Sec. 306  
 Civil Penalties [§335b]..... Sec. 307  
 Authority to Withdraw Approval of  
 Abbreviated Drug Applications [§335c]..... Sec. 308  
 Report of Minor Violations [§336]..... Sec. 309  
 Proceedings in Name of United States;  
 Provision as to Subpoenas [§337]..... Sec. 310

**Chapter IV — Food**

Adulterated Food [§342] ..... Sec. 402  
 Misbranded Food [§343]..... Sec. 403  
 National Uniform Nutrition Labeling  
 [§343-1]..... Sec. 403A

**Chapter V — Drugs and Devices**

Adulterated Drugs and Devices [§351]..... Sec. 501  
 Misbranded Drugs and Devices [§352]..... Sec. 502  
 Notification and Other Remedies [§360h] ..... Sec. 518  
 State and Local Requirements Respecting  
 Devices [§360k]..... Sec. 521  
 Definitions [§360hh] ..... Sec. 531  
 Notification of Defects in, and Repair or  
 Replacement of, Electronic Products  
 [§360ll]..... Sec. 535

## Table of Contents

### Appendix I (cont'd)

Imports [§360mm].....	Sec. 536
Inspection and Reports [§360nn] .....	Sec. 537
Prohibited Acts [§360oo] .....	Sec. 538
Enforcement [§360pp].....	Sec. 539
Effect on State Standards [§360ss].....	Sec. 542

### Chapter VI — Cosmetics

Adulterated Cosmetics [§361].....	Sec. 601
Misbranded Cosmetics [§362] .....	Sec. 602

### Chapter VII — General Administrative Provisions

Regulations and Hearings [§371].....	Sec. 701
Examinations and Investigations [§372].....	Sec. 702
Records of Interstate Shipment [§373].....	Sec. 703
Factory Inspection [§374] .....	Sec. 704
Publicity [§375].....	Sec. 705
Seafood Inspection .....	Sec. 706
Presumption of Existence of Jurisdiction [§379a] .....	Sec. 709

### Chapter VIII — Imports and Exports

Imports and Exports [§381].....	Sec. 801
Exports of Certain Unapproved Products [§382].....	Sec. 802

### Biologics Control Act, as Amended

#### Selected Sections

Regulation of Biological Products .....	§262
---	------

### Federal Rules of Civil Procedure

#### Selected Rules

Injunctions.....	Rule 65
------------------	---------

### Supplemental Rules to Federal Rules of Civil Procedure

#### Selected Rules

Actions In Rem: Special Provisions.....	Rule C
Actions In Rem and Quasi In Rem: General Provisions.....	Rule E

### Federal Rules of Criminal Procedure

#### Selected Rules

The Grand Jury.....	Rule 6
Search and Seizure .....	Rule 41

### Sentencing Guidelines

#### Selected Guidelines

### Chapter 2 — Offense Conduct

#### Part B — Basic Economic Offenses

##### 1. Theft, Embezzlement, Receipt of Stolen

##### Property, Property Destruction, and Offenses Involving Fraud or Deceit

Larceny, Embezzlement, and Other Forms of Theft; Offenses Involving Stolen Property; Property Damage or Destruction; Fraud and Deceit; Forgery; Offenses Involving Altered or Counterfeit Instruments Other than Counterfeit Bearer Obligations of the United States .....	§2B1.1
--	--------

### Part N — Offenses Involving Food, Drugs, Agricultural Products, Consumer Products, and Odometer Laws

#### 1. Tampering with Consumer Products

Tampering or Attempting to Tamper Involving Risk of Death or Bodily Injury .....	§2N1.1
Providing False Information or Threatening to Tamper with Consumer Products.....	§2N1.2
Tampering With Intent to Injure Business.....	§2N1.3

#### 2. Food, Drugs, Agricultural Products, and Consumer Products

Violations of Statutes and Regulations Dealing With Any Food, Drug, Biological Product, Device, Cosmetic, Agricultural Product, or Consumer Product .....	§2N2.1
--	--------

### Chapter 8 — Sentencing of Organizations

#### Part A — General Application Principles

Applicability of Chapter Eight .....	§8A1.1
Application Instructions — Organizations.....	§8A1.2

#### Part B — Remedying Harm From Criminal Conduct, and Effective Compliance and Ethics Program

##### 1. Remedying Harm From Criminal Conduct

Restitution — Organizations .....	§8B1.1
Remedial Orders — Organizations (Policy Statement).....	§8B1.2
Community Service — Organizations (Policy Statement).....	§8B1.3
Order of Notice to Victims — Organizations.....	§8B1.4

##### 2. Effective Compliance and Ethics Program

Effective Compliance and Ethics Program .....	§8B2.1
---	--------

#### Part C — Fines

##### 1. Determining the Fine — Criminal Purpose Organizations

Determining the Fine — Criminal Purpose Organizations .....	§8C1.1
--	--------

##### 2. Determining the Fine — Other Organizations

Applicability of Fine Guidelines .....	§8C2.1
Preliminary Determination of Inability to Pay Fine .....	§8C2.2
Offense Level .....	§8C2.3
Base Fine .....	§8C2.4
Culpability Score.....	§8C2.5
Minimum and Maximum Multipliers.....	§8C2.6
Guideline Fine Range — Organizations .....	§8C2.7
Determining the Fine Within the Range (Policy Statement).....	§8C2.8
Disgorgement .....	§8C2.9
Determining the Fine for Other Counts.....	§8C2.10

##### 3. Implementing the Sentence of a Fine

Imposing a Fine .....	§8C3.1
Payment of the Fine — Organizations .....	§8C3.2
Reduction of Fine Based on Inability to Pay.....	§8C3.3
Fines Paid by Owners of Closely Held Organizations .....	§8C3.4

##### 4. Departures From the Guideline Fine Range

Substantial Assistance to Authorities — Organizations(Policy Statement) .....	§8C4.1
Risk of Death or Bodily Injury (Policy Statement) .....	§8C4.2

*Appendix I (cont'd)*

Threat to National Security (Policy Statement) ..... §8C4.3

Threat to the Environment (Policy Statement) ..... §8C4.4

Threat to a Market (Policy Statement)..... §8C4.5

Official Corruption (Policy Statement)..... §8C4.6

Public Entity (Policy Statement) ..... §8C4.7

Members or Beneficiaries of the Organization as Victims (Policy Statement) ..... §8C4.8

Remedial Costs that Greatly Exceed Gain (Policy Statement)..... §8C4.9

Mandatory Programs to Prevent and Detect Violations of Law (Policy Statement)..... §8C4.10

Exceptional Organizational Culpability (Policy Statement).....§8C4.11

**Part D – Organizational Probation**

Imposition of Probation – Organizations ..... §8D1.1

Term of Probation – Organizations ..... §8D1.2

Conditions of Probation – Organizations ..... §8D1.3

Recommended Conditions of Probation – Organizations (Policy Statement) ..... §8D1.4

[Deleted] ..... §8D1.5

**Part E – Special Assessments, Forfeitures, and Costs**

Special Assessments – Organizations ..... §8E1.1

Forfeiture – Organizations ..... §8E1.2

Assessment of Costs – Organizations ..... §8E1.3

**Part F – Violations of Probation – Organizations**

Violations of Conditions of Probation – Organizations (Policy Statement) ..... §8F1.1

**Appendix II**

**Title 21 Code of Federal Regulations**

**Part 1 – General Enforcement Regulations**

**Subpart E – Imports and Exports**

Definitions ..... §1.83

Notice of Sampling ..... §1.90

Payment for Samples ..... §1.91

Hearing on Refusal of Admission ..... §1.94

Application for Authorization to Relabel and Recondition ..... §1.95

Granting of Authorization to Relabel and Recondition ..... §1.96

Bonds ..... §1.97

Costs Chargeable in Connection with Relabeling and Reconditioning Inadmissible Imports ..... §1.99

**Part 2 – General Administrative Ruling and Decisions**

**Subpart A – General Provisions**

Examination and Investigation Samples ..... §2.10

**Subpart B – Initiation of Proceedings**

Method of Analysis ..... §2.19

**Part 7 – Enforcement Policy**

**Subpart A – General Provisions**

Definitions ..... §7.3

Suggested Forms of Guaranty ..... §7.13

**Subpart C – Recalls (Including Product Corrections) – Guidelines on Policy, Procedures, and Industry Responsibilities**

Recall Policy ..... §7.40

Health Hazard Evaluation and Recall Classification..... §7.41

Recall Strategy ..... §7.42

Food and Drug Administration-requested Recall..... §7.45

Firm-initiated Recall..... §7.46

Recall Communications..... §7.49

Public Notification of Recall..... §7.50

Recall Status Reports ..... §7.53

Termination of a Recall ..... §7.55

General Industry Guidance ..... §7.59

**Subpart E – Criminal Violations**

Opportunity for Presentation of Views before Report of Criminal Violation ..... §7.84

Conduct of a Presentation of Views before Report of Criminal Violation ..... §7.85

Records Related to Opportunities for Presentation of Views Conducted before Report of Criminal Violation ..... §7.87

**Part 10 – Administrative Practices and Procedures**

**Subpart B – General Administrative Procedures**

Citizen Petition ..... §10.30

Administrative Reconsideration of Action..... §10.33

Documentation of Significant Decisions in Administrative File..... §10.70

Internal Agency Review of Decisions ..... §10.75

Advisory Opinions..... §10.85

Food and Drug Administration Regulations, Guidelines, Recommendations, and Agreements ..... §10.90

**Part 12 – Formal Evidentiary Public Hearings**

**Subpart A – General Provisions**

Scope ..... §12.1

**Subpart B – Initiation of Proceedings**

Initiation of a Hearing Involving the Issuance, Amendment, or Revocation of a Regulation ..... §12.20

**Part 16 – Regulatory Hearing before the Food and Drug Administration**

**Subpart A – General Provisions**

Scope ..... §16.1

**Part 17 – Civil Money Penalties Hearings**

Scope ..... §17.1

Maximum penalty amounts ..... §17.2

Definitions..... §17.3

Complaint..... §17.5

Service of complaint..... §17.7

Answer..... §17.9

Default upon failure to file an answer..... §17.11

Notice of hearing ..... §17.13

Parties to the hearing..... §17.15

Summary decisions ..... §17.17

Interlocutory appeal from ruling of presiding officer..... §17.18

## Table of Contents

### Appendix II (cont'd)

Authority of the presiding officer .....	§17.19
Ex parte contacts .....	§17.20
Prehearing conferences.....	§17.21
Discovery .....	§17.23
Exchange of witness lists, witness statements, and exhibits.....	§17.25
Hearing subpoenas .....	§17.27
Protective order.....	§17.28
Fees .....	§17.29
Computation of time.....	§17.30
Form, filing, and service of papers.....	§17.31
Motions .....	§17.32
The hearing and burden of proof.....	§17.33
Determining the amount of penalties and assessments .....	§17.34
Sanctions .....	§17.35
Witnesses .....	§17.37
Evidence.....	§17.39
The administrative record.....	§17.41
Posthearing briefs .....	§17.43
Initial decision .....	§17.45
Appeals .....	§17.47
Harmless error.....	§17.48
Judicial review.....	§17.51
Deposit in the Treasury of the United States .....	§17.54

## Title 45 Code of Federal Regulations

### Subtitle A

#### Part 17 - Release of Adverse Information to News Media

Definition.....	§17.1
Basic Policy.....	§17.2
Precautions to be Taken .....	§17.3
Regulatory Investigations and Trial-type Proceedings.....	§17.4
Context to be Reflected .....	§17.5
Advance Notice .....	§17.6
Retractions or Corrections .....	§17.7

### Appendix III

<i>United States v. Park</i> , 421 U.S. 658 (1975)
<i>Heckler v. Chaney</i> , 470 U.S. 821 (1985)
<i>United States v. Jamieson-McKames Pharmaceuticals Inc.</i> , 651 F.2d 532 (8th Cir. 1981)
<i>United States v. Gel Spice Co.</i> , 773 F.2d 427 (2d Cir. 1985)
<i>United States v. Odessa Union Warehouse Co-op</i> , 833 F.2d 172 (9th Cir. 1987)
<i>Estee Lauder Inc. v. United States</i> , 727 F. Supp. 1 (D.D.C. 1989)
<i>Medtronic Inc. v. Lohr</i> , 518 U.S. 470 (1996)
<i>United States v. Universal Management Services Inc.</i> , 191 F.3d 750 (6th Cir. 1999)
<i>United States v. Lane Labs-USA Inc.</i> , 427 F.3d 219 (3d Cir. 2005)

*United States v. Rx Depot, Inc.*, 438 F.3d 1052 (10th Cir.  
2006)

*Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008)

*Wyeth v. Levine*, 129 S. Ct. 1187 (2009)

### Appendix IV

Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy
Points to Consider for Internal Reviews and Corrective Action Operating Plans
Government-wide Quality Assurance Program Manual
Administrative Practices and Procedures; Advisory Opinions and Guidelines; Proposed Rule
Good Guidance Practices
Product Recalls, Including Removals and Corrections
Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioter- rorism Preparedness and Response Act of 2002
Using Electronic Means to Distribute Certain Product Information
Marketed Unapproved Drugs – Compliance Policy Guide
Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products (excerpts) (FDA statement on preemption of state law by agency approval of labeling)
Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices
Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco
Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products
Food and Drug Administration Enforcement Strategy (July 15, 2010)
Enforcement Action Plan for Promotion and Advertising Restrictions (Center for Tobacco Products)
Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers

### Appendix V

Form 463a (Affidavit)
Form 482 (Notice of Inspection)
Form 482a (Demand for Records)
Form 482b (Request for Information)
Form 482c (Notice of Inspection – Request for Records)
Form 483 (Inspectional Observations)
Form 484 (Receipt for Samples)
Notice of FDA Action
Resources for FDA Regulated Businesses

### Glossary [RESERVED]

### Index

Subject Index
Case Index

[The next page is Current Contents, Page 31.]