SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Food and Drug Administration Globalization Act of 2008''.

(b) REFERENCES TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—FOOD SAFETY

Subtitle A—Prevention

SEC. 101. CHANGES IN REGISTRATION OF FOOD FACILITIES.

(a) PROHIBITED ACTS.—Subsection (p) of section 301 (21 U.S.C. 331) is amended by inserting ''or section 415, or to pay a registration fee in accordance with section 741'' after ''the failure to register under section 510''.

(b) ANNUAL REGISTRATION AND PAYMENT OF REGISTRATION FEE.—

(1) IN GENERAL.—Section 415(a) (21 U.S.C. 350d(a)) is amended—

(A) in the first sentence of paragraph (1), by inserting ''annually'' after ''be registered'';

(B) in paragraph (1), by inserting ''and pay the registration fee required under section 741'' after ''submit a registration to the Secretary'' each place it appears in subparagraphs (A) and (B); and

(C) in paragraph (4), by inserting after the first sentence the following: ''The Secretary shall remove from such list the name of any facility that fails to reregister in accordance with this section and shall treat such removal as a suspension of the facility's registration.''.

(2) REGISTRATION FEE.—Chapter VII (21 U.S.C. 371 et seq.) is amended—

(A) by redesignating sections 741 and 742 as sections 744 and 745, respectively; and

(B) by adding at the end of subchapter C the following:

"PART 3—FEES RELATING TO FOOD

"SEC. 741. FACILITY REGISTRATION FEE.

''(a) IN GENERAL.—The Secretary shall assess and collect a fee for a facility registration under section 415 for food safety activities under this Act.

''(b) AMOUNT OF FEE.—

''(1) IN GENERAL.—Subject to paragraph (2), the amount of the fee under this section shall be $2,000 for the initial registration and each reregistration under section 415 of each facility operated by the registrant.

''(2) ANNUAL INCREASE.—

''(A) IN GENERAL.—Subject to the limitation specified in subparagraph (B), the amount of the fee under this section for registrations and re-registrations for a fiscal year after 2009 shall be the amount of such fee under this section for the previous fiscal year increased by the same percentage as the percentage inflation ad-

justment described in section 736(c)(1) for the fiscal year.

''(B) LIMITATION.—An increase in the amount of the fee under this paragraph shall not be made under this section for any fiscal year unless—

''(i) the amount appropriated for salaries and expenses of the Center for Food Safety and Applied Nutrition within Food and Drug Administration for such fiscal year is equal to or greater than the amount appropriated for salaries and expenses of such Center for fiscal year 2008 multiplied by the adjustment factor applicable to the fiscal year involved under section 736(c); and

''(ii) the amount appropriated for salaries and expenses of the Food and Drug Administration for such fiscal year is equal to or greater than the amount appropriated for salaries and expenses of such Administration for fiscal year 2008 multiplied by the adjustment factor applicable to the fiscal year involved under section 736(c); and, except that in making deter-

minations under this subparagraph for the fiscal year involved there shall be excluded the amounts of fees collected under this part, section 736, section 738, and section 740.

In applying clauses (i) and (ii) there shall not be taken into account salaries or expenses that are paid from fees, including those collected under subsection (a), section 736, 738, 740, 741B, and 741D.''.

(c) CONTENTS OF REGISTRATION.—Paragraph (2) of section 415(a) (21 U.S.C. 350d(a)) is amended by striking ''containing information'' and all that follows and inserting the following: ''containing information that identifies the following:

''(A) The name, address, and emergency contact information of each facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States that the registrant operates.

''(B) The primary purpose and business activity of each such facility, including the dates of operation if the facility is seasonal.

''(C) The general food category (as listed under section 170.3(n) of title 21, Code of Fed-

eral Regulations, or as the Secretary may otherwise designate for purposes of evaluating potential threats to food protection) of any food manufactured, processed, packed, or held at each such facility.

''(D) All trade names under which each such facility conducts business related to food.

''(E) The name, address, and 24-hour emergency contact information of the United States distribution agent for each such facility, which agent shall maintain information on the wholesale and retail distribution of food.

Such registration shall also include an assurance that the registrant will notify the Secretary of any change in the products, function, or legal status of each such facility (including cessation of business activities) not later than 30 days after the date of such change.''.

(d) SUSPENSION AUTHORITY.—Such section is further amended by adding at the end the following:

''(6) SUSPENSION OF REGISTRATION.—

''(A) IN GENERAL.—The Secretary may suspend the registration of any facility registered under this section, including the facility of an importer—

"(i) for violation of this Act that could result in serious adverse health consequences or death to humans or animals; or

"(ii) if the facility, or employee of the facility, delays, limits, or denies an inspection by the Secretary under this Act.

"(B) NOTICE AND OPPORTUNITY FOR HEARING.—Before suspending the registration of a facility under this paragraph, the Secretary shall provide notice to a registrant of an intent to suspend the registration and provide the registrant with an opportunity for an informal hearing. The Secretary may issue a written order of suspension following the hearing, if the Secretary finds that a violation described in subparagraph (A) has occurred.

"(C) REINSTATEMENT.—A registration that is suspended under this section may be reinstated pursuant to criteria published by the Secretary in the Federal Register and on a public website of the Food and Drug Administration.

"(D) APPEAL.—Any registrant whose registration is suspended under this section may

appeal that action in any appropriate district court of the United States.''.

(e) EFFECTIVE DATE.—

(1) MODIFICATION OF REGISTRATION FORM.—Not later than 30 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall modify the registration form under section 415 of the Federal Food, Drug, and Cosmetic Act to comply with the amendments made by subsection (c).

(2) APPLICATION.—The amendments made by this section, other than by subsection (c), shall take effect on the date that is 30 days after the date on which such modified registration form takes effect, but not later than 60 days after the date of the enactment of this Act.

SEC. 102. FOOD SAFETY PLAN; PROCESS CONTROLS; AND PERFORMANCE STANDARDS.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

''SEC. 418. FOOD SAFETY PLAN; PROCESS CONTROLS; AND PERFORMANCE STANDARDS.

''(a) IMPLEMENTATION OF FOOD SAFETY PLAN.—

''(1) IN GENERAL.—Before a facility (as defined in section 415(b)) introduces or delivers for in-

troduction into interstate commerce any shipment of food, the owner, operator, or agent in charge of the facility shall develop and implement a written food safety plan (in this section referred to as a 'food safety plan') that is based on an analysis of—

"(A) the specific practices for—

"(i) obtaining and ensuring the safety of raw materials and ingredients for food produced, manufactured, processed, packed, or held at a facility;

"(ii) producing, manufacturing, processing, packing, and holding food at the facility; and

"(iii) transporting food to and from the facility; and

"(B) any hazard that has been present in or on, or is reasonably likely to be present in or on, any food that is manufactured, processed, packed, or held at the facility.

"(2) CONTENTS.—The food safety plan shall include each of the following elements:

"(A) A description of the preventive controls being implemented that are reasonably appropriate to control or limit identified hazards and to comply with applicable hazard-specific

performance standards and other food safety regulatory requirements.

"(B) Validation that such preventive controls are effective to reduce, control, or eliminate such hazard.

"(C) A description of monitoring of such preventive controls being implemented, including sampling and testing relating to the control of hazards where appropriate to verify that the controls are effective.

"(D) A description of the recordkeeping being conducted, including evidence of corrective actions, sampling and testing records, monitoring and verification records, and validation records.

"(E) A description of established procedures for the recall of such articles of food, whether voluntarily or when required under section 423.

"(b) FOOD SAFETY PLAN REVISIONS.—

"(1) IN GENERAL.—The food safety plan shall be revised—

"(A) when major changes have been made by the owner facility; and

''(B) as deemed appropriate by the Secretary.

''(2) INCLUSION OF SPECIFIC HAZARD CONTROLS.—The Secretary may require that a food safety plan for a facility include specific hazard controls, if such controls are needed to ensure the protection of the public health including to prevent intentional adulteration of food.

''(c) INSPECTION OF FOOD SAFETY PLAN IN COURSE OF FACILITY INSPECTION.—In the course of a facility inspection under section 704A, the Secretary shall conduct a review of the food safety plan to ensure the plan—

''(1) is based on a thorough hazard analysis and is adequate to protect the public health;

''(2) meets relevant regulatory and food safety standards; and

''(3) limits the presence and growth of contaminants in food prepared in a facility to meet performance standards of subsection (d).

''(d) PERFORMANCE STANDARDS.—

''(1) IN GENERAL.—To protect the public health, the Secretary may establish by regulation and enforce performance standards that define, with respect to specific foods and contaminants in food,

the level of food safety performance that a facility shall meet.

''(2) CONSULTATION.—In establishing performance standards under this subsection, the Secretary shall consult with the Centers for Disease Control and Prevention and infectious disease experts outside the federal government, and hold public meetings for the purpose of receiving public input and comment.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to food shipments introduced or delivered for introduction into interstate commerce on and after the date that is 2 years after the date of the enactment of this Act.

SEC. 103. SAFETY STANDARDS FOR FRESH PRODUCE.

Chapter IV (21 U.S.C. 341 et seq.), as amended by section 102(a), is further amended by adding at the end the following:

''SEC. 419. SAFETY STANDARDS FOR FRESH PRODUCE.

''(a) IN GENERAL.—Section 418 (relating to food safety plan; process controls; and performance standards) shall apply with respect to the production of a type of fresh produce for consumption in the United States 1 year after the date on which the Secretary by regulation de-

scribes how a producer of such type of fresh produce may comply with such section.

''(b) LOCAL GROWING CONDITIONS.—The Secretary shall assist a State or foreign country in identifying how, considering local growing conditions, producers in such State or foreign country may comply with section 418, as applied under subsection (a).

''(c) VARIANCES.—If the Secretary issues a regulation under subsection (a) with respect to the production of a type of fresh produce, the Secretary shall provide for a variance from such a regulation for producers in a State or foreign country if the State or foreign country determines, and the Secretary concurs, that the variance—

''(1) is necessary in light of local growing conditions; and

''(2) will be at least as effective in controlling hazards as if the variance had not been provided.

''(d) FRESH PRODUCE DEFINED.—In this section, the term 'fresh produce' means any fruit or vegetable that is intended to be sold to the consumer—

''(1) in its unpeeled, natural form; or

''(2) with minimal processing (such as peeling, chopping, or trimming).''.

SEC. 104. PERIODIC INSPECTIONS OF FOOD FACILITIES.

(a) IN GENERAL.—Chapter VII is amended by adding after section 704 the following:

"SEC. 704A. PERIODIC INSPECTIONS OF FOOD FACILITIES.

"(a) NATURE OF INSPECTIONS.—

"(1) IN GENERAL.—The Secretary shall provide for an inspection system for the conduct of unannounced inspections of facilities (as defined in section 415(b)) to determine whether such facilities are operating in compliance with this Act and with good manufacturing practices, including the requirements of section 419. Inspections shall include review of records and sampling of food products.

"(2) TIMING OF INSPECTIONS.—

"(A) IN GENERAL.—Subject to subparagraph (B), inspections of facilities shall be conducted every 4 years.

"(B) NONCERTIFIED FACILITIES.—Inspections of facilities that are not certified under section 418 shall be conducted every 2 years.

"(3) SANCTION FOR INTERFERENCE WITH INSPECTIONS.—If a facility or employee of a facility delays, limits, or denies an inspection of the facility under this section, the Secretary shall make a determination that may result in the facility losing its registration under section 415.

''(b) CONDUCT OF INSPECTIONS.—

''(1) SCOPE.—An inspection under subsection (a) of any facility shall extend to all things therein that bear on whether food products are in compliance with this Act. Access to records may include the copying of such records.

''(2) AUTHORITY.—In conducting such inspections, officers or employees duly designated by the Secretary, upon presenting appropriate credentials to the owner, operator, or agent in charge, are authorized—

''(A) to enter at reasonable times any facility in or to enter any vehicle being used to transport or hold such food products;

''(B) to inspect in a reasonable manner such facility or vehicle and all pertinent equipment, finished and unfinished materials, containers, labeling, processes, controls, and premises;

''(C) to collect and retain samples of food products or ingredients or of any other items found during an inspection that may contribute to a finding of whether such food products are unsafe for human consumption or adulterated or misbranded under this Act;

''(D) to review food safety plan established under section 418; and

''(E) may take photographs and such photographs shall be treated as documents subject to section 301(j).

''(3) WRITTEN REPORT.—Within 24 hours after completion of inspection, the Secretary or certifying agent making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed which indicate that either processing controls are inadequate to prevent or minimize food safety hazards or that any food from such facility is unsafe for human consumption, or adulterated or misbranded under this Act.

''(c) PRODUCT DETENTION AND CONDEMNATION.—

''(1) ORDERS.—If, during an inspection conducted under this section, the Secretary or certifying agent has reason to believe that a food product is unsafe for human or animal consumption, or adulterated or misbranded under this Act, the Secretary may order the food product segregated, impounded, and if objection is not made within 48 hours, condemned. If objection is made, such food products that are in perishable form may be processed to the

extent necessary to prevent spoilage, and a hearing shall be commenced expeditiously.

''(2) RELABELING.—If the Secretary determines that, through re-labeling or other action, such food products can be brought into compliance with this Act , the food may be released following a determination by the Secretary that such re-labeling or other action as specified by the Secretary has been performed.

''(3) DESTRUCTION OF CONDEMNED FOOD.—Any food product condemned without objection, or after an informal hearing, shall be destroyed under supervision of the Secretary.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 415(a) (21 U.S.C. 350d(a)), as amended by section 101(b), is amended by adding at the end the following:

''(7) INSPECTION.—Every facility that is registered under this section shall be subject to inspection pursuant to section 704A.''.

(2) OTHER INSPECTION RIGHTS AND DUTIES.—Section 704 (21 U.S.C. 374) is amended by adding at the end the following new subsection:

''(h) The rights and duties under this section of duly designated officers and employees and of other persons

shall apply to the exercise of authority under section 704A.''.

SEC. 105. REINSPECTION FEE APPLICABLE TO FACILITIES.

(a) IN GENERAL.—Part 3 of chapter VII (21 U.S.C. 371 et seq.), as added by section 101(b)(2), is further amended by adding at the end the following:

''SEC. 741A. REINSPECTION FEE APPLICABLE TO FACILITIES.

''(a) IN GENERAL.—The Secretary shall assess and collect fees from each facility (as defined in section 415(b)) that—

''(1) during such fiscal year, commits a violation of any requirement of this Act relating to food, including any such requirement relating to good manufacturing practices; and

''(2) because of such violation, undergoes additional inspection by the Food and Drug Administration.

''(b) AMOUNT OF FEES.—The Secretary shall set the amount of the fees under this section to fully defray the costs of conducting the additional inspections referred to in subsection (a)(2).

''(c) USE OF FEES.—The Secretary shall make all of the fees collected pursuant to this section available sole-

ly to pay for the costs of additional inspections referred to in subsection (a)(2).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to additional inspections occurring after the date of the enactment of this Act.

SEC. 106. FOOD FACILITY CERTIFICATION PROGRAM.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.), as amended by sections 102(a) and 103, is amended by adding at the end the following:

''SEC. 420. FOOD FACILITY CERTIFICATION PROGRAM.

''(a) IN GENERAL.—

''(1) CERTIFICATION.—The Secretary shall establish a program for the certification of a facility as being in compliance with the applicable requirements of this Act. Such program shall provide for—

''(A) direct certification by the Secretary; or

''(B) certification by a certifying agent that has been accredited under subsection (b).

''(2) VOLUNTARY CERTIFICATION.—Any facility may apply to be certified to the Secretary under this section.

''(3) FACILITY DEFINED.—For purposes of this section, the term 'facility' has the meaning given

such term in section 415(b), and includes both foreign and domestic facilities.

''(4) CERTIFIED FACILITY DEFINED.—For purposes of this chapter, the term 'certified facility' means a facility that has been certified under the program established under this subsection.

''(b) LISTING AND NOTICES.—

''(1) PUBLIC LISTING OF CERTIFIED FACILITIES.—The Secretary shall make available to the public through the Internet Web Site of the Food and Drug Administration a list of each facility that is certified under this section and the date on which such certification will no longer be in effect.

''(2) DURATION OF CERTIFICATION.—The certification for a facility under this section shall be in effect for 2 years from the date the Secretary or certifying agent approves the application for such certification of the facility.

''(3) REQUIRED INSPECTION.—No facility shall be certified without having been inspected by the Secretary or a certifying agent.

''(4) NOTICES OF VIOLATIONS.—

''(A) IN GENERAL.—If a certifying agent in the process of inspecting a facility for certification determines that the facility's food safety

plan is in violation of this Act and that the facility has failed to take corrective action within 30 days, the agent shall notify the Secretary of such violation and such failure.

''(B) IMMEDIATE NOTICE.—A certifying agent shall notify the Secretary immediately during inspection of a facility if the food at the facility appears to be unsafe for human or animal consumption or adulterated or misbranded

''(5) SUSPENSION OF CERTIFICATION.—The Secretary may suspend the certification of a facility under this section if, after opportunity for an informal hearing, the Secretary finds that—

''(A) the food safety plan of the facility fails to comply with requirements of section 418; or

''(B) the facility is found on inspection not to be in compliance with other applicable requirements of this Act.

''(c) ACCREDITATION OF FOREIGN GOVERNMENTS AND CERTIFYING AGENTS.—

''(1) IN GENERAL.—Beginning not later than 2 years after the date of enactment of this section, the Secretary shall establish and implement an accreditation system under which a foreign government, a

State or regional food authority, a foreign or domestic cooperative that aggregates the products of growers or processors, or any other third party that the Secretary determines appropriate, may request permission to certify that facilities meet the applicable requirements of this Act.

''(2) REQUEST BY FOREIGN GOVERNMENT.—Prior to accrediting a foreign government as a certifying agent under this paragraph (1)(A), the Secretary shall perform such reviews and audits of food safety programs, systems, and standards of the government (including all statutes, regulations, and inspection authority) as the Secretary deems necessary to determine that they are adequate to ensure that facilities certified by such government meet the requirements of this Act with respect to food manufactured, processed, packed, or held for import to the United States.

''(3) REQUEST BY OTHER THIRD PARTY.—Prior to accrediting a third party under paragraph (1)(B), the Secretary shall perform such reviews and audits of the training and qualifications of inspectors used by the agent and conduct such reviews of internal systems and such other investigation of the party as the Secretary deems necessary to determine that

each facility certified by the party has systems and standards in use to ensure that such facility meets the requirements of this Act.

''(d) IMPORTATION.—As condition of accrediting such government or certifying agent, the government or certifying agent shall agree to issue a written and electronic certification to accompany each food shipment made for import from a facility certified by such government or certifying agent, subject to requirements set forth by the Secretary.

''(e) MONITORING.—Following any accreditation of a certifying agent under subsection (b), the Secretary may at any time—

''(1) conduct an on-site audit of any facility certified by the agent, with or without the certifying agent present; or

''(2) require the agent to submit to the Secretary, for any facility certified by the agent, an on-site inspection report and such other reports or documents the agent requires as part of the audit process, including for a facility located outside the United States documentation that the facility is in compliance with registration requirements and prior notice requirements for food imported to the United States.

''(f) DEFINITIONS.—For purposes of this section:

''(1) CERTIFYING AGENT.—The term 'certifying agent' means a foreign government or other third party that conducts certification of facilities.

''(2) INSPECTOR.—The term 'inspector' means a person who has completed training as required by the Secretary in the conduct of food safety inspections.

''(g) LIMITATION.—

''(1) TO SPECIFIED FOOD PRODUCTS.—The Secretary may limit the accreditation of a foreign government or a third party under this section to the certification of facilities for the import to the United States only of specified food products (or specified categories of food products), as determined by the Secretary.

''(2) TO AVOID CONFLICTS OF INTEREST WITH CERTIFYING AGENTS.—The Secretary shall promulgate regulations to ensure that there are adequate protections against conflicts of interest between a certifying agent and the facility to be certified by such agent.

''(h) WITHDRAWAL OF ACCREDITATION.—The Secretary may withdraw accreditation from a certifying agent under subsection (b)—

''(1) if food from facilities certified by such agent is linked to an outbreak of human or animal illness;

''(2) following an investigation and finding by the Secretary that the agent no longer meet the requirements of subsection (b) for accreditation; or

''(3) following a refusal to allow United States officials to conduct such audits and investigations as may be necessary to ensure continued compliance with the requirements set forth in this section.

''(i) RENEWAL OF ACCREDITATION.—The Secretary shall audit accredited certifying agents whenever needed, but no less than once every three years, to ensure the continued compliance with the requirements set forth in this section. Renewal of accreditation shall occur following each satisfactory audit.''.

(b) FEE.—Part 3 of chapter VII, as added by section 101(b) and amended by section 105(a), is amended by adding at the end the following:

''SEC. 741B. CERTIFYING AGENT FEE.

''(a) IN GENERAL.—The Secretary shall assess and collect a fee for the accreditation of a foreign government or third party as a certifying agent under section 420 for the purpose of defraying the costs of the implementation

of the accreditation programs required to carry out such section.

''(b) AMOUNT OF FEE.—The amount of a fee under this section shall be as determined by the Secretary.''.

SEC. 107. TESTING OF FOOD SHIPMENTS; ACCREDITED LABORATORIES.

(a) PROHIBITED ACT.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(oo) The introduction or delivery for introduction into interstate commerce by facility that is not certified under section 420 of any shipment of food before arranging for sampling and testing of such shipment and submitting the results of such sampling and testing to the Secretary in accordance with section 421.''.

(b) TESTING OF FOOD SHIPMENTS; ACCREDITED LABORATORIES.—Chapter IV (21 U.S.C. 341 et seq.), amended by sections 102(a), 103, and 106(a), is further amended by adding at the end the following:

''SEC. 421. TESTING OF FOOD SHIPMENTS; ACCREDITED LABORATORIES.

''(a) TESTING IN NON-CERTIFIED FACILITIES.—Before introducing or delivering for introduction into interstate commerce any shipment of food, a facility (as defined in section 415(b)) that is engaged in manufacturing, processing, packaging, or holding such food and that is not

certified under section 420 with respect to such food shall arrange for a laboratory accredited under subsection (c)—

''(1) to conduct sampling and testing of such shipment to ensure compliance with applicable food safety standards; and

''(2) to simultaneously submit electronically the results of such sampling and testing to the Secretary and to the owner of such facility.

''(b) TESTING IN CERTIFIED FACILITIES.—A facility certified under section 420 that is engaged with manufacturing, processing, packaging, or holding food shall arrange for a laboratory accredited under subsection (c)—

''(1) to conduct, on a periodic basis specified by the Secretary, sampling and testing of shipments of food being introduced or delivered for introduction into interstate commerce to ensure compliance with applicable food safety standards; and

''(2) to submit electronically the results of such sampling and testing to the Secretary and to the owner of such facility.

''(c) ACCREDITATION OF LABORATORIES.—

''(1) IN GENERAL.—The Secretary shall accredit laboratories for the purpose of conducting sampling and testing under subsections (a) and (b).

''(2) STANDARDS.—Not later than 1 year after the date of the enactment of this section, the Secretary shall establish and publish in the Federal Register standards to accredit or deny accreditation to laboratories under this subsection. A laboratory shall not be accredited unless it has paid the accreditation fee required under section 741C.

''(3) AUDITS.—To ensure that laboratories accredited under this subsection continue to meet the standards of accreditation, the Secretary shall—

''(A) make onsite visits on an annual basis to each accredited laboratory to audit the performance of such laboratory; and

''(B) take such additional measures as the Secretary determines to be appropriate.''.

(c) ACCREDITATION FEE.—Part 3 of chapter VII, as added by section 101(b) and amended by sections 105(a) and 106(b), is amended by adding at the end the following:

''SEC. 741C. LABORATORY ACCREDITATION FEE.

''The Secretary shall assess and collect an annual fee, specified by the Secretary, for accreditation under section 421(c) for the purpose of defraying the costs of the accreditation activities under such section.''.

(d) EFFECTIVE DATE.—Sections 301(oo) and 421(a) of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b), shall apply to shipments of food introduced or delivered for introduction into interstate commerce on or after such date, not later than 3 years after the date of the enactment of this Act, as the Secretary of Health and Human Services shall specify.

SEC. 108. SAFE AND SECURE FOOD IMPORTATION PROGRAM.

Chapter VIII (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

"SEC. 805. SAFE AND SECURE FOOD IMPORTATION PROGRAM.

''(a) IN GENERAL.—Beginning not later than 2 years after the date of the enactment of this section, the Secretary shall establish by regulation and carry out a program under which the Secretary expedites the movement of food through the importation process under this Act if each facility involved in the production, manufacture, processing, packaging, and holding of the food—

''(1) is certified under section 420; and

''(2) has agreed to abide by, and has been determined by the Secretary to be in compliance with, the food safety and security guidelines developed under subsection (b) with respect to such food.

''(b) GUIDELINES.—

''(1) DEVELOPMENT.—For purposes of the program established under subsection (a), the Secretary shall develop safety and security guidelines applicable to the importation of food.

''(2) FACTORS.—Such guidelines shall take into account the following factors:

''(A) The personnel of the person importing the food.

''(B) The physical and procedural safety and security of such person's food supply chain.

''(C) The sufficiency of access controls for food and ingredients purchased by such person.

''(D) The need for tracking and maintaining records on food and ingredients purchased by such person or moved through the supply chain.

''(E) Documentation processing through such person's supply chain.

''(F) Access by the Secretary to such person's business records for review.

''(G) Vendor and supplier information.

''(H) Such other factors as the Secretary determines necessary.''.

Subtitle B—Intervention

SEC. 111. IMPORTS AND COMMERCIAL FOOD IMPORTATION THROUGH SPECIFIC PORTS OF ENTRY.

Chapter IV (21 U.S.C. 341 et seq.), as amended by sections 102(a), 103, 106(a), and 107(b), is further amended by adding at the end the following:

"SEC. 422. IMPORTS AND COMMERCIAL FOOD IMPORTATION THROUGH SPECIFIC PORTS OF ENTRY.

''Beginning on a date (not later than 5 years after the date of enactment of this section) specified by the Secretary, food shall only enter the United States, other than only for personal use, through a port of entry that is located in a metropolitan area with a federal laboratory, unless each facility (as defined in section 415(b)) that has manufactured, processed, packed, and held the food is certified under section 420.''.

SEC. 112. RESEARCH ON TESTING TECHNIQUES FOR USE IN INSPECTIONS OF IMPORTED FOOD SAFETY; PRIORITY REGARDING DETECTION OF INTENTIONAL ADULTERATION.

Section 801 (21 U.S.C. 381) is amended by adding at the end the following: ''

''(p) RESEARCH ON TESTING TECHNIQUES FOR USE IN INSPECTIONS OF IMPORTED FOOD SAFETY.—

"(1) IN GENERAL.—The Secretary shall (directly or through grants or contracts) provide for research on the development of tests and sampling methodologies, for use in inspections of food under this section—

"(A) whose purpose is to determine whether food is adulterated by reason of being contaminated with microorganisms, chemical toxins, or pesticide chemicals or related residues; and

"(B) whose results are available not later than approximately 60 minutes after the administration of the tests.

"(2) PRIORITY.—

"(A) IN GENERAL.—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, with the greatest priority given to the development of such tests that the Secretary determines would be useful in detecting the intentional adulteration of food.

"(B) SPECIFIC PRIORITIES.— In providing for such research, the Secretary shall give pri-

ority under this paragraph to conducting research on the development of tests and sampling methodology for detecting the presence in or on food of—

"(i) pathogens, including Escherichia coli (STEC) 0157, salmonella, cyclospora, cryptosporidium, hepatitis A, Clostridium botulinum, or listeria;

"(ii) pesticide chemicals and related residues;

"(iii) chemical toxins; and

"(iv) such other pathogens or substances as the Secretary determines to be appropriate, including any pathogen or substance that the Secretary determines is a candidate for use to intentionally adulterate food.

"(C) GOAL.—The Secretary shall establish the goal of developing, by the expiration of the 3-year period beginning on the date of the enactment of this subsection, tests and methodologies under paragraph (1) for each of the pathogens and substances receiving priority under this paragraph.

"(3) PERIODIC REPORTS.—

"(A) IN GENERAL.—The Secretary shall submit to the Congress periodic reports describing the progress that has been made toward the goal referred to in paragraph (1)(C) and describing plans for future research toward the goal.

"(B) CONTENTS.— Each of the reports shall provide an estimate by the Secretary of the amount of funds needed to meet such goal, and shall provide a determination by the Secretary of whether there is a need for further research under this subsection.

"(C) DEADLINES.— The first report under this paragraph shall be submitted not later than 2 years after the date of the enactment of this subsection. Subsequent reports shall be submitted annually until such goal is met.

"(4) CONSULTATION.—The Secretary shall carry out the program of research under paragraph (1) in consultation with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the Administrator of the Environmental Protection Agency. The Secretary shall with respect to such research coordinate the activities of the Department of Health and

Human Services. The Secretary shall in addition consult with the Secretary of Agriculture (acting through the Food Safety and Inspection Service of the Department of Agriculture) in carrying out the program.''.

SEC. 113. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED ARTICLES OF FOOD.

(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331), as amended by section 107(a), is amended by adding at the end the following:

''(pp)(1) The failure to notify the Secretary in violation of section 423(a).

''(2) The failure to comply with—

''(A) an order issued under section 423(b) following any hearing requested under section 423(c); or

''(B) an amended order issued under section 423(d)(1).''.

(b) NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED ARTICLES OF FOOD.—Chapter IV (21 U.S.C. 341 et seq.), as amended by sections 102(a), 103, 106(a), 107(b), and 111, is further amended by adding at the end the following:

"SEC. 423. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED ARTICLES OF FOOD.

''(a) NOTIFICATION TO SECRETARY OF VIOLATION.—

''(1) IN GENERAL.—A person (other than a household consumer or other individual who is the intended consumer of an article of food) that has reason to believe that an article of food when introduced into or while in interstate commerce, or while held for sale (regardless of whether the first sale) after shipment in interstate commerce, is adulterated or misbranded in a manner that, if consumed, may result in illness or injury shall, as soon as practicable, notify the Secretary of the identity and location of the article.

''(2) MANNER OF NOTIFICATION.—Notification under paragraph (1) shall be made in such manner and by such means as the Secretary may require by regulation.

''(b) RECALL AND CONSUMER NOTIFICATION.—

''(1) VOLUNTARY ACTIONS.—On receiving notification under subsection (a) or by other means of a suspected adulteration or misbranding of food, if the Secretary finds that an article of food when introduced into or while in interstate commerce, or while held for sale (regardless of whether the first

sale) after shipment in interstate commerce, is adulterated or misbranded in a manner that, if consumed, may result in illness or injury (as determined by the Secretary), the Secretary shall provide all appropriate persons (including the manufacturer, importer, distributor, or retailer of the article) with an opportunity (as determined by the Secretary)—

"(A) to cease distribution of the article;

"(B) to notify all persons—

"(i) that produce, manufacture, pack, process, prepare, treat, package, distribute, or hold the article, to cease immediately those activities with respect to the article; or

"(ii) to which the article has been distributed, transported, or sold, to cease immediately distribution of the article;

"(C) to recall the article;

"(D) in consultation with the Secretary, to provide notice of the finding of the Secretary to all consumers to which the article was, or may have been, distributed and to appropriate State and local health officials; and

"(E) to notify State and local public health officials.

''(2) MANDATORY ACTIONS.—If the appropriate person referred to in paragraph (1) does not carry out the actions described in that paragraph with respect to an article within the time period and in the manner prescribed by the Secretary, the Secretary—

''(A) shall issue an order requiring the person—

''(i) to immediately cease distribution of the article; and

''(ii) to immediately make the notification described in paragraph (1)(B); and

''(B) may take control or possession of the article.

''(3) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—The Secretary shall, as the Secretary determines to be necessary, provide notice of the finding of the Secretary under paragraph (1) to consumers to which the article was, or may have been, distributed and to appropriate State and local health officials.

''(c) HEARINGS ON ORDERS.—

''(1) IN GENERAL.—The Secretary shall provide a person subject to an order under subsection (b)(2) with an opportunity for a hearing on—

''(A) the actions required by the order; and

"(B) any reasons why the article of food that is the subject of the order should not be recalled.

"(2) TIMING OF HEARINGS.—If a hearing is requested under paragraph (1) with respect to an order, the Secretary shall hold the hearing as soon as practicable, but not later than 2 business days, after the date of issuance of the order.

"(d) POST-HEARING RECALL ORDERS.—

"(1) AMENDMENT OF ORDERS.—If, after providing an opportunity for a hearing (and a hearing if requested) under subsection (c), the Secretary determines that an article of food when introduced into or while in interstate commerce, or while held for sale (regardless of whether the first sale) after shipment in interstate commerce, is adulterated or misbranded in a manner that, if consumed, may result in illness or injury, the Secretary may, as the Secretary determines to be necessary—

"(A) amend the order under subsection (b)(2)—

"(i) to require recall of the article or other appropriate action; and

"(ii) to specify a timetable during which the recall shall occur;

''(B) require periodic reports to the Secretary describing the progress of any such recall; and

''(C) provide notice of such a recall to consumers to which the article was, or may have been, distributed.

''(2) VACATION OF ORDERS.—If, after providing an opportunity for a hearing (and a hearing if requested) under subsection (c), the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary shall vacate the order.

''(e) REMEDIES NOT EXCLUSIVE.—The remedies authorized by this section shall be in addition to any other remedies that may be available.''.

(c) EFFECTIVE DATE.—Sections 301(pp)(1) and 423(a) of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b), shall apply with respect to articles of food as of such date, not later than 1 year after the date of the enactment of this Act, as the Secretary of Health and Human Services shall specify.

Subtitle C—Response

SEC. 121. CIVIL PENALTIES RELATING TO FOOD.

(a) IN GENERAL.—Chapter III (21 U.S.C. 331 et seq.) is amended by adding after section 303 the following:

"SEC. 303A. CIVIL PENALTIES RELATING TO FOODS.

"(a) IN GENERAL.—

"(1) ASSESSMENT.—The Secretary may assess against a person that commits an act prohibited by section 301 with respect to an article of food a civil penalty for each such act of not more than—

"(A) $100,000, in the case of an individual; and

"(B) $500,000, in the case of any other person.

"(2) SEPARATE OFFENSES.—Each prohibited act described in paragraph (1) and each day during which the act continues shall be considered to be a separate offense.

"(3) NOTICE AND OPPORTUNITY FOR HEARING.—The Secretary shall not assess a civil penalty under this section against a person unless the person is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5, United States Code.

"(4) DETERMINATION OF CIVIL PENALTY AMOUNT.—The amount of a civil penalty under this section—

"(A) shall be assessed by the Secretary by written order, taking into account—

"(i) the gravity of the violation;

"(ii) the degree of culpability of the person;

"(iii) the size and type of the business of the person; and

"(iv) any history of prior offenses by the person; and

"(B) shall be reviewed only in accordance with subsection (b).

"(b) JUDICIAL REVIEW.—

"(1) IN GENERAL.—An order assessing a civil penalty against a person under subsection (a) shall be final unless the person—

"(A) not later than 30 days after the effective date of the order, files a petition for judicial review of the order in—

"(i) the United States court of appeals for the circuit in which the person resides or has its principal place of business; or

"(ii) the United States Court of Appeals for the District of Columbia Circuit; and

"(B) simultaneously sends a copy of the petition by certified mail to the Secretary.

''(2) FILING OF COPY OF RECORD.—The Secretary shall promptly file in the court a certified copy of the record on which the order was issued.

''(3) STANDARD OF REVIEW.—The findings of the Secretary relating to the order shall be set aside only if the findings are found to be unsupported by substantial evidence on the record as a whole.

''(c) COLLECTION ACTIONS FOR FAILURE TO PAY ASSESSMENT.—

''(1) REFERRAL TO ATTORNEY GENERAL.—If a person fails to pay a civil penalty assessed under subsection (a) after the order assessing the civil penalty has become a final order, or after the court of appeals has entered final judgment in favor of the Secretary, the Secretary may refer the matter to the Attorney General.

''(2) ACTION BY ATTORNEY GENERAL.—The Attorney General shall bring a civil action to recover the amount of the civil penalty in United States district court.

''(3) SCOPE OF REVIEW.—In a civil action under paragraph (2), the validity and appropriateness of the order of the Secretary assessing the civil penalty shall not be subject to review.

''(d) PENALTIES DEPOSITED IN TREASURY.—All amounts collected as civil penalties under this section shall be deposited in the Treasury of the United States and shall be available to cover costs of the Administration in carrying out food safety activities under this Act.

''(e) PENALTIES IN LIEU OF OTHER ACTIONS.—Nothing in this Act requires the Secretary to report for prosecution, or for the commencement of any libel or injunction proceeding, any violation of this Act in any case in which the Secretary believes that the public interest will be adequately served by the assessment of a civil penalty under this section.

''(f) REMEDIES NOT EXCLUSIVE.—The remedies authorized by this section shall be in addition to any other remedies that may be available.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to prohibited acts committed on or after the date of the enactment of this Act .

SEC. 122. ENFORCEMENT AND RECALL.

Section 801 (21 U.S.C. 381), as amended by section 112, is further amended by adding at the end the following:

''(q)(1) The Secretary may deny importation of food, other than only for personal use, from any foreign country, or which is manufactured, processed, packed, or held by

a facility (as defined in section 415), if the government of such country, or such facility, respectively, does not timely consent to an investigation by the Administration when food from that country or facility is linked to a food-borne illness outbreak or is otherwise found to be adulterated or mislabeled. Any food imported for consumption in the United States may be detained and condemned pursuant to section 704A(c) or recalled pursuant to section 423.''.

Subtitle D—Miscellaneous

SEC. 131. LABELING REQUIREMENT FOR MEAT, POULTRY PRODUCTS, AND SEAFOOD THAT CONTAIN CARBON MONOXIDE.

(a) LABELING REQUIREMENT.—

(1) IN GENERAL.—Paragraph (t) of section 201 (21 U.S.C. 321) is amended by adding at the end the following:

''(4) In the case of food that is meat within the meaning of the Federal Meat Inspection Act, a poultry product within the meaning of the Poultry Products Inspection Act, or seafood (including all fresh or saltwater fish, molluscan shellfish, crustaceans, and other forms of aquatic animal life) intended for human consumption as food within the meaning of section 201(f) (referred to collectively in this paragraph as 'seafood'), the term 'color

additive' shall include carbon monoxide under conditions of use that may impart, maintain, preserve, stabilize, fix, or otherwise affect the color of fresh meat, poultry products, or seafood, unless the label of such food bears, prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by the ordinary person, the following statement to prevent consumer deception and serious risks to the public health: 'CONSUMER NOTICE: Carbon monoxide has been used to preserve the color of this product. Do not rely on color or the ''use or freeze by'' date alone to judge the freshness of the product.' ''.

(2) EFFECTIVE DATE.—The amendment made by this subsection shall apply to food labeled on or after the date that is 30 days after the date of the enactment of this Act.

(b) DISCRETIONARY AUTHORITY.—If, not earlier than 5 years after the effective date described in subsection (a)(2), the Secretary of Health and Human Services finds, based on competent and reliable scientific evidence, that the statement prescribed in section 201(t)(4) of the Federal Food, Drug, and Cosmetic Act is no longer required to prevent consumer deception and other harms, then the Secretary is authorized to issue regulations establishing alternative labeling requirements that are shown

to be adequate and effective in preventing consumer deception and other harms related to the conditions of use of carbon monoxide, including with respect to preventing any consumer deception or other harm that may result from the actual conditions of carbon monoxide use and its potential to impart a persistent color to meat, poultry products, or seafood described in such section through a reaction with natural pigment.

SEC. 132. FOOD SUBSTANCES GENERALLY RECOGNIZED AS SAFE.

Section 409 (21 U.S.C. 348) is amended by adding at the end the following:

''Substances Generally Recognized as Safe

''(k)(1) Not later than 60 days after the date of receipt by the Secretary after the date of the enactment of this subsection of a request for a substance to be determined by the Secretary to be a GRAS food substance, the Secretary shall publish such notice in the Federal Register.

''(2) Not later than 90 days after the date of publication of a notice concerning a GRAS food substance, the Secretary shall determine whether the substance is considered generally recognized as safe.

''(3) In this subsection, the term 'GRAS food substance' means a substance excluded from the definition of

the term 'food additive' in section 201(s) because such substance is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substances used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

''(4) A determination whether a substance is generally recognized as safe by the Secretary shall be published in the Federal Register.''.

SEC. 133. COUNTRY OF ORIGIN LABELING; DISCLOSURE OF SOURCE OF INGREDIENTS.

(a) FOOD.—Section 403 (21 U.S.C. 343) is amended by adding at the end the following:

''(z) In the case of a processed food if—

''(1) the labeling of the food fails to identify the country in which the final processing of the food occurs; and

''(2) the website for the manufacturer of the food fails to identify the country (or countries) of origin for each ingredient in the food.

''(aa) In the case of non-processed food if—

''(1) the labeling of the food fails to identify the country of origin of the food; and

''(2) the website for the original packer of the food fails to identify the country of origin for the food.''.

(b) REGULATIONS.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate final regulations to carry out the paragraphs (z) and (aa) of section 403(z) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(c) EFFECTIVE DATE.—The requirements of paragraphs (z) and (aa) of section 403 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), takes effect on the date that is 2 years after the date of the enactment of this Act.

SEC. 134. NEW FOOD AND ANIMAL FEED EXPORT CERTIFICATION FEE TO IMPROVE THE ABILITY OF UNITED STATES FIRMS TO EXPORT THEIR PRODUCTS.

Part 3 of chapter VII (21 U.S.C. 371 et seq.), , as added by section 101(b) and amended by sections 105(a), 106(b), and 107(c), is further amended by adding at the end the following:

"SEC. 741D. NEW FOOD AND ANIMAL FEED EXPORT CERTIFICATION FEE TO IMPROVE THE ABILITY OF UNITED STATES FIRMS TO EXPORT THEIR PRODUCTS.

''(a) IN GENERAL.—If the Secretary provides for the issuance of export certificates for foods and animal feeds in cases where exportation is restricted without such a certificate, the Secretary may impose a fee for the issuance of such a certificate.

''(b) AMOUNT.—The amount of the fee under this section shall be an amount that is reasonably related to the cost of issuing such certificates.

''(c) USE OF FEES.—The Secretary shall make all of the fees collected pursuant to this section available solely to pay for the costs of issuance of such certificates.''.

TITLE II—DRUG AND DEVICE SAFETY

SEC. 201. REGISTRATION FEE APPLICABLE TO PRODUCERS OF DRUGS AND DEVICES.

(a) PROHIBITED ACT.—Subsection (p) of section 301 (21 U.S.C. 331), as amended by section 101(a), is amended by striking ''501(k);'' and inserting ''501(k), the failure to pay an annual registration fee in violation of 736C,''.

(b) REGISTRATION FEE.—Part 2 of subchapter C of chapter VII is amended by adding at the end the following:

"SEC. 736C. REGISTRATION FEE.

"(a) IN GENERAL.—The Secretary shall assess and collect an annual fee for registration under subsection (b), (c), (d), or (i) of section 510 for the purpose of defraying the costs of inspecting establishments registered under such subsection to ensure that such establishments are in compliance with the requirements of this Act relating to drugs and devices.

"(b) AMOUNT OF FEE.—The amount of a fee under this section shall be—

"(1) such amount as the Secretary determines for establishments with respect to drugs; and

"(2) such amount as the Secretary determines for establishments with respect to devices.".

(c) EFFECTIVE DATE.—The Secretary of Health and Human Services shall first impose the fee established under section 736C of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), for fiscal years beginning with fiscal year 2009.

SEC. 202. INSPECTION OF PRODUCERS OF DRUGS, ACTIVE PHARMACEUTICAL INGREDIENTS, DEVICES, AND DEVICE PARTS.

(a) PROHIBITED ACT.—Subsection (p) of section 301 (21 U.S.C. 331), as amended by sections 101(a) and 201(a), is amended by inserting before "or the failure to provide a notice required by section 510(j)(2)" the fol-

lowing: ''the introduction or delivery for introduction into interstate commerce of any drug, any active pharmaceutical ingredient, any class II or III device, or device part to such a device, as determined by the Secretary, before an initial inspection is complete in violation of section 510(h)(2),''.

(b) INSPECTION.—Subsection (h) of section 510 (21 U.S.C. 351) is amended—

(1) by striking ''(h)'' and inserting ''(h)(1)'';

(2) by striking ''Every establishment in any State registered with the Secretary pursuant to this section'' and inserting ''Every establishment registered with the Secretary pursuant to subsection (b), (c), (d), or (i)''; and

(3) by adding at the end the following:

''(2) Upon receipt of an initial registration under subsection (b), (c), (d), or (i) for an establishment, the Secretary shall ensure that such establishment is promptly inspected pursuant to section 704. Until such initial inspection is complete, any drug (including any active pharmaceutical ingredient) or class II or III device or any device part of such a device (as determined by the Secretary that is manufactured, prepared, propagated, compounded, or processed by such establishment shall not be introduced or delivered for introduction into interstate commerce.

There shall be a new initial inspection of a drug or device establishment when the establishment begins to manufacture, prepare, propagate, compound, or process a drug, active pharmaceutical ingredient, class II or III device, or a part of such a device (as determined by the Secretary) before its introduction or delivery into interstate commerce unless the product constitutes only a minor modification to a product previously manufactured, prepared, propagated, compounded, or processed at the establishment..

''(3) A drug or device establishment, or employee of such an establishment, that delays, limits, or denies an inspection under this Act is subject to suspension of registration under section 510. If the Secretary determines that such an establishment delays, limits, or denies such an inspection, the establishment shall not place into interstate commerce any drug or device it manufactures, prepares, propagates, compounds, or processes.''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply to drugs introduced or delivered for introduction into interstate commerce on or after the date that is 2 years after the date of the enactment of this Act

(2) ESTABLISHMENTS ALREADY REGISTERED, BUT NOT INSPECTED.—In the case of any establish-

ment that is registered under subsection (b), (c), (d), or (i) of section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) as of the effective date specified in paragraph (1) but has not been inspected pursuant to section 704 of such Act (21 U.S.C. 374) as of such date, such amendments shall not apply until 2 years after such effective date.

SEC. 203. DOCUMENTATION FOR ADMISSIBILITY OF DRUG IMPORTS.

Section 801 (21 U.S.C. 381), as amended by sections 112 and 122, is amended by adding at the end the following:

''(r) Beginning 3 years after the date of enactment of this subsection, a drug shall only enter the United States, other than only for personal use, through a port of entry that is located in a metropolitan area with a federal testing laboratory, unless the party offering that drug for import provides the Secretary, at the time of offering the drug for import, documentation demonstrating compliance with applicable requirements pertaining to identity, strength, quality, purity, approval, listing, labeling, and registration. The Secretary may require that such documentation include verification of compliance by an accredited third party or by the Secretary during an inspection within the past two years, and such other information as

the Secretary determines is necessary for protection of the public health.''.

SEC. 204. ORIGIN OF INGREDIENTS.

(a) IN GENERAL.—Section 501(a)(2) (21 U.S.C. 351(a)(2)) is amended by inserting after ''; or'' at the end the following: ''or (D) if it is a drug and it bears, contains, or consists of an active or inactive ingredient and the manufacturer of that ingredient and of each drug that contains that ingredient does not have, and provide to the Secretary upon request, adequate documentation to establish where the ingredient was made, including all previous producers and manufacturers, that the ingredient is not adulterated or misbranded, that the ingredient will perform in accordance with specifications, is not contaminated, and does not have any undisclosed additives, and that the ingredient was manufactured, distributed, shipped, warehoused, processed, brokered, imported, and conveyed under conditions that ensure the identity, strength, quality, and purity of the drug; or''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on a date, specified by the Secretary of Health and Human Services, not later than 3 years after the date of the enactment of this Act.

SEC. 205. TESTING FOR DRUG PURITY AND IDENTITY.

(a) IN GENERAL.—Section 501(a)(2) (21 U.S.C. 351(a)(2)), as amended section 204(a), is amended by inserting after ''; or'' at the end the following: ''or (E) if it is a drug, unless each manufacturer of the finished dosage form, active ingredients, and inactive ingredients contained in or consisting of that drug verifies its product's purity and identity using scientifically sound and appropriate methods of sufficient analytical precision and specificity to detect and quantify the product separate from contaminants, impurities, and adulterants; or (F) if it is a drug, unless each manufacturer of an active pharmaceutical ingredient contained in or consisting of that drug periodically evaluates its ingredient's impurity profile to verify that it remains substantially similar to or better than the profile of the lot (or lots) used in the clinical studies and/or toxicological evaluation. If no clinical studies or toxicological evaluation was conducted, then the impurity profile shall determined according to standards to be established by the Secretary; or''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on a date, specified by the Secretary of Health and Human Services, not later than 3 years after the date of the enactment of this Act.

SEC. 206. COUNTRY OF ORIGIN LABELING.

(a) DRUGS AND DEVICES.—Section 502 (21 U.S.C. 352) is amended by adding at the end the following:

''(y) If it is a drug or device and—

''(1) its labeling fails to identify the country (or countries) which is the source of the active pharmaceutical ingredient in whole or in part and of its place of manufacture in the case of a drug, or the country of manufacture in the case of a device; or

''(2) in the case of a drug the website of the manufacturer of the drug does not list the country of origin for any drug ingredient of such drug.''.

(b) REGULATIONS.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall promulgate final regulations to carry out section 502(y) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(c) EFFECTIVE DATE.—The requirement of section 502(y) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), takes effect 2 years after the date of the enactment of this Act.

SEC. 207. RECALL AUTHORITY FOR DRUGS.

Subchapter E of chapter V is amended by adding at the end the following:

''SEC. 568. RECALL AUTHORITY FOR DRUGS.

''The Secretary shall have the same authority with respect to drugs as the Secretary has with respect to devices under section 518(e). In applying the previous sentence, any reference in such section to a device shall be deemed a reference to a drug.''.

SEC. 208. DESTRUCTION OF ADULTERATED, MISBRANDED OR COUNTERFEIT DRUGS OFFERED FOR IMPORT.

(a) IN GENERAL.—The fifth sentence of section 801(a) (21 U.S.C. 381(a)) is amended by inserting before the period at the end the following: '', except that any product that is refused admission may, at the discretion of the Secretary, be destroyed and not exported if (1) it appears to pose a risk of injury or death, or (2) has a value of less than $2,000, as determined by the Secretary''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect the date of the enactment of this Act, regardless of when the product may have been refused admission.

SEC. 209. ADMINISTRATIVE DETENTION OF DRUGS THAT APPEAR TO VIOLATE THE LAW.

(a) IN GENERAL.—Section 304(g) (21 U.S.C. 334(g)) is amended—

(1) by inserting ''drug or'' before ''device'' each place it appears; and

(2) in paragraph (1), by inserting after ''adulterated or misbranded'' the following: ''or, in the case of a drug, which in the determination of the officer or employee making the inspection appears to be in violation of section 505,''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on a date, specified by the Secretary of Health and Human Services, not later than 1 year after the date of the enactment of this Act.

(c) TRANSITION.—Until such time as the Food and Drug Administration issues regulations to carry out the amendments made by subsection (a), the regulations applicable under section 304(g) of the Federal Food, Drug, and Cosmetic Act shall apply to drugs, as included by the amendment made by such amendments.

SEC. 210. CIVIL MONEY PENALTIES FOR VIOLATIVE DRUGS AND DEVICES AND IMPROPER IMPORT ENTRY FILINGS.

(a) IN GENERAL.—Section 303 (21 U.S.C. 333) is amended by adding at the end the following:

''(h)(1) Any person who violates a requirement of this Act that relates to drugs and devices for human use shall be liable to the United States for a civil penalty not to

exceed $100,000 per violation. Each day during which a violation continues shall be considered a separate violation.

''(2) Any person, including a manufacturer, distributor, importer, broker, or filer, who knowingly reports or enters false data on documents related to the introduction of drugs and devices in interstate commerce shall be liable to the United States for a civil penalty not to exceed $150,000. Each act of reporting or entering false data shall be considered a separate violation.

''(3) The provisions of paragraphs (2), (5), (6), and (7) of subsection (g) shall apply to a civil money penalty under paragraph (1) or (2) of this subsection in the same manner as they apply to a civil money penalty under subsection (g)(1).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to violations occurring on or after the date of the enactment of this Act.

TITLE III—COSMETIC SAFETY

SEC. 301. REGISTRATION OF COSMETIC FACILITIES.

(a) IN GENERAL.—Chapter VI is amended by adding at the end the following new section:

''SEC. 604. REGISTRATION OF FACILITIES.

''(a) IN GENERAL.—The Secretary shall by regulation require that any facility engaged in manufacturing,

processing, packing, or holding of cosmetics in the United States or for import to the United States be registered with the Secretary.

''(b) APPLICATION OF FOOD REGISTRATION RULES AND REGISTRATION FEE.—Except as provided in this section, the provisions of section 415 and section 741 shall apply to registration of cosmetic facilities under subsection (a) in the same manner as they apply to registration of facilities (as defined in section 415(b)) under such respective section, except that, with respect to registration fees imposed under this subsection, any reference in section 741 to 'food' is deemed a reference to 'cosmetics'. Each facility shall list in the registration the cosmetic products it manufactures, processes, packs, or holds and, in the case of a manufacturing facility, a list of the ingredients for each product so listed that it manufactures.

''(c) ADVERSE EVENT REGISTRY.—The Secretary shall by regulation require a facility that manufactures cosmetics to report to the Secretary all anticipated and unanticipated serious adverse events relating to the use of cosmetics it has manufactured.

''(d) GOOD MANUFACTURING PRACTICES.—The Secretary shall by regulation require that the methods used in, and the facilities and controls used for the manufacture, process, packing, or holding of a cosmetic conform

to good manufacturing practices as prescribed in such regulations.''.

(b) EFFECTIVE DATES.—

(1) REGISTRATION AND FEES.—Cosmetic facilities shall be required to register (and pay registration fees) under subsections (a) and (b) of section 604 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), beginning 6 months after the date of the enactment of this Act.

(2) ADVERSE EVENT REGISTRY AND GOOD MANUFACTURING PRACTICES.—The Secretary of Health and Human Services shall establish the adverse event registry and the good manufacturing practices under the amendment made by subsection (a) not later than 18 months after the date of the enactment of this Act.

TITLE IV—MISCELLANEOUS

SEC. 401. REGISTRATION AND FEE FOR COMMERCIAL IMPORTERS OF FOOD, DRUGS, DEVICES, AND COSMETICS.

(a) PROHIBITIONS.—Section 301 (21 U.S.C. 331), as amended by sections 107(a) and 113(a), is further amended by adding at the end the following:

''(qq) The importation of food, drugs, devices, or cosmetics other than only for personal use by an importer

that is not registered with respect to such food, drugs, devices, or cosmetics under section 415, 510, or 604, respectively, unless the importer is registered under section 801(s).''.

(b) REGISTRATION.—Section 801, as amended by sections 112, 122, and 203, is amended by adding at the end the following:

''(s) The Secretary shall by regulation require that an importer of food, drugs, devices, or cosmetics, other than only for personal use, that is not registered with respect to such food, drugs, devices, or cosmetics under section 415, 510, or 604, respectively, shall be registered with the Secretary in a form and manner specified by the Secretary. The Secretary shall assign a unique identification number to each importer so registered.''.

(c) FEE.—Subchapter C of chapter VII is amended by adding at the end the following:

''PART 6—IMPORTERS OF FOOD, DRUGS, DEVICES, AND COSMETICS

''SEC. 742. IMPORTERS OF FOOD, DRUGS, DEVICES, AND COSMETICS.

''(a) IN GENERAL.—The Secretary shall assess and collect an annual fee for the registration of an importer of food, drugs, devices, or cosmetics under section 801(s).

''(b) AMOUNT OF FEE.—The amount of the fee under this section shall be $10,000.''.

(d) EFFECTIVE DATE.—

(1) REGISTRATION.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall establish procedures for the registration of importers under section 801(s) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(2) REGISTRATION.—The amendments made by this section shall first apply not later than 1 year after the date of the enactment of this Act.

SEC. 402. UNIQUE IDENTIFICATION NUMBER FOR FOOD, DRUG, AND DEVICE FACILITIES AND ESTABLISHMENTS.

(a) FOOD AND COSMETICS.—Section 415(a)(3) (21 U.S.C. 350d(a)(3)) is amended by adding at the end the following: ''Such a registration number shall be a unique identification number for each such facility that may be used for purposes other than registration under this subsection.''.

(b) DRUGS AND DEVICES.—Section 510(e) (21 U.S.C. 360(e)) is amended by adding after the first sentence the following: ''Such a registration number shall be a unique identification number for each such establish-

ment that may be used for purposes other than registration under this subsection.''.

(c) APPLICATION TO COSMETICS.—The amendment made by subsection (a) applies to cosmetics through the operation of section 604 of the Federal Food, Drug, and Cosmetic Act, as added by section 301(a).

(d) APPLICATION TO IMPORTERS.—See section 402(b) of this Act for the requirement for a unique identification number for importers that are registered.

(e) EFFECTIVE DATE.—The Secretary of Health and Human Services shall implement the amendments made by this section not later than 1 year after the date of the enactment of this Act.

SEC. 403. DEDICATED FOREIGN INSPECTORATE.

Section 704 (21 U.S.C. 374) is amended by adding at the end the following:

''(h) The Secretary shall establish and maintain a corps of inspectors dedicated to inspections of foreign food, drug, device, and cosmetics facilities and establishments. This corps shall be staffed and funded by the Secretary at a level sufficient to allow it to conduct inspections of foreign food, drug, device and cosmetic facilities and establishments at a frequency at least equivalent to the inspection rate of domestic food, drug, device, and cosmetic facilities and establishments.''.

SEC. 404. CONTINUED OPERATION OF FIELD LABORATORIES.

(a) IN GENERAL.—Subject to subsections (b) and (d), the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall not—

(1) terminate any of the 13 field laboratories that were operated by the Office of Regulatory Affairs of the Food and Drug Administration as of January 1, 2007;

(2) consolidate any such laboratory with any other laboratory;

(3) terminate any of the 20 district offices or any of the inspection or compliance functions of any of the 20 district offices of the Food and Drug Administration functioning as of January 1, 2007; or

(4) consolidate—

(A) any such district office with an office in any other district; or

(B) transfer any of the compliance or inspection functions of any such district office to any other district.

(b) REPORT BY SECRETARY.—

(1) SUBMISSION.—The Secretary shall submit a reorganization plan involving the termination or consolidation of the laboratories, the district offices, or the functions of such district offices specified in sub-

section (a) to the Comptroller General of the United States, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate.

(2) CONSULTATION.—In preparing the reorganization plan described in paragraph (1), the Secretary shall consult with personnel and unions to be affected by the plan.

(c) REPORT BY GAO.—The Comptroller General shall study the cost effectiveness of the reorganization plan described in subsection (b) and its impact on the safety of food, drug, and other products regulated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.) and report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(d) REORGANIZATION.—

(1) CONGRESSIONAL REVIEW.—The reorganization plan described in subsection (b) is deemed to be a major rule (as defined in section 804(2) of title 5, United States Code) for purposes of chapter 8 of such title.

(2) EFFECTIVE DATE.—Notwithstanding section 801(a)(3) of title 5, United States Code, the reorganization plan described in subsection (b) shall take effect (unless disapproved under section 802 of such title) on the date that is specified in such plan, but not earlier than 180 days after the date on which the Comptroller General submits the report required by subsection (c).

SEC. 405. FALSE OR MISLEADING REPORTING TO FDA.

(a) IN GENERAL.—Section 301(q)(2) (21 U.S.C. 331(q)(2)) is amended by inserting after ''device'' the following: ''food, drug, or biological product''.

(b) EFFECTIVE DATE.— The amendment made by subsection (a) shall apply to submissions made on or after the date of the enactment of this Act.

SEC. 406. APPLICATION TO BIOLOGICAL PRODUCTS.

Under section 351(j) of the Public Health Service Act (42 U.S.C. 262(j)), the amendments made to the Federal Food, Drug, and Cosmetic Act by this Act shall also apply to biological products.

SEC. 407. LIMITATION TO COMMERCIAL IMPORTATION.

Nothing in this Act, or the amendments made by this Act, shall be construed as applying to importation other than commercial (and not personal) importation.