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	2
2-1-3	The U.S. Supreme Court	3
2-2	SELECTED AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT	3
2-2-1	FDA Food Safety Modernization Act of 2011	4
2-2-2	Family Smoking Prevention and Tobacco Control Act	5
2-2-3	FDA Amendments Act of 2007	9
2-2-4	Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006	13
2-2-5	Food Allergen Labeling and Consumer Protection Act of 2004	13
2-2-6	Minor Use and Minor Species Animal Health Act of 2004	14
2-2-7	Project BioShield Act of 2004	15
2-2-8	Pediatric Research Equity Act of 2003	15
2-2-9	Animal Drug User Fee Act of 2003 (ADUFA)	15
2-2-10	Public Health Security and Bioterrorism Preparedness and Response Act of 2002	16
2-2-11	Best Pharmaceuticals for Children Act – 2002	17
2-2-12	Medical Device User Fee and Modernization Act of 2002	17
2-2-13	FDA Modernization Act of 1997	18
2-2-14	Food Quality Protection Act of 1996	20
2-2-15	FDA Export Reform and Enhancement Act of 1996	21
2-2-16	Dietary Supplement Health and Education Act of 1994	21
2-2-17	Animal Medicinal Drug Use Clarification Act of 1994	22
2-2-18	Prescription Drug User Fee Act of 1992	23
2-2-19	Generic Drug Enforcement Act of 1992	23
2-2-20	Medical Device Amendments of 1992	23
2-2-21	Safe Medical Devices Act of 1990	24
2-2-22	Medical Device Reporting as Amended by The Food and Drug Administration Modernization Act	25
2-2-23	Nutrition Labeling and Education Act of 1990	26
2-2-24	Electronic Product Radiation Control – 1990	27
2-2-25	Anti-Drug Abuse Act of 1988	27
2-2-26	Orphan Drug Amendments of 1988	28
2-2-27	Prescription Drug Marketing Act of 1987	28
2-2-28	Health Promotion and Disease Prevention Amendments of 1984	29
2-2-29	Drug Price Competition and Patent Term Restoration Act of 1984	29
2-2-30	Orphan Drug Act - 1983	29
2-2-31	Infant Formula Act of 1980	30
2-2-32	Medical Device Amendments of 1976	31
2-3	OTHER LAWS	32
2-3-1	Public Health Service Act - Biological Products (Part F, Subpart 1)	32

2-3-2 Public Health Service Act - Control of Communicable Diseases (Part G) 33
2-3-3 Mammography Quality Standards Act of 1992 33
2-3-4 Federal Anti-Tampering Act – 1983 33
2-3-5 Freedom of Information Act – 1966 34
2-3-6 Electronic Freedom of Information Amendments of 1996 34
2-3-7 Sanitary Food Transportation Act of 1990 35
2-3-8 Pesticides Monitoring Improvements Act of 1988 35
2-3-9 AIDS Amendments of 1988 36
2-3-10 Lead-Based Paint Poisoning Prevention Act – 1971 37
2-3-11 Egg Products Inspection Act - 1970 37
2-3-12 Fair Packaging and Labeling Act - 1966 37
2-3-13 Federal Import Milk Act 38
2-3-14 Health Insurance Portability and Accountability Act of 1996 38
2-3-15 Equal Access to Justice Act - 1980 39
2-3-16 Sentencing Reform Act of 1984 39
2-3-17 Crimes And Criminal Procedure 40

2-1 THE U.S. FEDERAL JUDICIAL SYSTEM

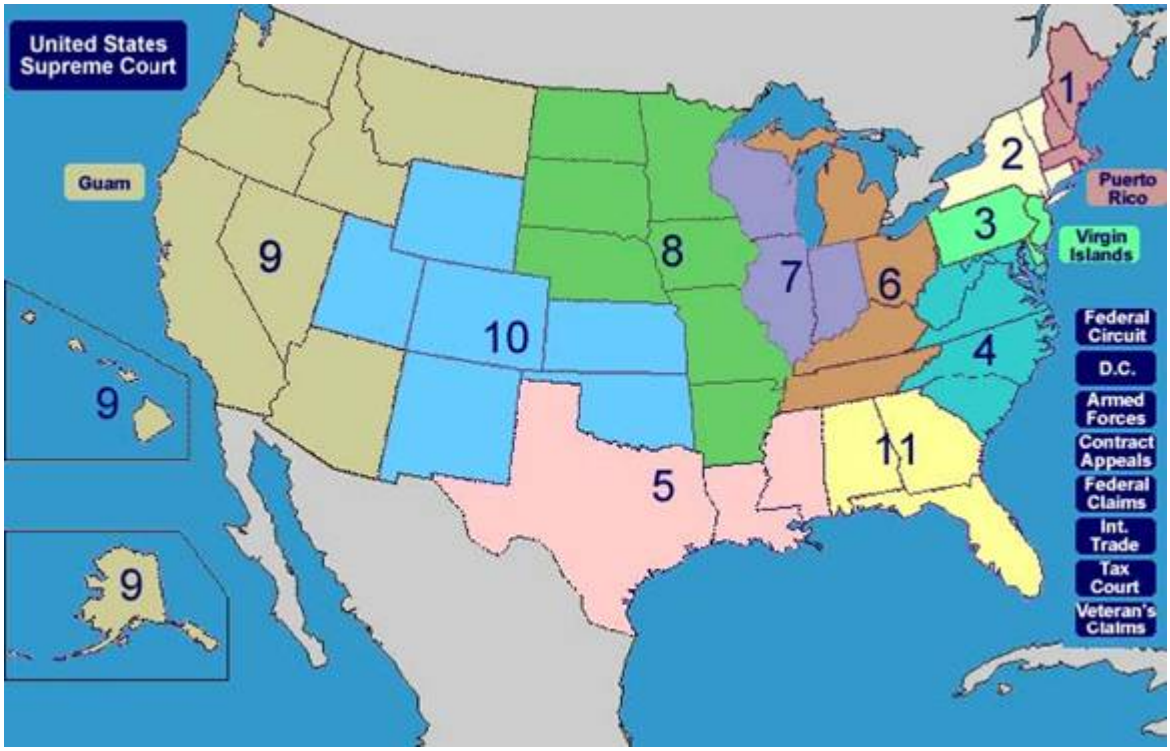
2-1-1 U.S. District Courts

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: 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: http://www.uscourts.gov/RulesAndPolicies/FederalRulemaking/LocalCourtRules.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: 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 http://www.supremecourtus.gov .

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

Background

The following is a description of major legislation amending the Federal Food, Drug, and Cosmetic Act. The amendments are listed in reverse chronological order beginning with the year 2011..

2-2-1 FDA Food Safety Modernization Act of 2011

The FDA Food Safety Modernization Act (FSMA) (P.L. 111-353), enacted on January 4, 2011, is available on the Internet at http://www.fda.gov/Food/FoodSafety/FSMA/ucm247548.htm. FSMA amended the FD&C Act to expand and enhance FDA's ability to protect the public health by strengthening the food safety system. Below are some of the important food safety enhancements included in the legislation:

Prevention: For the first time, FDA will have a legislative mandate to require comprehensive, science-based preventive controls across the food supply. This mandate includes:

- Mandatory preventive controls for food facilities
- Mandatory produce safety standards
- Authority to prevent intentional contamination

Inspection and Compliance: FSMA provides FDA with important new tools for inspection and compliance, including:

- Mandated inspection frequency: establishes a mandated inspection frequency, based on risk, for food facilities that takes effect immediately.
- Records access: FDA will have access to records, including industry food safety plans and the records firms will be required to keep documenting implementation of their plans.
- Testing by accredited laboratories: requires certain food testing to be carried out by accredited laboratories and directs FDA to establish a program for laboratory accreditation.
- Fees: authorizes FDA to collect fees for various food safety activities, including certain reinspection-related costs and costs related to noncompliance with a recall order.

Response: FSMA recognizes that FDA must have the tools to respond effectively when problems emerge despite preventive controls. New authorities include:

- Mandatory recall: provides FDA with authority to issue a mandatory recall under certain circumstances when a responsible party fails to voluntarily recall an article of food after being provided with an opportunity to do so by FDA.
- Expanded administrative detention: provides FDA with a more flexible standard for administratively detaining products that are potentially in violation of the law.
- Suspension of registration: FDA can suspend the registration of a facility if it determines that the food manufactured, processed, packed, received, or held by that facility poses a reasonable probability of causing serious adverse health consequences or death to humans or animals, and the facility was responsible for or knew of such reasonable probability.

Imports: FSMA gives FDA unprecedented authority to better ensure that imported products are safe for U.S. consumers. New authorities include:

- Importer accountability: importers have an explicit responsibility to verify that their foreign suppliers produce food that is as safe as food produced in the U.S.
- Third Party Certification: establishes a program through which qualified third parties can certify that foreign food facilities comply with U.S. food safety standards.
- Voluntary qualified importer program: FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers.

Enhanced Partnerships: FSMA builds a formal system of collaboration with other government agencies, both domestic and foreign. The following are examples of enhanced collaboration:

- State and local capacity building: FDA must develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies.
- Foreign capacity building: FDA must develop a comprehensive plan to expand the technical, scientific, and food safety capacity of foreign governments and their food industries.
- Reliance on inspections by other agencies: FDA is explicitly authorized to rely on inspections of other Federal, State and local agencies to meet its inspection mandate for domestic facilities.
- Additional partnerships are required to develop and implement a national agriculture and food defense strategy, to establish an integrated consortium of laboratory networks, and to improve foodborne illness surveillance.

Improving seafood safety: FDA and other Federal agencies may enter into interagency agreements to improve seafood safety. Such agreements may include, among other things, coordination of inspections of foreign facilities and cooperative arrangements for examining and testing seafood imports.

2-2-2 Family Smoking Prevention and Tobacco Control Act

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted on June 22, 2009 (Public Law 111-31), available on the FDA website link: www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm261829.htm

The Tobacco Control Act provides FDA with authority to regulate the manufacture, marketing, and distribution of tobacco products under the Federal Food, Drug, and Cosmetic Act (FDC Act). It authorizes FDA to, among other things; impose restrictions on the sale and distribution of tobacco products, including access to, and the advertising and promotion of, tobacco products; establish good manufacturing practice requirements to control the manufacture of tobacco products; establish tobacco product standards to regulate the levels of an additive, constituent (including a smoke constituent), or other components of a tobacco product; and require tobacco product manufacturers to submit certain records, reports, and information to FDA.

The Tobacco Control Act includes provisions to address issues of particular concern to public health officials, such as the use of tobacco by young people and the health consequences for claims of “low tar” and “light” cigarettes that can reduce the motivation to quit smoking and, thereby, lead to disease and death. The Tobacco Control Act prohibits the distribution of tobacco products labeled or advertised as "light," "low," or "mild" or any similar description unless FDA has issued an order permitting the use of such terms. The Tobacco Control Act also removes an avenue that young people can use to begin regular tobacco use by banning the sale of cigarettes and their component parts, such as filters and papers, which contain certain characterizing flavors.

The Tobacco Control Act amends existing sections of the Act and adds new Chapter IX - Tobacco Products (sections 900-919). It also amends sections of certain other statutes, such as the Federal Cigarette Labeling and Advertising Act. A number of these amendments are discussed below. Citations are to the Federal Food, Drug, and Cosmetic Act (FDC Act), as amended by the Tobacco Control Act.

1. Section 201 (Definitions) – Amended to define “tobacco products.” Section 201(rr), subparagraph (1) states: The term ‘tobacco product’ means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).
2. Section 301 (Prohibited Acts) – Amended by inserting “tobacco products” or references to tobacco product requirements in existing subsections (a), (b), (c), (e), (g), (h), (j), (k), (p), (q)(1) and (2), and (r), and adding new subsections 301(oo)-(tt).
3. Section 303(f) (Penalties) – Amended to provide authority to assess civil money penalties and/or no-tobacco-sale orders for violations of tobacco product requirements.
4. Section 304 (Seizure) – Amended to provide authority to seize adulterated or misbranded tobacco products and to administratively detain such products.
5. Sections 703 (Records of Interstate Shipment), 704(a)(1) and (b) (Factory Inspection), 705 (Publicity), 709 (Presumption); and
6. Section 801 (Imports and Exports) – Amended by inserting “tobacco products” and references to tobacco product requirements.

New sections added to the FDC Act as Chapter IX -Tobacco Products include:

1. Section 900 (Definitions) – Provides definitions pertaining to tobacco products.
2. Section 901 (Authority) – Establishes the Center for Tobacco Products, provides FDA authority over certain tobacco products.
3. Sections 902 (Adulterated Tobacco Products) and 903 (Misbranded Tobacco Products)
4. Section 904 (Submission of Health Information to the Secretary)
    a. 904(a)(1) - Requires each tobacco product manufacturer or importer, or agent thereof, to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and sub brand.
    b. 904(a)(4) - Requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009 that relate to health, toxicological, behavioral, or physiologic effects of current or future

tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.

c. 904(e) – Requires the FDA to establish, and periodically revise, a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and sub brand. It also requires the FDA to publish a public notice requesting the submission by interested persons of scientific and other information concerning the harmful and potentially harmful constituents in tobacco products and tobacco smoke.

5. Section 905 – Provides registration, listing, and premarket notification requirements for tobacco products.
   a. 905(b)-(d) (Registration of Owners and Operators, New Owners and Operators, and Added Establishments) - Requires that every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products register with FDA the name, places of business, and all establishments engaged in these activities owned or operated by that person.
   b. 905(g) (Biennial Inspection of Registered Establishments) – Requires that every establishment registered with the FDA be subject to inspection under section 704 or 905(h) at least once in the 2-year period beginning from date of registration and every successive 2-year period thereafter.
   c. 905(h) (Registration by Foreign Establishments) – Requires any establishment within any foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products, to register with FDA under this section once FDA has promulgated regulations.
   d. 905(i)(1) (Product List) - Requires that all registrants “at the time of registration . . . file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution,” along with certain accompanying information, including all labeling.
   e. 905(j) (Report Preceding Introduction of Certain Substantially Equivalent Products Into Interstate Commerce) – Requires any person who proposes to begin introduction, or delivery for introduction, into interstate commerce of a tobacco product that was not commercially marketed (other than for test marketing) in the United States as of February 15, 2007 to, at least 90 days before making such introduction or delivery, report, among other things, the basis for that person’s determination that the product is substantially equivalent to a product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or to a tobacco product that FDA has previously determined is substantially equivalent.
6. Section 906(d) (Restrictions on Sale and Distribution) – Provides FDA authority to promulgate regulations restricting sales and distribution of a tobacco product including restrictions on the access to, and the advertising and promotion of, the tobacco product. It also requires FDA to promulgate regulations regarding the sale, distribution, promotion, and marketing of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer.
7. Section 906(e) (Good Manufacturing Practice Requirements) – Requires FDA to promulgate regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation, packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology. States that the regulations may also

provide for the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established.

8. Section 907 (Tobacco Product Standards) –
    a. 907(a)(1)(A) - Bans the sale of cigarettes and their component parts, such as filters and papers, which contain artificial or natural flavors that is a characterizing flavor.
    b. 907(a)(1)(B) – Bans, beginning June 22, 2011, the use of tobacco by a tobacco product manufacturer, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.
    c. 907(a)(3) - Provides FDA with the authority to adopt additional tobacco product standards if FDA finds that a tobacco product standard is appropriate for the protection of the public health.
9. Section 908 (Notification and Recall Authority) –
    a. 908(a) – Provides authority to issue a notification order if a determination is made that a tobacco product presents an unreasonable risk of substantial harm to the public health and that a notification is necessary to eliminate the unreasonable risk of such harm.
    b. 908(c) – Provides authority for mandatory recall if there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death.
10. Section 909 (Records and Reports) -
    a. 909(a) (In General) - Requires a tobacco product manufacturer or importer to establish and maintain such records, make such reports, and provide such information, as FDA may by regulation reasonably require to assure that a tobacco product is not adulterated or misbranded and to otherwise protect public health.
    b. 909(b) (Reports of Removals and Corrections) – Provides that FDA shall by regulation require a tobacco product manufacturer or importer to report any corrective action taken or removal from the market of a tobacco product undertaken to reduce a risk to health posed by the tobacco product or remedy a violation caused by the tobacco product which may present a risk to health.
11. Section 910 (Premarket Review of “New Tobacco Products”) –
    a. Defines the term “new tobacco product” as any tobacco product (including those products in test markets) that was not marketed in the United States as of February 15, 2007, or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product, where the modified product was marketed after February 15, 2007. Requires that a manufacturer submit an application for premarket review for a “new tobacco product” and that the product be subject to an order from FDA before it is commercially distributed—unless the manufacturer has submitted a report under section 905(j) and FDA has issued an order that the product is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the U.S. as of February 15, 2007, and is in compliance with the requirements of the FDC Act; or FDA has issued an order that the product is exempt from the requirements of section 905(j) pursuant to a regulation issued under section 905(j)(3).

b. Defines the term "substantially equivalent" to mean that FDA has by order found that a tobacco product has the same characteristics as another (predicate) tobacco product, or has different characteristics and the manufacturer has submitted information, including clinical data if deemed necessary by FDA, that demonstrates that the product does not raise different questions of public health. Explains that "characteristics" means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

12. Section 911 (Modified Risk Tobacco Products)
    a. Section 911(a) – Prohibits any person from introducing or delivering for introduction into interstate commerce any modified risk tobacco product (defined in section 911(b)(1) as any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products) unless an order issued pursuant to section 911(g) is in effect for the product.
    b. Section 911(b) – Among other things, prohibits the use of the descriptors "light," "mild," or "low," or similar descriptors in tobacco product labels, labeling, or advertising unless an order issued pursuant to section 911(g) is in effect for the product.
    c. Section 911(g) – Provides authority for FDA to issue an order for modified risk tobacco products or for certain tobacco products that may not be commercially as a modified risk tobacco product.

2-2-3 FDA Amendments Act of 2007

The Food and Drug Administration Amendments Act of 2007 (FDAAA) was enacted on September 27, 2007. (Public Law 110-85, available on the internet at: http://www.fda.gov/RegulatoryInformation/Legislation/default.htm).

FDAAA reauthorizes several critical programs, provides FDA with new authorities, and increases our responsibilities. For example, FDAAA:

1. Reauthorizes and expands the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act, providing user fees for the review of new drug and new medical devices through fiscal year 2012.

2. Reauthorizes the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, and enacts the Pediatric Medical Device Safety and Improvement Act of 2007. These acts encourage research and development of pediatric drugs, biological products, and medical devices, respectively.

3. Establishes a nonprofit corporation, the Reagan-Udall Foundation, to modernize development of products regulated by FDA, accelerate medical innovation, and enhance product safety.

4. Expands the existing government database on clinical trials of drugs and biologics (excepting Phase 1 clinical trials of these products), and devices. It also establishes new prohibited acts involving the failure to comply with applicable requirements and the submission of false or misleading clinical trial information, each of which will be subject to civil money penalties.

5. Enhances the safety of drugs by providing FDA with new authorities to require postmarket studies and clinical trials to address safety issues, safety labeling changes, and Risk Evaluation and Mitigation Strategies (REMS), if the agency determines this is necessary to ensure that the benefits of the drug outweighs the risks.

6. Establishes requirements for a "Reportable Food Registry" to allow FDA to track patterns of adulteration in food.

FDA's new or revised authorities under FDAAA include those shown below. Citations are to the Federal Food, Drug, and Cosmetic Act (FDC Act), as amended by FDAAA, unless otherwise noted.

1. Civil Money Penalty Authorities:

   FDAAA expands FDA's CMP authorities to address failures to comply with new requirements applicable to:

   a. the submission of data to the clinical trial registry and certification;
   b. postmarket studies and risk evaluation and mitigation strategies for drugs; and
   c. direct-to-consumer advertisements for drugs.

   Sections 303(f)(3)(A) and (B), 303(f)(4)(A), and 303(g)(1) (21 U.S.C. §§ 333(f)(3)(A) and (B), 333(f)(4)(A), and 333(g)(1)). (See items 2-4 below, and the "Civil Money Penalties" section of Chapter 5 for further information.)

2. Clinical Trial Registry and Results Certification:

   FDAAA amended the Public Health Service Act (PHS Act), section 402(j) (42 U.S.C. § 282(j)) to require the responsible party for each applicable clinical trial to submit clinical trial information to a clinical trial registry data bank and to certify that all applicable requirements of section 402(j) have been met when certain human drug, biological product, and device applications and submissions are submitted to FDA. Section 402(j)(5)(B) of the Public Health Service Act (42 U.S.C. § 282(j)(5)(B)). See section 505(b)(6) (21 U.S.C. § 355(b)(6)), section 510(k) (21 U.S.C. § 360(k)), section 515(c)(1)(G) (21 U.S.C. § 360e(c)(1)(G)), and section 520(m)(2) (21 U.S.C. § 360j(m)(2)) for certification requirements in the FDC Act.

   The failure to submit a required certification, the failure to submit required clinical trial information, or the submission of clinical trial information that is false or misleading is a prohibited act under section 301(jj) (21 U.S.C. § 331(jj)) and subjects violators to civil money penalties under section 303(f)(3)(A) and (B) (21 U.S.C. §§ 333(f)(3)(A) and (B)).

3. Postmarket studies and clinical trials for drugs; labeling:

   FDAAA gives FDA the authority to require a "responsible person" (a holder of an approved New Drug Application for a prescription drug or an approved Biologics License Application, or a person who has submitted an application that is pending) to conduct post approval studies or clinical trials to assess a known serious risk or signals

of serious risk related to the use of a drug, or to identify an unexpected serious risk when available data indicate the potential for a serious risk. Section 505(o)(3) (21 U.S.C. § 355(o)(3)).

FDA may also issue an order directing the responsible person or the holder of an approved Abbreviated New Drug Application to make labeling changes deemed appropriate to address new safety information. Section 505(o)(4)(E) (21 U.S.C. § 355(o)(4)(E)).

A drug is misbranded within the meaning of section 502(z) (21 U.S.C. § 352(z)) if the responsible person fails to comply with a requirement of section 505(o)(3) (relating to postmarket studies and clinical trials) or 505(o)(4) (relating to labeling).

A responsible person may not introduce or deliver for introduction into interstate commerce the new drug involved if the person is in violation of a requirement established under section 505(o)(3) or (4) (21 U.S.C. § 355(o)(3) or (4)). Section 505(o)(1) (21 U.S.C. § 355(o)(1)).

The failure to comply with a requirement of section 505(o) also subjects a responsible person to a civil money penalty under section 303(f)(4)(A) (21 U.S.C. § 333(f)(4)(A)).

4. Risk Evaluation & Mitigation Strategies for Drugs:

FDAAA gives FDA the authority to require a person who submits a drug application to submit a proposed Risk Evaluation and Mitigation Strategy (REMS) as part of the drug application. FDA may also require a proposed REMS to be submitted after approving a covered application (a New Drug Application or an Abbreviated New Drug Application for a prescription drug, or a Biologics License Application), including applications approved before the effective date of this requirement in FDAAA. Section 505-1(a) (21 U.S.C. § 355-1(a)).

A proposed risk mitigation strategy must include the timetable required under section 505-1(d); and, to the extent required by FDA, the additional elements described in section 505-1(e) and (f). Section 505-1(c) (21 U.S.C. § 355-1(c)).

A person may not introduce or deliver for introduction into interstate commerce a new drug if it is subject to a REMS, and the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 505-1, including requirements regarding assessments of approved strategies. Section 505(p)(1) (21 U.S.C. § 355(p)(1)).

The failure to conduct a postmarket study under section 506 (Fast Track Products) (21 U.S.C. § 356), 21 C.F.R. part 314, subpart H (Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses), or 21 C.F.R. part 601, subpart E (Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses), is considered to be a violation of section 505(p)(1) (21 U.S.C. § 355(p)(1)).

A drug is misbranded within the meaning of section 502(y) (21 U.S.C. § 352(y)) if it is subject to an approved risk evaluation and mitigation strategy pursuant to section

505(p) and the "responsible person" (a person submitting a New Drug Application or an Abbreviated New Drug Application for a prescription drug, or a Biologics License Application; or the holder of an approved application) fails to comply with a requirement of section 505-1(d), (e), or (f).

The failure to comply with a requirement of section 505(p) or 505-1 also subjects a responsible person to a civil money penalty. Section 303(f)(4)(A) (21 U.S.C. § 333(f)(4)(A)).

5. Registration and listing of drugs and devices: FDAAA amends sections 510(b), (i), (j), and (p) (21 U.S.C. §§ 360(b), (i), (j), and (p)), as follows:

   a. For drugs and devices: The timing for the initial registration of foreign establishments was changed from "on or before December 31" to "immediately" upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States. Annual registration is required thereafter. Section 510(i)(1) (21 U.S.C. § 360(i)(1).

      Registrations and listings are required to be submitted electronically, unless a waiver has been granted. Section 510(p) (21 U.S.C. § 360(p)).

   b. For devices: The timing for the initial registration of domestic establishments was changed from "on or before December 31" to "During the period beginning on October 1 and ending on December 31 of each year." Section 510(b)(2) (21 U.S.C. § 360(b)(2)).

      The listing requirement for devices was changed from twice a year to once each year "during the period beginning on October 1 and ending on December 31." Section 510(j)(2) (21 U.S.C. § 360(j)(2)).

6. Reporting device malfunctions: FDAAA allows manufacturers to report malfunctions involving Class I devices, and Class II devices that are not permanently implantable or life supporting or life-sustaining, in a summary form on a quarterly basis in accordance with criteria established by FDA, unless the manufacturer has been notified by letter or Federal Register notice that the type of device is subject to the Medical Device Reporting requirements in part 803 in order to protect the public health. Section 519(a)(1)(B) (21 U.S.C. § 360i(a)(1)(B)).

7. Reportable Food Registry: FDAAA establishes requirements for a Reportable Food Registry (RFR) that requires a responsible party to file a report through an FDA internet portal within 24 hours of learning there is reason to believe that a food product can cause serious adverse health consequences or death to people and/or animals. The FDA defines "responsible party" as the person who submits the registration information to the FDA for a food facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States. The RFR applies to all foods regulated by the FDA, except infant formula and dietary supplements, which are covered by other regulatory requirements. See Section 417 (21 U.S.C. § 350f).

FDA may require a responsible party to provide notification to the immediate previous source of the article of food, and to the immediate subsequent recipient of the article of food, as described in section 417(d)(6) and (7) (21 U.S.C. §§ 350f(d)(6) and (7)).

The responsible party must maintain records related to each report received, notification made, and report submitted to the FDA under section 417 for two years; and must permit inspection of these records as provided for by section 414. Section 417(g) (21 U.S.C. § 350f(g)).

The failure to comply with the requirements of section 417 is a prohibited act under section 301 (21 U.S.C. § 331) as follows:

a. The failure to submit a report or provide a notification required under section 417(d). Section 301(mm) (21 U.S.C. § 331(mm)).

b. The falsification of a report or notification required under section 417(d). Section 301(nn) (21 U.S.C. § 331(nn)).

c. The refusal to permit access to or copying of any record required by section 417(g), the failure to establish or maintain any record, or make any report required under section 417, or the refusal to permit access to or verification or copying of any such required record.

2-2-4 Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006

The Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 was enacted on December 22, 2006, to require certain firms to report serious adverse events associated with the use of non-application, nonprescription drug products and dietary supplements. (Public Law 109-462. On the internet at: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/ucm148035.htm.

The requirements set forth in the Dietary Supplement and Nonprescription Drug Consumer Protection Act went into effect on December 23, 2007. This Act amended the Federal Food, Drug, and Cosmetic Act by adding Subchapter H, entitled "Serious Adverse Event Reports," to Chapter VII of the FD&C Act. The newly added Subchapter H contains Section 760, entitled "Serious Adverse Event Reporting for Nonprescription Drugs," and Section 761, entitled "Serious Adverse Event Reporting for Dietary Supplements."

2-2-5 Food Allergen Labeling and Consumer Protection Act of 2004

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) was enacted in August 2004 to address the labeling of packaged foods that contain major food allergens. (Public Law 108-282. On the internet at: http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/ucm106187.)

FALCPA amended the Federal Food, Drug, and Cosmetic Act as follows:

Section 201(qq) was added to define the term "major food allergen." The term means any of the following foods, or a food ingredient that contains protein derived from any of the following foods: milk; eggs; fish; crustacean shellfish; tree nuts; wheat; peanuts; and soybeans.

Section 403(w) was added to address the labeling of foods that contain a major food allergen. Effective January 1, 2006, all food labels must clearly state if food products contain any ingredients that contain protein derived from the eight major allergenic foods. Manufacturers are required to identify in plain English the presence of ingredients that contain protein derived from milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, or soybeans in the list of ingredients; or to say "contains" followed by name of the source of the food allergen after or adjacent to the list of ingredients.

2-2-6 Minor Use and Minor Species Animal Health Act of 2004

On August 2, 2004, the Minor Use and Minor Species Animal Health Act of 2004 (MUMS) was signed into law. (Public Law 108-282. On the internet at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ282.108.pdf .

MUMS amended the Federal Food, Drug, and Cosmetic Act (the Act) by adding Subchapter F—New Animal Drugs for Minor Use and Minor Species, consisting of Sections 571-573.

MUMS amended the Act to provide special procedures to bring medications to treat minor animal species (minor species) and uncommon diseases in the major animal species (minor use) to market. Minor use drugs are drugs for use in major species (cattle, horses, swine, chickens, turkeys, dogs, and cats) for an indication that occurs infrequently and in only a small number of animals, or in limited geographical areas and in only a small number of animals annually. Minor species are all animals other than the major species, which includes zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include sheep, goats, catfish, and honeybees.

MUMS added the following three new procedures:

1. ***Conditional Approval:***
   Under MUMS, the sponsor of a veterinary drug can ask the Center for Veterinary Medicine for “conditional approval.” This allows the sponsor to make the drug available before collecting all of the necessary effectiveness data, but after proving the drug is safe. The drug sponsor can keep the product on the market for up to five years, through annual renewals, while collecting the required effectiveness data. (Section 571 of the Act.)

2. ***Indexing:***
   In some cases, the potential market for a minor species drug is too small to ever support the costs of the drug approval process, even under a conditional approval. In such cases, FDA now may add the drug to an index of legally marketed unapproved new animal drugs. The index is limited to new animal drugs for use in a minor species: (1) where the animal or edible products from the animal will not be consumed by humans or food-producing animals; or (2) where the drug is used in a hatchery, tank, pond, or other similar man-made structure in an early, non-food life state of a food-producing minor species, where safety for humans is demonstrated. (Section 572 of

the Act.)

3. ***Designation:***
   The manufacturer or sponsor of a new animal drug for a minor use or use in a minor species may request that the Secretary declare the drug a "designated new animal drug." The Secretary may make grants and enter into contracts to help defray the cost of conducting safety and effectiveness testing and developing processes and procedures for manufacturing the designated new animal drug. Companies who gain approval for designated new animal drugs will also be granted seven years of marketing exclusivity. (Section 573 of the Act.)

2-2-7 Project BioShield Act of 2004

The Project BioShield Act of 2004 was enacted in July 2004. (Public Law 108-276. On the internet at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ276.108) .

Section 4 amends the Federal Food, Drug, and Cosmetic Act (Section 564 - Authorization for Medical Products for Use in Emergencies) to provide that the Secretary of Health and Human Services may declare an emergency justifying an authorization to use unapproved drugs, devices, or biological products ("products") and approved products for unapproved uses.

2-2-8 Pediatric Research Equity Act of 2003

On December 3, 2003, the Pediatric Research Equity Act of 2003 (PREA) was signed into law. (Public Law 108-155. On the internet at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ155.108). PREA amends the Federal Food, Drug, and Cosmetic Act (the Act) by adding section 505B.

Section 505B(a) of the Act requires the conduct of pediatric studies for certain drug and biological products. Specifically, new drug applications (NDAs) and biologics licensing applications (BLAs) (or supplements to applications) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to contain a pediatric assessment unless the applicant has obtained a waiver or deferral.

Section 505B(b) of the Act authorizes FDA to require holders of applications for previously approved marketed drugs and biological products who are not seeking approval for one of the changes enumerated above to submit a pediatric assessment under certain circumstances.

The amendments made by PREA take effect on December 3, 2003, except that all NDAs or BLAs for new active ingredients, new indications, new dosage forms, new dosing regimens, and new routes of administration submitted on or after April 1, 1999, are subject to PREA. (Section 4(b) of PREA).

2-2-9 Animal Drug User Fee Act of 2003 (ADUFA)

ADUFA amends the Federal Food, Drug, and Cosmetic Act and authorizes FDA to collect fees for certain animal drug applications, and for the establishments, products, and sponsors associated with these and previously approved animal drug applications, in support of the review of animal drugs. This program is similar to the Prescription Drug User Fee Act (PDUFA). Additional information can be found on the CVM homepage, at:

http://www.fda.gov/cvm/adufa.htm#law .

2-2-10 Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (107 P.L. 188) (the Bioterrorism Act) is divided into five titles. FDA is responsible for carrying out certain provisions of the Bioterrorism Act, particularly Title III, Subtitle A--Protection of Food Supply and Subtitle B--Protection of Drug Supply.

Title III, Subtitle A, Protection of Food Supply, amends the Act by giving an officer or qualified FDA employee the authority to issue administrative detention orders for food. Additionally, it grants FDA permissive debarment authority for food importers for a period of up to five years, if an individual or entity has been convicted of a felony relating to food importation or has been engaged in a pattern of importing or offering for import adulterated food that presents a serious threat of serious adverse health consequences or death to human or animals.

Section 314 of Subtitle A amends the Act to authorize FDA to commission other Federal officials to conduct investigations under the Act. As a result of the change, FDA may commission other Federal officials pursuant to a memorandum of understanding between the Secretary and the head of the other Federal Department or Agency.

Section 305 of Subtitle A requires FDA registration of all facilities that are engaged in manufacturing, processing, packing, or holding food for U.S. consumption. If FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, each person that manufactures, processes, packs, distributes , receives, holds, or imports the food, would be required to permit access to, and copying of, all records relating to the food that are needed to assist FDA in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. These provisions also require FDA to compile and maintain an up-to-date list of registered food facilities. That list or information derived from that list is not subject to disclosure under the Freedom of Information Act to the extent that it discloses the identity or location of a specific registered person. However, FDA's regulation (21 CFR 1.243) generally permits the agency to disclose that registration information if the agency obtained it by other means or if the information has previously been disclosed to the public and the information is not protected from disclosure by a FOI exemption.

Additionally, the FDA is required to promulgate regulations to require that prior to the importation of any food, a notice be given of: the identity of the food; the manufacturer and shipper; if known, the grower; the country of origin; the country from which the food is shipped; and the anticipated port of entry. Failure to do so would result in refusal to admit the food. Finally, Subtitle A of the Act allows FDA to mark food that has been refused admission with a container label.

Title III, Subtitle B of the Bioterrorism Act relating to the protection of drug supply amends the Act by requiring an annual registration of foreign manufacturers shipping drugs and devices into the United States; and additional information regarding imported components that are intended for use in exported products. When a drug or device component, food additive, color additive, or dietary supplement is imported under section 801(d)(3), the importer is required to submit a statement to FDA at the time of each importation that includes the following:

1. that the article (the components, parts, accessories, or articles) is intended to be further processed by, or incorporated into a drug, biological product, device, food, food additive, color additive, or dietary supplement, by the initial owner or consignee, who will then export the article from the United States in accordance with section 801(e) or section 802 of the Act or section 351(h) of the Public Health Service Act; and,

2. identification of the manufacturer of such article and each processor, packer, distributor or other entity that had possession of the article in the chain of possession from the manufacturer to such importer of the article.

The statement must be accompanied by such certificates of analysis as are necessary to identify such article unless the article is a device or is an article described in section 801(d)(4).

On FDA's Internet site: http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm .

2-2-11 Best Pharmaceuticals for Children Act – 2002

On January 4, 2002, President Bush signed into law the Best Pharmaceuticals for Children Act (P.L. 107-109). This legislation reauthorizes the pediatric studies provision of the Food and Drug Administration Modernization and Accountability Act of 1997. The law encourages pharmaceutical companies to conduct pediatric studies of new and already marketed drugs that are currently used in pediatric populations but are not labeled for such use by extending their market exclusivity. The law authorizes $200 million in FY 2002 and such sums as are necessary for each of the five succeeding fiscal years, for pediatric studies of drugs.

On the FDA Internet site at:
http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/ucm148011.htm.

2-2-12 Medical Device User Fee and Modernization Act of 2002

October 26, 2002, the President signed into law the Medical Device User Fee and Modernization Act of 2002 (P.L. 107-250). The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), amends the Federal Food, Drug, and Cosmetic Act to provide FDA new responsibilities, resources, and challenges.

The act has three particularly significant provisions:

1. User fees for premarket reviews of PMAs, PDPs, premarket reports (a new category of premarket application for reprocessed single-use devices), BLAs, certain supplements, and 510(k)s. Fees will add $25.1 million to FDA's medical device budget authority during FY 2003, rising to $35 million in FY 2007. These sums are protected from inflation and changes in workloads through a set of adjustments. The revenues from these fees, and from additional appropriations for infrastructure, will allow FDA to pursue a set of ambitious performance goals; these goals will be summarized in letters from the Secretary of the Department of Health and Human Services to Congress and are incorporated by reference in the new law. The payment of a premarket review fee is not related in any way to FDA's final decision on a submission.

2. Establishment inspections may be conducted by accredited persons (third-parties),

under carefully prescribed conditions.

3. New regulatory requirements for reprocessed single-use devices, including a new category of premarket submission, the premarket report.

4. Additional provisions of the new law include:

    a. The third-party review program is continued through FY 2006.

    b. The review of combination products will be coordinated by a new office in the Office of the Commissioner.

    c. Electronic labeling is authorized for prescription devices intended to be used in health care facilities.

    d. FDA may require electronic registration of device establishments, when feasible.

    e. The sunset provision applicable to section 513(i)(1)(E) (intended use based upon labeling) is revoked.

    f. The law now explicitly provides for modular review of PMAs.

    g. New provisions are added concerning devices intended for pediatric use.

    h. The act authorizes additional appropriations for postmarket surveillance -- $3 million for FY 2003, $6 million for FY 2004, and "such sums as may be necessary" in subsequent years.

    i. Government Accounting Office (GAO) and National Institutes of Health (NIH) are directed to prepare reports concerning breast implants.

    j. The manufacturer of a device must be identified on the device itself, with certain exceptions.

On the FDA Internet at: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm109133.htm

2-2-13 FDA Modernization Act of 1997

The FDA Modernization Act of 1997 (P.L. 105-115) is major legislation focused on reforming the regulation of food, medical products, and cosmetics. The following are the most important provisions of the act:

1. ***Prescription Drug User Fees***
   The FDA Modernization Act of 1997 reauthorizes, for five more years, the Prescription Drug User Fee Act of 1992 (PDUFA). In the past five years, the program has enabled the agency to reduce to 15 months the 30-month average time that used to be required for a drug review before PDUFA. This accomplishment was made possible by FDA managerial reforms and the addition of 696 employees to the agency's drugs and biologics program, which was financed by $329 million in user fees from the pharmaceutical industry.

2. ***FDA Initiatives and Programs***
   The law enacts many FDA initiatives undertaken in recent years under the “Reinventing

Government" program. The codified initiatives include measures to modernize the regulation of biological products by bringing them in harmony with the regulations for drugs and eliminating the need for establishment license application; eliminate the batch certification and monograph requirements for insulin and antibiotics; streamline the approval processes for drug and biological manufacturing changes; and reduce the need for environmental assessment as part of a product application.

The Act also codifies FDA's regulations and practice to increase patient access to experimental drugs and medical devices and to accelerate review of important new medications. In addition, the law provides for an expanded database on clinical trials which will be accessible by patients. With the sponsor's consent, the results of such clinical trials will be included in the database. Under a separate provision, patients will receive advance notice when a manufacturer plans to discontinue a drug on which they depend for life support or sustenance, or for a treatment of a serious or debilitating disease or condition.

3. ***Information on Off-label Use and Drug Economics***
The law creates a narrow "safe harbor" exception to the long-standing prohibition on dissemination by manufacturers of information about unapproved uses of prescription drugs and medical devices. The act allows a manufacturer to disseminate peer-reviewed journal articles that concern an off-label indication of its product, and are not otherwise false or misleading, to healthcare practitioners, provided the company commits itself to file, within a specified time frame, a supplemental application based on appropriate research to establish the safety and effectiveness of the unapproved use, and complies with the other requirements of the law, including submitting the articles to the FDA 60 days in advance of dissemination and including certain disclosures and other information with the disseminated articles.

The act also allows drug companies to provide health care economic information about approved uses of their products, based on competent and reliable scientific evidence, to formulary committees, managed care organizations, and similar large-scale buyers of health-care products. The provision is intended to provide such entities with facts about the potential economic consequences of their procurement decisions.

4. ***Pharmacy Compounding***
Section 127 of the FDA Modernization Act of 1997 amended the Federal Food, Drug, and Cosmetic Act (the Act) by adding section 503A, which specified certain conditions under which compounded human drugs could be exempt from particular requirements of the Act. In April 2002, however, the United States Supreme Court struck down the commercial speech restrictions in section 503A of the Act as unconstitutional. Accordingly, all of section 503A is now invalid.

As a result, the agency utilizes its longstanding policy of exercising its enforcement discretion regarding certain types of pharmacy compounding. This policy is articulated in Compliance Policy Guide, section 460.200, issued on May 29, 2002.

5. ***Risk-based Regulation of Medical Devices***
The act complements and builds on FDA's recent measures to focus its resources on medical devices that present the greatest risks to patients. For example, the law

exempts from premarket notification class I devices that are not intended for a use that is of substantial importance in preventing impairment of human health, or that do not present a potential unreasonable risk of illness or injury. The law also directs FDA to focus its postmarket surveillance on higher risk devices, and allows the agency to implement a reporting system that concentrates on a representative sample of user facilities -- such as hospitals and nursing homes -- that experience deaths and serious illnesses or injuries linked with the use of devices.

Finally, the law expands an ongoing pilot program under which FDA accredits outside -- so-called "third party" -- experts to conduct the initial review of all class I and low-to-intermediate risk class II devices. The act, however, specifies that an accredited person may not review devices that are permanently implantable, life-supporting, life-sustaining, or for which clinical data are required.

6. ***Food Safety and Labeling***
   The act eliminates the requirement of FDA's premarket approval for most packaging and other substances that come in contact with food and may migrate into it. Instead, the law establishes a process whereby the manufacturer can notify the agency about its intent to use certain food contact substances and, unless FDA objects within 120 days, may proceed with the marketing of the new product. Implementation of the notification process is contingent on additional appropriations to cover its cost to the agency. The act also expands procedures under which FDA can authorize health claims and nutrient content claims without reducing the statutory standard.

7. ***Standards for Medical Products***
   While the act reduces or simplifies many regulatory obligations of manufacturers, it does not lower the standards by which medical products are introduced into the market place. In the area of drugs, the law codifies the agency's current practice of allowing in certain circumstances one clinical investigation as the basis for product approval. The act, however, does preserve the presumption that, as a general rule, two adequate and well-controlled studies are needed to prove the product's safety and effectiveness.

   In the area of medical devices, the act specifies that FDA may keep out of the market products having manufacturing processes that are so deficient that they could present a serious health hazard. The law also gives the agency authority to take appropriate action if the technology of a device suggests that it is likely to be used for a potentially harmful unlabeled use.

On the FDA Internet at:
http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDAMA/default.htm .

2-2-14 Food Quality Protection Act of 1996

In August of 1996, Congress passed and the President signed into law the Food Quality Protection Act (P.L. 104-170) (FQPA). FQPA represents a major breakthrough in pesticide regulation and resolves many of the inconsistencies between the two major pesticide statues FIFRA (Federal, Insecticide, Fungicide, and Rodenticide Act) and FFD&C Act (Federal Food, Drug, and Cosmetic Act).

FQPA amends FIFRA and FFD&C Act to mandate a single, health based standard for all

pesticides in foods, provide special protection for infants and children, expedites approval of safer pesticides, and requires periodic re-evaluation of pesticide registrations and tolerances to ensure that the scientific data supporting pesticides registrations will remain current. The FQPA also amends the provisions in section 408 of the FFD&C Act in reference to pesticide residues resulting from use of pesticides under section 18 of the FIFRA and residues of cancelled pesticides.

Additional information is available on the FDA Internet at: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/ucm148008.htm .

2-2-15 FDA Export Reform and Enhancement Act of 1996

The FDA Export Reform and Enhancement Act (P.L. 104-134) was enacted in 1996 and amended by P. L. 104-180. This law amended sections 801 and 802 of the Federal Food, Drug, and Cosmetic Act (the act), as well as section 351(h) of the Public Health Service Act, simplifying the requirements for exporting unapproved human drugs, biologics, and devices. In addition, the FDA Export Reform and Enhancement Act substantially reduced the requirements for exporting unapproved new animal drugs, provided a new option for exporting unapproved devices, and added a new provision, at section 801(d)(3) of the act, that permits the importation of certain components, parts, and accessories of human drugs, biologics, devices, food additives, color additives, and dietary supplements for further processing or incorporation into products intended for export.

Additional information is available on the FDA Web at: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/ucm148005.htm .

2-2-16 Dietary Supplement Health and Education Act of 1994

The Dietary Supplement Health and Education Act of 1994 (P.L. 103-417) was signed into law by the President on October 25, 1994. DSHEA amends the FFD&C Act to alter significantly the way the FDA regulates dietary supplements and requires the Agency to undertake significant rulemaking and other actions to fully implement the scope of the DSHEA. In summary, DSHEA:

1. redefines "dietary supplement" to include the following dietary ingredients:
    a. a vitamin;
    b. a mineral;
    c. an herb or other botanical;
    d. an amino acid;
    e. another dietary substance for use by man to supplement the diet by increasing the total dietary intake; or,
    f. a concentrate, metabolite, constituent, extract, or combination of these ingredients.

"Dietary supplements" will include articles previously approved as a drug, antibiotic, or biologic, or authorized for clinical investigation, if they had been marketed prior to such approval or authorization as a dietary supplement, unless the Secretary issues regulations finding the article to be unsafe under the FFD&C Act;

2. places the burden of proof on FDA to prove that a product is unsafe before it can be removed from the marketplace;

3. exempts certain third party literature from treatment as labeling if certain conditions are met with regard to content and presentation of the literature;

4. establishes a series of labeling requirements with which manufacturers must comply by December 31, 1996;

5. allows dietary supplement manufacturers to make statements of nutritional support ("structure" or "function" claims), under certain conditions without preclearance and without subjecting product to regulation as a drug. Statements claiming to diagnose, treat, cure, or prevent disease continue to subject product to regulation as a drug;

6. makes null and void the Advance Notice of Proposed Rulemaking (ANPR) published June 18, 1993;

7. provides authority for the Agency to develop and enforce good manufacturing practices for the dietary supplement industry;

8. establishes a Commission on Dietary Supplement Labels to develop recommendations on labeling claims for dietary supplements and requires the Secretary to publish through notice and comment rulemaking the Commission's recommendations. If such rulemaking is not completed within 2 years of the issuance of the report, the NLEA final regulations for health claims for dietary supplements, published January 4, 1994, will be null and void; and,

9. creates an Office of Dietary Supplements within the National Institutes of Health (NIH) to explore and study the role of dietary supplements in improving health and health care.

DSHEA does not apply to products intended for animal use. The Center for Veterinary Medicine, Division of Compliance (HFV-230), should be consulted for appropriate guidance. 240-276-9200.

2-2-17 Animal Medicinal Drug Use Clarification Act of 1994

The Animal Medicinal Drug Use Clarification Act of 1994 (P.L. 104-250) (AMDUCA) allows veterinarians to prescribe extra label uses of certain approved animal drugs and approved human drugs for animals under certain conditions. Extra label (or extra-label) use refers to the use of an approved drug in a manner that is not in accordance with the approved label directions. The key constraints of AMDUCA are that any extra label use must be by or on the order of a veterinarian within the context of a veterinarian-client-patient relationship, must not result in violative residues in food-producing animals, and the use must be in conformance with the implementing regulations published at 21 CFR Part 530. A list of drugs specifically prohibited from extra-label use appears in the Code of Federal Regulations.

2-2-18 Prescription Drug User Fee Act of 1992

Title I of the Prescription Drug User Fee Act of 1992 (P.L. 102-571) amends the Federal Food, Drug, and Cosmetic Act (FD&C) Act to authorize human drug application, prescription drug establishment, and prescription drug product fees. The funds would be devoted to expediting the prescription drug review process.

A fee is assessed on human drug applications or supplements submitted on or after September 1, 1992. This includes prescription drugs approved for over-the-counter (OTC) use, and new drug applications for OTC drugs. A human drug application or supplement submitted by a person subject to the fees will be incomplete and will not be accepted for filing until all fees are paid.

Each person who owns a prescription drug establishment where at least one prescription drug product is manufactured (which is not the same as a product approved under Section 505(b)(2) (a paper NDA) or Section 505(j) (a generic ANDA), and after September 1, 1992 had pending before the Secretary a human drug application or supplement is subject to an annual fee payable on or before January 31 of each year.

Each person named as an applicant in a human drug application for a prescription drug product listed under Section 510, and who after September 1, 1992 had a human drug application or supplement pending before the Secretary shall pay an annual fee for each prescription drug product. The fee is payable, at the time of listing the product, in each calendar year. The fee is paid only once a year for each prescription drug product listed irrespective of the number of times the product is listed under Section 510.

A business with fewer than 500 employees (including employees of affiliates) and which does not have a prescription drug product introduced or delivered for introduction into interstate commerce shall pay one-half of the fee amount for the human drug applications it submits, but shall pay the full fee for supplements. Such a business would not be required to pay any portion of the fee until 1 year after the date of the submission of the application.

2-2-19 Generic Drug Enforcement Act of 1992

The Generic Drug Enforcement Act (P.L. 102-282), signed into law on May 13, 1992, amended the Federal Food, Drug, and Cosmetic Act (Sections 306-308) to authorize the FDA to debar an individual, convicted of certain crimes or found to have engaged in certain types of conduct, from providing any services to a drug product applicant. The GDEA also authorizes FDA to debar a firm convicted of certain crimes from obtaining or participating in certain subsequent drug approvals. This debarment extends to persons working for applicants of human, animal, and biological drug products.

If an applicant knowingly uses a debarred individual or firm, the applicant may be fined up to $1 million. If a debarred individual works for an applicant, the individual may be fined up to $250,000. Applicants for drug product approval are required to certify that they did not and will not use the services of a debarred individual or firm in any capacity in connection with the application. Section 306(k) further requires that applicants for approval of certain generic drugs provide information concerning criminal convictions of individuals and firms involved in the applications.

2-2-20 Medical Device Amendments of 1992

On June 16, 1992, the President signed into law the Medical Devices Amendments of 1992 (Public Law 102-300; the Amendments of 1992), amending certain provisions (section 519 of the Food, Drug, and Cosmetic Act) relating to reporting of adverse events. The primary impact of the 1992 Amendments on device user facility reporting was to clarify certain terms and to establish a single reporting standard for device user facilities, manufacturers, importers, and distributors. A final rule published in the Federal Register on December 11, 1995, addresses the comments received by the FDA and the changes mandated by the Amendments of 1992.

2-2-21 Safe Medical Devices Act of 1990

The Safe Medical Devices Act of 1990 (P.L. 101-629), which amended the FFD&C Act (21 U.S.C. 201 et seq.), was signed into law on November 28, 1990.

1. Manufacturers who submit a premarket notification claiming substantial equivalence to a class III device introduced into interstate commerce before December 1, 1990 and for which FDA has not yet required premarket approval under Section 515(b) of the FFD&C Act are required to certify that they have conducted a reasonable search of all information known or otherwise available to them about the class III device and other similar legally marketed devices.

   Manufacturers are also required to submit a summary of the types of safety and effectiveness problems associated with the devices being compared. All manufacturers who submit a premarket notification under Section 510(k) of the FFD&C Act are required to submit to FDA a summary of the safety and effectiveness information upon which an equivalence determination is based or certify that any information on safety and effectiveness will be made available to interested persons upon request.

2. Class II has been redefined. Previously, Class II devices were devices for which a performance standard could be developed to provide reasonable assurance of safety and effectiveness. Under the new provision, Class II devices will be regulated by "Special Controls. "Special Controls" include the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations and other appropriate actions. The procedure for developing performance standards under Section 514 of the FFD&C Act has been simplified.

3. FDA has been given additional authority to order the recall of devices and the notification of users, to temporarily suspend premarket approval of a device and to impose civil penalties.

4. Section 520(f) of the FFD&C Act has been revised to clarify that FDA has the authority to regulate preproduction design validation as part of GMPs.

5. A manufacturer who submits a premarket notification may not enter the product into commercial distribution until FDA issues an order permitting distribution.

6. The Radiation Control for Health and Safety Act of 1968 has been combined into the FFD&C Act. This change does not affect the regulation of these products.

7. Certain device user facilities (hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities which are not physician's offices) will be required to

report deaths related to medical devices to FDA and certain serious illnesses or injuries related to devices to the manufacturer or to FDA, if the manufacturer is not known. FDA is required to provide education (including publications) on these provisions to device users and other affected persons.

8. FDA must review the classification of all devices classified in Class III under section 520(l) of the FFD&C Act (transitional devices) and Class III devices on the market before May 28, 1976 and substantially equivalent devices for which FDA has not required premarket approval under Section 515(b) of the FFD&C Act and determine whether these devices should remain in Class III or be classified into Class II or Class I.

9. Manufacturers will be required to report to FDA device removals and corrections to reduce a risk to health posed by a device or to remedy a violation of the FFD&C Act which may present a risk to health.

10. Manufacturers that introduce into interstate commerce for the first time after January 1,1991 a permanently implantable device, a life supporting or life sustaining device or a device that potentially presents a serious risk to health will be required to conduct postmarket surveillance of the device. FDA may also require any other manufacturer of a device to conduct postmarket surveillance.

11. FDA may use, for purposes of reclassifying or approving devices, certain data in premarket approval applications where four devices of a kind have been approved.

12. FDA is authorized to grant humanitarian device exemptions from the standards and premarket approval requirements of the FFD&C Act for manufacturers of devices used to treat or diagnose conditions or illnesses affecting fewer than 4,000 individuals.

13. The Secretary is directed to establish an Office of International Relations to enter into agreements with foreign countries to facilitate commerce in devices between the U.S. and such foreign countries.

14. FDA is directed to designate a component of FDA to regulate products that constitute a combination of a drug, device or biological product. The component that is to regulate the product is to be determined by the primary mode of action of the product. The definitions of "drug" and "device" have been revised to accommodate this change.

2-2-22 Medical Device Reporting as Amended by The Food and Drug Administration Modernization Act

The Food and Drug Administration Modernization Act (FDAMA) was signed on November 21, 1997 and became effective on February 19, 1998. There were four changes that affected MDR:

1. Manufacturers and distributors/importers do not need to submit annual certification;

2. Domestic distributors are no longer required to file MDR reports, but must continue to maintain complaint files. [Importers (initial distributors for devices manufactured overseas and imported into the USA) must continue to file MDR reports.];

3. User facilities must now file an annual report instead of semiannual reports to

summarize their adverse event reports; and,

4. Sentinel reporting by user facilities was proposed.

The MDR regulation (21 CFR Part 803) was revised on 1/26/2000 and 5/8/2001 to incorporate the changes under FDAMA.

2-2-23 Nutrition Labeling and Education Act of 1990

In general, Nutrition Labeling and Education Act of 1990 (NLEA)(P.L. 101-535) amends the Federal Food, Drug, and Cosmetic Act, and grants the Secretary explicit authority to require that all foods (except for meat and poultry) bear nutrition labeling. In addition, NLEA gives the Secretary explicit authority to regulate health claims made on food labels.

Specifically, the law does the following:

1. ***Nutrition Labeling***
   Deems a food misbranded unless its labeling discloses serving size; total calories and calories derived from fat; and amounts of various nutrients. Requires that the Secretary develop and make available to retailers, nutrition information for each of the 20 most commonly consumed raw fruits, vegetables, and seafood. Exempts various foods from nutrition labeling requirements, e.g., restaurant and deli foods, infant formula, medical foods, etc.

2. ***Health Claims***
   Deems food misbranded unless claims (regarding the amount of any nutrient or relating a nutrient to a health related condition) are made according to regulations promulgated by the Secretary, provided also that the food does not contain any nutrient in an amount that increases to persons in the general population the risk of a disease or health-related condition that is diet related, unless specifically allowed by the Secretary.

   Requires that the Secretary establish a "procedure and standard" for establishing the validity of claims relating to dietary supplements, vitamins and minerals, and determine whether claims for four specific condition-supplement relationships are valid: folic acid and neural tube defects, antioxidant vitamins and cancer, omega-3 fatty acids and heart disease, and zinc and immune function in the elderly. Requires that the Secretary issue regulations defining the following terms: free, low, light or lite, reduced, less, and high. Requires that the Secretary determine whether claims regarding calcium and osteoporosis, dietary fiber and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and heart disease are appropriate.

3. ***State Enforcement***
   Allows States to bring actions to restrain violations of various labeling sections of the NLEA, provided that notice has been given to the Secretary and the Secretary is not already diligently prosecuting an enforcement action against the food.

4. ***Conforming Amendments***
   Prohibits foods from being considered drugs solely because the label bears a health claim that conforms to the requirements of NLEA.

5. ***National Uniform Nutrition Labeling***

Preempts States from passing labeling laws that are not identical to Federal requirements, e.g., food standards, nutrition labeling and health claims labeling, etc. Requires the Secretary to enter into a contract with a public or nonprofit private entity to conduct a study of State and local food labeling laws.

6. ***Ingredients***
   Requires that the labels of beverages containing fruit and vegetable juices declare the total percentage of juice contained therein. Requires label declaration of certain color additives. Requires that the labels of standardized foods declare all ingredients [rather than just optional ingredients].

7. ***Standard of Identity Regulation***
   Removes establishment of standards for all foods, other than dairy products and maple syrup, from formal rulemaking requirements under Section 701(e).

2-2-24 Electronic Product Radiation Control – 1990

In 1990, the Radiation Control for Health and Safety Act, 42 U.S.C. 263c-263n, was renamed Electronic Product Radiation Control and recodified as Subchapter C of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360hh-360ss ("Radiation Control Program"). The Radiation Control Program applies to products such as x-ray units, suntanning bulbs, sonography equipment, microwaves, lasers, and televisions, 21 U.S.C. 360hh(1), (2), and to persons who import, assemble, sell and manufacture electronic products. See 21 U.S.C. 360hh(3).

The Secretary of Health and Human Services implements and enforces the Radiation Control Program, 21 U.S.C. 360ii, and has delegated those functions to FDA. See 21 CFR 5.10(a)(3). The statute authorizes FDA to issue performance standards for electronic products. See 21 U.S.C. 360kk. FDA's regulations, 21 CFR Subchapter J, include performance standards for products such as x-ray units, CT scan equipment, microwave emitting products, lasers, sonic, and ultrasonic products. See 21 CFR Part 1010 - 1050.

The Radiation Control Program establishes record keeping requirements for manufacturers and importers of regulated products. It also mandates that assemblers and installers file reports with FDA. Manufacturers must also repair, replace or refund the cost of defective products. See 21 U.S.C. 360ll(f).

The Radiation Control Program prohibits regulated persons from failing to:

1. keep required records;

2. furnish required reports; or,

3. repair, replace or refund the cost of a defective electronic product.

21 U.S.C. 360oo. Section 360pp specifically authorizes the United States to file actions in federal district court for civil penalties and for injunctive relief. Any person who violates 21 U.S.C. 360oo is subject to a civil penalty of up to $1,000 per violation, and up to a maximum civil penalty of $300,000 for any related series of violations. The corporation and the responsible individuals may be held separately liable for civil penalties.

2-2-25 Anti-Drug Abuse Act of 1988

The Anti-Drug Abuse Act of 1988 (P.L. 100-690) amends the FFD&C Act by providing severe criminal penalties for the distribution of anabolic steroids and human growth hormones without a doctor's prescription. It subjects persons convicted of illegally distributing these drugs to up to six years in prison and fines. Convicted violators subject to a sentence of more than a year in prison will be thereby subject to the Controlled Substances Act (law governing addictive substances) and will be subject to criminal forfeiture of property (cars, boats, and home) used to support the illegal distribution or purchased with the profits.

2-2-26 Orphan Drug Amendments of 1988

On April 18, 1988, the President signed into law the Orphan Drug Amendments (P.L. 100-290) to the Orphan Drug Act (ODA). The ODA of 1988 extends the authorization for the orphan drug grant program for three years, and expands the scope of the grants program to include medical foods and devices. The ODA of 1988 also directs the Secretary of Health and Human Services (Secretary) to study whether the other incentives in the FFD&C Act and other laws, e.g., tax credits and marketing exclusivity, should be available to orphan medical foods and orphan devices, and requires that companies that choose to stop production of an approved orphan drug provide notice to FDA one year prior to discontinuing the drug.

2-2-27 Prescription Drug Marketing Act of 1987

The Prescription Drug Marketing Act (PDMA) of 1987, as modified by the Prescription Drug Amendments of 1992, and the FDA Modernization Act of 1997 (the Modernization Act), establishes requirements for the distribution of prescription drugs. Section 503 (e)(1)(A) of the Act requires each person, who is engaged in the wholesale distribution of a prescription drug and who is not the manufacturer or an authorized distributor of record for the drug, to provide the person receiving the drug a statement identifying each prior sale, purchase, or trade of the drug, including the date of the transaction and the names and addresses of all parties to the transaction before each wholesale distribution. Further Section 503 (e)(4)(A) of the Act defines the term "authorized distributors of record as those distributors with whom a manufacturer has established an "ongoing relationship" to distribute the manufacturer's products.

The final regulations implementing PDMA were published in the Federal Register on December 3, 1999 (21 CFR Part 203) regarding the reimportation and wholesale distribution of prescription drugs; the sale, purchase, or trade of, or the offer to sell, purchase, or trade, prescription drugs that were purchased by hospitals or health care entities, or donated to charitable organizations; and the distribution of prescription drug samples.

On January 31, 2003 (68 FR 4912), the effective dates of Sec. 203.3(u) and 203.50, and the applicability of Sec. 203.3(q) to wholesale distribution of blood derivatives by health care entities were delayed until April 1, 2004, to give Congress additional time to determine if legislative action is appropriate. The further delay of the effective date will also give the agency additional time to consider whether regulatory changes regarding those sections are warranted. At the same time, FDA also amended certain sections of the regulations entitled ``Guidelines for State Licensing of Wholesale Prescription Drug Distributors'' (21 CFR Part 205) to make them consistent with this final regulation.

In summary, all drug wholesalers must be licensed under state licensing systems, which must in turn meet the regulations at 21 CFR Part 205. The regulations set forth minimum requirements for prescription drug storage (21 CFR Part 205.50 (a) and (c)) and security (21

CFR Part 205.50 (b)), as well as for the treatment of returned, damaged, and outdated prescription drugs (21 CFR Part 205.50 (e)). Further, under 21 CFR Part 205.50 (f), wholesale drug distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution of prescription drugs and make these available for inspection and copying by authorized federal, state, or local law enforcement officials.

2-2-28 Health Promotion and Disease Prevention Amendments of 1984

The Health Promotion and Disease Prevention Amendments of 1984 (P.L. 98-551) were signed into law by the President on October 30, 1984. The law extended the provisions of the Public Health Service Act relating to health promotion and disease prevention, and to provide for the establishment of centers for research and demonstrations concerning health promotion and disease prevention.

Of particular interest to FDA is a provision that amends the definition of an orphan drug in two of the three places in which it appears in the Orphan Drug Act. Under the new definition, a drug would qualify as an orphan if it is for a disease or condition that affects fewer than 200,000 persons in the U.S. The old definition required evidence that costs of development would not be recouped by sales. This definition based on profitability is retained, however, in the section that governs the award of tax credits.

2-2-29 Drug Price Competition and Patent Term Restoration Act of 1984

On September 24, 1984, the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417) (DPCPTRA) was enacted. The DPCPTRA consists of two different titles. Title I authorizes the approval of duplicate versions of approved drug products (other than those reviewed and approved under Section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) 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. Congress intends these provisions to provide a careful balance between promoting competition among brand-name and duplicate or "generic" drugs and encouraging research and innovation.

Title I also amends Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) by requiring all New Drug Application (NDA) applicants and holders to provide certain patent information, requiring ANDA applicants to certify as to the status of patents claiming the drug product they intend to copy, providing for the submission and approval of applications for which the investigations relied on by the applicant to satisfy the "full reports" of safety and effectiveness requirements were not conducted by the applicant or for which the applicant had not obtained a right of reference or use from the person who conducted the investigations, establishing rules for disclosure of safety and effectiveness data submitted as part of an NDA, and providing specific time periods during which an NDA or an ANDA cannot be submitted or approved. The DPCPTRA also required the FDA to promulgate new regulations implementing the statute. Additional information is available on the FDA Internet at: http://thomas.loc.gov/cgi-bin/bdquery/z?d098:SN01538:@@@D&summ2=m&|TOM:/bss/d098query.html| .

2-2-30 Orphan Drug Act - 1983

The Orphan Drug Act of 1983 (ODA) (P.L. 97-414) consists of amendments to the Act as well as tax credit and grants provisions. The amendments to the Act (Sections 525, 526, 527, and

528) encourage the development of products rather than regulate products and practices. These sections provide incentives for sponsors seeking to develop products for rare diseases or conditions.

Under these provisions and upon request, the agency will provide written recommendations for the non-clinical and clinical investigations of a drug intended to treat a rare disease or condition. These recommendations may specify the investigations that will be adequate or required to obtain marketing approval for the drug.

Additionally, a sponsor of a drug may request a ruling on a drug's designation as an orphan drug for a rare disease or condition. Orphan drug designation is a prerequisite for obtaining most of the incentives under the ODA. "Rare disease or condition" is one that affects less than 200,000 persons in the United States (U.S.), or affects more than 200,000 persons, but the drug sponsor has no reasonable expectation of recovering development costs through U.S. sales.

If the Agency agrees that a drug meets the statutory definition for a designated orphan drug, the sponsor is entitled to a tax credit for the cost of clinical trials conducted with the drug on the orphan indications before marketing approval. Upon the date of new drug approval or biological licensure of a designated orphan drug, FDA will not approve for seven years another sponsor's application for marketing the same drug for the same orphan use. In order to maintain exclusivity, the sponsor must ensure an adequate supply of the drug.

The Agency encourages sponsors who are designing investigational studies on orphan drugs to include provisions for adding to the study those who need the drug.

Under Section 5 of the ODA, the Agency may make grants to and enter into contracts with public and private entities and individuals to assist in defraying the costs of qualified clinical testing expenses incurred in connection with the development of drugs, biological products, devices, and medical foods for rare diseases and conditions.

2-2-31 Infant Formula Act of 1980

The Infant Formula Act (IFA) (P.L. 96 – 359) of 1980 and subsequent amendments in 1986 (Section 412) to the Federal Food, Drug, and Cosmetic Act establish nutrient requirements for infant formulas as defined by Section 201(aa) of the Federal Food, Drug, and Cosmetic Act, and provide FDA authority to establish good manufacturing practices (GMPs) and requirements for nutrient quantity, nutrient quality control, recordkeeping, and reporting and recall of infant formulas which pose a potential hazard to health. The IFA also extends FDA's factory inspection authority to permit access to complaint files and other manufacturers' records, quality control records, and test results necessary to determine compliance with the IFA.

The IFA specifies that an infant formula is adulterated: (1) if it fails to provide nutrients as required; (2) if it fails to meet the nutrient quality factors required by regulation; (3) if the processing is not in compliance with the appropriate GMP and quality control procedures or record retention requirements as prescribed by regulation; or (4) if it otherwise fails to comply with Section 402 of the Federal Food, Drug, and Cosmetic Act.

The IFA also requires manufacturers of infant formulas to notify FDA 90 days before any charitable or commercial distribution of any new infant formula or any infant formula that has

had a major change in its formulation or processing. Under authority of the IFA, FDA has promulgated regulations which specify infant formula nutrient quality control procedures (21 CFR 106); the labeling of infant formula; the terms and conditions under which certain infant formula may be exempt from some of the IFA's requirements; and nutrient specifications for infant formula, and infant formula recall regulations (21 CFR 107).

2-2-32 Medical Device Amendments of 1976

The Medical Device Amendments of 1976 (P.L. 94 - 295) to the Federal Food, Drug, and Cosmetic Act (the Act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury. Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the Act, all devices placed into Class III are subject to premarket approval requirements. Premarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices.

An approved Premarket Approval Application (PMA) -- like an approved New Drug Application (NDA) -- is, in effect, a private license granted to the applicant for marketing a particular medical device. A Class III device that fails to meet PMA requirements is considered to be adulterated under Section 501(f) of the Act and cannot be marketed. Premarket approval requirements apply differently to preamendments devices, postamendments devices, and transitional Class III devices.

A preamendments device is one that was in commercial distribution before May 28, 1976, the enactment date of the Medical Device Amendments. Manufacturers of Class III preamendments devices are not required to submit a PMA until 30 months after the promulgation of a final classification regulation or until 90 days after the publication of a final regulation requiring the submission of a PMA, whichever period is later. FDA may allow more than 90 days after promulgation of a final rule for submission of a PMA.

A postamendments device is one that was first distributed commercially on or after May 28, 1976. Postamendments devices that FDA determines are substantially equivalent to preamendments Class III devices are subject to the same requirements as the preamendments devices. FDA determines substantial equivalence after reviewing an applicant's premarket notification submitted in accordance with Section 510(k) of the act. Postamendments devices determined by FDA to be not substantially equivalent to either preamendments devices or postamendments devices classified into Class I or II are "new" devices and fall automatically into Class III. Before such devices can be marketed, they must have an approved premarket approval application or be reclassified into Class I (general controls) or Class II (standards).

Class III transitional devices and "new" devices (described in the paragraph above) are automatically classified into Class III by statute and require premarket approval by FDA before they may be commercially distributed. Applicants may either submit a PMA or Product Development Protocol (PDP), or they may petition FDA to reclassify the devices into Class I or

Class II. Clinical studies in support of a PMA, PDP, or a reclassification petition are subject to the investigational device exemption (IDE) regulations. (For further details on these regulations, refer to 21 CFR 812 for general devices or 21 CFR 813 for intraocular lenses.)

New section 515 (d)(6) of the Act added by the FDA Modernization Act of 1997, provides that PMA supplements are required for all changes that affect safety and effectiveness unless such change involves modifications to manufacturing procedures or method of manufacture. These types of manufacturing changes require a 30-day Notice or, where FDA finds such notice inadequate, a 135-day PMA supplement.

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-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.htm.

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/default.htm
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.