with the States and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))).".

(d) TESTING FOR RAPID DETECTION OF ADULTERATION OF FOOD.—Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a) of this section, is amended by adding at the end the following:

"(i)(1) For use in inspections of food under this section, the Secretary shall provide for research on the development of tests and sampling methodologies—

"(A) whose purpose is to test food in order to rapidly detect the adulteration of the food, with the greatest priority given to detect the intentional adulteration of food; and

"(B) whose results offer significant improvements over the available technology in terms of accuracy, timing, or costs.

"(2) In providing for research under paragraph (1), the Secretary shall give priority to conducting research on the development of tests that are suitable for inspections of food at ports of entry into the United States.

"(3) In providing for research under paragraph (1), the Secretary shall as appropriate coordinate with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, the Administrator of the Environmental Protection Agency, and the Secretary of Agriculture.

"(4) The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the progress made in research under paragraph (1), including progress regarding paragraph (2).". Reports.

(e) ASSESSMENT OF THREAT OF INTENTIONAL ADULTERATION OF FOOD.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall ensure that, not later than six months after the date of the enactment of this Act— Deadline.

(1) the assessment that (as of such date of enactment) is being conducted on the threat of the intentional adulteration of food is completed; and

(2) a report describing the findings of the assessment is submitted to the Committee on Energy and Commerce of the House of Representatives and to the Committee on Health, Education, Labor, and Pensions of the Senate. Reports.

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section and the amendments made by this section, there are authorized to be appropriated $100,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006, in addition to other authorizations of appropriations that are available for such purpose.

SEC. 303. ADMINISTRATIVE DETENTION.

(a) EXPANDED AUTHORITY.—Section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) is amended by adding at the end the following subsection:

"(h) ADMINISTRATIVE DETENTION OF FOODS.—

"(1) DETENTION AUTHORITY.—

"(A) IN GENERAL.—An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

"(B) SECRETARY'S APPROVAL.—An article of food may be ordered detained under subparagraph (A) only if the Secretary or an official designated by the Secretary approves the order. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

"(2) PERIOD OF DETENTION.—An article of food may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable the Secretary to institute an action under subsection (a) or section 302. The Secretary shall by regulation provide for procedures for instituting such action on an expedited basis with respect to perishable foods. Regulation.

"(3) SECURITY OF DETAINED ARTICLE.—An order under paragraph (1) with respect to an article of food may require that such article be labeled or marked as detained, and shall require that the article be removed to a secure facility, as appropriate. An article subject to such an order shall not be transferred by any person from the place at which the article is ordered detained, or from the place to which the article is so removed, as the case may be, until released by the Secretary or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the article pursuant to the execution of a bond while the article is subject to the order, and section 801(b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is subject to the order.

"(4) APPEAL OF DETENTION ORDER.—

"(A) IN GENERAL.—With respect to an article of food ordered detained under paragraph (1), any person who would be entitled to be a claimant for such article if the article were seized under subsection (a) may appeal the order to the Secretary. Within five days after such an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Secretary shall be considered a final agency action for purposes of section 702 of title 5, United States Code. If during such five-day period the Secretary fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

"(B) EFFECT OF INSTITUTING COURT ACTION.—The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Secretary institutes an action under subsection (a) or section 302 regarding the article of food involved.".

(b) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

"(bb) The transfer of an article of food in violation of an order under section 304(h), or the removal or alteration of any mark or label required by the order to identify the article as detained.".

(c) TEMPORARY HOLDS AT PORTS OF ENTRY.—Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 302(d)of this Act, is amended by adding at the end the following: 21 USC 381.

"(j)(1) If an officer or qualified employee of the Food and Drug Administration has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, and such officer or qualified employee is unable to inspect, examine, or investigate such article upon the article being offered for import at a port of entry into the United States, the officer or qualified employee shall request the Secretary of Treasury to hold the food at the port of entry for a reasonable period of time, not to exceed 24 hours, for the purpose of enabling the Secretary to inspect, examine, or investigate the article as appropriate.

"(2) The Secretary shall request the Secretary of Treasury to remove an article held pursuant to paragraph (1) to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held.

"(3) An officer or qualified employee of the Food and Drug Administration may make a request under paragraph (1) only if the Secretary or an official designated by the Secretary approves the request. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

"(4) With respect to an article of food for which a request under paragraph (1) is made, the Secretary, promptly after the request is made, shall notify the State in which the port of entry involved is located that the request has been made, and as applicable, that such article is being held under this subsection.".

SEC. 304. DEBARMENT FOR REPEATED OR SERIOUS FOOD IMPORT VIOLATIONS.

(a) DEBARMENT AUTHORITY.—

(1) PERMISSIVE DEBARMENT.—Section 306(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)(1)) is amended—

(A) in subparagraph (A), by striking "or" after the comma at the end;

(B) in subparagraph (B), by striking the period at the end and inserting ", or"; and

(C) by adding at the end the following subparagraph:

"(C) a person from importing an article of food or offering such an article for import into the United States.".

(2) AMENDMENT REGARDING DEBARMENT GROUNDS.—Section 306(b)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)) is amended—

(A) in paragraph (2), in the matter preceding subparagraph (A), by inserting "subparagraph (A) or (B) of" before "paragraph (1)";

(B) by redesignating paragraph (3) as paragraph (4); and

(C) by inserting after paragraph (2) the following paragraph:

"(3) PERSONS SUBJECT TO PERMISSIVE DEBARMENT; FOOD IMPORTATION.—A person is subject to debarment under paragraph (1)(C) if—

"(A) the person has been convicted of a felony for conduct relating to the importation into the United States of any food; or

"(B) the person has 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.".

(b) CONFORMING AMENDMENTS.—Section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is amended—

(1) in subsection (a), in the heading for the subsection, by striking "MANDATORY DEBARMENT.—" and inserting "MANDATORY DEBARMENT; CERTAIN DRUG APPLICATIONS.—";

(2) in subsection (b)—

(A) in the heading for the subsection, by striking "PERMISSIVE DEBARMENT.—" and inserting "PERMISSIVE DEBARMENT; CERTAIN DRUG APPLICATIONS; FOOD IMPORTS.—"; and

(B) in paragraph (2), in the heading for the paragraph, by striking "PERMISSIVE DEBARMENT.—" and inserting "PERMISSIVE DEBARMENT; CERTAIN DRUG APPLICATIONS.—";

(3) in subsection (c)(2)(A)(iii), by striking "subsection (b)(2)" and inserting "paragraph (2) or (3) of subsection (b)";

(4) in subsection (d)(3)—

(A) in subparagraph (A)(i), by striking "or (b)(2)(A)" and inserting " or paragraph (2)(A) or (3) of subsection (b)";

(B) in subparagraph (A)(ii)(II), by inserting "in applicable cases," before "sufficient audits";

(C) in subparagraph (B), in each of clauses (i) and (ii), by inserting "or subsection (b)(3)" after "subsection (b)(2)(B)"; and

(D) in subparagraph (B)(ii), by inserting before the period the following: "or the food importation process, as the case may be".

(c) EFFECTIVE DATES.—Section 306(l)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(l)(2)) is amended— 21 USC 335a.

(1) in the first sentence—

(A) by striking "and" after "subsection (b)(2),"; and

(B) by inserting ", and subsection (b)(3)(A)" after "subsection (b)(2)(B)"; and

(2) in the second sentence, by inserting ", subsection (b)(3)(B)," after "subsection (b)(2)(B)".

(d) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act, as amended by section 303(b) of this Act, is amended by adding at the end the following:

"(cc) 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).".

(e) IMPORTATION BY DEBARRED PERSONS.—Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 303(c) of this Act, is amended by adding at the end the following subsection: 21 USC 381.

"(k)(1) If an article of food is being imported or offered for import into the United States, and the importer, owner, or consignee of the article is a person who has been debarred under section 306(b)(3), such article shall be held at the port of entry for the article, and may not be delivered to such person. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

"(2) An article of food held under paragraph (1) may be delivered to a person who is not a debarred person under section 306(b)(3) if such person affirmatively establishes, at the expense of the person, that the article complies with the requirements of this Act, as determined by the Secretary.".

SEC. 305. REGISTRATION OF FOOD FACILITIES.

(a) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

"SEC. 415. REGISTRATION OF FOOD FACILITIES. 21 USC 350d.

"(a) REGISTRATION.—

"(1) IN GENERAL.—The Secretary shall by regulation require that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary. To be registered— Regulations.

"(A) for a domestic facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary; and

"(B) for a foreign facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary and shall include with the registration the name of the United States agent for the facility.

"(2) REGISTRATION.—An entity (referred to in this section as the 'registrant') shall submit a registration under paragraph (1) to the Secretary containing information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the registrant conducts business and, when determined necessary by the Secretary through guidance, the general food category (as identified under section 170.3 of title 21, Code of Federal Regulations) of any food manufactured, processed, packed, or held at such facility. The registrant shall notify the Secretary in a timely manner of changes to such information. Notification.

"(3) PROCEDURE.—Upon receipt of a completed registration described in paragraph (1), the Secretary shall notify the registrant of the receipt of such registration and assign a registration number to each registered facility. Notification.

"(4) LIST.—The Secretary shall compile and maintain an up-to-date list of facilities that are registered under this section. Such list and any registration documents submitted pursuant Records.

to this subsection shall not be subject to disclosure under section 552 of title 5, United States Code. Information derived from such list or registration documents shall not be subject to disclosure under section 552 of title 5, United States Code, to the extent that it discloses the identity or location of a specific registered person.

"(b) FACILITY.—For purposes of this section:

"(1) The term 'facility' includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in section 123.3(k) of title 21, Code of Federal Regulations).

"(2) The term 'domestic facility' means a facility located in any of the States or Territories.

"(3)(A) The term 'foreign facility' means a facility that manufacturers, processes, packs, or holds food, but only if food from such facility is exported to the United States without further processing or packaging outside the United States.

"(B) A food may not be considered to have undergone further processing or packaging for purposes of subparagraph (A) solely on the basis that labeling was added or that any similar activity of a de minimis nature was carried out with respect to the food.

"(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to authorize the Secretary to require an application, review, or licensing process.".

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 304(d) of this Act, is amended by adding at the end the following:

"(dd) The failure to register in accordance with section 415.".

(c) IMPORTATION; FAILURE TO REGISTER.—Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 304(e) of this Act, is amended by adding at the end the following subsection: 21 USC 381.

"(l)(1) If an article of food is being imported or offered for import into the United States, and such article is from a foreign facility for which a registration has not been submitted to the Secretary under section 415, such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is so registered. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.".

(d) ELECTRONIC FILING.—For the purpose of reducing paperwork and reporting burdens, the Secretary of Health and Human Services may provide for, and encourage the use of, electronic methods of submitting to the Secretary registrations required pursuant to this section. In providing for the electronic submission of 21 USC 350d note.

such registrations, the Secretary shall ensure adequate authentication protocols are used to enable identification of the registrant and validation of the data as appropriate.

(e) RULEMAKING; EFFECTIVE DATE.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed and final regulations for the requirement of registration under section 415 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section). Such requirement of registration takes effect— Deadline.

(1) upon the effective date of such final regulations; or

(2) upon the expiration of such 18-month period if the final regulations have not been made effective as of the expiration of such period, subject to compliance with the final regulations when the final regulations are made effective.

SEC. 306. MAINTENANCE AND INSPECTION OF RECORDS FOR FOODS.

(a) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act, as amended by section 305 of this Act, is amended by inserting before section 415 the following section:

"SEC. 414. MAINTENANCE AND INSPECTION OF RECORDS. 21 USC 350c.

"(a) RECORDS INSPECTION.—If the Secretary 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 (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The requirement under the preceding sentence applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location. Applicability.

"(b) REGULATIONS CONCERNING RECORDKEEPING.—The Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, may by regulation establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. The Secretary shall take into account the size of a business in promulgating regulations under this section.

"(c) PROTECTION OF SENSITIVE INFORMATION.—The Secretary shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section.

"(d) LIMITATIONS.—This section shall not be construed—

"(1) to limit the authority of the Secretary to inspect records or to require establishment and maintenance of records under any other provision of this Act;

"(2) to authorize the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.);

"(3) to have any legal effect on section 552 of title 5, United States Code, or section 1905 of title 18, United States Code; or

"(4) to extend to recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).".

(b) FACTORY INSPECTION.—Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) is amended—

(1) in paragraph (1), by inserting after the first sentence the following new sentence: "In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414 when the Secretary 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, subject to the limitations established in section 414(d).''; and

(2) in paragraph (2), in the matter preceding subparagraph (A), by striking "second sentence" and inserting "third sentence".

(c) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended—

(1) in paragraph (e)—

(A) by striking "by section 412, 504, or 703" and inserting "by section 412, 414, 504, 703, or 704(a)"; and

(B) by striking "under section 412" and inserting "under section 412, 414(b)"; and

(2) in paragraph (j), by inserting "414," after "412,".

(d) EXPEDITED RULEMAKING.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall promulgate proposed and final regulations establishing recordkeeping requirements under subsection 414(b) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)). Deadline. 21 USC 350c note.

SEC. 307. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.

(a) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 305(c) of this Act, is amended by adding at the end the following subsection:

"(m)(1) In the case of an article of food that is being imported or offered for import into the United States, the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; if known within the specified period of time that notice is required to be Regulations.

provided, 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. An article of food imported or offered for import without submission of such notice in accordance with the requirements under this paragraph shall be refused admission into the United States. Nothing in this section may be construed as a limitation on the port of entry for an article of food.

"(2)(A) Regulations under paragraph (1) shall require that a notice under such paragraph be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days. In determining the specified period of time required under this subparagraph, the Secretary may consider, but is not limited to consideration of, the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States, and any other such consideration. Nothing in the preceding sentence may be construed as a limitation on the obligation of the Secretary to receive, review, and appropriately respond to any notice under paragraph (1).

"(B)(i) If an article of food is being imported or offered for import into the United States and a notice under paragraph (1) is not provided in advance in accordance with the requirements under paragraph (1), such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such notice is submitted to the Secretary, and the Secretary examines the notice and determines that the notice is in accordance with the requirements under paragraph (1). Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

"(ii) In carrying out clause (i) with respect to an article of food, the Secretary shall determine whether there is in the possession of the Secretary any credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

"(3)(A) This subsection may not be construed as limiting the authority of the Secretary to obtain information under any other provision of this Act.

"(B) This subsection may not be construed as authorizing the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).".

21 USC 331.

(b) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act, as amended by section 305(b) of this Act, is amended by adding at the end the following:

"(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 801(m).".

21 USC 351 note.
Deadline.

(c) RULEMAKING; EFFECTIVE DATE.—

(1) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed and final regulations for the requirement of providing notice in accordance with section 801(m) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section). Such requirement of notification takes effect—

(A) upon the effective date of such final regulations; or

(B) upon the expiration of such 18-month period if the final regulations have not been made effective as of the expiration of such period, subject to compliance with the final regulations when the final regulations are made effective.

(2) DEFAULT; MINIMUM PERIOD OF ADVANCE NOTICE.—If under paragraph (1) the requirement for providing notice in accordance with section 801(m) of the Federal Food, Drug, and Cosmetic Act takes effect without final regulations having been made effective, then for purposes of such requirement, the specified period of time that the notice is required to be made in advance of the time of the importation of the article of food involved or the offering of the food for import shall be not fewer than eight hours and not more than five days, which shall remain in effect until the final regulations are made effective.

SEC. 308. AUTHORITY TO MARK ARTICLES REFUSED ADMISSION INTO UNITED STATES.

(a) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)), as amended by section 307(a) of this Act, is amended by adding at the end the following:

"(n)(1) If a food has been refused admission under subsection (a), other than such a food that is required to be destroyed, the Secretary may require the owner or consignee of the food to affix to the container of the food a label that clearly and conspicuously bears the statement: 'UNITED STATES: REFUSED ENTRY'.

"(2) All expenses in connection with affixing a label under paragraph (1) shall be paid by the owner or consignee of the food involved, and in default of such payment, shall constitute a lien against future importations made by such owner or consignee.

"(3) A requirement under paragraph (1) remains in effect until the Secretary determines that the food involved has been brought into compliance with this Act.".

(b) MISBRANDED FOODS.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

"(v) If—

"(1) it fails to bear a label required by the Secretary under section 801(n)(1) (relating to food refused admission into the United States);

"(2) the Secretary finds that the food presents a threat of serious adverse health consequences or death to humans or animals; and

"(3) upon or after notifying the owner or consignee involved that the label is required under section 801, the Secretary informs the owner or consignee that the food presents such a threat.".

(c) RULE OF CONSTRUCTION.—With respect to articles of food that are imported or offered for import into the United States, nothing in this section shall be construed to limit the authority of the Secretary of Health and Human Services or the Secretary of the Treasury to require the marking of refused articles of food under any other provision of law. 21 USC 381 note.

SEC. 309. PROHIBITION AGAINST PORT SHOPPING.

Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by adding at the end the following:

"(h) If it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section 801(a), unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article complies with the applicable requirements of this Act, as determined by the Secretary.".

SEC. 310. NOTICES TO STATES REGARDING IMPORTED FOOD.

Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following section:

"SEC. 908. NOTICES TO STATES REGARDING IMPORTED FOOD. 21 USC 398.

"(a) IN GENERAL.—If the Secretary has credible evidence or information indicating that a shipment of imported food or portion thereof presents a threat of serious adverse health consequences or death to humans or animals, the Secretary shall provide notice regarding such threat to the States in which the food is held or will be held, and to the States in which the manufacturer, packer, or distributor of the food is located, to the extent that the Secretary has knowledge of which States are so involved. In providing notice to a State, the Secretary shall request the State to take such action as the State considers appropriate, if any, to protect the public health regarding the food involved.

"(b) RULE OF CONSTRUCTION.—Subsection (a) may not be construed as limiting the authority of the Secretary with respect to food under any other provision of this Act.".

SEC. 311. GRANTS TO STATES FOR INSPECTIONS.

Chapter IX of the Federal Food, Drug, and Cosmetic Act, as amended by section 310 of this Act, is amended by adding at the end the following section:

"SEC. 909. GRANTS TO STATES FOR INSPECTIONS. 21 USC 399.

"(a) IN GENERAL.—The Secretary is authorized to make grants to States, territories, and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))) that undertake examinations, inspections, and investigations, and related activities under section 702. The funds provided under such grants shall only be available for the costs

of conducting such examinations, inspections, investigations, and related activities.

"(b) NOTICES REGARDING ADULTERATED IMPORTED FOOD.—The Secretary may make grants to the States for the purpose of assisting the States with the costs of taking appropriate action to protect the public health in response to notification under section 908, including planning and otherwise preparing to take such action.

"(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $10,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006.".

SEC. 312. SURVEILLANCE AND INFORMATION GRANTS AND AUTHORITIES.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317P the following:

42 USC 247b–20. **"SEC. 317R. FOOD SAFETY GRANTS.**

"(a) IN GENERAL.—The Secretary may award grants to States and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))) to expand participation in networks to enhance Federal, State, and local food safety efforts, including meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation.

"(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $19,500,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006.".

7 USC 8319. **SEC. 313. SURVEILLANCE OF ZOONOTIC DISEASES.**

The Secretary of Health and Human Services, through the Commissioner of Food and Drugs and the Director of the Centers for Disease Control and Prevention, and the Secretary of Agriculture shall coordinate the surveillance of zoonotic diseases.

SEC. 314. AUTHORITY TO COMMISSION OTHER FEDERAL OFFICIALS TO CONDUCT INSPECTIONS.

Section 702(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372(a)) is amended—

(1) by striking "(a)" and inserting "(a)(1)";

(2) by striking "In the case of food packed" and inserting the following:

"(3) In the case of food packed";

(3) by striking "For the purposes of this subsection" and inserting the following:

"(4) For the purposes of this subsection,"; and

(4) by inserting after paragraph (1) (as designated by paragraph (1) of this section) the following paragraph:

"(2)(A) In addition to the authority established in paragraph (1), the Secretary, pursuant to a memorandum of understanding between the Secretary and the head of another Federal department or agency, is authorized to conduct examinations and investigations for the purposes of this Act through the officers and employees of such other department or agency, subject to subparagraph (B). Such a memorandum shall include provisions to ensure adequate training of such officers and employees to conduct the examinations

and investigations. The memorandum of understanding shall contain provisions regarding reimbursement. Such provisions may, at the sole discretion of the head of the other department or agency, require reimbursement, in whole or in part, from the Secretary for the examinations or investigations performed under this section by the officers or employees of the other department or agency.

"(B) A memorandum of understanding under subparagraph (A) between the Secretary and another Federal department or agency is effective only in the case of examinations or inspections at facilities or other locations that are jointly regulated by the Secretary and such department or agency.

"(C) For any fiscal year in which the Secretary and the head of another Federal department or agency carries out one or more examinations or inspections under a memorandum of understanding under subparagraph (A), the Secretary and the head of such department or agency shall with respect to their respective departments or agencies submit to the committees of jurisdiction (authorizing and appropriating) in the House of Representatives and the Senate a report that provides, for such year— Reports.

"(i) the number of officers or employees that carried out one or more programs, projects, or activities under such memorandum;

"(ii) the number of additional articles that were inspected or examined as a result of such memorandum; and

"(iii) the number of additional examinations or investigations that were carried out pursuant to such memorandum.".

SEC. 315. RULE OF CONSTRUCTION. 21 USC 331 note.

Nothing in this title, or an amendment made by this title, shall be construed to alter the jurisdiction between the Secretaries of Agriculture and of Health and Human Services, under applicable statutes and regulations.

Subtitle B—Protection of Drug Supply

SEC. 321. ANNUAL REGISTRATION OF FOREIGN MANUFACTURERS; SHIPPING INFORMATION; DRUG AND DEVICE LISTING.

(a) ANNUAL REGISTRATION; LISTING.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended—

(1) in subsection (i)(1)—

(A) by striking "Any establishment" and inserting "On or before December 31 of each year, any establishment"; and

(B) by striking "shall register" and all that follows and inserting the following: "shall, through electronic means in accordance with the criteria of the Secretary, register with the Secretary the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such drug or device in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug or device to the United States for purposes of importation."; and

(2) in subsection (j)(1), in the first sentence, by striking "or (d)" and inserting "(d), or (i)".

(b) IMPORTATION; STATEMENT REGARDING REGISTRATION OF MANUFACTURER.—

(1) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 308(a) of this Act, is amended by adding at the end the following subsection:

"(o) If an article that is a drug or device is being imported or offered for import into the United States, and the importer, owner, or consignee of such article does not, at the time of offering the article for import, submit to the Secretary a statement that identifies the registration under section 510(i) of each establishment that with respect to such article is required under such section to register with the Secretary, the article may be refused admission. If the article is refused admission for failure to submit such a statement, the article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such a statement is submitted to the Secretary. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.".

(2) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act, as amended by section 307(b) of this Act, is amended by adding at the end the following:

"(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 801(o).".

(c) EFFECTIVE DATE.—The amendments made by this section take effect upon the expiration of the 180-day period beginning on the date of the enactment of this Act. 21 USC 331 note.

SEC. 322. REQUIREMENT OF ADDITIONAL INFORMATION REGARDING IMPORT COMPONENTS INTENDED FOR USE IN EXPORT PRODUCTS.

(a) IN GENERAL.—Section 801(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)(3)) is amended to read as follows:

"(3)(A) Subject to subparagraph (B), no component of a drug, no component part or accessory of a device, or other article of device requiring further processing, which is ready or suitable for use for health-related purposes, and no article of a food additive, color additive, or dietary supplement, including a product in bulk form, shall be excluded from importation into the United States under subsection (a) if each of the following conditions is met:

"(i) The importer of such article of a drug or device or importer of such article of a food additive, color additive, or dietary supplement submits to the Secretary, at the time of initial importation, a statement in accordance with the following:

"(I) Such statement provides that such article is intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive,

color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) or section 802, or with section 351(h) of the Public Health Service Act.

"(II) The statement identifies the manufacturer of such article and each processor, packer, distributor, or other entity that had possession of the article in the chain of possession of the article from the manufacturer to such importer of the article.

"(III) The statement is 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 paragraph (4).

"(ii) At the time of initial importation and before the delivery of such article to the importer or the initial owner or consignee, such owner or consignee executes a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury.

"(iii) Such article is used and exported by the initial owner or consignee in accordance with the intent described under clause (i)(I), except for any portions of the article that are destroyed.

"(iv) The initial owner or consignee maintains records on the use or destruction of such article or portions thereof, as the case may be, and submits to the Secretary any such records requested by the Secretary. Records.

"(v) Upon request of the Secretary, the initial owner or consignee submits a report that provides an accounting of the exportation or destruction of such article or portions thereof, and the manner in which such owner or consignee complied with the requirements of this subparagraph. Reports.

"(B) Notwithstanding subparagraph (A), the Secretary may refuse admission to an article that otherwise would be imported into the United States under such subparagraph if the Secretary determines that there is credible evidence or information indicating that such article is not intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) or section 802, or with section 351(h) of the Public Health Service Act.

"(C) This section may not be construed as affecting the responsibility of the Secretary to ensure that articles imported into the United States under authority of subparagraph (A) meet each of the conditions established in such subparagraph for importation.".

(b) PROHIBITED ACT.—Section 301(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(w)) is amended to read as follows:

"(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 801(d)(3); the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in

accordance with section 801(e) or 802, or with section 351(h) of the Public Health Service Act; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.".

21 USC 331 note.

(c) EFFECTIVE DATE.—The amendments made by this section take effect upon the expiration of the 90-day period beginning on the date of the enactment of this Act.

Subtitle C—General Provisions Relating to Upgrade of Agricultural Security

7 USC 8320.

SEC. 331. EXPANSION OF ANIMAL AND PLANT HEALTH INSPECTION SERVICE ACTIVITIES.

(a) IN GENERAL.—The Secretary of Agriculture (referred to in this section as the "Secretary") may utilize existing authorities to give high priority to enhancing and expanding the capacity of the Animal and Plant Health Inspection Service to conduct activities to—

(1) increase the inspection capacity of the Service at international points of origin;

(2) improve surveillance at ports of entry and customs;

(3) enhance methods of protecting against the introduction of plant and animal disease organisms by terrorists;

(4) develop new and improve existing strategies and technologies for dealing with intentional outbreaks of plant and animal disease arising from acts of terrorism or from unintentional introduction, including—

(A) establishing cooperative agreements among Veterinary Services of the Animal and Plant Health Inspection Service, State animal health commissions and regulatory agencies for livestock and poultry health, and private veterinary practitioners to enhance the preparedness and ability of Veterinary Services and the commissions and agencies to respond to outbreaks of such animal diseases; and

(B) strengthening planning and coordination with State and local agencies, including—

(i) State animal health commissions and regulatory agencies for livestock and poultry health; and

(ii) State agriculture departments; and

(5) otherwise improve the capacity of the Service to protect against the threat of bioterrorism.

(b) AUTOMATED RECORDKEEPING SYSTEM.—The Administrator of the Animal and Plant Health Inspection Service may implement a central automated recordkeeping system to provide for the reliable tracking of the status of animal and plant shipments, including those shipments on hold at ports of entry and customs. The Secretary shall ensure that such a system shall be fully accessible to or fully integrated with the Food Safety Inspection Service.

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $30,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

SEC. 332. EXPANSION OF FOOD SAFETY INSPECTION SERVICE ACTIVITIES.

21 USC 679c.

(a) IN GENERAL.—The Secretary of Agriculture may utilize existing authorities to give high priority to enhancing and expanding the capacity of the Food Safety Inspection Service to conduct activities to—

(1) enhance the ability of the Service to inspect and ensure the safety and wholesomeness of meat and poultry products;

(2) improve the capacity of the Service to inspect international meat and meat products, poultry and poultry products, and egg products at points of origin and at ports of entry;

(3) strengthen the ability of the Service to collaborate with relevant agencies within the Department of Agriculture and with other entities in the Federal Government, the States, and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))) through the sharing of information and technology; and

(4) otherwise expand the capacity of the Service to protect against the threat of bioterrorism.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $15,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

SEC. 333. BIOSECURITY UPGRADES AT THE DEPARTMENT OF AGRICULTURE.

Appropriation authorization. State listing.

There is authorized to be appropriated for fiscal year 2002, $180,000,000 for the purpose of enabling the Agricultural Research Service to conduct building upgrades to modernize existing facilities, of which (1) $100,000,000 shall be allocated for renovation, updating, and expansion of the Biosafety Level 3 laboratory and animal research facilities at the Plum Island Animal Disease Center (Greenport, New York), and of which (2) $80,000,000 shall be allocated for the Agricultural Research Service/Animal and Plant Health Inspection Service facility in Ames, Iowa. There are authorized to be appropriated such sums as may be necessary for fiscal years 2003 through 2006 for the purpose described in the preceding sentence, for the planning and design of an Agricultural Research Service biocontainment laboratory for poultry research in Athens, Georgia, and for the planning, updating, and renovation of the Arthropod-Borne Animal Disease Laboratory in Laramie, Wyoming.

SEC. 334. AGRICULTURAL BIOSECURITY.

7 USC 3353.

(a) SECURITY AT COLLEGES AND UNIVERSITIES.—

(1) GRANTS.—The Secretary of Agriculture (referred to in this section as the "Secretary") may award grants to covered entities to review security standards and practices at their facilities in order to protect against bioterrorist attacks.

(2) COVERED ENTITIES.—Covered entities under this subsection are colleges or universities that—

(A) are colleges or universities as defined in section 1404 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3103); and

(B) have programs in food and agricultural sciences, as defined in such section.

(3) LIMITATION.—Each individual covered entity may be awarded one grant under paragraph (1), the amount of which shall not exceed $50,000.

(4) CONTRACT AUTHORITY.—Colleges and universities receiving grants under paragraph (1) may use such grants to enter into contracts with independent private organizations with established and demonstrated security expertise to conduct the security reviews specified in such paragraph.

(b) GUIDELINES FOR AGRICULTURAL BIOSECURITY.—

(1) IN GENERAL.—The Secretary may award grants to associations of food producers or consortia of such associations for the development and implementation of educational programs to improve biosecurity on farms in order to ensure the security of farm facilities against potential bioterrorist attacks.

(2) LIMITATION.—Each individual association eligible under paragraph (1) may be awarded one grant under such paragraph, the amount of which shall not exceed $100,000. Each consortium eligible under paragraph (1) may be awarded one grant under such paragraph, the amount of which shall not exceed $100,000 per association participating in the consortium.

(3) CONTRACT AUTHORITY.—Associations of food producers receiving grants under paragraph (1) may use such grants to enter into contracts with independent private organizations with established and demonstrated expertise in biosecurity to assist in the development and implementation of educational programs to improve biosecurity specified in such paragraph.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each fiscal year.

7 USC 3354.

SEC. 335. AGRICULTURAL BIOTERRORISM RESEARCH AND DEVELOPMENT.

(a) IN GENERAL.—The Secretary of Agriculture (referred to in this section as the "Secretary") may utilize existing research authorities and research programs to protect the food supply of the United States by conducting and supporting research activities to—

(1) enhance the capability of the Secretary to respond in a timely manner to emerging or existing bioterrorist threats to the food and agricultural system of the United States;

(2) develop new and continue partnerships with institutions of higher education and other institutions to help form stable, long-term programs to enhance the biosecurity and food safety of the United States, including the coordination of the development, implementation, and enhancement of diverse capabilities for addressing threats to the nation's agricultural economy and food supply, with special emphasis on planning, training, outreach, and research activities related to vulnerability analyses, incident response, detection, and prevention technologies;

(3) strengthen coordination with the intelligence community to better identify research needs and evaluate materials or information acquired by the intelligence community relating to potential threats to United States agriculture;

(4) expand the involvement of the Secretary with international organizations dealing with plant and animal disease control;

(5) continue research to develop rapid detection field test kits to detect biological threats to plants and animals and to provide such test kits to State and local agencies preparing for or responding to bioterrorism;

(6) develop an agricultural bioterrorism early warning surveillance system through enhancing the capacity of and coordination between State veterinary diagnostic laboratories, Federal and State agricultural research facilities, and public health agencies; and

(7) otherwise improve the capacity of the Secretary to protect against the threat of bioterrorism.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $190,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

SEC. 336. ANIMAL ENTERPRISE TERRORISM PENALTIES.

(a) IN GENERAL.—Section 43(a) of title 18, United States Code, is amended to read as follows:

"(a) OFFENSE.—Whoever—

"(1) travels in interstate or foreign commerce, or uses or causes to be used 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

"(2) intentionally damages or causes the loss of any property (including animals or records) used by the animal enterprise, or conspires to do so,

shall be punished as provided for in subsection (b).".

(b) PENALTIES.—Section 43(b) of title 18, United States Code, is amended to read as follows:

"(b) PENALTIES.—

"(1) ECONOMIC DAMAGE.—Any person who, in the course of a violation of subsection (a), causes economic damage not exceeding $10,000 to an animal enterprise shall be fined under this title or imprisoned not more than 6 months, or both.

"(2) MAJOR ECONOMIC DAMAGE.—Any person who, in the course of a violation of subsection (a), causes economic damage exceeding $10,000 to an animal enterprise shall be fined under this title or imprisoned not more than 3 years, or both.

"(3) SERIOUS BODILY INJURY.—Any person who, in the course of a violation of subsection (a), causes serious bodily injury to another individual shall be fined under this title or imprisoned not more than 20 years, or both.

"(4) DEATH.—Any person who, in the course of a violation of subsection (a), causes the death of an individual shall be fined under this title and imprisoned for life or for any term of years.".

(c) RESTITUTION.—Section 43(c) of title 18, United States Code, is amended—

(1) in paragraph (1), by striking "and" at the end;

(2) in paragraph (2), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(3) for any other economic damage resulting from the offense.".

TITLE IV—DRINKING WATER SECURITY AND SAFETY

SEC. 401. TERRORIST AND OTHER INTENTIONAL ACTS.

The Safe Drinking Water Act (title XIV of the Public Health Service Act) is amended by inserting the following new section after section 1432:

42 USC 300i–2.

"SEC. 1433. TERRORIST AND OTHER INTENTIONAL ACTS.

"(a) VULNERABILITY ASSESSMENTS.—(1) Each community water system serving a population of greater than 3,300 persons shall conduct an assessment of the vulnerability of its system to a terrorist attack or other intentional acts intended to substantially disrupt the ability of the system to provide a safe and reliable supply of drinking water. The vulnerability assessment shall include, but not be limited to, a review of pipes and constructed conveyances, physical barriers, water collection, pretreatment, treatment, storage and distribution facilities, electronic, computer or other automated systems which are utilized by the public water system, the use, storage, or handling of various chemicals, and the operation and maintenance of such system. The Administrator, not later than August 1, 2002, after consultation with appropriate departments and agencies of the Federal Government and with State and local governments, shall provide baseline information to community water systems required to conduct vulnerability assessments regarding which kinds of terrorist attacks or other intentional acts are the probable threats to—

Deadline.

"(A) substantially disrupt the ability of the system to provide a safe and reliable supply of drinking water; or

"(B) otherwise present significant public health concerns.

"(2) Each community water system referred to in paragraph (1) shall certify to the Administrator that the system has conducted an assessment complying with paragraph (1) and shall submit to the Administrator a written copy of the assessment. Such certification and submission shall be made prior to:

Certification. Deadlines.

"(A) March 31, 2003, in the case of systems serving a population of 100,000 or more.

"(B) December 31, 2003, in the case of systems serving a population of 50,000 or more but less than 100,000.

"(C) June 30, 2004, in the case of systems serving a population greater than 3,300 but less than 50,000.

"(3) Except for information contained in a certification under this subsection identifying the system submitting the certification and the date of the certification, all information provided to the Administrator under this subsection and all information derived therefrom shall be exempt from disclosure under section 552 of title 5 of the United States Code.

"(4) No community water system shall be required under State or local law to provide an assessment described in this section to any State, regional, or local governmental entity solely by reason of the requirement set forth in paragraph (2) that the system submit such assessment to the Administrator.

"(5) Not later than November 30, 2002, the Administrator, in consultation with appropriate Federal law enforcement and intelligence officials, shall develop such protocols as may be necessary to protect the copies of the assessments required to be submitted

Deadlines. Protocols.

under this subsection (and the information contained therein) from unauthorized disclosure. Such protocols shall ensure that—

"(A) each copy of such assessment, and all information contained in or derived from the assessment, is kept in a secure location;

"(B) only individuals designated by the Administrator may have access to the copies of the assessments; and

"(C) no copy of an assessment, or part of an assessment, or information contained in or derived from an assessment shall be available to anyone other than an individual designated by the Administrator.

At the earliest possible time prior to November 30, 2002, the Administrator shall complete the development of such protocols for the purpose of having them in place prior to receiving any vulnerability assessments from community water systems under this subsection.

"(6)(A) Except as provided in subparagraph (B), any individual referred to in paragraph (5)(B) who acquires the assessment submitted under paragraph (2), or any reproduction of such assessment, or any information derived from such assessment, and who knowingly or recklessly reveals such assessment, reproduction, or information other than—

"(i) to an individual designated by the Administrator under paragraph (5),

"(ii) for purposes of section 1445 or for actions under section 1431, or

"(iii) for use in any administrative or judicial proceeding to impose a penalty for failure to comply with this section,

shall upon conviction be imprisoned for not more than one year or fined in accordance with the provisions of chapter 227 of title 18, United States Code, applicable to class A misdemeanors, or both, and shall be removed from Federal office or employment.

"(B) Notwithstanding subparagraph (A), an individual referred to in paragraph (5)(B) who is an officer or employee of the United States may discuss the contents of a vulnerability assessment submitted under this section with a State or local official.

"(7) Nothing in this section authorizes any person to withhold any information from Congress or from any committee or subcommittee of Congress.

"(b) EMERGENCY RESPONSE PLAN.—Each community water system serving a population greater than 3,300 shall prepare or revise, where necessary, an emergency response plan that incorporates the results of vulnerability assessments that have been completed. Each such community water system shall certify to the Administrator, as soon as reasonably possible after the enactment of this section, but not later than 6 months after the completion of the vulnerability assessment under subsection (a), that the system has completed such plan. The emergency response plan shall include, but not be limited to, plans, procedures, and identification of equipment that can be implemented or utilized in the event of a terrorist or other intentional attack on the public water system. The emergency response plan shall also include actions, procedures, and identification of equipment which can obviate or significantly lessen the impact of terrorist attacks or other intentional actions on the public health and the safety and supply of drinking water provided to communities and individuals. Community water systems

Certification.
Deadline.

shall, to the extent possible, coordinate with existing Local Emergency Planning Committees established under the Emergency Planning and Community Right-to-Know Act (42 U.S.C. 11001 et seq.) when preparing or revising an emergency response plan under this subsection.

"(c) RECORD MAINTENANCE.—Each community water system shall maintain a copy of the emergency response plan completed pursuant to subsection (b) for 5 years after such plan has been certified to the Administrator under this section.

"(d) GUIDANCE TO SMALL PUBLIC WATER SYSTEMS.—The Administrator shall provide guidance to community water systems serving a population of less than 3,300 persons on how to conduct vulnerability assessments, prepare emergency response plans, and address threats from terrorist attacks or other intentional actions designed to disrupt the provision of safe drinking water or significantly affect the public health or significantly affect the safety or supply of drinking water provided to communities and individuals.

"(e) FUNDING.—(1) There are authorized to be appropriated to carry out this section not more than $160,000,000 for the fiscal year 2002 and such sums as may be necessary for the fiscal years 2003 through 2005.

"(2) The Administrator, in coordination with State and local governments, may use funds made available under paragraph (1) to provide financial assistance to community water systems for purposes of compliance with the requirements of subsections (a) and (b) and to community water systems for expenses and contracts designed to address basic security enhancements of critical importance and significant threats to public health and the supply of drinking water as determined by a vulnerability assessment conducted under subsection (a). Such basic security enhancements may include, but shall not be limited to the following:

"(A) the purchase and installation of equipment for detection of intruders;

"(B) the purchase and installation of fencing, gating, lighting, or security cameras;

"(C) the tamper-proofing of manhole covers, fire hydrants, and valve boxes;

"(D) the rekeying of doors and locks;

"(E) improvements to electronic, computer, or other automated systems and remote security systems;

"(F) participation in training programs, and the purchase of training manuals and guidance materials, relating to security against terrorist attacks;

"(G) improvements in the use, storage, or handling of various chemicals; and

"(H) security screening of employees or contractor support services.

Funding under this subsection for basic security enhancements shall not include expenditures for personnel costs, or monitoring, operation, or maintenance of facilities, equipment, or systems.

"(3) The Administrator may use not more than $5,000,000 from the funds made available under paragraph (1) to make grants to community water systems to assist in responding to and alleviating any vulnerability to a terrorist attack or other intentional acts intended to substantially disrupt the ability of the system to provide a safe and reliable supply of drinking water (including

sources of water for such systems) which the Administrator determines to present an immediate and urgent security need.

"(4) The Administrator may use not more than $5,000,000 from the funds made available under paragraph (1) to make grants to community water systems serving a population of less than 3,300 persons for activities and projects undertaken in accordance with the guidance provided to such systems under subsection (d).

SEC. 402. OTHER SAFE DRINKING WATER ACT AMENDMENTS.

The Safe Drinking Water Act (title XIV of the Public Health Service Act) is amended by inserting the following new sections after section 1433 (as added by section 401 of this Act):

"SEC. 1434. CONTAMINANT PREVENTION, DETECTION AND RESPONSE.

42 USC 300i–3.

Contracts.

"(a) IN GENERAL.—The Administrator, in consultation with the Centers for Disease Control and, after consultation with appropriate departments and agencies of the Federal Government and with State and local governments, shall review (or enter into contracts or cooperative agreements to provide for a review of) 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 community water systems, including each of the following:

"(1) Methods, means and equipment, including real time monitoring systems, designed to monitor and detect various levels of chemical, biological, and radiological contaminants or indicators of contaminants and reduce the likelihood that such contaminants can be successfully introduced into public water systems and source water intended to be used for drinking water.

"(2) Methods and means to provide sufficient notice to operators of public water systems, and individuals served by such systems, of the introduction of chemical, biological or radiological contaminants and the possible effect of such introduction on public health and the safety and supply of drinking water.

"(3) Methods and means for developing educational and awareness programs for community water systems.

"(4) Procedures and equipment necessary to prevent the flow of contaminated drinking water to individuals served by public water systems.

"(5) Methods, means, and equipment which could negate or mitigate deleterious effects on public health and the safety and supply caused by the introduction of contaminants into water intended to be used for drinking water, including an examination of the effectiveness of various drinking water technologies in removing, inactivating, or neutralizing biological, chemical, and radiological contaminants.

"(6) Biomedical research into the short-term and long-term impact on public health of various chemical, biological and radiological contaminants that may be introduced into public water systems through terrorist or other intentional acts.

"(b) FUNDING.—For the authorization of appropriations to carry out this section, see section 1435(e).

42 USC 300i–4.

Contracts.

"SEC. 1435. SUPPLY DISRUPTION PREVENTION, DETECTION AND RESPONSE.

"(a) DISRUPTION OF SUPPLY OR SAFETY.—The Administrator, in coordination with the appropriate departments and agencies of the Federal Government, shall review (or enter into contracts or cooperative agreements to provide for a review of) methods and means by which terrorists or other individuals or groups could disrupt the supply of safe drinking water or take other actions against water collection, pretreatment, treatment, storage and distribution facilities which could render such water significantly less safe for human consumption, including each of the following:

"(1) Methods and means by which pipes and other constructed conveyances utilized in public water systems could be destroyed or otherwise prevented from providing adequate supplies of drinking water meeting applicable public health standards.

"(2) Methods and means by which collection, pretreatment, treatment, storage and distribution facilities utilized or used in connection with public water systems and collection and pretreatment storage facilities used in connection with public water systems could be destroyed or otherwise prevented from providing adequate supplies of drinking water meeting applicable public health standards.

"(3) Methods and means by which pipes, constructed conveyances, collection, pretreatment, treatment, storage and distribution systems that are utilized in connection with public water systems could be altered or affected so as to be subject to cross-contamination of drinking water supplies.

"(4) Methods and means by which pipes, constructed conveyances, collection, pretreatment, treatment, storage and distribution systems that are utilized in connection with public water systems could be reasonably protected from terrorist attacks or other acts intended to disrupt the supply or affect the safety of drinking water.

"(5) Methods and means by which information systems, including process controls and supervisory control and data acquisition and cyber systems at community water systems could be disrupted by terrorists or other groups.

"(b) ALTERNATIVE SOURCES.—The review under this section shall also include a review of the methods and means by which alternative supplies of drinking water could be provided in the event of the destruction, impairment or contamination of public water systems.

"(c) REQUIREMENTS AND CONSIDERATIONS.—In carrying out this section and section 1434—

"(1) the Administrator shall ensure that reviews carried out under this section reflect the needs of community water systems of various sizes and various geographic areas of the United States; and

"(2) the Administrator may consider the vulnerability of, or potential for forced interruption of service for, a region or service area, including community water systems that provide service to the National Capital area.

"(d) INFORMATION SHARING.—As soon as practicable after reviews carried out under this section or section 1434 have been evaluated, the Administrator shall disseminate, as appropriate as determined by the Administrator, to community water systems

information on the results of the project through the Information Sharing and Analysis Center, or other appropriate means.

"(e) FUNDING.—There are authorized to be appropriated to carry out this section and section 1434 not more than $15,000,000 for the fiscal year 2002 and such sums as may be necessary for the fiscal years 2003 through 2005.".

SEC. 403. MISCELLANEOUS AND TECHNICAL AMENDMENTS.

The Safe Drinking Water Act is amended as follows:

(1) Section 1414(i)(1) is amended by inserting "1433" after "1417". 42 USC 300g–3.

(2) Section 1431 is amended by inserting in the first sentence after "drinking water" the following: ", or that there is a threatened or potential terrorist attack (or other intentional act designed to disrupt the provision of safe drinking water or to impact adversely the safety of drinking water supplied to communities and individuals), which". 42 USC 300i.

(3) Section 1432 is amended as follows: 42 USC 300i–1.

(A) By striking "5 years" in subsection (a) and inserting "20 years".

(B) By striking "3 years" in subsection (b) and inserting "10 years".

(C) By striking "$50,000" in subsection (c) and inserting "$1,000,000".

(D) By striking "$20,000" in subsection (c) and inserting "$100,000".

(4) Section 1442 is amended as follows: 42 USC 300j–1.

(A) By striking "this subparagraph" in subsection (b) and inserting "this subsection".

(B) By amending subsection (d) to read as follows:

"(d) There are authorized to be appropriated to carry out subsection (b) not more than $35,000,000 for the fiscal year 2002 and such sums as may be necessary for each fiscal year thereafter.". Appropriation authorization.

TITLE V—ADDITIONAL PROVISIONS

Subtitle A—Prescription Drug User Fees

Prescription Drug User Fee Amendments of 2002. 21 USC 301 note.

SEC. 501. SHORT TITLE.

This subtitle may be cited as the "Prescription Drug User Fee Amendments of 2002".

SEC. 502. FINDINGS. 21 USC 379g note.

The Congress finds that—

(1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for the review of human drug applications and the assurance of drug safety;

(3) the provisions added by the Prescription Drug User Fee Act of 1992, as amended by the Food and Drug Administration Modernization Act of 1997, have been successful in

substantially reducing review times for human drug applications and should be—

(A) reauthorized for an additional 5 years, with certain technical improvements; and

(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration, including—

(i) strengthening and improving the review and monitoring of drug safety;

(ii) considering greater interaction between the agency and sponsors during the review of drugs and biologics intended to treat serious diseases and life-threatening diseases; and

(iii) developing principles for improving first-cycle reviews; and

(4) the fees authorized by amendments made in this subtitle will be dedicated towards expediting the drug development process and the process for the review of human drug applications as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the chairman of the Committee on Energy and Commerce of the House of Representatives and the chairman of the Committee on Health, Education, Labor and Pensions of the Senate, as set forth in the Congressional Record.

SEC. 503. DEFINITIONS.

Section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) is amended—

(1) in paragraph (1), in the matter after and below subparagraph (C), by striking "licensure, as described in subparagraph (D)" and inserting "licensure, as described in subparagraph (C)";

(2) in paragraph (3)—

(A) in subparagraph (A), by striking "and" at the end;

(B) in subparagraph (B), by striking the period and inserting ", and";

(C) by inserting after subparagraph (B) the following subparagraph:

"(C) which is on the list of products described in section 505(j)(7)(A) or is on a list created and maintained by the Secretary of products approved under human drug applications under section 351 of the Public Health Service Act."; and

(D) in the matter after and below subparagraph (C) (as added by subparagraph (C) of this paragraph), by striking "Service Act," and all that follows through "biological product" and inserting the following: "Service Act. Such term does not include a biological product";

(3) in paragraph (6), by adding at the end the following subparagraph:

"(F) In the case of drugs approved after October 1, 2002, under human drug applications or supplements: collecting, developing, and reviewing safety information on the drugs, including adverse event reports, during a period

of time after approval of such applications or supplements, not to exceed three years."; and

(4) in paragraph (8)—

(A) by striking the matter after and below subparagraph (B);

(B) by striking subparagraph (B);

(C) by striking "is the lower of" and all that follows through "Consumer Price Index" and inserting "is the Consumer Price Index"; and

(D) by striking "1997, or" and inserting "1997.".

SEC. 504. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Section 736(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)) is amended—

(1) in the matter preceding paragraph (1), by striking "fiscal year 1998" and inserting "fiscal year 2003";

(2) in paragraph (1)(A)—

(A) in each of clauses (i) and (ii), by striking "in subsection (b)" and inserting "under subsection (c)(4)"; and

(B) in clause (ii), by adding at the end the following sentence: "Such fee shall be half of the amount of the fee established under clause (i).";

(3) in paragraph (2)(A), in the matter after and below clause (ii)—

(A) by striking "in subsection (b)" and inserting "under subsection (c)(4)"; and

(B) by striking "payable on or before January 31" and inserting "payable on or before October 1"; and

(4) in paragraph (3)—

(A) by amending subparagraph (A) to read as follows:

"(A) IN GENERAL.—Except as provided in subparagraph (B), each person who is named as the applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay for each such prescription drug product the annual fee established under subsection (c)(4). Such fee shall be payable on or before October 1 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable."; and

(B) in subparagraph (B), by striking "The listing" and all that follows through "filed under section 505(b)(2)" and inserting the following: "A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is identified on the list compiled under section 505(j)(7)(A) with a potency described in terms of per 100 mL, or if such product is the same product as another product approved under an application filed under section 505(b)".

(b) FEE AMOUNTS.—Section 736(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(b)) is amended to read as follows:

"(b) FEE REVENUE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), fees under subsection (a) shall be established to generate the following revenue amounts:

"Type of Fee Revenue	Fiscal Year 2003	Fiscal Year 2004	Fiscal Year 2005	Fiscal Year 2006	Fiscal Year 2007
Application/Supplement	$74,300,000	$77,000,000	$84,000,000	$86,434,000	$86,434,000
Establishment	$74,300,000	$77,000,000	$84,000,000	$86,433,000	$86,433,000
Product	$74,300,000	$77,000,000	$84,000,000	$86,433,000	$86,433,000
Total Fee Revenue	$222,900,000	$231,000,000	$252,000,000	$259,300,000	$259,300,000

If, after the date of the enactment of the Prescription Drug User Fee Amendments of 2002, legislation is enacted requiring the Secretary to fund additional costs of the retirement of Federal personnel, fee revenue amounts shall be increased in each year by the amount necessary to fully fund the portion of such additional costs that are attributable to the process for the review of human drug applications.".

(c) ADJUSTMENTS.—Section 736(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A), by striking "fees and total fee revenues" and inserting "revenues";

(B) in subparagraph (A)—

(i) by striking "during the preceding fiscal year"; and

(ii) by striking ", or" and inserting the following: "for the 12 month period ending June 30 preceding the fiscal year for which fees are being established, or";

(C) in subparagraph (B), by striking "for such fiscal year" and inserting "for the previous fiscal year"; and

(D) in the matter after and below subparagraph (B), by striking "fiscal year 1997"; and inserting "fiscal year 2003";

(2) by redesignating paragraphs (2) and (3) as paragraphs (4) and (5), respectively;

(3) by inserting after paragraph (1) the following paragraphs:

Effective date.

"(2) WORKLOAD ADJUSTMENT.—Beginning with fiscal year 2004, after the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of human drug applications. With respect to such adjustment:

"(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of human drug applications, commercial investigational new drug applications, efficacy supplements, and manufacturing supplements submitted to the Secretary. The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

Federal Register, publication.

"(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues for the fiscal year established in subsection (b), as adjusted for inflation under paragraph (1).

"(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2007, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than three months of operating reserves of carryover user fees for the process for the review of human drug applications for the first three months of fiscal year 2008. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2007. If the Secretary has carryover balances for such process in excess of three months of such operating reserves, the adjustment under this paragraph shall not be made."; and

(4) in paragraph (4) (as redesignated by paragraph (2) of this subsection), by amending such paragraph to read as follows:

"(4) ANNUAL FEE SETTING.—The Secretary shall, 60 days before the start of each fiscal year that begins after September 30, 2002, establish, for the next fiscal year, application, product, and establishment fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.". Effective date.

(d) FEE WAIVER OR REDUCTION.—Section 736(d)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(d)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (C), by inserting "or" after the comma at the end;

(B) by striking subparagraph (D); and

(C) by redesignating subparagraph (E) as subparagraph (D); and

(2) in paragraph (3), in each of subparagraphs (A) and (B), by striking "paragraph (1)(E)" each place such term appears and inserting "paragraph (1)(D)".

(e) ASSESSMENT OF FEES.—Section 736(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(f)) is amended—

(1) in the heading for the subsection, by striking "ASSESSMENT OF FEES.—" and inserting "LIMITATIONS.—"; and

(2) in paragraph (1), by striking the heading for the paragraph and all that follows through "fiscal year beginning" and inserting the following: "IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning".

(f) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Section 736(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(g)(1)) is amended by striking "Fees collected for a fiscal year" and all that follows through "fiscal year limitation." and inserting the following: "Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.".

(2) COLLECTIONS AND APPROPRIATION ACTS.—Section 736(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(g)(2)) is amended—

(A) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively;

(B) by striking "(2) COLLECTIONS" and all that follows through "the amount specified" in clause (i) (as so redesignated) and inserting the following:

"(2) COLLECTIONS AND APPROPRIATION ACTS.—

"(A) IN GENERAL.—The fees authorized by this section—

"(i) shall be retained in each fiscal year in an amount not to exceed the amount specified";

(C) by moving clause (ii) (as so redesignated) two ems to the right; and

(D) by adding at the end the following subparagraph:

"(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of human drug applications—

"(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

"(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

"(II) such costs are not more than 5 percent below the level specified in such subparagraph.".

(3) AUTHORIZATION OF APPROPRIATIONS.—Section 736(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(g)(3)) is amended by striking subparagraphs (A) through (E) and inserting the following:

"(A) $222,900,000 for fiscal year 2003;

"(B) $231,000,000 for fiscal year 2004;

"(C) $252,000,000 for fiscal year 2005;

"(D) $259,300,000 for fiscal year 2006; and

"(E) $259,300,000 for fiscal year 2007;". Effective dates.

SEC. 505. ACCOUNTABILITY AND REPORTS. Deadlines. 21 USC 379g note.

(a) PUBLIC ACCOUNTABILITY.—

(1) CONSULTATION.—In developing recommendations to the Congress for the goals and plans for meeting the goals for the process for the review of human drug applications for the fiscal years after fiscal year 2007, and for the reauthorization of sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall consult with the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry.

(2) RECOMMENDATIONS.—The Secretary shall publish in the Federal Register recommendations under paragraph (1), after negotiations with the regulated industry; shall present such recommendations to the congressional committees specified in such paragraph; shall hold a meeting at which the public may present its views on such recommendations; and shall provide Federal Register, publication.

for a period of 30 days for the public to provide written comments on such recommendations.

(b) PERFORMANCE REPORT.—Beginning with fiscal year 2003, not later than 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the President, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 502(4) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(c) FISCAL REPORT.—Beginning with fiscal year 2003, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (b), the Secretary of Health and Human Services shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

SEC. 506. REPORTS OF POSTMARKETING STUDIES.

Section 506B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356b) is amended by adding at the end the following subsections:

"(d) DISCLOSURE.—If a sponsor fails to complete an agreed upon study required by this section by its original or otherwise negotiated deadline, the Secretary shall publish a statement on the Internet site of the Food and Drug Administration stating that the study was not completed and, if the reasons for such failure to complete the study were not satisfactory to the Secretary, a statement that such reasons were not satisfactory to the Secretary.

"(e) NOTIFICATION.—With respect to studies of the type required under section 506(b)(2)(A) or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as each of such sections was in effect on the day before the effective date of this subsection, the Secretary may require that a sponsor who, for reasons not satisfactory to the Secretary, fails to complete by its deadline a study under any of such sections of such type for a drug or biological product (including such a study conducted after such effective date) notify practitioners who prescribe such drug or biological product of the failure to complete such study and the questions of clinical benefit, and, where appropriate, questions of safety, that remain unanswered as a result of the failure to complete such study. Nothing in this subsection shall be construed as altering the requirements of the types of studies required under section 506(b)(2)(A) or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as so in effect, or as prohibiting the Secretary from modifying such sections of title 21 of such Code to provide for studies in addition to those of such type.".

21 USC 379g note.

SEC. 507. SAVINGS CLAUSE.

Notwithstanding section 107 of the Food and Drug Administration Modernization Act of 1997, and notwithstanding the amendments made by this subtitle, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this Act, continues to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that, on or after October 1, 1997, but before October 1, 2002, were accepted by the Food and Drug Administration for filing and with respect to assessing and collecting any fee required by such Act for a fiscal year prior to fiscal year 2003.

21 USC 356b note.

SEC. 508. EFFECTIVE DATE.

The amendments made by this subtitle shall take effect October 1, 2002.

21 USC 379g note.

SEC. 509. SUNSET CLAUSE.

The amendments made by sections 503 and 504 cease to be effective October 1, 2007, and section 505 ceases to be effective 120 days after such date.

Subtitle B—Funding Provisions Regarding Food and Drug Administration

SEC. 521. OFFICE OF DRUG SAFETY.

Of the amounts appropriated for the Food and Drug Administration for a fiscal year, the Secretary of Health and Human Services shall reserve for the Office of Drug Safety (within such Administration), the following amounts:

(1) For fiscal year 2003, an amount equal to the sum of $5,000,000 and the amount made available under appropriations Acts for such Office for fiscal year 2002.

(2) For fiscal year 2004, an amount equal to the sum of $10,000,000 and the amount made available under appropriations Acts for such Office for fiscal year 2002.

(3) For each subsequent fiscal year, an amount equal to the sum of the amount made available under appropriations Acts for such Office for fiscal year 2004 and an amount sufficient to offset the effects of inflation occurring after the beginning of fiscal year 2004.

Appropriation authorization.

SEC. 522. DIVISION OF DRUG MARKETING, ADVERTISING, AND COMMUNICATIONS.

For the Division of Drug Marketing, Advertising, and Communications (within the Office of Medical Policy, Food and Drug Administration), there are authorized to be appropriated the following amounts, stated as increases above the amount made available under appropriations Acts for such Division for fiscal year 2002:

(1) For fiscal year 2003, an increase of $2,500,000.
(2) For fiscal year 2004, an increase of $4,000,000.
(3) For fiscal year 2005, an increase of $5,500,000.
(4) For fiscal year 2006, an increase of $7,500,000.
(5) For fiscal year 2007, an increase of $7,500,000.

SEC. 523. OFFICE OF GENERIC DRUGS.

Appropriation authorization.

For the Office of Generic Drugs (within the Food and Drug Administration), there are authorized to be appropriated the following amounts, stated as increases above the amount made available under appropriations Acts for such Office for fiscal year 2002:

(1) For fiscal year 2003, an increase of $3,000,000.
(2) For fiscal year 2004, an increase of $6,000,000.
(3) For fiscal year 2005, an increase of $9,000,000.
(4) For fiscal year 2006, an increase of $12,000,000.
(5) For fiscal year 2007, an increase of $15,000,000.

Subtitle C—Additional Provisions

SEC. 531. TRANSITION TO DIGITAL TELEVISION.

47 USC 336 note.

Deadline.

(a) PAIR ASSIGNMENT REQUIRED.—In order to further promote the orderly transition to digital television, and to promote the equitable allocation and use of digital channels by television broadcast permittees and licensees, the Federal Communications Commission, at the request of an eligible licensee or permittee, shall, within 90 days after the date of enactment of this Act, allot, if necessary, and assign a paired digital television channel to that licensee or permittee, provided that—

(1) such channel can be allotted and assigned without further modification of the tables of allotments as set forth in sections 73.606 and 73.622 of the Commission's regulations (47 CFR 73.606, 73.622); and

(2) such allotment and assignment is otherwise consistent with the Commission's rules (47 CFR part 73).

(b) ELIGIBLE TRANSITION LICENSEE OR PERMITTEE.—For purposes of subsection (a), the term "eligible licensee or permittee" means only a full power television broadcast licensee or permittee (or its successor in interest) that—

(1) had an application pending for an analog television station construction permit as of October 24, 1991, which application was granted after April 3, 1997; and

(2) as of the date of enactment of this Act, is the permittee or licensee of that station.

(c) REQUIREMENTS ON LICENSEE OR PERMITTEE.—

(1) CONSTRUCTION DEADLINE.—Any licensee or permittee receiving a paired digital channel pursuant to this section—

(A) shall be required to construct the digital television broadcast facility within 18 months of the date on which the Federal Communications Commission issues a construction permit therefore, and

(B) shall be prohibited from obtaining or receiving an extension of time from the Commission beyond the construction deadline established by paragraph (1).

(2) PROHIBITION OF ANALOG OPERATION USING DIGITAL PAIR.—Any licensee or permittee receiving a paired digital channel pursuant to this section shall be prohibited from giving up its current paired analog assignment and becoming a single-channel broadcaster and operating in analog on such paired digital channel.

(d) RELIEF RESTRICTED.—Any paired digital allotment and assignment made under this section shall not be available to any other applicant unless such applicant is an eligible licensee or permittee within the meaning of subsection (b).

SEC. 532. 3-YEAR DELAY IN LOCK IN PROCEDURES FOR MEDICARE+CHOICE PLANS; CHANGE IN CERTAIN MEDICARE+CHOICE DEADLINES AND ANNUAL, COORDINATED ELECTION PERIOD FOR 2003, 2004, AND 2005.

(a) LOCK-IN DELAY.—Section 1851(e) of the Social Security Act (42 U.S.C. 1395w–21(e)) is amended—

(1) in paragraph (2)(A), by striking "THROUGH 2001" and "during 1998, 1999, 2000, and 2001" and inserting "THROUGH 2004" and "during the period beginning January 1, 1998, and ending on December 31, 2004", respectively;

(2) in the heading to paragraph (2)(B), by striking "DURING 2002" and inserting "DURING 2005";

(3) in paragraphs (2)(B)(i) and (2)(C)(i), by striking "2002" and inserting "2005" each place it appears;

(4) in paragraph (2)(D), by striking "2001" and inserting "2004"; and

(5) in paragraph (4), by striking "2002" and inserting "2005" each place it appears.

(b) CHANGE IN REPORTING DEADLINE.—

(1) IN GENERAL.—Section 1854(a)(1) of such Act (42 U.S.C. 1395w–24(a)(1)) is amended by striking "Not later than July 1 of each year" and inserting "Not later than the second Monday in September of 2002, 2003, and 2004 (or July 1 of each other year)".

Applicability. 42 USC 1395w–24 note.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to information submitted for years beginning with 2003.

(c) DELAY IN ANNUAL, COORDINATED ELECTION PERIOD.—

(1) IN GENERAL.—Section 1851(e) of such Act (42 U.S.C. 1395w–21(e)) is amended—

(A) in paragraph (3)(B), by striking "means" and all that follows and inserting the following: "means, with respect to a year before 2003 and after 2005, the month of November before such year and with respect to 2003, 2004, and 2005, the period beginning on November 15 and ending on December 31 of the year before such year."; and

(B) in paragraph (6)(A), by striking "each subsequent year (as provided in paragraph (3))" and inserting "during the annual, coordinated election period under paragraph (3) for each subsequent year".

Applicability. 42 USC 1395w–21 note.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to the annual, coordinated election period for years beginning with 2003.

(d) CHANGE TO ANNUAL ANNOUNCEMENT OF PAYMENT RATES.—

(1) IN GENERAL.—Section 1853(b)(1) of such Act (42 U.S.C. 1395w–23(b)(1)) is amended by striking "not later than March 1 before the calendar year concerned" and inserting "for years before 2004 and after 2005 not later than March 1 before the calendar year concerned and for 2004 and 2005 not later than the second Monday in May before the respective calendar year".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall first apply to announcements for years after 2003. Applicability. 42 USC 1395w–23 note.

Approved June 12, 2002.

LEGISLATIVE HISTORY—H.R. 3448:

HOUSE REPORTS: No. 107–481 (Comm. of Conference).
CONGRESSIONAL RECORD:
Vol. 147 (2001): Dec. 11, 12, considered and passed House.
Dec. 20, considered and passed Senate, amended.
Vol. 148 (2002): May 22, House agreed to conference report.
May 23, Senate agreed to conference report.
WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 38 (2002):
June 12, Presidential remarks.

○

参考資料 3 FDA: "FDA Actions on New Bioterrorism Legislation"

・New Rule on Establishment and Maintenance of Records

Final Rule: Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 December 9, 2004

Fact Sheet: FDA's New Food Bioterrorism Regulation: Establishment and Maintenance of Records Revised November 2005

・New Rule on Administrative Detention

Final Rule: Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 June 4, 2004

Fact Sheet: FDA's New Food Bioterrorism Regulation Final Rule: Administrative Detention May 27, 2004

・New Rules on Registration and Prior Notice

・Registration of Food Facilities

Fact Sheet: FDA's New Food Bioterrorism Regulation: Interim Final Rule -- Registration of Food Facilities October 2003

Final Rule: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 October 3, 2005

・Prior Notice of Imported Food Shipments

Fact Sheet: FDA's New Food Bioterrorism Regulation: Interim Final Rule - Prior Notice of Imported Food Shipments October 2003

Interim Final Rule: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 October 10, 2003

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November 2005: Revised Registration Compliance Information
November 2005: Revised Compliance Policy Guide, Prior Notice of Imported Foods
November 2005: Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records (Edition 2)
November 2005: Guidance for Industry and FDA Staff: Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

New Rule on Establishment and Maintenance of Records

- *Press Release:* FDA Issues Final Rule on the Establishment and Maintenance of Records to Enhance the Security of the U.S. Food Supply Under the Bioterrorism Act December 6, 2004
  FDA also issues draft guidance regarding records access
- *Final Rule:* Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 December 9, 2004
  - *Correction* to the Final Rule February 23, 2005
- *Booklet (SECG):* What You Need to Know About Establishment and Maintenance of Records December 2004 (also available in French and Spanish)
- *Fact Sheet:* FDA's New Food Bioterrorism Regulation: Establishment and Maintenance of Records Revised November 2005
- *Guidance for Industry:* Questions and Answers Regarding Establishment and Maintenance of Records (Edition 2) November 10, 2005
  (Federal Register Notice of Availability November 22, 2005)
- *Guidance for Industry and FDA Staff:* Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 November 2005
- *Domestic Outreach Grassroot Meetings (June 2005)* FDA Updates: "Ensuring Compliance With the New Rule for Establishment and Maintenance of Records Implementing Section 306 of the Bioterrorism Act" May 2005
  - *Public Meetings:* Federal Register notice May 13, 2005
  - Meeting Agenda
  - *Slide Presentation:* Overview of Bioterrorism Act's Establishment and Maintenance of Records Final Rule June 2005
  - *Transcript* of June 9, 2005 meeting in College Park
- *Domestic Outreach Grassroot Meetings (January & February 2005)* Proposed Schedule for BT Final Rules: "What You Need to Know to Assure Compliance with the New FDA BT Final Regulation for Establishment and Maintenance of Records Final Rule that Implements Section - 306 of the Bioterrorism Act" December 6, 2004
  - *Public Meetings:* Federal Register notice December 9, 2004
  - Meeting Agenda
    - *Video* of January 13, 2005 meeting in College Park (requires Quicktime)
    - *Transcript* of Meeting (also available in French and Spanish)
    - *Slide Presentation:* Overview of Bioterrorism Act Establishment and Maintenance of Records Final Rule January 13, 2005 (also available in French and Spanish)

New Rule on Administrative Detention

- *Press Release:* FDA Finalizes Rule on Administrative Detention of Suspect Food; Final Rule Increases Security and Safety of U.S. Food Supply May 27, 2004
- *Final Rule:* Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 June 4, 2004
- *Booklet:* What You Need to Know About Administrative Detention of Foods November 2004
- *Fact Sheet:* FDA's New Food Bioterrorism Regulation Final Rule: Administrative Detention May 27, 2004
- *"Dear Colleague" Letter* on Administrative Detention Final Rule May 27, 2004

New Rules on Registration and Prior Notice

- HHS Issues New Rules to Enhance Security of the U.S. Food Supply October 9, 2003

Some of the documents below are also available in Arabic, Chinese, French, Hindi, Japanese, Korean, Malay, Polish, Portuguese, Russian, Spanish, and Thai as noted.

Registration of Food Facilities

- *Compliance Policy Guide:* Guidance for FDA Staff November 2004
  (Federal Register Notice of Availability November 9, 2004)
- *Compliance Information:* Registration November 17, 2005
- *Fact Sheet:* FDA's New Food Bioterrorism Regulation: Interim Final Rule -- Registration of Food Facilities October 2003
  (also available in French, Malay, Polish, Portuguese, Spanish, Arabic (PDF*), Chinese (PDF*), Hindi (PDF*), and Japanese (PDF*))
- *Booklet (SECG):* What You Need to Know About Registration of Food Facilities November 2003 (also available in French and Spanish)
  (Federal Register Notice of Availability December 12, 2003)
- *Final Rule:* Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 October 3, 2005
- *Slide Presentation:* Overview of Registration Interim Final Rule Implementing the Bioterrorism Act October 15, 2003
  (also available in Arabic, French, Malay, and Spanish)
- *Guidance for Industry:* Necessity of the Use of Food Product Categories in Registration of Food Facilities July 2003
- *Guidance for Industry:* Questions and Answers Regarding Registration of Food Facilities *(Edition 4)* August 6, 2004
  (Federal Register Notice of Availability August 6, 2004)
- *Press Release:* FDA Introduces New Technology to Improve Food Security: Electronic Food Facility Registration Goes "Live" October 16, 2003
- **How To Register**
  - *Electronic* Registration via the Internet October 16, 2003
    - Electronic Registration Index of Help Files and Tutorials
  - *New Features* in the Food Facility Registration Module (FFRM) March 27, 2004
  - *Mail or Fax:* Registering by Paper or CD-ROM (and download forms) October 16, 2003
    (also available in Spanish)
  - *Verification:* Registration of Food Facility Database