

## Chapter 2 FDA Authority

This chapter includes the following sections:

Section	Topic	Page
2-1	THE U.S. FEDERAL JUDICIAL SYSTEM.....	2
2-1-1	U.S. District Courts .....	2
2-1-2	U.S. Circuit Court of Appeals.....	3
2-1-3	The U.S. Supreme Court.....	3
2-2	SELECTED AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT .....	5
2.2.1.	Animal Drug User Fee (ADUFA).....	8
2.2.2.	Anti-Drug Abuse Act.....	8
2.2.3.	Best Pharmaceuticals for Children Act (BFCA).....	8
2.2.4.	Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNPDCPA).....	8
2.2.5.	Drug Price Competition and Patent Term Restoration Act (DPCPTRA) .....	7
2.2.6.	Drug Quality and Security Act (DQSA) .....	9
2.2.7.	Electronic Product Radiation Control Act .....	9
2.2.8.	Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).....	10
2.2.9.	Food Allergen Labeling and Consumer Protection Act (FALCPA) .....	10
2.2.10.	Food and Drug Administration Amendments Act of 2007 (FDAAA) .....	10
2.2.11.	Food and Drug Administration Export Reform and Enhancement Act (FDAEREA) .....	10
2.2.12.	Food and Drug Administration Modernization Act of 1997 (FDAMA).....	10
2.2.13.	Food and Drug Administration Safety and Innovation Act (FDASIA) .....	11
2.2.14.	Food Quality Protection Act (FQPA).....	11
2.2.15.	Food Safety Modernization Act (FSMA).....	11
2.2.16.	Generic Drug Enforcement Act (GDEA).....	11
2.2.17.	Health Promotion and Disease Prevention Amendments (HPDPA) .....	11
2.2.18.	Infant Formula Act (IFA).....	11
2.2.19.	Medical Device Amendments .....	11
2.2.20.	Medical Device User Fee and Modernization Act (MDUFMA III).....	12
2.2.21.	Minor Use and Minor Species Animal Health Act (MUMS) .....	12

2.2.22.	Nutrition Labeling and Education Act (NLEA) .....	12
2.2.23.	Orphan Drug Act (ODA).....	12
2.2.24.	Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA).....	13
2.2.25.	Pediatric Research Equity Act. (PREA) .....	13
2.2.26.	Prescription Drug Marketing Act of 1987 (PDMA).....	13
2.2.27.	Prescription Drug User Fee Act (PDUFA) .....	14
2.2.28.	Project Bioshield Act .....	14
2-3	OTHER LAWS .....	14
2.3.1.	Public Health Service Act - Biological Products (Part F, Subpart 1) .....	14
2.3.2.	Public Health Service Act - Control of Communicable Diseases (Part G).....	15
2.3.3.	Mammography Quality Standards Act of 1992 .....	15
2.3.4.	Federal Anti-Tampering Act – 1983 .....	16
2.3.5.	Freedom of Information Act – 1966 .....	16
2.3.6.	Electronic Freedom of Information Amendments of 1996.....	17
2.3.7.	Sanitary Food Transportation Act of 1990.....	18
2.3.8.	Pesticides Monitoring Improvements Act of 1988 .....	18
2.3.9.	AIDS Amendments of 1988 .....	19
2.3.10.	Lead-Based Paint Poisoning Prevention Act – 1971 .....	20
2.3.11.	Egg Products Inspection Act - 1970.....	20
2.3.12.	Fair Packaging and Labeling Act - 1966.....	21
2.3.13.	Federal Import Milk Act .....	21
2.3.14.	Health Insurance Portability and Accountability Act of 1996.....	21
2.3.15.	Equal Access to Justice Act - 1980 .....	22
2.3.16.	Sentencing Reform Act of 1984 .....	23
2.3.17.	Crimes And Criminal Procedure .....	24

## 2-1 THE U.S. FEDERAL JUDICIAL SYSTEM

### 2-1-1 U.S. District Courts

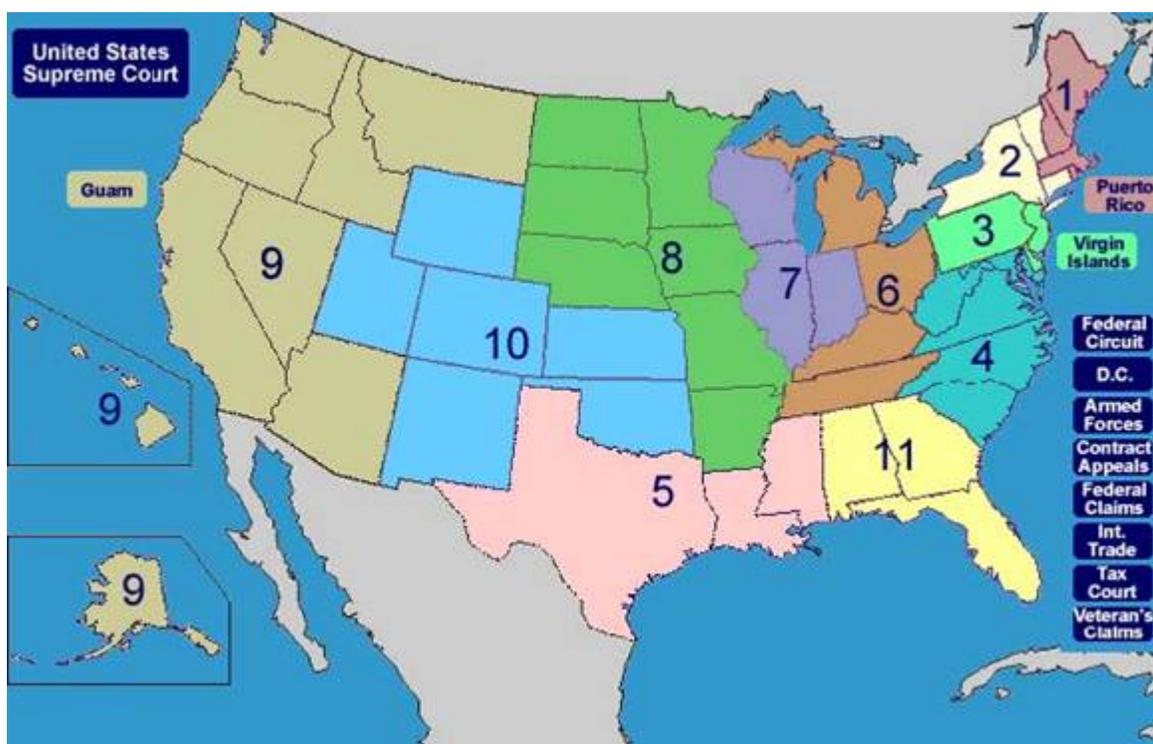
There are 89 districts in the 50 states, which are listed with their divisions in Title 28 of the U.S. Code, Sections 81-144. District courts also exist in Puerto Rico, the Virgin Islands, the District of Columbia, Guam, and the Northern Mariana Islands. In total

there are 94 U.S. district courts. Some states, such as Alaska, are composed of a single judicial district. Others, such as California, are composed of multiple judicial districts. The number of judgeships allotted to each district is set forth in Title 28 of the U.S. Code, Section 133. For a list of U.S. district courts and their rules, on the Internet go to: [List of US District Courts http://www.uscourts.gov/rules/distr-localrules.html](http://www.uscourts.gov/rules/distr-localrules.html).

### 2-1-2 U.S. Circuit Court of Appeals

There are 13 judicial circuits, each with a court of appeals. The smallest court is the First Circuit with six judgeships, and the largest court is in the Ninth Circuit, with 28 judgeships. A list of the states that compose each circuit is set forth in Title 28 of the U.S. Code, Section 41. The number of judgeships in each circuit is set forth in Title 28 of the U.S. Code, Section 44. Court rules for each circuit court are available on the Internet at [Court Rules http://www.uscourts.gov/RulesAndPolicies/rules/current-rules.aspx](http://www.uscourts.gov/RulesAndPolicies/rules/current-rules.aspx).

#### U.S. Circuit Court of Appeals



The U.S. Court of Appeals Federal Circuit and the District of Columbia bring the total number of circuit courts to 13. Additional information is available at the following Internet site [Additional Information on Courts http://www.loc.gov/law/guide/usjudic.html](http://www.loc.gov/law/guide/usjudic.html).

### 2-1-3 The U.S. Supreme Court

The United States Supreme Court consists of the Chief Justice of the United States and eight associate justices. At its discretion, and within certain guidelines established by

Congress, the Supreme Court each year hears a limited number of the cases it is asked to decide. Those cases may begin in the federal or state courts, and they usually involve important questions about the Constitution or federal law. For more information about the Supreme Court, visit [Supreme Court http://www.supremecourt.gov](http://www.supremecourt.gov).

## 2-2 SELECTED AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

The following is a list of selected Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act). The amendments are listed in alphabetical order with the corresponding enactment date noted.

The Amendments may also be listed with [Significant Amendments to the Act](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAct/SignificantAmendmentstotheFDCAct) at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAct/SignificantAmendmentstotheFDCAct>.

Chapter Sub-section number	Act name and date	Web page title	Internet address
2.2.1.	<b><u>Animal Drug User Fee (ADUFA)</u></b> Aug 14, 2008	CVM's <a href="#">ADUFA</a> page	<a href="http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA">http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA</a>
2.2.2.	<b><u>Animal Medicinal Drug Use Clarification Act (AMDUCA)</u></b> Oct 22, 1994	CVM's <a href="#">Acts, Rules and Regulations</a> page	<a href="http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ActsRulesRegulations/">http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ActsRulesRegulations/</a>
2.2.3.	<b><u>Anti-Drug Abuse Act</u></b> Aug 14, 2008	CVM's <a href="#">ADUFA</a> page	<a href="http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA">http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA</a>
2.2.4.	<b><u>Best Pharmaceuticals for Children Act (BFCA)</u></b> Jan. 4, 2002  The BPCA reauthorizes the	<a href="#">Pediatric Product Development</a> page	<a href="http://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/ucm049867.htm">http://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/ucm049867.htm</a>

Chapter Sub-section number	Act name and date	Web page title	Internet address
	pediatric studies provision of the FDA Modernization and Accountability Act (FDAMAA) of 1997.		
2.2.5.	<p><b><u>Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNPDCPA)</u></b></p> <p>Dec. 22, 2006</p>	<p><a href="#">OTC Products and Dietary Supplements</a> page</p>	<p><a href="http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085680.htm">http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085680.htm</a>.</p>
2.2.6.	<p><b><u>Dietary Supplement Health and Education Act (DSHEA)</u></b></p> <p>Oct. 25, 1994</p>	<p><a href="#">Dietary Supplements</a> page</p>	<p><a href="http://www.fda.gov/food/dietary-supplements">http://www.fda.gov/food/dietary-supplements</a>.</p>
	<p><b>NOTE: DSHEA does not apply to products intended for animal use.</b></p> <p>Telephone CVM OCE at 240-276-9200 for appropriate guidance on these products for animal use</p>	<p>FDA's <a href="#">Center for Veterinary Medicine</a> (CVM), <a href="#">Office of Compliance and Enforcement</a> (OCE)</p>	<p><a href="http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement">http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement</a></p>

Chapter Sub-section number	Act name and date	Web page title	Internet address
2.2.7.	<p><b><u>Drug Price Competition and Patent Term Restoration Act (DPCPTRA)</u></b></p> <p>Sept. 24, 1984</p>	<p><a href="#">DPCPTRA</a> on the <a href="#">Government Printing Office's</a> page</p>	<p><a href="http://www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg1585.pdf">http://www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg1585.pdf</a></p>
	<p><a href="#">DPCPTRA</a> consists of two titles:</p> <ul style="list-style-type: none"> <li>Title I authorizes the approval of generic drugs under an Abbreviated New Drug Application (ANDA) procedure.</li> </ul>	<p>Information on the bill at Thomas.gov's <a href="#">summary of the bill</a></p>	<p><a href="http://thomas.loc.gov/cgi-bin/bdquery/z?d098:SN01538:@@D&amp;summ2=m&amp;TOM:/bs/d098query.html">http://thomas.loc.gov/cgi-bin/bdquery/z?d098:SN01538:@@D&amp;summ2=m&amp;TOM:/bs/d098query.html</a></p>
	<ul style="list-style-type: none"> <li>Title II authorizes the extension of patent terms for approved new drug products including antibiotics and biological drug products, some medical devices, food additives, and color additives.</li> </ul>	<p>Patent information on the FDA <a href="#">Orange Book</a> page</p>	<p><a href="http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm">http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm</a></p>

**2.2.8. Animal Drug User Fee (ADUFA)**

Information on ADUFA, Aug 14, 2008, is available on CVM's [ADUFA](http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA) page at <http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA>.

**2.2.9. Animal Medicinal Drug Use Clarification Act (AMDUCA)**

Information on AMDUCA, , is available on CVM's [Acts, Rules and Regulations](http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ActsRulesRegulations/) page at <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ActsRulesRegulations/>.

**2.2.10. Anti-Drug Abuse Act**

Information on the [Controlled Substances Act](http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm), Nov 11, 1988, is available at <http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm>. It includes the [Anti-Drug Abuse Act](http://www.gpo.gov/fdsys/pkg/STATUTE-102/pdf/STATUTE-102-Pg4181.pdf), available at <http://www.gpo.gov/fdsys/pkg/STATUTE-102/pdf/STATUTE-102-Pg4181.pdf> and which is administered by FDA.

**2.2.11. Best Pharmaceuticals for Children Act (BPCA)**

The BPCA, Jan. 4, 2002, reauthorizes the pediatric studies provision of the Food and Drug Administration Modernization and Accountability Act (FDAMAA) of 1997. Information is available on the [Pediatric Product Development](http://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/ucm049867.htm) page at <http://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/ucm049867.htm>.

**2.2.12. Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNPDCPA)**

Information on DSNPDCPA, Dec. 22, 2006, is available on the [OTC Products and Dietary Supplements](http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085680.htm) page at <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085680.htm>.

**2.2.13. Dietary Supplement Health and Education Act (DSHEA)**

Information on DSHEA, Oct. 25, 1994, is available the [Dietary Supplements](http://www.fda.gov/food/dietarysupplements) page at <http://www.fda.gov/food/dietarysupplements>.

NOTE: DSHEA does not apply to products intended for animal use. The FDA's [Center for Veterinary Medicine](http://www.fda.gov/AnimalVeterinary) (CVM) (<http://www.fda.gov/AnimalVeterinary>), [Division of Compliance](http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement) (<http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement>), telephone 240-276-9200, should be consulted for appropriate guidance on these products for animal use.

**2.2.14.**

[DPCPTR](http://www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg1585.pdf) (<http://www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg1585.pdf>), Sept. 24, 1984, consists of two titles:

- Title I authorizes the approval of generic drugs under an Abbreviated New Drug Application (ANDA) procedure.
- Title II authorizes the extension of patent terms for approved new drug products including antibiotics and biological drug products, some medical devices, food additives, and color additives.

Information is available on the [summary of the bill](http://thomas.loc.gov/cgi-bin/bdquery/z?d098:SN01538:@@D&summ2=m&TOM:/bss/d098query.html) at <http://thomas.loc.gov/cgi-bin/bdquery/z?d098:SN01538:@@D&summ2=m&TOM:/bss/d098query.html> and [FDA testimony on the bill](http://www.fda.gov/newsevents/testimony/ucm115033.htm) at <http://www.fda.gov/newsevents/testimony/ucm115033.htm>. Patent information is available on the FDA [Orange Book](http://www.fda.gov/OrangeBook) page at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.

**2.2.15. Drug Quality and Security Act (DQSA)**

[DQSA](https://www.congress.gov/bill/113th-congress/house-bill/3204/text), Nov 27, 2013, (<https://www.congress.gov/bill/113th-congress/house-bill/3204/text>) contains two titles:

- [Title I of DQSA, Compounding Quality Act](http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding) at <http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding> addresses compounding of human drugs. Information is available on the FDA [Compounding](http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding) page at <http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding>.
- [Title II of DQSA, Drug Supply Chain Security Act \(DSCSA\)](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity) at <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity> outlines steps for an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

Additional information is available on the [Drug Supply Chain Integrity](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity) page at <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity>.

**2.2.16. Electronic Product Radiation Control Act**

The EPRCA of 1990, 21 U.S.C. 360hh-360ss, is the new name for the [Radiation Control for Health and Safety Act](http://www.gpo.gov/fdsys/pkg/STATUTE-82/pdf/STATUTE-82-Pg1173.pdf) (<http://www.gpo.gov/fdsys/pkg/STATUTE-82/pdf/STATUTE-82-Pg1173.pdf>), Oct. 18, 1968 (formerly at 42 U.S.C. 263c-263n). The change was made as part of the [Safe Medical Devices Act of 1990 \(SMDA\)](http://www.gpo.gov/fdsys/pkg/STATUTE-104/pdf/STATUTE-104-Pg4511.pdf) (<http://www.gpo.gov/fdsys/pkg/STATUTE-104/pdf/STATUTE-104-Pg4511.pdf>) which was itself amended by the [FDA Amendments Act](http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdca/significantamendmentstothefdcaact/foodanddrugadministrationamendmentsof2007/default.htm) at <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdca/significantamendmentstothefdcaact/foodanddrugadministrationamendmentsof2007/default.htm>. Additional information is on the [Summary of the Electronic Product Radiation Control Provisions](http://www.fda.gov/radiation-) page at <http://www.fda.gov/radiation->



**2.2.22. Food and Drug Administration Safety and Innovation Act (FDASIA)**

Information on [FDASIA](http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf) (<http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf>) July 9, 2012, is available on FDA's [FDASIA](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/FDASIA) page at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/FDASIA>.

**2.2.23. Food Quality Protection Act (FQPA)**

Information on [FQPA](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/ucm148008.htm), Aug. 3, 1996, is available at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/ucm148008.htm>.

**2.2.24. Food Safety Modernization Act (FSMA)**

Information on [FSMA](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/ucm148008.htm), Jan. 4, 2011 is available at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/ucm148008.htm>.

**2.2.25. Generic Drug Enforcement Act (GDEA)**

Additional information on [GDEA](http://www.gpo.gov/fdsys/pkg/STATUTE-106/pdf/STATUTE-106-Pg149.pdf) (<http://www.gpo.gov/fdsys/pkg/STATUTE-106/pdf/STATUTE-106-Pg149.pdf>), May 13, 1992 is available on the FDA [debarment](http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList) page at <http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList>.

**2.2.26. Health Promotion and Disease Prevention Amendments (HPDPA)**

Information on [HPDPA](http://www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg2815.pdf), Oct. 30, 1984, is available at <http://www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg2815.pdf>.

**2.2.27. Infant Formula Act (IFA)**

The [IFA](http://www.gpo.gov/fdsys/pkg/STATUTE-94/pdf/STATUTE-94-Pg1190.pdf), (<http://www.gpo.gov/fdsys/pkg/STATUTE-94/pdf/STATUTE-94-Pg1190.pdf>), Sept. 26, 1980, and subsequent amendments in 1986 (Section 412) establish nutrient requirements for infant formulas. Information is available on the pages for [Guidelines Concerning Notification and Testing of Infant Formulas](http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/ucm169730.htm) (<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/ucm169730.htm>) and [Briefing Materials for the Food Advisory Committee Meeting on Infant Formula](http://www.fda.gov/ohrms/dockets/ac/02/briefing/3852b1_01.htm) ([http://www.fda.gov/ohrms/dockets/ac/02/briefing/3852b1\\_01.htm](http://www.fda.gov/ohrms/dockets/ac/02/briefing/3852b1_01.htm)).

**2.2.28. Medical Device Amendments**

Information on the Medical Device Amendments, May 24, 1976, is available on the pages for [Overview of Device Regulation](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview>) and [Overview of Medical Device Classification and Reclassification](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm378714.htm) (<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm378714.htm>).

**2.2.29. Medical Device User Fee and Modernization Act (MDUFMA I, II and III)**

Information on [MDUFMA III](http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/html/PLAW-112publ144.htm) (<http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/html/PLAW-112publ144.htm>), July 9, 2012, is included in FDASIA. Additional information is available on the pages for [MDUFMA](http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/medicaldeviceuserfeeandmodernizationactmdufma) (<http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/medicaldeviceuserfeeandmodernizationactmdufma>) and [MDUFMA III](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFMAII) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFMAII>).

MDUFMA III amended [MDUFMA I](http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/medicaldeviceuserfeeandmodernizationactmdufma/ucm109133.htm) (<http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/medicaldeviceuserfeeandmodernizationactmdufma/ucm109133.htm>), Oct. 26, 2002.

[MDUFMA II](http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/medicaldeviceuserfeeandmodernizationactmdufma/ucm109316.htm) (<http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/medicaldeviceuserfeeandmodernizationactmdufma/ucm109316.htm>) was included in the [Food and Drug Administration Amendments Act of 2007](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/FoodandDrugAdministrationAmendmentsActof2007/FullTextofFDAAALaw) (<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/FoodandDrugAdministrationAmendmentsActof2007/FullTextofFDAAALaw>) (FDAAA), Sept. 27, 2007.

**2.2.30. Minor Use and Minor Species Animal Health Act (MUMS)**

Information on [MUMS](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/MinorUseandMinorSpeciesAnimalHealthActof2004) (<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/MinorUseandMinorSpeciesAnimalHealthActof2004>), Aug. 2, 2004, is available on the [MUMS resource](http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies) page at <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies>.

**2.2.31. Nutrition Labeling and Education Act (NLEA)**

Information on the [NLEA](http://www.fda.gov/iceci/inspections/inspectionguides/ucm074948.htm) (<http://www.fda.gov/iceci/inspections/inspectionguides/ucm074948.htm>), Nov. 8, 1990, is available on the pages for [Labeling & Nutrition Guidance Documents & Regulatory Information](http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition) at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition> and for [Inspection Guide to NLEA Requirements](http://www.fda.gov/iceci/inspections/inspectionguides/ucm074948.htm) at <http://www.fda.gov/iceci/inspections/inspectionguides/ucm074948.htm>.

**2.2.32. Orphan Drug Act (ODA)**

Information on the [ODA](http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcaact/significantamendmentstothefdcaact/orphandrugact) (<http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcaact/significantamendmentstothefdcaact/orphandrugact>), April 18, 1988, is available on the pages for [regulatory history of Orphan Drugs](http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/Howto) (<http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/Howto>

[pplyforOrphanProductDesignation/ucm356481.htm](http://www.fda.gov/forindustry/DevelopingProductsforRareDiseasesConditions)) and [requirements for industry \(http://www.fda.gov/forindustry/DevelopingProductsforRareDiseasesConditions\)](http://www.fda.gov/forindustry/DevelopingProductsforRareDiseasesConditions). The ODA of 1988 amended the [Orphan Drug Act](http://www.gpo.gov/fdsys/pkg/STATUTE-96/pdf/STATUTE-96-Pg2049.pdf) of 1983 (<http://www.gpo.gov/fdsys/pkg/STATUTE-96/pdf/STATUTE-96-Pg2049.pdf>) Jan. 4, 1983.

### **2.2.33. Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA)**

Information on [PAHPRA \(http://www.gpo.gov/fdsys/pkg/PLAW-113publ5/pdf/PLAW-113publ5.pdf\)](http://www.gpo.gov/fdsys/pkg/PLAW-113publ5/pdf/PLAW-113publ5.pdf), March 13, 2013 is available on the [MCM-related Legislation](http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm2007271.htm#PAHPRA) page at <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm2007271.htm#PAHPRA>.

PAHPRA updated and reauthorized related provisions of the [Pandemic and All-Hazards Preparedness Act of 2006 \(http://www.gpo.gov/fdsys/pkg/PLAW-109publ417/pdf/PLAW-109publ417.pdf\)](http://www.gpo.gov/fdsys/pkg/PLAW-109publ417/pdf/PLAW-109publ417.pdf) (PAHPA), Dec. 19, 2006; the [Public Readiness and Emergency Preparedness Act of 2005 \(http://www.gpo.gov/fdsys/pkg/PLAW-109publ148/pdf/PLAW-109publ148.pdf\)](http://www.gpo.gov/fdsys/pkg/PLAW-109publ148/pdf/PLAW-109publ148.pdf) (PREP Act), Dec. 30, 2005; and the [Public Health Security and Bioterrorism Preparedness and Response Act \(http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm\)](http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm) (the Bioterrorism Act), June 12, 2002. General information about medical counter measures (MCM), emergency preparedness and response, and the various recent counter-terrorism legislation is available on the [MCM-related Legislation](http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm2007271.htm) page at <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm2007271.htm>.

### **2.2.34. Pediatric Research Equity Act (PREA)**

#### PREA

<http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM077853.pdf>), Dec. 2, 2003, has been amended by subsequent legislation. See the pages for the [pediatric provisions in FDASIA \(http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/FDASIA/ucm311038.htm\)](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/FDASIA/ucm311038.htm) and for the [Food and Drug Administration Amendments Act \(FDAAA\) \(http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/FoodandDrugAdministrationAmendmentsActof2007/FullTextofFDAAALaw\)](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/FoodandDrugAdministrationAmendmentsActof2007/FullTextofFDAAALaw), Sept. 27, 2007.

### **2.2.35. Prescription Drug Marketing Act of 1987 (PDMA)**

Information on [PDMA](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/PrescriptionDrugMarketingActof1987/), April 22, 1988 is at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/PrescriptionDrugMarketingActof1987/>.

### **2.2.36. Prescription Drug User Fee Act (PDUFA)**

Information on [PDUFA](#)

(<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/PrescriptionDrugAmendmentsof1992PrescriptionDrugUserFeeActof1992>) Oct. 29, 1992, is available on the PDUFA pages [for industry](#) (<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee>) and for [small business](#) (<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069943.htm>).

### **2.2.37. Project Bioshield Act**

Information [Project Bioshield Act](#) (<http://www.gpo.gov/fdsys/pkg/PLAW-108publ276/pdf/PLAW-108publ276.pdf>), July 21, 2004, FDA's emergency preparedness and response, and the more recent counter-terrorism legislation is available on the [MCM-related Legislation](#) page at <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm2007271.htm>.

## **2-3 OTHER LAWS**

### **2.3.1. Public Health Service Act - Biological Products (Part F, Subpart 1)**

Biological products are approved for marketing under provisions of the Public Health Service Act (PHS Act). However, because most biological products also meet the definition of "drugs" under the Federal Food, Drug, and Cosmetic Act (FD&C Act), they are also subject to regulation under FD&C Act provisions.

A biological product is a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. For example, biologics include vaccines, various toxoids, skin test antigens, allergenic extracts, blood and blood products, and certain in vitro test kits intended for testing of biological products. The PHS Act requires individuals or companies who manufacture biologics for introduction into interstate commerce to hold a license for the products. These licenses are issued by FDA's Center for Biologics Evaluation and Research (CBER). Biological products intended for veterinary use are regulated under a separate law, the Virus, Serum, and Toxin Act, which is administered by the U.S. Department of Agriculture.

In May 1996, FDA amended the biologics regulations to eliminate the Establishment License Application (ELA) for certain biotechnology and synthetic biological products subject to licensing under the PHS Act. Manufacturers of those products are now required to submit only a biologics license application (BLA), thereby enabling

companies to devote more resources to ensuring that manufacturing processes are properly validated and fewer resources to submitting documentation to the agency. A BLA may be used for submissions for specified biotechnology products such as products manufactured by recombinant DNA technology and monoclonal antibody products. This regulatory change will reduce unnecessary burdens for industry without diminishing public health protection.

The PHS Act also provides authority to immediately suspend licenses in situations where there exists a danger to public health. This statute also allows us to prepare or procure products in the event of shortages and critical public health needs and authorizes the creation and enforcement of regulations to prevent the introduction, or spread of communicable disease in the US and/or between states. This law also provides important flexibility in regulation of biotechnology products, which facilitates the introduction and development of new medicines.

The PHS Act specifies that manufacturers must plainly label the biological products with the proper name of the article, the name, address, and license number of the manufacturer, and the appropriate expiration date of the product. No person shall falsely label any package containing a biological product. The PHS Act authorizes the inspection of biological product manufacturers. Section 351 provides for civil money penalties, fines and imprisonment for violations, and specifies export requirements for biological products.

### **2.3.2. Public Health Service Act - Control of Communicable Diseases (Part G)**

Section 361 of the Public Health Service Act (PHS Act) authorizes the creation and enforcement of regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the U.S. or possessions or between states and possessions. These regulations may provide for inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles found infected or contaminated and as sources of dangerous infection to human beings.

See PHS Act 42 U.S.C. 264-272, 42 U.S.C. 264-272, July 1, 1944, as amended 1957, 1958, 1960 and 1976.

### **2.3.3. Mammography Quality Standards Act of 1992**

The Mammography Quality Standards Act (MQSA) was signed into law on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary) or by an approved State certification body. The authority to

approve accreditation bodies, State certification bodies, and to certify facilities was delegated by the Secretary to the FDA.

On October 28, 1997, the FDA published regulations to implement the MQSA in the Federal Register. The regulations (21 CFR Part 900) became effective April 28, 1999. The FDA compiled all final guidance related to MQSA into a computerized searchable Policy Guidance Help System in November 1998. The Policy Guidance Help System is available on the Internet at: <http://www.fda.gov/Radiation-Emitting-Products/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem>.

Also on the FDA Internet at: <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148794.htm>.

#### **2.3.4. Federal Anti-Tampering Act – 1983**

On October 13, 1983, the President signed the Federal Anti-Tampering Act (P.L. 98-127). This Act amends Title 18 of the United States Code (U.S.C.) to establish graduated penalties for tampering with a consumer product with intent to cause injury or death. The penalties range from a maximum of \$25,000 and 10 years imprisonment in the case of an attempt to tamper, to a maximum of \$100,000 and life imprisonment, in a case where death results from the tampering.

In addition, FATA establishes penalties for:

1. Tampering with or mislabeling consumer products with intent to injure a business;
2. Knowingly communicating false information about tainting of a consumer product, if such tainting occurred, that would create a risk of death or bodily injury;
3. Threatening to tamper with a consumer product in a manner to create a risk of death or bodily injury; and,
4. Conspiracy to tamper with a consumer product.

A “consumer product” is any article subject to the Act and FDA is the designated authority to investigate violations.

Additional information is available on the FDA Internet at: <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148785.htm>.

#### **2.3.5. Freedom of Information Act – 1966**

The Freedom of Information Act (FOIA) (P.L. 104-231) was passed by Congress in 1966 and amended in 1974 (5 U.S.C. 552). The FOIA created procedures by which any member of the public may obtain the records of the agencies of the federal government. Section 552 (a) of FOIA directs government agencies to disclose certain types of records and describes the manner of disclosure required.

The FOIA applies only to federal agencies and does not create a right of access to records held by Congress, the courts, or by state or local government agencies. Each state has its own public access laws that should be consulted for access to state and local records.

Like all federal agencies, the Food and Drug Administration is required under the Freedom of Information Act (FOIA) to disclose records requested in writing by any person. However, agencies may withhold information pursuant to nine exemptions and three exclusions contained in the statute.

The FOIA contains six subsections, the first two of which establish certain categories of information that must automatically be disclosed by federal agencies. Subsection (a)(1) of the FOIA requires disclosure through publication in the *Federal Register* of information such as descriptions of agency organization, functions, procedures, substantive rules, and statements of general policy. This requirement provides automatic public access to very basic information regarding the transaction of agency business.

Subsection (a)(2) of the FOIA requires that certain types of records--final opinions rendered in the adjudication of cases, specific policy statements, certain administrative staff manuals and some records previously processed for disclosure under the Act--be routinely made "available for public inspection and copying." At the Food and Drug Administration (FDA), this is generally accomplished through FDA's two "reading rooms," and as a result of the Electronic FOIA Amendments (hereafter referred to as (EFOIA)), many of the records in the reading rooms also are located in FDA's "electronic reading room."

On the FDA Internet at: <http://www.fda.gov/foi/foia2.htm>, <http://www.usdoj.gov/oip/amended-foia-redlined.pdf> and <http://www.fda.gov/RegulatoryInformation/FOI/ReferenceMaterials>. For additional information and guidance on the FOIA, see FDA's Information Disclosure Manual on the FDA Intranet.

### **2.3.6. Electronic Freedom of Information Amendments of 1996**

The Electronic Freedom of Information Act (E-FOIA) Amendments signed into law in 1996 amended the Freedom of Information Act (FOIA), adding a requirement that agencies had to establish an electronic reading room. The reading room must include agency policy manuals, opinions made in the adjudication of cases, and an index of records released by FOIA that are likely to become the subject of subsequent FOIA requests.

In addition, E-FOIA:

1. extends from 10 to 20 business days (excluding holidays) the time agencies have to respond to requests for information;

2. requires agencies to make reasonable efforts to make records available in the form desired by requesters;
3. requires agencies to submit an FDA FOIA Report by the fiscal year;
4. requires agencies to make the reports available to the public by computer telecommunications or other electronic means;
5. requires agencies to list their major information systems record locator system and a reference guide or guide for obtaining information; and,
6. requires that the provisions of the E-FOIA be implemented by specific dates.

### **2.3.7. Sanitary Food Transportation Act of 1990**

The Sanitary Food Transportation Act (P.L. 101-500) requires the Department of Transportation (DOT), in consultation with the Department of Health and Human Services, Environmental Protection Agency, and the United States Department of Agriculture, to issue regulations to provide for the safe transportation of food, food additives, cosmetics, drugs, and medical devices. The requirement includes safe transportation that occurs in vehicles used to transport nonfood products or waste, and the use of dedicated vehicles to transport hazardous materials such as asbestos or municipal waste. SFTA authorizes funding for food transportation inspections from funds designated to carry out the motor carrier safety assistance program if the Recipient State agrees to assist in enforcement. DOT is required to issue regulations.

Codified at: 49 U.S.C. 5701 et. Seq. Additional information is available on the FDA Internet at: <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148790.htm>.

### **2.3.8. Pesticides Monitoring Improvements Act of 1988**

On August 23, 1988, the President signed into law the Omnibus Trade and Competitiveness Act (P.L. 100-418). Included in this law is the Pesticide Monitoring Improvements Act of 1988 which is intended to improve the analytical approaches used by the FDA to determine residues of pesticides in foods. Specifically, Subtitle G requires FDA to computerize its pesticide monitoring activities, to compile a summary of the information gathered through computerized monitoring activities, and to make its summary and report available to Federal and State agencies and other interested persons.

The PMIA also requires the Secretary of Health and Human Services (HHS) to attempt to enter into cooperative agreements with governments of foreign countries that are major sources of food imports into the U.S., for the purpose of better enabling FDA to assure compliance with pesticide tolerances, or otherwise to obtain, information on pesticides used on imported foods where such agreements cannot be obtained. Finally, the PMIA requires the Secretary of HHS to develop, in consultation with the Environmental Protection Agency (EPA), a long-range plan for the development of new and improved methods for detecting

pesticide residues, and to make a report and recommendations to appropriate congressional committees.

The PMIA is codified at 21 U.S.C. Sections 1401-1403 Part 4702, 4703, and 4704, included as part of the Omnibus Trade and Competitiveness Act.

### **2.3.9. AIDS Amendments of 1988**

The AIDS amendments (P.L. 100-607) set up broad programs for research, counseling, testing, education and information programs, and health care for acquired immune deficiency syndrome (AIDS) patients. Of interest to FDA are provisions that specify requirements of the Secretary.

1. Require the Secretary to encourage manufacturers of drugs with potential effectiveness as AIDS treatments to apply for investigational exemptions under the Act. The Secretary has authorization to provide technical assistance through grants or contracts to manufacturers, researchers, and physicians to expedite submission of applications and the availability of new drugs under treatment INDS.
2. Require the Secretary to establish a data bank that includes a registry of clinical trials and information on AIDS drugs available under INDS, including treatment INDS, superseding the confidentiality provisions of the Act with respect to these drugs.
3. Authorize the Secretary to add 780 new positions to the Public Health Service (PHS) before October 1, 1990, and require the Secretary to report to Congress after three months on the allocation among the agencies.
4. Require the Office of Personnel Management or the General Services Administration (GSA) to respond to priority requests for personnel and administrative support from FDA and PHS agencies within 21 days after the request.
5. Establish a National Commission on AIDS that would, among other things, evaluate the adequacy of clinical trials and make recommendations on streamlining regulations relating to FDA approval of new drugs and medical devices, including procedures for the release of experimental drugs.
6. Require the Secretary to submit an annual report to Congress on all expenditures by the Department with respect to AIDS.
7. Require the National Institute of Allergy and Infectious Diseases (NIAID), after consulting with FDA, to establish the AIDS Clinical Research Review Committee. The Committee is physicians in clinical practice. They advise NIAID on appropriate research activities to undertake, including research on drugs, with respect to clinical treatment of AIDS.
8. Authorize NIH, after consulting with FDA, to provide grants and contracts to community- based organizations to conduct clinical trials approved by FDA,

and require that FDA, among others, approve applications for financial assistance.

9. Require the Secretary to establish a program to evaluate the effectiveness and risks associated with unapproved drugs in use by AIDS patients.
10. Require the Secretary, after consultation with FDA, among others, to establish a program of research and education regarding blood donations and transfusions.
11. Require that the grant programs for clinical care of AIDS patients must provide patients with information and counseling on the availability of treatments both approved and not yet approved by FDA.
12. Require the Secretary to expedite the award of grants, contracts, and cooperative agreements for research projects relating to AIDS and require the submission of a quarterly report to Congress.
13. Require the Secretary to request the National Academy of Science and others to report on the potential use of consortia for research and development of vaccines and drugs.

### **2.3.10. Lead-Based Paint Poisoning Prevention Act – 1971**

The Lead-Based Paint Poisoning Prevention Act required the Secretary of Health and Human Services to take such steps and impose such conditions as may be necessary or appropriate to prohibit the application of lead-based paint to any cooking utensil, drinking utensil, or eating utensil manufactured and distributed after January 13, 1971.

Codified at 42 U.S.C. 4831. Additional information is available on the FDA Internet at: <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148755.htm> .

### **2.3.11. Egg Products Inspection Act - 1970**

The Egg Products Inspection Act enacted in 1970 is administered by the U.S. Department of Agriculture and imposes specific inspection requirements for the two categories of eggs—egg products and shell eggs to assure wholesome shell eggs and egg products in the marketplace.

The Act gives enforcement authority to the USDA and to the Food and Drug Administration. Federal agriculture officials or state officials acting on behalf of USDA visit egg packers and hatcheries at least every three months to see that they are in compliance with the law. Firms which transport, ship or receive shell eggs and egg products may also be checked periodically. Under the Egg Products Inspection Act, plants that break, dry and process shell eggs into liquid, frozen or dried egg products must operate under the continuous inspection program of the USDA. An official inspector must be present at all times when eggs are being processed. The law applies to all egg-breaking plants, regardless of size, and to those selling products

locally, across state lines and in foreign commerce. Disposition of undesirable shell eggs is controlled to prevent their entering consumer food channels.

Egg Products Inspection Act, 21 U.S.C. Sections 1031 et seq., see <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148752.htm> .

### **2.3.12. Fair Packaging and Labeling Act - 1966**

The Fair Packaging and Labeling Act enacted in 1966 and substantially amended in 1992, prohibits any person who packages or labels consumer commodities, as defined, from distributing commodities that are not packaged and labeled as required by this law and its implementing regulations. See 15 U.S.C. 1452. The law is designed to ensure that consumers receive accurate and usable information about consumer commodities from the labeling on their packages. Consumer commodities include any food, drug, device or cosmetic, as defined by the Federal Food, Drug, and Cosmetics Act, and any other article, product or commodity customarily produced or distributed through retail sales agencies for use or consumption by individuals. 15 U.S.C. 1459(a). Meat, poultry, tobacco products, and specified beverages, drugs, and agricultural products regulated under other statutes and programs are excluded from the definition of consumer commodity. 15 U.S.C. 1459(a)(1)-(5).

Codified at 15 U.S.C. 1451 et seq. On the FDA Internet at: <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148722.htm>.

### **2.3.13. Federal Import Milk Act**

In addition to being subject to the requirements of the FFD&C Act, milk and cream (including sweetened condensed milk) offered for import into the U.S. are subject to the Federal Import Milk Act (P.L. 69-625) enforced by the FDA. Such products may be imported only under permit after certain sanitary and other prerequisites have been fulfilled.

### **2.3.14. Health Insurance Portability and Accountability Act of 1996**

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Title II (Administration Simplification) requires the Secretary to issue several regulations, one of which would protect the privacy of individually identifiable health information. The Final "Privacy" Rule published on December 20, 2000 and was amended on May 31, 2002 and August 14, 2002. The Privacy Rule provides that a "covered entity" may not use or disclose protected health information ("PHI") except as permitted or required by the Rule. It permits the continued use of PHI for treatment, payment, or operations purposes. There are only two required disclosures: (1) to the individual pursuant to the access requirements; and, (2) to the Secretary to determine compliance with the Rule. Covered entities are defined as health plans,

health care clearinghouses, and health care providers who engaged in certain electronic transactions. FDA is not a covered entity. PHI includes individually identifiable health information that is electronically transmitted or maintained by a covered entity in any form or medium.

The Privacy Rule permits covered entities to disclose PHI without the individual's consent or authorization, to a person or entity subject to FDA jurisdiction, for public health purposes related to quality, safety or effectiveness of the FDA regulated product or activity. Such purposes include the reporting of adverse events or product defects or problems; the tracking of FDA regulated products; the ability to effectuate products recalls, repairs, replacement or lookback (traceback); and conducting post marketing surveillance. The Privacy Rule is not intended to discourage or prevent adverse event reporting or otherwise disrupt the flow of essential information needed by the FDA to carry out its public health activities.

The Privacy Rule also permits covered entities to disclose PHI to the FDA without consent or authorization pursuant to several other exemptions in the rule. These include where the use or disclosure is required by law; for the purpose of preventing or controlling disease, injury, or disability (including, but not limited to the conduct of public health surveillance, public health investigations, and public health interventions); for oversight activities authorized by law (including audits, civil, administrative or criminal investigations, inspections, disciplinary actions, civil, administrative, or criminal proceedings or other actions, or other activities necessary for appropriate oversight of the health care system); and for law enforcement purposes, when certain conditions are met. The information disclosed in these instances may only be the minimum amount necessary for the purpose. Before disclosing protected health information to their "business associate," covered entities must have a contract assuring that the business associate will safeguard the information pursuant to the Privacy Rule. At times, some covered entities, such as hospitals, mistakenly believe that FDA is their business associate and ask FDA to sign a confidentiality statement before the hospital gives FDA individually identifiable health information. FDA is not a business associate and is not required to sign such a statement. Additional information about HIPAA and the Privacy Rule is on the Internet at: <http://www.hhs.gov/ocr/hipaa> .

### **2.3.15. Equal Access to Justice Act - 1980**

The winning party has traditionally been awarded court costs. However, these costs do not include fees and expenses for attorneys and expert witnesses. The purpose of the EAJA of 1980 (P.L. 96-481) and the subsequent 1985 amendments (P.L. 99-80) was to prevent overbearing conduct on the part of the government against individuals and small firms who might not have the financial resources to oppose improper government acts.

Under the EAJA (28 U.S.C. 2412), a "party" is defined as an individual whose net worth does not exceed \$2,000,000 or the owner of an unincorporated business or any

partnership, corporation, association, or unit of local government whose net worth does not exceed \$7,000,000 and which does not have more than 500 employees. Cooperative agricultural associations and tax exempt organizations may be parties without regard to these parameters.

A party prevailing against the government is entitled to be reimbursed for reasonable attorney fees, expenses for expert witnesses and the cost of any study, analysis, engineering report, test, or project which is found by the court to be necessary for the preparation of the party's case. The EAJA applies to civil litigation but does not include torts (injury claims for a civil wrong). The EAJA does not apply to criminal cases.

Pursuant to the EAJA, costs will be awarded to a private party "unless the court finds that the position of the United States was substantially justified or that special circumstances make an award unjust."

### **2.3.16. Sentencing Reform Act of 1984**

The Sentencing Reform Act of 1984 (Title II of the Comprehensive Crime Control Act of 1984) provides for the development of guidelines that will further the basic purposes of criminal punishment: deterrence, incapacitation, just punishment, and rehabilitation. The Act delegates broad authority to the Commission to review and rationalize the federal sentencing process.

The Act contains detailed instructions as to how this determination should be made, the most important of which directs the Commission to create categories of offense behavior and offender characteristics. An offense behavior category might consist, for example, of "bank robbery/committed with a gun/\$2500 taken." An offender characteristic category might be "offender with one prior conviction not resulting in imprisonment." The Commission is required to prescribe guideline ranges that specify an appropriate sentence for each class of convicted persons determined by coordinating the offense behavior categories with the offender characteristic categories. Where the guidelines call for imprisonment, the range must be narrow: the maximum of the range cannot exceed the minimum by more than the greater of 25 percent or six months.

Pursuant to the Act, the sentencing court must select a sentence from within the guideline range. If, however, a particular case presents atypical features, the Act allows the court to depart from the guidelines and sentence outside the prescribed range. In that case, the court must specify reasons for departure. 18 U.S.C. 3553(b). If the court sentences within the guideline range, an appellate court may review the sentence to determine whether the guidelines were correctly applied. If the court departs from the guideline range, an appellate court may review the reasonableness of the departure. 18 U.S.C. 3742. The Act also abolishes parole, and substantially reduces and restructures good behavior adjustments.

The guidelines took effect on November 1, 1987, and apply to all offenses committed on or after that date. The Commission has the authority to submit guideline amendments each year to Congress between the beginning of a regular Congressional session and May 1. Such amendments automatically take effect 180 days after submission unless a law is enacted to the contrary. 28 U.S.C. 994(p).

### **2.3.17. Crimes And Criminal Procedure**

#### **CRIMES – Title 18**

##### **Sec. 111. - Assaulting, resisting, or impeding certain officers or employees**

###### **(a) In General - Whoever –**

- (1) forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any person designated in section 1114 of this title while engaged in or on account of the performance of official duties; or
- (2) forcibly assaults or intimidates any person who formerly served as a person designated in section 1114 on account of the performance of official duties during such person's term of service, shall, where the acts in violation of this section constitute only simple assault, be fined under this title or imprisoned not more than one year, or both, and in all other cases, be fined under this title or imprisoned not more than 8 years, or both.

###### **(b) Enhanced Penalty –**

Whoever, in the commission of any acts described in subsection (a), uses a deadly or dangerous weapon (including a weapon intended to cause death or danger but that fails to do so by reason of a defective component) or inflicts bodily injury, shall be fined under this title or imprisoned not more than 20 years, or both.

##### **Sec. 1114. - Protection of officers and employees of the United States**

Whoever kills or attempts to kill any officer or employee of the United States or of any agency in any branch of the United States Government (including any member of the uniformed services) while such officer or employee is engaged in or on account of the performance of official duties, or any person assisting such an officer or employee in the performance of such duties or on account of that assistance, shall be punished...

##### **Sec. 371. - Conspiracy to commit offense or to defraud United States**

If two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or

for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.

If, however, the offense, the commission of which is the object of the conspiracy, is a misdemeanor only, the punishment for such conspiracy shall not exceed the maximum punishment provided for such misdemeanor.

### **Sec. 1001. - Statements or entries generally**

- (a) Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully -
- (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;
  - (2) makes any materially false, fictitious, or fraudulent statement or representation;
- or
- (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry;

shall be fined under this title or imprisoned not more than 5 years, or both.

- (b) Subsection (a) does not apply to a party to a judicial proceeding, or that party's counsel, for statements, representations, writings or documents submitted by such party or counsel to a judge or magistrate in that proceeding.

- (c) With respect to any matter within the jurisdiction of the legislative branch, subsection (a) shall apply only to –

- (1) administrative matters, including a claim for payment, a matter related to the procurement of property or services, personnel or employment practices, or support services, or a document required by law, rule, or regulation to be submitted to the Congress or any office or officer within the legislative branch; or
- (2) any investigation or review, conducted pursuant to the authority of any committee, subcommittee, commission or office of the Congress, consistent with applicable rules of the House or Senate.

### **Sec. 1341. - Frauds and swindles**

Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses,

representations, or promises, or to sell, dispose of, loan, exchange, alter, give away, distribute, supply, or furnish or procure for unlawful use any counterfeit or spurious coin, obligation, security, or other article, or anything represented to be or intimated or held out to be such counterfeit or spurious article, for the purpose of executing such scheme or artifice or attempting so to do, places in any post office or authorized depository for mail matter, any matter or thing whatever to be sent or delivered by the Postal Service, or deposits or causes to be deposited any matter or thing whatever to be sent or delivered by any private or commercial interstate carrier, or takes or receives therefrom, any such matter or thing, or knowingly causes to be delivered by mail or such carrier according to the direction thereon, or at the place at which it is directed to be delivered by the person to whom it is addressed, any such matter or thing, shall be fined under this title or imprisoned not more than 20 years, or both. If the violation affects a financial institution, such person shall be fined not more than \$1,000,000 or imprisoned not more than 30 years, or both.

#### **Sec. 1343. - Fraud by wire, radio, or television**

Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises, transmits or causes to be transmitted by means of wire, radio, or television communication in interstate or foreign commerce, any writings, signs, signals, pictures, or sounds for the purpose of executing such scheme or artifice, shall be fined under this title or imprisoned not more than 20 years, or both. If the violation affects a financial institution, such person shall be fined not more than \$1,000,000 or imprisoned not more than 30 years, or both.

#### **Sec. 1505. - Obstruction of proceedings before departments, agencies, and committees**

Whoever, with intent to avoid, evade, prevent, or obstruct compliance, in whole or in part, with any civil investigative demand duly and properly made under the Antitrust Civil Process Act, willfully withholds, misrepresents, removes from any place, conceals, covers up, destroys, mutilates, alters, or by other means falsifies any documentary material, answers to written interrogatories, or oral testimony, which is the subject of such demand; or attempts to do so or solicits another to do so; or

Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress -

Shall be fined under this title or imprisoned not more than five years, or both.

**Sec. 1905. - Disclosure of confidential information generally**

Whoever, being an officer or employee of the United States or of any department or agency thereof, any person acting on behalf of the Office of Federal Housing Enterprise Oversight, or agent of the Department of Justice as defined in the Antitrust Civil Process Act (15 U.S.C. 1311-1314), or being an employee of a private sector organization who is or was assigned to an agency under chapter 37 of title 5, publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined under this title, or imprisoned not more than one year, or both; and shall be removed from office or employment.