

TABLE OF CONTENTS

Volume One

How to Use The Service

Newsletters

Tab 100: Overview of FDA Enforcement

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

Tab 200: FDA's Enforcement Organization:

Who Does What

Executive Summary	¶ 200
FDA as Part of Executive Branch of Government	¶ 210
FDA Budget: Implications for Enforcement.....	¶ 211
FDA Field Offices: Their Operations and Role in Enforcement	¶ 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

Enforcement	¶ 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

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

Sources of Information About FDA

Enforcement	¶ 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
Dispute Resolution	¶ 290

Tab 300: Inspections

Executive Summary	¶ 300
FDA Annual Inspection Statistics.....	¶ 301
General Characteristics of FDA Inspections.....	¶ 302
FDA's Authorities During Inspections	¶ 310
FDA's Authority To Obtain Product Records.....	¶ 311
FDA's Authority To Inspect Carriers.....	¶ 312
Inspections Without Warrants.....	¶ 313
Consent.....	¶ 314
FDA's Reasons for Inspecting Companies	¶ 320
Company Circumstances That Trigger Inspections.....	¶ 321
FDA's Expert Investigators.....	¶ 322
The FDA Inspection	¶ 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
Company Responses to Inspections.....	¶ 340
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
Refusals of Inspection.....	¶ 350
Actions FDA May Consider As Refusals.....	¶ 351
FDA Response to a Refusal.....	¶ 352
Administrative Warrants.....	¶ 353
FDA Information About Completed	
Inspections.....	¶ 360

Tab 400: Warning Letters

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

Tab 500: Adverse Publicity Disseminated by FDA

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

Tab 600: Recalls and Administrative Injunction

Executive Summary.....	¶ 600
Voluntary vs. Mandatory Recalls.....	¶ 601
Company Recall Plans.....	¶ 602
Definition of a Recall.....	¶ 610
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
Company-initiated Recalls.....	¶ 620
FDA-requested Recalls.....	¶ 630
Recall Strategy.....	¶ 640
Depth of Recall.....	¶ 641
Public Warning.....	¶ 642
Effectiveness Checks.....	¶ 643
FDA Requirements for Company	
Communications.....	¶ 644
Implementing a Recall Plan.....	¶ 645
Consequences of a Recall.....	¶ 650
Need to Protect Information.....	¶ 651
Need to Prepare for Inspection.....	¶ 652
FDA-ordered Recalls.....	¶ 660
Medical Devices.....	¶ 661
Infant Formula.....	¶ 662
Biological Products.....	¶ 663
Foods.....	¶ 664
Tobacco Products.....	¶ 665

Tab 700: Product Approvals

Executive Summary.....	¶ 700
Suspensions and Withdrawals.....	¶ 701
Deferral, Delay and Denial of Approval.....	¶ 702
The "Debarment" Law.....	¶ 703
Approvals Subject to Suspension.....	¶ 710
New Human or Animal Drugs.....	¶ 711
Biological Products.....	¶ 712
Low-acid Canned Foods.....	¶ 713
Medical Devices.....	¶ 714
Withdrawal of Product Approvals.....	¶ 720
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
When FDA Finds Fraud in Product	
Applications.....	¶ 730
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
Debarment	¶740
What Debarment Means	¶741
Debarment of Companies	¶742
Debarment of Individuals	¶743
Implementation of Debarment Authority.....	¶744
Debarment Status Chart	¶745
Additional Actions Affecting Product Approvals	¶750
FDA Refusal To File.....	¶751
Preapproval Inspections.....	¶752
Compliance Tracking Systems	¶753
Downgrading Therapeutic Equivalence Evaluations of Drugs	¶754

Tab 800: Government Contracts

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

Tab 900: Imports

Executive Summary	¶900
Trends in Import Enforcement.....	¶901
Statutory Authority Over Imports	¶910
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
Import Alerts and Detention	¶920
Detention	¶921
Automatic Detention.....	¶922
The Question of Detentions as Rulemakings.....	¶923
Responding to Detention	¶924
Import Hearings.....	¶925
The Import Process.....	¶930
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
Exportation	¶940
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**

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

Tab 1100: Seizures

Executive Summary	¶1100
Avoiding Seizure.....	¶1110
State Embargoes	¶1111
Medical Devices	¶1112
Counterfeit Drugs	¶1113
Foods	¶1114
Tobacco Products.....	¶1115
The Seizure Process	¶1120
Judicial Procedure	¶1121
Simple Seizures	¶1122
Mass Seizures	¶1123
Test Case Seizures	¶1124
Court Decisions on Seizures.....	¶1125
How a Seizure Begins	¶1130
How Products Are Seized.....	¶1140
Claiming Seized Products	¶1150
Challenging a Seizure.....	¶1151
Disposition of Seized Products	¶1160
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
Multiple Seizures	¶ 1170
Seizures and Injunctions.....	¶ 1171
Seizure of Labeling.....	¶ 1172

Tab 1200: Injunctions

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

Tab 1300: Criminal Liability

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

Opportunity to Present Views	¶ 1360
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
Violations With Knowledge or Intent.....	¶ 1370
Federal Crimes Involving the FDA.....	¶ 1380
Counterfeiting.....	¶ 1381

Tab 1400: Criminal Case Development

Executive Summary.....	¶ 1400
How the FDA Investigates Criminal Cases.....	¶ 1410
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
How the FDA Processes Criminal Cases	¶ 1420
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
Role of the Department of Justice.....	¶ 1430
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
Roles of Other Federal Organizations in FDA	
Investigations.....	¶ 1440

Tab 1500: Sentencing

Executive Summary.....	¶ 1500
Importance of Corporate Compliance and	
Ethics Programs	¶ 1501
Federal Sentencing Laws.....	¶ 1510
Fines	¶ 1511
Restitution	¶ 1512
Forfeiture	¶ 1513
Probation	¶ 1514
Imprisonment.....	¶ 1515
Statutory Criteria for Sentencing	¶ 1516
The Sentencing Guidelines	¶ 1520
Sentencing for Violations of the Federal Food,	
Drug and Cosmetic Act	¶ 1521
Sentencing Individuals Under the	
Guidelines	¶ 1530
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)

<i>United States v. Rx Depot, Inc.</i> , 438 F.3d 1052 (10th Cir. 2006)
<i>Riegel v. Medtronic, Inc.</i> , 128 S. Ct. 999 (2008)
<i>Wyeth v. Levine</i> , 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.]