PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

Pertinent Highlights of the Act

- Provides for a drug, biologic product, medical device, vaccine, vaccine adjuvant, antiviral or diagnostic test to be deemed a priority to treat, identify or prevent infections or diagnose conditions from certain biological agents or toxins, and be designated a "priority countermeasure" eligible for accelerated approval, licensing or clearance.

- Requires national identification database of biological agents and toxins that could pose severe threat to human, animal or plant health; security safeguards and registration of any possession, use, or transfer of such agents and toxins; and inspections, with limited exceptions for clinical or diagnostic laboratories and certain investigational, approved or licensed products.

- Requires registration of domestic and foreign facilities that manufacture, process, pack, or hold food for U.S. consumption; inspections upon "a reasonable belief that a food article is adulterated and presents a threat of serious adverse health consequences or death to human or animals;" maintenance of records; administrative detention of adulterated foods; pre-importation notifications; prohibition against port shopping; and debarment for repeated violations.

- Requires submission of information and data upon importation of drug components, device components or accessories, food additives, color additives and dietary supplements (including those in bulk form) for further processing or incorporation into a drug, biological product, device, food, food additive, color additive or dietary supplement product, and subsequent export.

- Requires notification of the public and physicians when a sponsor fails to complete agreed upon postmarketing studies by the negotiated deadline.

- Extends prescription drug user fees through the year 2007 (PDUFA III) with minor changes, and directs FDA to prepare annual progress and fiscal reports, and develop recommendations for post 2007 (PDUFA IV).

- Most final regulations due 18 months after enactment date (June 12, 2002); possessors of biological agents and toxins must submit notice and importers of components for products to be exported must submit information 90 days after enactment; and foreign drug and device manufacturers must register 180 days after enactment.

PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

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PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

TITLE I: NATIONAL PREPAREDNES FOR BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES.

Subtitle A: National Preparedness and Response Planning; Coordinating and Reporting. (§101 – §111)

Section 101. National preparedness and response.

Section 101 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Act") amends the Public Health Service Act ("the PHSA") by inserting Section 2801, which outlines the national preparedness plan and goals, with primary focus on development of more efficient methods to prepare for and respond to the threat of bioterrorism, including fortifying and streamlining public health emergency capabilities. The overriding purpose of the Act is to ensure that governments at all levels have the capacity to detect and respond effectively to public health emergencies related to bioterrorist attacks. Bearing mention among the preparedness goals is "developing, and maintaining medical countermeasures (such as drugs, vaccines, and other biological products, medical devices and other supplies) against biological agents and toxins that may be involved in such emergencies," as stated in Section 2801(b)(3).

Section 102. Assistant Secretary for Public Health Emergency Preparedness; National Disaster Medical System.

Section 102 of the Act adds Section 2811 to the PHSA, which establishes the position and duties of an Assistant Secretary for Public Health Emergency Preparedness in the Department of Health and Human Services, and the framework for a National Disaster Medical System.

Section 103. Improving ability of Centers for Disease Control and Prevention.

Section 103 of the Act amends Section 319D of the PHSA to enhance the facilities, public health surveillance and reporting capabilities of the Centers for Disease Control ("CDC"). The Act authorizes the Secretary of Health and Human Services (the "Secretary") to award grants and contracts and to negotiate cooperative agreements to create a communications network among Federal and State health officials, public and private health-related laboratories, and any other appropriate entities.

Sections 104-107.

Sections 104-107 of the Act amend Section 319F and insert a new Section 319H of the PHSA to create a number of official advisory committees, a Federal Internet Site on Bioterrorism, education and training programs for health care personnel, and a registration system for voluntary health professionals. In addition, Section 108 amends Section 319F of the PHSA to requires the formation of a "working group" of Federal officials to consult with experts in the pharmaceutical, biotechnology, and medical device industries, and to award grants and contracts for development, manufacture, and distribution of bioterrorist attack countermeasures. Section 109 amends Section 319E of the PHSA to authorize federal research on the sequencing of genomes and other DHA research on priority pathogens. Section 110 inserts 319J to the PHSA, which allows grants of supplies and services in lieu of funds.

Subtitle B: Strategic National Stockpile; Development of Priority Countermeasures. (§121 – §159)

Section 121. Strategic national stockpile.

Section 121 of the Act directs the Secretary to maintain a stockpile of drugs, vaccines, including specifically small pox vaccine, medical devices and biologics for emergency use in the event of a bioterrorism attack. Section 122 provides for accelerated approval of priority countermeasures, i.e. drugs, biological products, devices, vaccines, vaccine adjuvants, antivirals or diagnostic tests for treating biological agent infections or exposures to toxin. For example, the Secretary is authorized to designate a drug product as "fast-track," or grant a device "review priority." This may occur prior to a request made by a sponsor or applicant and before the submission of an application for investigation of a drug. With this designation, which the sponsor or applicant may decline, the drug or device receives expedited process for approval under Section 505(b), 506 or 515(d)(5) of the FFDCA (21 U.S.C. §§ 355(b), 356, 360e(d)(5)).

Section 123. Issuance of rule on animal trials.

Section 123 directs the Secretary to issue a final rule allowing reliance on animal data to demonstrate efficacy of new drugs and biologics intended for use against lethal or permanently disabled toxic substances when human efficacy studies cannot be conducted. The final rule must be issued no later than 90 days after the date of enactment of the Act. (The Food and Drug Administration ("FDA") published this rule on May 31, 2002.)

Sections 124-125.

Sections 124-125 amend Section 319J and add Section 319K to the PHSA to provide for security measures to protect persons or facilities developing, producing, distributing or storing a "priority countermeasures," as well as accelerated research on priority pathogens and development of "priority countermeasures." A "priority countermeasure" is defined in Section 125 as a drug, biologic, device, vaccine, vaccine adjuvant, antiviral or diagnostic test that is determined by the Secretary to be a priority to treat, identify, or prevent infection by a biological agent or toxin or harm from any other agent that may cause a public health emergency, or a priority to diagnose conditions that may result in adverse health consequences or death and may be caused by administration of a priority countermeasure.

Section 126. Evaluation of new and emerging technologies regarding bioterrorist attack and other public health emergencies.

Section 126 establishes a program to evaluate new and emerging technologies designed to conduct public health surveillance activities relating to a bioterrorist attack or other public health emergency.

Section 127. Potassium Iodide

Section 127 requires potassium iodide tablets to be stockpiled for distribution to populations within 20 miles of a nuclear power plant, as well as the development of guidelines, reporting obligations and a National Academy of Sciences study regarding such stockpiling and distribution.

Subtitle C: Improving State, Local, and Hospital Preparedness for and Response to Bioterrorism and Other Public Health Emergencies. (§ 131)

Section 131. Grants to improve State, local, and hospital preparedness for and response to bioterrorism and other public health emergencies.

Section 131 adds Sections 319C-1 and 319C-2 to the PHSA, which define eligible entities and establishes a procedure for States, political subdivisions, hospitals, clinics, health centers and primary care facilities to obtain federal grants, and the conditions for use of such grants to improve preparedness and responses to bioterrorist attacks and other public health emergencies.

Subtitle D: Emergency Authorities; Additional Provisions. (§§ 141-144)

Sections 141-144.

Section 141 amends Section 319 of the PHSA to authorize the Secretary to waive or extend data submittal and reporting deadlines in the event of a public health emergency. Section 142 streamlines the communicable disease quarantine rules and requirements for apprehension of individuals in cases of exposure to disease and in wartime. Section 143 adds Section 1135 to The Social Security Act to authorize the Secretary to grant an emergency waiver of Medicare, Medicaid and the States' children's health insurance program ("SCHIP") requirements. Section 144 amends Section 319(a) by adding a procedure for termination or extension of a public health emergency by the Secretary.

Subtitle E: Additional Provisions. (§§ 151-159)

Sections 151-159.

Section 151 amends Section 613(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act to require States to prepare a plan for providing information to the public in a coordinated manner to qualify for federal disaster relief and emergency assistance. Sections 152 and 153 direct the Secretary of Energy to expand research into detection and identification of pathogens likely to be used in a bioterrorist attack, and the Director of the National Institute of Occupational Safety and Health ("NIOSH") to expand research on the safety of workers at risk for bioterrorist threats or attacks. Sections 154-158 provide for enhanced preparedness by the Department of Veteran Affairs, reauthorization of existing programs, Congressional recognition of the importance of existing public and private university-based programs and preparation of a Government Accounting Office ("GAO") report. Grants are made available for establishment of public access defibrillation programs under Section 159. Conforming amendments to the PHSA are added.

TITLE II: ENHANCING CONTROLS ON DANGEROUS BIOLOGICAL AGENTS AND TOXINS.

Subtitle A: Department of Health and Human Services. (§ 201-204)

Section 201. Regulation of certain biological agents and toxins.

Section 201 amends the PHSA by inserting Section 351A, which directs the Secretary to prepare a list of biological agents and toxins that could pose a severe threat

to public health and safety, publish regulations governing transfer of the listed agents and toxins, require security safeguards and registration of any possession, use and transfer of such agents and toxins, and maintain a national identification database. Use of this and other electronic databases by the Attorney General, administrative review of registration denials, submission of ex parte materials in judicial proceedings, notifications regarding theft, loss or release of listed agents or toxins, inspections to ensure compliance, civil monetary penalties and public disclosure of information are also addressed in Section 351A.

Section 351A(g) exempts clinical or diagnostic laboratories, and other persons who possess, use or transfer listed biologic agents or toxins that are contained in specimens for diagnosis, verification or proficiency testing, from certain safety, possession and use requirements, provided the appropriate Federal, State or local authorities are notified and the agents are transferred or destroyed in accordance with applicable regulations. Products that are, bear or contain listed agents or toxins and are cleared, approved, licensed or registered under Section 351A of the Act, the Federal Food, Drug, and Cosmetic Act ("FFDCA"), The Virus-Serum-Toxin Act ("VSTA"), or The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") may also qualify for the limited exemption, as may certain investigational products. In addition, the Secretary is authorized to grant temporary exemptions in response to a public health or agricultural emergency.

Sections 202-204.

Sections 202-204 establish deadlines for promulgation of implementing regulations, effective dates for such regulations and conforming amendments to Section 511 of the Antiterrorism and Effective Death Penalty Act of 1996.

Subtitle B: Department of Agriculture. (§§ 211-213)

Section 211. Short title.

Section 211 assigns a short title to this Subtitle, the "Agricultural Bioterrorism Protection Act of 2002."

Section 212. Regulation of certain biological agents and toxins.

Section 212 directs the Secretary of Agriculture to establish and maintain by regulation a list of biological agents and toxins that could pose a severe threat to animal or plant health, or to animal or plant products, publish regulations governing transfer of the listed agents and toxins, require security safeguards and registration of any possession, use and transfer of such agents and toxins, and maintain a national identification database. Use of this and other electronic databases by the Attorney

General, expedited review of registrations, administrative review of registration denials, submission of ex parte materials in judicial proceedings, notifications regarding theft, loss or release of listed agents or toxins, inspections to ensure compliance, civil monetary penalties and public disclosure of information are also addressed in Section 212.

Clinical or diagnostic laboratories, and other persons who possess, use or transfer "overlap agents or toxins" (biological agents or toxins listed by both the Secretary and the Secretary of Agriculture) that are contained in specimens for diagnosis, verification or proficiency testing are exempted from certain safety, possession and use requirements, provided the appropriate Federal, State or local authorities are notified and the agents are transferred or destroyed in accordance with applicable regulations. Products that are, bear or contain overlap agents or toxins and are cleared, approved, licensed or registered under Section 351A of the Act, the FFDCA, VSTA or FIFRA may qualify for the limited exemption, as may certain investigational products. In addition, the Secretary of Agriculture is authorized to grant exemptions for listed agents or toxins that are not overlap agents or toxins, if he determines that such exemptions are consistent with protecting animal and plant health, and animal and plant products.

Section 213. Implementation by Department of Agriculture.

Section 213 establishes deadlines for publication of an interim final rule establishing the initial list of biological agents and toxins, and submission of notifications, and effective dates for implementing regulations, and criminal and civil penalties.

Subtitle C: Intragency Coordination Regarding Overlap Agents and Toxins. (§ 221)

Section 221. Interagency coordination.

Section 221 directs the Secretary and the Secretary of Agriculture to enter into a "memorandum of understanding" regarding regulation of overlap agents and toxins, providing for a single system of registration for persons who possess, use or transfer such agents or toxins, coordination of inspections and enforcement, and joint issuance of implementing regulations.

Subtitle D: Criminal Penalties Regarding Certain Biological Agents and Toxins. (§ 231)

Section 231. Criminal penalties.

Section 231 of the Act amends 18 U.S.C. § 175b to establish criminal penalties (fines and up to 5 years imprisonment) for the knowing possession, transfer, or receipt of

an unregistered biological agent or toxin listed pursuant to Section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002, or Section 351A(a)(1) of PHSA, or transfer of such agents or toxins to a person who the transferor knows or has reasonable cause to believe is not registered as required. This provision takes effect not later than 18 months after the date on which the system of registration is implemented.

TITLE III: PROTECTING SAFETY AND SECURITY OF FOOD AND DRUG SUPPLY.

Subtitle A: Protection of Food Supply. (§§ 301 - 315)

Section 301. Food safety and security strategy.

Section 301 of the Act directs the President's Council on Food Safety to develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply. The President's Council is to work with the Secretary of Transportation, the Secretary of the Treasury, other relevant Federal agencies, the food industry , consumer and producer groups, scientific organizations and the States in developing the strategy.

Section 302. Protection against adulteration of food.

Section 302 amends Section 801 of the FFDCA (21 U.S.C. § 381) to increase inspections of imported foods at ports of entry with highest priority given to inspections to detect international adulteration of food, improve information management within the FDA, as well as with other agencies that share responsibility for food safety, and increase research and development of rapid detection methods for discovering the adulteration of food.

Section 303. Administrative detention.

Section 303 amends Section 304 of the FFDCA (21 U.S.C. § 334) to allow for administrative detention of a food article that is found during an inspection, examination or investigation by an officer or qualified employee if such officer or employee has "credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals." If the officer or employee has such credible evidence or information and is unable to inspect, examine or investigate the food, he shall request the Secretary of Treasury to temporarily hold the food at the port of entry for up to 24 hours to enable such inspection. Administrative detentions may not exceed 20 days unless the Secretary determines that a greater period, not to exceed 30 days, is needed. The Secretary shall by regulation provide for expedited procedures in instances involving perishable foods. Detained articles must be so labeled, moved to a secure facility, and may only be moved at the expiration of the detention period or after its release by the Secretary. A claimant may appeal the detainment, and the Secretary

must respond within 5 days after the appeal is filed, or the detainment order is deemed terminated. The transfer of an article of food in violation of a detainment order, or the removal or alteration of a label indicating such detention is prohibited by the Act. Related provisions are amended to Section 301 of the FFDCA (21 U.S.C. § 331).

Section 304. Debarment for repeated or serious food import violations.

Section 304 of the Act amends the permissive debarment provisions of Section 306 of FFDCA (21 U.S.C. § 335a), adding felony conviction relating to the importation of food into the U.S. to the list of offenses that may subject a person to debarment. A person may also be debarred if found to have engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals. Section 304 also amends Section 301 of the FFDCA (21 U.S.C.§ 331) by adding to the list of prohibited acts "the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of, a person debarred under section 306(b)(3)." Food articles imported or offered for import and intended for a debarred importer, owner or consignee may not be delivered to such person and shall be held at the port of entry and, if needed, removed to a secure facility. A food article so held may be delivered to a person who is not debarred if such person affirmatively establishes, at his own expense, that the article complies with the requirements of this Act.

Section 305. Registration of food facilities.

Section 305 amends the FFDCA by adding Section 415, which requires that "any facility engaged in manufacturing, processing, packing or holding food for consumption in the United States be registered with the Secretary." Facilities subject to registration include "any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs or holds foods," but exclude farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared for or served directly to consumers, and fishing vessels. A foreign facility must register if it manufacturers, processes, packs, or holds food that is exported to the United States without further processing or packaging outside the United States. A food may not be considered to have undergone further processing or packaging solely on the basis that labeling was added, or similar minimis processing or packaging occurs with respect to the food.

For domestic facilities, the owner, operator, or designated agent must submit the registration; for foreign facilities, the owner, operator, or agent in charge of the facility shall submit the registration and include the name of the U.S. agent for the facility. The registration must include the name and address of each facility at which, and the trade names under which, the registrant conducts business, and the general food category of any food manufactured, processed, packed or held at such facility. Any changes in such

information shall be notified to the Secretary. Each facility will be given an identification number and information submitted for all registered facilities will be compiled and maintained in a confidential registry. Electronic filing may be permitted for facility registrations, provided the protocols assure adequate authentication and protection of data. Final regulations governing registrations must be promulgated no later than 18 months following the date of enactment of the Act.

Section 305 amends Section 301 of the FFDCA (21 U.S.C. § 331) by adding failure to register to the list of prohibited acts, and also amends Section 801 of the FFDCA (21 U.S.C. § 381) to provide that any food imported or offered for import into the United States by an unregistered facility may not be delivered and will be detained at the port of entry and/or held at a secure facility until the foreign facility is registered.

Section 306. Maintenance and inspection of records for foods.

Section 306 of the Act adds Section 414 to the FFDCA to provide for maintenance and inspection of records for foods. Section 414 provides that if the Secretary has "a reasonable belief that a food article is adulterated and presents a threat of serious adverse health consequences or death to humans or animals," each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article must permit a designated officer or employee to access and copy all records pertaining to the manufacture, processing, packing, distribution, receipt, holding or importation of such article maintained by or on behalf of such person in any format and at any location.. Such records shall not include recipes for food, financial data, pricing data, personnel data, research data or sales data (other than shipment data regarding sales). The officer or employee must present appropriate credentials and give written notice prior to the inspection, and conduct the inspection at a reasonable time, within reasonable limits, and in a reasonable manner. The Secretary is directed to take appropriate measures to prevent unauthorized disclosure of any trade secret or confidential information obtained pursuant to such inspections.

Section 306 further provides that the Secretary may establish requirements for establishment and maintenance (up to 2 years only) of records needed to identify the immediate previous sources and the immediate subsequent recipients of a food, including its packaging, so as to address credible threats of serious adverse health consequences or death to humans or animals. The Secretary may not impose any such requirements for foods within the exclusive jurisdiction of the Secretary of Agriculture. Final regulations must be promulgated no later than 18 months after the date of enactment of the Act. Sections 301 and 704(a) of the FFDCA (21 U.S.C. §§ 331, 374(a)) are amended accordingly.

Section 307. Prior notice of imported food shipments.

Section 307 of the Act amends Section 801 of the FFDCA (21 U.S.C. § 381) to require submission of notice to the Secretary prior to arrival of imported foods at a port of entry into the United States. The notice must indicate the identity of the food article, the manufacturer and the shipper of the article. If known when within the specified time for submission, the notice must also identify the grower of the article, the country from which the article originates, the country from which the article is shipped, and the anticipated port of entry for the article. Without such advance notice, the article of food shall be refused admission into the United States.

The Secretary is directed to establish by regulation the specified period of time within which the advance notice of import must be submitted. Such period shall allow adequate time the Secretary to examine and respond to a notice, but shall not exceed a maximum of 5 days prior to arrival at the port of entry. Should final regulations not be in place 18 months after enactment of the Act, the advance notice requirements shall take effect with a default period for submission of the notice no less than 8 hours and no more than 5 days prior to arrival at a U. S. port of entry.

Food articles detained due to lack of advance notice may not be delivered to the importer, owner, or consignee of the article until such notice is submitted. Release of the article upon the execution of a bond is not permitted; the article is to be removed to a secure facility and not to be transferred otherwise. The Secretary shall make a determination as to whether any credible evidence or information indicates that the food article poses a threat of serious adverse health consequences or death to humans or animals. The Secretary may not impose advance notice requirements on imported foods subject to the exclusive jurisdiction of the Secretary of Agriculture.

Section 307 amends Section 301 of the FFDCA (21 U.S.C. § 331) by adding to the list of prohibited acts the importing or offering for import of a food article into the United States in violation of the advance notice requirements. The Secretary is directed to promulgate final regulations for advance import notice no later than 18 months following enactment of the Act. Should the Secretary fail to do so, the advance import notice requirements will automatically become effective upon expiration of such 18-month period.

Section 308. Authority to mark articles refused admission into United States.

Section 308 of the Act amends Section 801 of the FFDCA (21 U.S.C. § 381) to require the owner or consignee of a food article refused admission to the United States, other than such an article required to be destroyed, to mark the article with a clear and conspicuous label statement, “UNITED STATES: REFUSED ENTRY,” until the article

is brought into compliance. The owner or consignee must pay all expenses incurred in affixing the label. Default on such payments constitutes a lien against future importations.

Section 308 also amends Section 403 of the FFDCA (21 U.S.C. 343) to deem a food article refused entry to be misbranded if it fails to bear such a label, the Secretary finds that the food presents a threat of serious adverse health consequences or death to humans or animals, and the owner or consignee has been notified of both the need for such a label and the Secretary's conclusion that the article presents such a threat.

Section 309. Prohibition against port shopping.

Section 309 of the Act amends Section 402 of the FFDCA (21 U.S.C. § 342) to deem a food article adulterated if the article is imported or offered for import after being refused entry into the United States, unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee, that the article complies with the applicable requirements of this Act.

Section 310. Notices to States regarding imported foods.

Section 310 of the Act adds Section 908 to the FFDCA, which requires the Secretary to notify the State(s) in which a shipment of imported food, or any portion thereof, is or will be held upon finding credible evidence or information indicating that such food presents a threat of serious adverse health consequences or death to humans or animals. The Secretary must also notify the States in which the manufacturer, packer or distributor of the food is located, if known, and request that the States take such action as needed to protect the public health regarding the food article.

Section 311. Grants to States for inspections.

Section 311 of the Act adds Section 909 to the FFDCA to authorize the Secretary to make grants available to States, territories and Indian tribes that undertake examinations, inspections, investigations and related activities (including taking appropriate action, including preparations, to protect the public health in response to Section 908 notice of a threat from a food article) under Section 702 of the FFDCA.

Section 312. Surveillance and information grants and authorities.

Section 312 of the Act adds Section 317R to the PHSA, which authorizes the Secretary to award grants to States and Indian tribe to expand participation in networks to enhance food safety efforts, including establishment and maintenance of food safety surveillance, technical and laboratory capabilities.

Section 313. Surveillance of zoonotic diseases.

Section 313 of the Act directs the Secretary (through FDA and CDC) and the Secretary of Agriculture to coordinate the surveillance of zoonotic diseases.

Section 314. Authority to commission other Federal officials to conduct inspections.

Section 314 of the Act amends Section 702 of the FFDCA to allow the Secretary, pursuant to a "memorandum of understanding," to authorize another Federal department or agency to conduct examinations and investigations at facilities and other locations that are jointly regulated by the Secretary and such department or agency.

Section 315. Rule of construction.

Section 315 of the Act confirms that nothing in Title III of the Act alters the jurisdiction between the Secretary and the Secretary of Agriculture.

Subtitle B: Protection of Drug Supply. (§§ 321-322)

Section 321. Annual registration of foreign manufacturers; shipping information; drug and device listing.

Section 321 of the Act amends Section 510 of the FFDCA (21 U.S.C. § 360) to require annual registration of foreign manufacturers of drugs and devices imported or offered for import into the United States. Such registration, through electronic means, must provide: 1) the name and place of business of the establishment, 2) the name of the U.S. agent for the establishment, 3) the name of each importer of the drug or device in the U.S. known to the establishment, and 4) the name of each person who imports or offers for import such drug or device.

Section 321 of the Act also amends Section 801 of FFDCA (21 U.S.C. § 381), providing that admission into the U.S. may be refused for any drug or device for which the owner or consignee cannot provide a statement identifying the proper registration upon importation. Any such drug or device that is not properly registered is to be removed to a secure facility and may not be delivered to the importer, owner or consignee pursuant to execution of a bond. Section 321 also amends Section 301 of the FFDCA (21 U.S.C. § 331) to make failure to submit the requisite statement upon importation a prohibited act. These Section 321 amendments take effect 180 days after the enactment of this Act.

Section 322. Requirement of additional information regarding import components intended for use in export products.

Section 322 of the Act amends Section 801(d)(3) of FFDCA (21 U.S.C. § 381(d)(3)) to allow import of drug components, device components or accessories, food additives, color additives, and dietary supplements, including those in bulk form, that are intended to be further processed or incorporated into a drug, biological, device, food, food additive, color additive or dietary supplement and exported from the United States by the initial owner or consignee, provided certain conditions are met. At the time of importation, the owner or consignee of such articles must submit a statement to the Secretary confirming that the articles are to be further processed or incorporated into other products and exported, identifying the manufacturer and each processor, packer, distributor, or other entity in the chain of possession of the article, and including certificates of analysis for the article (unless the article is a device, blood or tissue product). The initial owner or consignee must also execute a bond for payment of liquidated damages in the event of default; use and export the article in accordance with the intent expressed in the submitted statement; maintain records on use or destruction of the article or parts thereof; and if requested by the Secretary, submit a report accounting for the exportation or destruction of the article or parts thereof.

The Secretary may refuse admission to an article that otherwise would be imported under the above conditions if the Secretary finds credible evidence or information indicating that such article is not intended to be further processed or incorporated into other products for export by the initial owner or consignee. Section 322 amends Section 301(w) of the FFDCA (21 U.S.C. § 331(w)) to add falsification of the requisite statement or certificate of analysis, or failure to submit such requisite documents, to the prohibited acts. The Section 322 requirements become effective 90 days after enactment of the Act.

Subtitle C: General Provisions Relating to Upgrade of Agricultural Security. (§331 – §336)

Sections 331-335.

Sections 331-335 of the Act authorize additional funds to expand animal and plant health inspections by the Department of Agriculture's Animal and Plant Health Inspection Service ("APHIS") and Food Safety Inspection Service ("FSIS"); implement biosecurity upgrades to modernize existing facilities, including security standards and practices at colleges and universities with food and agricultural research programs; and increase bioterrorism research and development.

Section 336. Animal enterprise terrorism penalties.

Section 336 of the Act amends Section 43(a) of Title 18, United States Code, making it a criminal offense to travel in interstate or foreign commerce, or use the mail or any facility in interstate or foreign commerce, for the purpose of causing physical disruption to the functioning of an animal enterprise; and intentionally damage or cause loss of any property (including animals or records) used by the animal enterprise, or conspire to do so. Criminal penalties range from $10,000 fine and/or 6 months imprisonment for minor economic damage to the animal enterprise to an unlimited fine and/or life imprisonment for causing the death of an individual in the course of a violation.

TITLE IV: DRINKING WATER SECURITY AND SAFETY. (§§ 401-403)

Section 401. Terrorist and other intentional acts.

Section 401 of the Act adds Section 1433 to the Safe Drinking Water Act (Title XIV of the PHSA) to require each community water system serving more than 3,300 people to conduct a vulnerability assessment for submission to the Administrator of the Environmental Protection Agency and prepare an emergency response plan incorporating results of the vulnerability assessment. Section 1433 directs the Administrator to provide guidance to smaller public water systems on how to conduct such assessments and prepare such plans. The Administrator must also develop measures to secure the location and protect the confidentiality of the vulnerability assessments. Unauthorized acquisition or reproduction of the assessments by persons with authorized access shall be a criminal offense.

Section 402. Other Safe Drinking Water Act amendments.

Section 402 of the Act adds Sections 1434 and 1435 to the Safe Drinking Water Act, which require the Administrator to review current and future methods to prevent, detect and respond to the intentional introduction of chemical, biological or radiological contaminants into community water systems and source water for such systems, as well as methods and means by which terrorists or other individuals could disrupt the supply of safe drinking water, or water collection, pretreatment, treatment, storage and distribution facilities. The results of such reviews shall be disseminated to community water systems as appropriate.

Section 403. Miscellaneous and technical amendments.

Section 403 provides for technical amendments to Sections 1414, 1431,1432 and 1442 of the Safe Drinking Water Act.

TITLE V: ADDITIONAL PROVISIONS. (§§ 501-532)

The following provisions become effective October 1, 2002. The following provisions cease to be effective on October 1, 2007, due to a "Sunset Clause" under Section 508 of this Act.

Subtitle A: Prescription Drug User Fees. (§501 – §509)

Section 501. Short title.

The short title for Subtitle A is the "Prescription Drug User Fee Amendments of 2002."

Section 502. Findings.

Section 502 of the Act summarizes the Congressional findings supporting reauthorization of prescription drug user fees for an additional 5 years until the year 2007 ("PDUFA III"). Congress cites the public health benefit from prompt approval of safe and effective new drugs and the successful reduction of review times for human drugs under the Prescription Drug User Fee Act of 1992 ("PDUFA I"), as amended by the Food and Drug Administration Modernization Act of 1997 ("FDAMA"; "PDUFA II"). Congress also recommends more ambitious and comprehensive improvements in the FDA regulatory process, including: 1) improving the review and monitoring of drug safety, 2) encouraging greater agency/sponsor communication with regard to drugs and biologics intended to treat serious or life-threatening diseases, and 3) improving first-cycle reviews. The authorized user fees are to be dedicated to the effort for carrying out these goals.

Section 503. Definitions.

Section 503 amends Section 735 of the FFDCA (21 U.S.C. § 379g) to include in the definition of a "prescription drug product," the requirement that the product be on the list of products described in Section 505(j)(7)(A) of the FFDCA (21 U.S.C. § 355(j)) or on a list created and maintained by the Secretary of products approved under human drug applications under Section 351 of the PHSA (42 U.S.C. § 262). Section 503 also eliminates the large volume parenteral drug product exclusion from the definition .

Section 503 also re-defines the term "process for the review of human drug applications" to include collecting, developing, and reviewing safety information on drugs approved after October 1, 2002, including adverse event reports, for a period not to exceed three years after approval of the drug application or supplement. In addition, the term "adjustment factor" is limited to "the Consumer Price Index for all urban consumers (all items; United States city average) for April of the preceding fiscal year divided by such Index for April, 1997."

Section 504. Authority to assess and use drug fees.

Section 504 of the Act amends Section 736 of the FFDCA (21 U.S.C. § 379h) to provide that a human drug application for which clinical data are not required, or a supplement for which safety and efficacy clinical data are required, will be assessed only one-half of the human drug application fee for a particular fiscal year. Section 504 also changes the date upon which payment of the establishment and product fees are due from "on or before January 31 of each year" to "on or before October 1 of each year." A product user fee will not be charged for a prescription drug product with a potency described in terms of per 100 mL that is identified in a list compiled under Section 505(j)(7)(A) of the FFDCA (21 U.S.C. § 355(j)(7)(A)), or a product that is the same product as another approved under an application filed under Section 505(b) of the FFDCA (21 U.S.C. § 355(b)).

Section 504 provides total user fee funds for fiscal years 2003 through 2007 as follows:

Type of Fee	Fiscal Year 2003	Fiscal Year 2004	Fiscal Year 2005	Fiscal Year 2006	Fiscal Year 2007
Application/ Supplement	$74.3 Million	$77 Million	$84 Million	$86.434 Million	$86.434 Million
Establishment	$74.3 Million	$77 Million	$84 Million	$86.433 Million	$86.433 Million
Product	$74.3 Million	$77 Million	$84 Million	$86.433 Million	$86.433 Million
TOTAL	$222.9 Million	$231 Million	$252 Million	$259.3 Million	$259.3 Million

These figures are base figures that may be adjusted if additional revenues are required. Individual user fees will be established by the Secretary 60 days prior to the start of each fiscal year. The individual fees may be adjusted according to inflation, but may not exceed the total cost of the resources allocated to the process of review of human drug applications during that fiscal year. Section 504 also eliminates the fee waiver or

reduction for applications or supplements for a drug that contains the same active ingredient as another drug that could not be assessed fees.

Section 505. Accountability and Reports.

Section 505 of the Act requires the Secretary to: (1) consult with the House Committee on Energy and Commerce, the Senate Committee on Health, Education, Labor, and Pensions, scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry to develop recommendations concerning the goals and plans for prescription drug user fees after the year 2007 ("PDUFA IV"); and (2) report his recommendations for PDUFA IV to such Congressional committees and publish them in the Federal Register for public comment; (3) submit annual performance reports to the President and such Congressional committees, and annual fiscal reports to such Committees,

Section 506. Reports of Postmarketing Studies.

Section 506 of the Act amends Section 506B of the FFDCA (21 U.S.C. § 356b) by adding new disclosure and notification requirements. The Secretary is directed to publish a statement on the FDA's Internet site if a sponsor fails to complete an agreed upon postmarketing study by the established deadline. If the Secretary finds that the reasons for failing to complete the study are not satisfactory, the finding must be included in the published statement. With respect to studies required under Section 506(b)(2)(A) of the FFDCA (21 U.S.C. § 356(b)(2)(A)),or under 21 C.F.R. § 314.510 or 21 C.F.R. § 601.41, the Secretary may require a sponsor who fails to complete such a study for reasons unsatisfactory to the Secretary, to notify practitioners of the failure to complete such studies and the questions of clinical benefit and safety that remain unanswered as a result of the incomplete study.

Section 507. Savings Clause.

Section 507 of the Act authorizes user fees to be assessed and collected after October 1, 2002 for human drug applications and supplements accepted for filing after October 1, 1997 but prior to October 1, 2002. Also authorized is the assessment and collection of product and establishment user fees after October 1, 2002 that are owed but not yet collected.

Sections 508 and 509.

Section 508 of the Act provides that PDUFA III will take effect on October 1, 2002. Section 509 of the Act provides that amendments made in Sections 503 and 504 of the Act will cease to be effective on October 1. 2007. This section further provides that

amendments made by Section 505 of the Act will cease to be effective 120 days after October 1, 2007.

Subtitle B: Funding Provisions Regarding Food and Drug Administration. (§§ 521-523)

Sections 521-523 dedicates funds for FDA's Office of Drug Safety, Division of Drug Marketing, Advertising and Communications and Office of Generic Drugs through fiscal year 2007.

Subtitle C: Additional Provisions. (§§ 531-532)

Section 531 directs the Federal Communications Commission to provide for orderly transition to digital television, and equitable allocation and use of digital channels. Section 532 provides for a 3-year delay in lock in procedures for Medicare+Choice plans, and changes certain related deadlines.