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111TH CONGRESS
1ST SESSION

H. R. 759

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food, drugs, devices, and cosmetics in the global market, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 28, 2009

Mr. DINGELL (for himself, Mr. STUPAK, and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of food, drugs, devices, and cosmetics in the global market, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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 2009''.

(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:

SEC. 2. RELATIONSHIP TO STATE LAW.

This Act and the amendments made by this Act may not be construed as modifying or otherwise affecting any action or the liability of any person (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act) under the law of any State.

TITLE I—FOOD SAFETY

Subtitle A—Prevention

SEC. 101. CHANGES IN REGISTRATION OF FOOD FACILITIES.

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

''(z) If it was manufactured, processed, packed, or held in a facility that is not duly registered under section 415 or is in violation of section 741 (requiring payment of a fee for such registration).''.

(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 5—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 to defray increases (as described in subsection (f)(2)(A)(ii)) in the costs of inspecting establishments registered under section 415 and for related activities to ensure compliance by such establishments with the requirements of this Act relating to food (including increases in such costs for management of information, and the acquisition, maintenance, and repair of information technology resources).

''(b) FEE REVENUE AMOUNTS.—

''(1) IN GENERAL.—For each of fiscal years 2010 through 2014, fees under subsection (a) shall, except as provided in subsections (c), (e), and (f), be

established to generate a total revenue amount under subsection (a).

''(2) TOTAL REVENUE AMOUNT.—Not later than September 1, 2009, the Secretary shall transmit to the Congress the total revenue amount under paragraph (1) and how such amount was calculated.

''(3) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of each fiscal year that begins after September 30, 2009, establish, for the next fiscal year, registration fees under subsection (a) based on the total revenue amount applicable under paragraph (1).

''(c) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—For fiscal year 2011 and subsequent fiscal years, the revenues established under subsection (b)(1) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

''(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average) for the 12-month period ending June 30 preceding the fiscal year for which fees are being established;

"(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia; or

"(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 5 years of the preceding 6 fiscal years.

The adjustment made each fiscal year under this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2009 under this subsection.

"(2) WORKLOAD ADJUSTMENT.—For fiscal year 2011 and subsequent fiscal years, after the fee revenues established under subsection (b)(1) 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 inspections and

related activities described in subsection (a). 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 amount of inspections and related activities described in subsection (a). The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

"(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 under subsection (b)(1), as adjusted for inflation under paragraph (1). Any adjustment for changes in inspections and related activities described in subsection (a) made in setting fees and revenue amounts for fiscal year 2011 or any subsequent year may not result in the total workload adjustment being more than 2 percentage points higher than it would have been in the absence of the adjustment for changes in inspections and related activities.

''(C) The Secretary shall contract with an independent accounting firm to study the adjustment for changes in inspections and related activities described in subsection (a) applied in setting fees and revenue amounts for fiscal year 2011 and to make recommendations, if warranted, for future changes in the methodology for calculating the adjustment. After review of the recommendations, the Secretary shall, if warranted, make appropriate changes to the methodology, and the changes shall be effective for each of fiscal years 2012 through 2014. The Secretary shall not make any adjustment for changes in inspections and related activities described in subsection (a) for any fiscal year after 2011 unless such study has been completed.

''(3) RENT AND RENT-RELATED COST ADJUSTMENT.—For fiscal year 2012 and each subsequent fiscal year, the Secretary shall, before making adjustments under paragraphs (1) and (2), decrease the fee revenue amount established under subsection (b)(1) if actual costs paid for rent and rent-related expenses for the preceding fiscal year are less than estimates made for such year in fiscal year 2008.

Any reduction made under this paragraph shall not exceed the amount by which such costs fall below the estimates made in fiscal year 2008 for such fiscal year, and shall not exceed $11,721,000 for any fiscal year.

''(4) FINAL YEAR ADJUSTMENT.—For fiscal year 2014, the Secretary may, in addition to adjustments under paragraphs (1), (2), (3), and (5), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for inspections described in subsection (a) for the first 3 months of fiscal year 2015. 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 2014. If the Secretary has carryover balances for such inspections in excess of 3 months of such operating reserves, the adjustment under this paragraph shall not be made.

''(5) COST ESTIMATE ADJUSTMENT.—For fiscal year 2011 and subsequent fiscal years, the Secretary by notice, published in the Federal Register, shall—

''(A) provide an estimate of the amount of the total increases described in subsection (a) for such fiscal year; and

''(B) after making adjustments under paragraphs (1), (2), and (3), adjust the revenues established under subsection (b)(1) to be equal to such amount.

''(6) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total increases described in subsection (a) for such fiscal year.

''(d) WAIVERS.—The Secretary shall waive the fee under this section with respect to any facility that is a small business, as defined by the Secretary.

''(e) LIMITATIONS.—

''(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2010 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2010 (excluding the amount of fees appropriated for such fiscal year)

multiplied by the adjustment factor applicable to the fiscal year involved.

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for registration under section 415 at any time in such fiscal year.

''(f) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—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. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

''(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 in appropriation Acts, or otherwise made available for obligation, for such fiscal year; and

"(ii) shall only be collected and available to defray increases in the costs of inspecting establishments registered under section 415 and related activities to ensure compliance by such establishments with the requirements of this Act relating to food (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such inspections and for management of information, and the acquisition, maintenance, and repair of information technology resources) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2009 multiplied by the adjustment factor.

"(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 inspections described in subsection (a)—

"(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.—For each of the fiscal years 2010 through 2014, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b)(1) for the fiscal year, as adjusted or otherwise affected under subsection (c) and paragraph (4) of this subsection.

"(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2010 through 2013 and the amount of

fees estimated to be collected under this section for fiscal year 2014 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2010 through 2013, the excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section for fiscal year 2014.

''(g) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(h) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in inspections described in subsection (a), be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(i) ANNUAL FISCAL REPORTS.—Beginning with fiscal year 2011, not later than 120 days after the end of each fiscal year for which fees are collected under this sec-

tion, the Secretary 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 for such fiscal year.

''(j) DEFINITION.—In this section, the term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2009.''.

(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 Federal 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.

The registrant shall 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.—Section 415(a) (21 U.S.C. 350d(a)), as amended by subsection (c), is further amended by adding at the end the following:

''(5) SUSPENSION OF REGISTRATION.—

''(A) IN GENERAL.—The Secretary may suspend the registration of any facility reg-

istered 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 an employee of the facility, delays or limits an inspection, or refuses to permit entry or 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 pub-

lic 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 DATES.—

(1) FEES.—

(A) EFFECTIVE DATE.—The Secretary of Health and Human Services shall first impose the fee established under section 741 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b)(2), for fiscal years beginning with fiscal year 2010.

(B) SUNSET DATE.—Section 741 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b)(2), does not authorize the assessment or collection of a fee for registration under section 415 of such Act (21 U.S.C. 360) occurring after fiscal year 2014.

(2) 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 (21 U.S.C. 350d) to comply with the amendments made by subsection (c).

(3) APPLICATION.—The amendments made by this section, other than subsections (b)(2) and (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. HAZARD ANALYSIS, RISK-BASED PREVENTIVE CONTROLS, AND FOOD SAFETY PLAN.

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

''(oo) The operation of a facility that manufactures, processes, packs, transports, or holds food for consumption in the United States if the owner, operator, or agent in charge of such facility is not in compliance with sections 418 and 418A.''.

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

''SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

''(a) IN GENERAL.—The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, transported, or held by such fa-

cility, identify and implement preventive controls to significantly minimize, prevent, or eliminate the occurrence of such hazards, monitor the performance of such controls, and maintain records of such monitoring.

''(b) HAZARD ANALYSIS.—The owner, operator, or agent in charge of a facility shall identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including—

''(1) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives;

''(2) hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism; and

''(3) relevant hazards identified under section 419.

''(c) PREVENTIVE CONTROLS.—

''(1) IN GENERAL.—The owner, operator, or agent in charge of a facility shall identify, implement, and validate preventive controls, including at critical control points, if any, to significantly minimize, prevent, or eliminate hazards identified in the hazard analysis conducted under subsection (b).

''(2) SPECIFIC PRODUCT TYPES.—The Secretary may establish by regulation or guidance additional preventive controls under this section for specific product types to prevent intentional or unintentional contamination throughout the supply chain.

''(d) MONITORING OF EFFECTIVENESS.—The owner, operator, or agent in charge of a facility shall monitor the effectiveness of the preventive controls implemented under subsection (c).

''(e) CORRECTIVE ACTIONS.—The owner, operator, or agent in charge of a facility shall establish procedures that the facility will implement if the preventive controls implemented under subsection (c) are found to be ineffective through monitoring under subsection (d).

''(f) VERIFICATION.—The owner, operator, or agent in charge of a facility shall verify that—

''(1) the preventive controls implemented under subsection (c) have been validated as adequate to control the hazards identified under subsection (b);

''(2) the owner, operator, or agent is conducting monitoring in accordance with subsection (d); and

''(3) the owner, operator, or agent is taking effective corrective actions under subsection (e).

''(g) RECORD KEEPING.—The owner, operator, or agent in charge of a facility shall maintain, for not less

than 2 years, records documenting the monitoring and verification of the effectiveness of the actions described in subsections (a) through (f).

''(h) REQUIREMENT TO REANALYZE.—Each owner, operator, or agent in charge of a facility shall—

''(1) conduct a reanalysis under subsection (b)—

''(A) whenever there is a reasonable potential for a new hazard or a significant increase in a previously identified hazard;

''(B) not less frequently than once every 2 years; and

''(C) if the Secretary determines it to be appropriate for the protection of the public health; and

''(2) revise the preventive controls under subsection (c) to significantly minimize, prevent, or eliminate such hazard or document the basis for the conclusion that no such revision is needed.

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

''(1) CRITICAL CONTROL POINT.—The term 'critical control point' means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

''(2) FACILITY.—The term 'facility' means a domestic facility or a foreign facility that is required to register under section 415.

''(3) PREVENTIVE CONTROLS.—The term 'preventive controls' means those risk-based procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, transporting, or holding of food would have employed to significantly minimize, prevent, or eliminate the hazards identified under the hazard analysis conducted under subsection (a) and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, transporting, or holding at the time of the analysis. Those procedures, practices, and processes may include the following:

''(A) Sanitation procedures for food contact surfaces and utensils and food-contact surfaces of equipment.

''(B) Supervisor, manager, and employee hygiene training.

''(C) An environmental monitoring program to verify the effectiveness of pathogen controls.

''(D) An allergen control program.

''(E) A recall contingency plan.

''(F) Good manufacturing practices.

''(G) Supplier verification activities.

''SEC. 418A. FOOD SAFETY PLAN.

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

''(1) IN GENERAL.—Before a facility (as defined in section 418(i)) introduces or delivers for introduction 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').

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

''(A) The hazard analysis conducted under section 418.

''(B) A description of the preventive controls being implemented under section 418(c), including any those for specific product types under section 418(c)(2).

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

''(D) A description of monitoring of such preventive controls being implemented, includ-

ing sampling and testing relating to the control of hazards where appropriate to verify that the controls are effective.

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

"(F) A description of established procedures for the recall of articles of food, whether voluntarily or when required under section 422.

"(G) A description of established procedures for the trace back of articles of food, whether voluntarily or when required under section 403(g).

"(H) A description of established procedures to ensure a safe and secure supply chain for the ingredients or components used in making the food produced, processed, packed, transported, or held by such facility.

"(I) A description of established procedures to implement the science-based performance standards issued under section 419.

"(b) INSPECTION OF FOOD SAFETY PLAN IN COURSE OF FACILITY INSPECTION.—In the course of a facility in-

spection under section 704, the Secretary shall conduct a review of the food safety plan to ensure the plan meets relevant requirements of section 418, this section, and section 419 and is adequate to protect the public health.''.

(c) GUIDANCE OR REGULATIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall issue guidance or promulgate regulations to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls under sections 418 and 418A of the Federal Food, Drug, and Cosmetic Act (as added by subsection (b)).

(2) CONSIDERATION.—In issuing guidance or promulgating regulations under this section, the Secretary shall consider the capacity of small businesses.

(d) NO EFFECT ON HACCP AUTHORITIES.—Nothing in the amendments made by this section limits the authority of the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.) to revise, issue, or enforce product and category-specific regulations, such

as the Seafood Hazard Analysis Critical Controls Points Program, the Juice Hazard Analysis Critical Control Program, and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards.

(e) EFFECTIVE DATE.—

(1) GENERAL RULE.—The amendments made by this section shall take effect 18 months after the date of the enactment of this Act.

(2) EXCEPTIONS.—Notwithstanding paragraph (1)—

(A) the amendments made by this section shall apply to a small business (as defined by the Secretary) after the date that is 2 years after the date of the enactment of this Act; and

(B) the amendments made by this section shall apply to a very small business (as defined by the Secretary) after the date that is 3 years after the date of the enactment of this Act.

SEC. 103. PERFORMANCE STANDARDS.

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

"SEC. 419. PERFORMANCE STANDARDS.

''The Secretary shall, not less frequently than every 2 years, review and evaluate epidemiological data and

other appropriate sources of information, including research under section 113 of the Food and Drug Administration Globalization Act of 2009, to identify the most significant food-borne contaminants and the most significant resulting hazards, and shall issue, through guidance or by regulation, science-based performance standards (which may include action levels) to significantly minimize, prevent, or eliminate the occurrence of such hazards. Such standards shall be applicable to products and product classes and shall not be specific to an individual facility.''.

SEC. 104. SAFETY STANDARDS FOR FRESH PRODUCE.

(a) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by sections 102 and 103, is amended by adding at the end the following:

''(pp) The production or harvesting of produce not in accordance with minimum standards as provided by regulation under section 419A(a) or a variance issued under section 419A(e).''.

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

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

''(a) STANDARDS.—The Secretary shall establish by regulation science-based minimum standards for the safe production and harvesting of those types of fruits and

vegetables that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death.

''(b) CONTENTS.—The regulations under subsection (a)—

''(1) shall set forth such procedures, processes, and practices as the Secretary determines to be reasonably necessary—

''(A) to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards, including hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism, into fruits and vegetables that are raw agricultural commodities; and

''(B) to provide reasonable assurances that the produce is not adulterated under section 402;

''(2) shall include, with respect to growing, harvesting, packing, sorting, and storage operations, minimum standards for safety;

''(3) shall include standards addressing manure use, water quality, employee hygiene, sanitation and animal control, temperature controls, and nutrients;

''(4) may include standards for such other elements as the Secretary determines necessary to carry out subsection (a);

''(5) shall provide a reasonable period of time for compliance, taking into account the needs of small businesses for additional time to comply; and

''(6) shall provide for coordination of education and enforcement activities by State and local officials, as designated by the Governors of the respective States.

''(c) PRIORITIZATION.—The Secretary shall prioritize the implementation of the regulations under subsection (a) for specific fruits and vegetables that are raw agricultural commodities and have been associated with food-borne illness outbreaks.

''(d) ENFORCEMENT.—The Secretary may coordinate with the Secretary of Agriculture and shall contract and coordinate with the agency or department designated by the Governor of each State to perform activities to ensure compliance with this section.''.

(c) GUIDANCE; RULEMAKING.—

(1) GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary shall publish, after consultation with the Secretary of Agriculture and representatives of State departments of agriculture, updated good agricultural practices and guidance for the safe production and harvesting of specific types of fresh produce.

(2) PROPOSED RULEMAKING.—

(A) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Secretary, in consultation with the Secretary of Agriculture and representatives of State departments of agriculture, shall publish a notice of proposed rulemaking under section 419A of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b).

(B) PUBLIC INPUT.—During the comment period on the notice of proposed rulemaking under subparagraph (A), the Secretary shall conduct not less than 3 public meetings in diverse geographical areas of the United States to provide persons in different regions an opportunity to comment.

(3) FINAL REGULATION.—Not later than 1 year after the close of the comment period for the pro-

posed rulemaking under paragraph (2), the Secretary shall adopt a final regulation under section 419A of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b).

(d) NO EFFECT ON HACCP AUTHORITIES.—Nothing in the amendments made by this section limits the authority of the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.) to revise, issue, or enforce product and category-specific regulations, such as the Seafood Hazard Analysis Critical Controls Points Program, the Juice Hazard Analysis Critical Control Program, and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards.

SEC. 105. RISK-BASED INSPECTION.

(a) RISK-BASED INSPECTION SCHEDULE.—

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

''(h)(1) Each facility registered under section 415 shall be inspected by one or more officers duly designated by the Secretary at a frequency determined pursuant to a risk-based schedule.

''(2) The Secretary shall establish such risk-based schedule not later than 18 months after the date of the

enactment of this subsection and may subsequently revise such schedule in accordance with this section.

''(3) Such risk-based schedule shall provide for a frequency of inspections commensurate with the risk presented by the facility, but in no case shall inspections of a facility occur less than once every 4 years beginning on the date of the facility's initial registration pursuant to section 415.

''(4) In determining the appropriate frequency of inspection, the Secretary shall consider—

''(A) the type of food manufactured, processed, packed, or held at the facility;

''(B) the compliance history of the facility;

''(C) whether the facility is certified by a certifying agent accredited pursuant to section 420(a); and

''(D) such other factors as the Secretary determines by guidance to be relevant to assessing the risk presented by the facility.''.

(2) FACILITIES ALREADY REGISTERED.—In section 704(h)(3) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1), the term ''initial registration pursuant to section 415'' means, with respect to a facility that is registered pursuant to section 415 of such Act as of the date of the en-

actment of this Act, the first annual registration of the facility pursuant to such section 415 that occurs on or after such date of enactment.

(3) REPORTS ON RISK-BASED INSPECTIONS OF FOOD FACILITIES.—

(A) INITIAL REPORT.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit a 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 describing the risk-based inspection schedule established under section 704(h)(2) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1). Such report shall include a description of the frequency of inspections for different classes of risk, the number of facilities in each class, and an estimate of the projected 5-year costs of implementing such inspection schedule.

(B) SUBSEQUENT REPORTS.—Annually after the submission of the report required by subparagraph (A), the Secretary shall submit a report to the Congress on—

(i) the number of foreign and domestic facilities inspected under the risk-based inspection schedule established under section 704(h)(2) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1), in the preceding 12 months; and

(ii) the costs of implementing the risk-based inspection schedule for the preceding 12 months.

(b) FOOD OFFERED FOR IMPORT.—The third sentence of subsection (a) of section 801 (21 U.S.C. 381) is amended by inserting ''or (4) such article is food that has been processed, packed, or held at a facility that is in violation of section 301(f) (prohibiting the delay or limitation of an inspection, or the refusal to permit entry or inspection, under section 704),'' before ''then such article shall be refused admission''.

SEC. 106. ACCESS TO RECORDS.

(a) RECORDS INSPECTION.—Section 414(a) (21 U.S.C. 350c) is amended—

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

(2) by striking the term ''such article'' the first place such term appears and inserting ''an article of food'';

(3) by striking ''and a written notice to such person''; and

(4) by striking ''and presents a threat of serious adverse health consequences or death to humans or animals'' and inserting '', misbranded, or otherwise in violation of this Act''; and

(b) CONFORMING AMENDMENT.—Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended by striking ''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'' and inserting ''bearing on whether such food is adulterated, misbranded, or otherwise in violation of this Act''.

SEC. 107. TRACEABILITY OF FOOD.

(a) FARM AND RESTAURANT RECORDS.—

(1) INSPECTION.—Section 414(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c(a)), as amended by section 106, is amended by striking ''(excluding farms and restaurants)''.

(2) MAINTENANCE OF RECORDS.—Section 414(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c(b)), as amended by section 106, is

amended by striking ''(excluding farms and restaurants)''.

(b) STANDARDIZED ELECTRONIC FORMAT.—Section 414 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c(a)), as amended by section 106 and subsection (a), is amended—

(1) in subsection (a), by striking ''in any format (including paper and electronic formats) and''; and

(2) in subsection (b), by adding at the end the following: ''The Secretary shall require such persons to maintain such records in a standardized electronic format.''.

(c) IDENTIFICATION OF SOURCE OF RAW AGRICULTURAL PRODUCTS.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

''(z) If it is a raw agricultural product, unless each commercial shipment of the product contains information enabling the Secretary to identify—

''(1) the grower of the product;

''(2) the lot on which the product was produced;

''(3) the harvesting and packing dates of the product; and

''(4) any other information determined appropriate by the Secretary to facilitate identification of the source of raw agricultural products.''.

(d) STUDY.—Not later than 2 years after the date of the enactment of this Act, the Commissioner of Food and Drugs shall—

(1) complete a study on the effectiveness of technologies for determining the source of raw agricultural products; and

(2) submit a report to the Congress on the results of such study.

SEC. 108. REINSPECTION FEE APPLICABLE TO FACILITIES.

(a) IN GENERAL.—Part 5 of subchapter C 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 solely 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. 109. CERTIFICATION OF FOOD FACILITIES.

(a) MISBRANDING.—

(1) IN GENERAL.—Section 403 (21 U.S.C. 343), as amended by section 101(a), is amended by adding at the end the following:

''(aa) If it is part of a shipment offered for import into the United States and such shipment is in violation of section 420(b)(5) (requiring a certification to accompany certain food shipments).''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to shipments offered

for import on or after the date that is 3 years after the date of the enactment of this Act.

(b) ACCREDITATION OF CERTIFYING AGENTS; CERTIFICATION OF LABORATORIES AND ACCREDITATION OF LABORATORY CERTIFYING AGENTS.—Chapter IV (21 U.S.C. 341 et seq.), as amended by sections 102(b), 103, and 104, is amended by adding at the end the following:

"SEC. 420. ACCREDITATION OF CERTIFYING AGENTS.

''(a) ACCREDITATION AS CERTIFYING AGENT.—

''(1) IN GENERAL.—Beginning not later than 2 years after the date of the 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, and any other third party that the Secretary determines appropriate, may request to be accredited as a certifying agent to certify facilities as meeting the applicable requirements of this Act.

''(2) QUALIFICATIONS OF CERTIFYING AGENTS.—Prior to accrediting an third party as a certifying agent under paragraph (1), the Secretary shall perform such reviews and audits of the training and qualifications of auditors used by the third

party, and conduct such reviews of internal systems and such other investigation of the third party, as the Secretary deems necessary to determine whether the third party—

"(A) meets the requirements of this section; and

"(B) is qualified to evaluate the compliance of a facility with the applicable requirements of this Act.

"(3) LIMITATION OF ACCREDITATION.—The Secretary may limit the accreditation under paragraph (1) of a certifying agent to the certification of facilities that produce, manufacture, process, or hold only specified food products (or categories of food products).

"(4) PERFORMANCE OF AUDITS AND RENEWAL OF ACCREDITATION.—The Secretary shall audit the performance of certifying agents on a periodic basis, but not less than every 4 years, for the purpose of renewing the accreditation of such agents.

"(5) WITHDRAWAL OF ACCREDITATION.—The Secretary—

"(A) may withdraw accreditation under paragraph (1) from a certifying agent if—

"(i) a facility certified by the agent is linked to an outbreak of human or animal illness; or

"(ii) the Secretary finds that the agent no longer meets the requirements for accreditation; and

"(B) shall withdraw accreditation under paragraph (1) from a certifying agent if the Secretary finds that the certifying agent has refused to allow the Secretary to conduct such audits and investigations as may be necessary to ensure continued compliance with the requirements of this section.

"(6) PUBLICATION OF LIST OF CERTIFYING AGENTS.—The Secretary shall publish and maintain on the website of the Food and Drug Administration a current list of certifying agents accredited under this section, including—

"(A) each such agent's name and location; and

"(B) any other information deemed necessary by the Secretary.

"(b) ADDITIONAL REQUIREMENTS APPLICABLE TO CERTIFYING AGENTS.—As conditions of accreditation

under subsection (a), a certifying agent shall agree to the following:

''(1) AUDIT REQUIREMENTS.—A certifying agent shall not certify a facility unless the certifying agent has—

''(A) conducted an on-site audit of the facility, which shall be unannounced for a domestic facility;

''(B) reviewed the facility's food safety plan under section 418A to ensure the plan meets applicable requirements of this Act and is adequate to protect the public health;

''(C) prepared an audit report in a form and manner designated by the Secretary; and

''(D) conducted any other review, analysis, or testing determined by the Secretary to be appropriate for determining such facility's compliance with the applicable requirements of this Act.

''(2) ACCESS TO REPORTS AND RECORDS.—A certifying agent shall provide to the Secretary, upon request—

''(A) a copy of any audit report prepared under paragraph (1)(C);

''(B) any records relating to corrective actions planned or taken by the audited facility; and

''(C) any other records related to—

''(i) the certification or decertification of a facility;

''(ii) compliance of a facility with the requirements of this Act; or

''(iii) the accreditation of the certifying agent.

''(3) CONFLICTS OF INTEREST.—

''(A) IN GENERAL.—A certifying agent shall—

''(i) not have an ownership, management, or other financial interest in any facility to be certified by the certifying agent or in such facility's suppliers or vendors;

''(ii) have procedures to ensure against the use, in carrying out audits of a facility under this section, of any officer or employee who has a financial conflict of interest regarding such facility; and

''(iii) have written conflict of interest policies that include prompt disclosure to

the Secretary of all conflicts or potential conflicts of interest.

''(B) REGULATIONS.—Not later than 18 months after the date of the enactment of this section, the Secretary shall promulgate regulations to implement the requirements of subparagraph (A). Such regulations shall include a structure, including timing and public disclosure, for fees paid by facilities to certifying agents.

''(4) DECERTIFICATION OF FACILITIES.—A certifying agent shall decertify a facility if the certifying agent, after providing a reasonable opportunity for corrective action, finds that the facility no longer meets the applicable requirements of this Act.

''(5) REQUIRED CERTIFICATION OF IMPORTS.—A certifying agent shall issue a written and electronic certification to accompany each shipment offered for import into the United States containing food that was manufactured, processed, packed, or held by a facility certified by the agent, subject to requirements set forth by the Secretary.

''(6) RISKS TO PUBLIC HEALTH.—If, at any time during an audit, an auditor of a certifying agent finds a condition at a facility that could cause

or contribute to illness or injury to an individual consuming an article of food manufactured, processed, packed, or held by the facility, the certifying agent shall immediately notify the Secretary of the identity of the facility and such condition.

''(c) FALSE OR MISLEADING STATEMENTS.—For purposes of section 301(q)(2), any statement or representation made by an employee or agent of a facility to an auditor of a certifying agent or a certifying agent is deemed to be a report required by or under this Act.

''(d) DEFINITIONS.—In this section:

''(1) The term 'certifying agent' means a third party accredited as a certifying agent pursuant to subsection (a)(1).

''(2) The term 'facility' means a facility required to be registered under section 415.

''SEC. 421. CERTIFICATION OF LABORATORIES; ACCREDITATION OF LABORATORY CERTIFYING AGENTS.

''(a) IN GENERAL.—Not later than 2 years after the date of the enactment of this section, the Secretary shall establish a program for the certification of laboratories for the purpose of conducting sampling and testing of food to ensure compliance with the requirements of this Act.

''(b) STANDARDS.—Not later than 18 months after the date of the enactment of this section, the Secretary

shall develop standards to certify laboratories under this section. Such standards shall include—

''(1) standards for sampling and analytical procedures;

''(2) training and qualification levels for individuals who conduct the analyses;

''(3) standards for internal quality systems; and

''(4) any other standards determined appropriate by the Secretary.

''(c) ACCREDITATION OF THIRD PARTIES AS LABORATORY CERTIFYING AGENTS.—

''(1) IN GENERAL.—The Secretary may establish an accreditation system under which third parties, as determined appropriate by the Secretary, may request to be accredited as a laboratory certifying agent to certify laboratories as meeting the applicable requirements of this Act.

''(2) APPLICATION OF REQUIREMENTS RELATING TO QUALIFICATIONS OF AGENTS, PERFORMANCE OF AUDITS AND RENEWAL OF ACCREDITATION, AND WITHDRAWAL OF ACCREDITATION.—The provisions of paragraphs (2), (4), and (5), other than paragraph (5)(A)(i), of section 420(a) shall apply to the accreditation of laboratory certifying agents with respect to laboratories in the same manner as such

provisions apply to the accreditation of certifying agents with respect to facilities.

''(3) APPLICATION OF ADDITIONAL REQUIREMENTS.—The provisions of paragraphs (1) (other than subparagraph (B) and other than the requirement under subparagraph (A) that an audit be unannounced), (2), (3), and (4) of section 420(b) shall apply to laboratory certifying agents under this subsection with respect to laboratories in the same manner as such provisions apply to the certifying agents with respect to facilities.

''(4) LABORATORY CERTIFYING AGENT DEFINED.—In this section, the term 'laboratory certifying agent' means a third party accredited as a laboratory certifying agent under this subsection.

''(d) PUBLICATION OF LIST OF CERTIFYING AGENTS AND CERTIFIED LABORATORIES.—The provisions of paragraph (6) of section 420(a) shall apply to third parties accredited as laboratory certifying agents under subsection (c) and to laboratories certified under subsection (a) in the same manner as such provisions apply to third parties accredited as certifying agents under such section.

''(e) FOOD TESTING BY CERTIFIED LABORATORIES.—

''(1) IN GENERAL.—Beginning 3 years after the date of the enactment of this section, testing of food described in paragraph (2) shall be conducted only by Federal laboratories or by laboratories certified under subsection (a).

''(2) TESTING OF FOOD COVERED.—The testing of food described in this paragraph is testing of food—

''(A) conducted in support of an admission of an article of food under section 801;

''(B) conducted in support of a reoffer of food previously denied admission under section 402(h);

''(C) conducted under an import alert that requires successive consecutive tests;

''(D) conducted to show compliance with an order of the Secretary;

''(E) conducted in support of an appeal of an order of the Secretary; or

''(F) as otherwise required to be conducted by the Secretary, as the Secretary deems appropriate.

''(3) ACCESS TO TESTING RESULTS.—The results of any testing of food described in paragraph (2) by a laboratory certified under this section shall

be promptly transmitted by such laboratory in electronic format to the Secretary.

''(f) FALSE OR MISLEADING STATEMENTS.—For purposes of section 301(q)(2), as amended by section 406, any statement or representation made by an employee or agent of a laboratory to a laboratory certifying agent is deemed to be a report required by or under this Act.''.

(c) FEES.—Part 5 of subchapter C of chapter VII, as added by section 101(b) and amended by section 108(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 an entity as a certifying agent under section 420(a) for the purpose of defraying the costs of implementing the system established for such accreditation.

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

''SEC. 741C. LABORATORY CERTIFYING AGENT ACCREDITATION FEE.

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

SEC. 110. 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 by a certifying agent accredited pursuant to section 420(a)(1); 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) Vendor and supplier information.

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

Subtitle B—Intervention

SEC. 111. PUBLIC HEALTH ASSESSMENT SYSTEM.

(a) ACTIVE SURVEILLANCE SYSTEM.—The Secretary of Health and Human Services (in this subtitle referred to as the ''Secretary''), acting through the Centers for Disease Control and Prevention, shall establish and implement an active surveillance system for food, based on a representative proportion of the population of the United States, to assess more accurately the frequency and sources of human illness in the United States associated with the consumption of food.

(b) SAMPLING SYSTEM.—

(1) IN GENERAL.—The Secretary shall establish and implement a sampling system under which the Secretary takes and analyzes samples of food products—

(A) to assist the Secretary in carrying out this Act and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(B) to more accurately assess the nature, frequency of occurrence, and amounts of contaminants in food products.

(2) REQUIREMENTS.—Such sampling system shall provide—

(A) statistically valid monitoring, including market-basket studies, on the nature, frequency of occurrence, and amounts of contaminants in food products available to consumers; and

(B) at the request of the Secretary, such other information, including analysis of monitoring and verification samples, as the Secretary determines may be useful in assessing the occurrence of contaminants in food products.

(3) GUIDELINES.—Within 12 months after the date of the enactment of this Act, the Secretary shall establish guidelines for the sampling system under this subsection.

(c) ASSESSMENT OF HEALTH HAZARDS.—Through the surveillance system under subsection (a) and the sampling system under subsection (b), the Secretary shall

rank food categories based on their hazard to human health and identify appropriate industry and regulatory approaches to minimize hazards in the food supply. Such analysis may include—

(1) the safety of commercial harvesting and processing, as compared with the health hazards associated with food products that are harvested for recreational or subsistence purposes and prepared noncommercially;

(2) the safety of food products that are domestically harvested and processed, as compared with the health hazards associated with food products that are harvested or processed outside the United States;

(3) contamination originating from handling practices that occur prior to or after sale of food products to consumers; and

(4) use of comparative risk assessments.

SEC. 112. PUBLIC EDUCATION AND ADVISORY SYSTEM.

(a) PUBLIC EDUCATION.—The Secretary, in cooperation with private and public organizations, including the appropriate State entities, shall design and implement a national public education program on food safety. The program shall provide—

(1) information to the public regarding Federal standards and good practice requirements and promotion of public awareness, understanding, and acceptance of such standards and requirements;

(2) information to health professionals so that they may improve diagnosis and treatment of food-related illness and advise individuals whose health conditions place them in particular risk; and

(3) such other information or advice to consumers and other persons as the Secretary determines will promote the purposes of this Act.

(b) HEALTH ADVISORIES.—The Secretary shall work with the States and other appropriate entities to—

(1) develop and distribute regional and national advisories concerning food safety;

(2) develop standardized formats for written and broadcast advisories; and

(3) incorporate State and local advisories into the national public education program required under subsection (a).

SEC. 113. RESEARCH.

(a) IN GENERAL.—The Secretary shall conduct research to assist in the implementation of this Act, including studies to—

(1) improve sanitation and food safety practices in the processing of food products;

(2) develop improved techniques for the monitoring of food and inspection of food products;

(3) develop efficient, rapid, and sensitive methods for determining and detecting the presence of contaminants in food products;

(4) determine the sources of contamination of food and food products with contaminants;

(5) develop consumption data with respect to food products;

(6) draw upon research and educational programs that exist at the State and local level;

(7) utilize the DNA matching system and other processes to identify and control pathogens;

(8) address common and emerging zoonotic diseases;

(9) develop methods to reduce or destroy pathogens before, during, and after processing;

(10) analyze the incidence of antibiotic resistance as it pertains to the food supply and develop new methods to reduce the transfer of antibiotic resistance to humans; and

(11) conduct other research that supports the purposes of this Act.

(b) CONTRACT AUTHORITY.—The Secretary is authorized to enter into contracts and agreements with any State, university, government agency, or other person to carry out this section.

SEC. 114. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED ARTICLES OF FOOD.

(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331), as amended by sections 102 and 104, is amended by adding at the end the following:

''(qq)(1) The failure to notify the Secretary in violation of section 422(a).

''(2) The failure to comply with—

''(A) an order issued under section 422(b) following any hearing requested under section 422(c); or

''(B) an amended order issued under section 422(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(b), 104, and 108(c), is amended by adding at the end the following:

"SEC. 422. 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(qq)(1) and 422 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. ADMINISTRATIVE DETENTION.

(a) IN GENERAL.—Section 304(h)(1)(A) (21 U.S.C. 334(h)(1)(A)) is amended by—

(1) striking ''credible evidence or information indicating'' and inserting ''reason to believe''; and

(2) striking ''presents a threat of serious adverse health consequences or death to humans or animals'' and inserting ''is adulterated or misbranded''.

(b) REGULATIONS.—Not later than 120 days after the date of enactment of this Act, the Secretary shall issue an interim final rule amending subpart K of part 1 of title 21, Code of Federal Regulations, to implement the amendment made by this section.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect 180 days after the date of enactment of this Act.

SEC. 122. 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 in-

junction 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. 123. FAILURE TO CONSENT TO INVESTIGATION.

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

''(p) 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 foodborne illness outbreak or is otherwise found to be adulterated or mislabeled.''.

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 notice of such request in the Federal Register.

''(2) Not later than 90 days after the date of publication of a notice under paragraph (1), the Secretary shall determine whether the substance is a GRAS food substance.

''(3) A determination by the Secretary of whether a substance is a GRAS food substance shall be published in the Federal Register.

''(4) 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.''.

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

(a) FOOD.—Section 403 (21 U.S.C. 343), as amended by sections 101(a) and 108(b), is amended by adding at the end the following:

''(bb) 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.

''(cc) 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 paragraphs (bb) and (cc) of section 403

of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(c) EFFECTIVE DATE.—The requirements of paragraphs (bb) and (cc) of section 403 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), take 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 5 of subchapter C of chapter VII (21 U.S.C. 371 et seq.), as added by section 101(b) and amended by sections 108 and 109, 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 OF PRODUCERS OF DRUGS AND DEVICES; APPLICABLE FEE.

(a) REGISTRATION.—

(1) MISBRANDING.—Paragraph (o) of section 502 (21 U.S.C. 352) is amended by striking ''in any State''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) applies only with respect to registration under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) occurring on or after the date of the enactment of this Act.

(b) REGISTRATION FEE.—

(1) MISBRANDING.—Paragraph (o) of section 502 (21 U.S.C. 352), as amended by subsection (a)(2), is further amended by inserting after ''not duly registered under section 510'' the following: ''or in violation of section 736C for failure to pay a fee''.

(2) ESTABLISHMENT.—Part 2 of subchapter C of chapter VII (21 U.S.C. 379g et seq.) is amended by adding at the end the following:

"SEC. 736C. REGISTRATION FEE.

"(a) IN GENERAL.—Except as provided in subsection (b) of this section, the Secretary shall assess and collect an annual fee for registration under subsection (b), (c), (d), or (i) of section 510 to defray increases (as described in subsection (g)(2)(A)(ii)) in the costs of inspecting establishments registered under subsection (b), (c), (d), or (i) of section 510 to ensure compliance by such establishments with the requirements of this Act relating to drugs or devices.

"(b) EXCEPTION.—The Secretary shall not assess or collect a fee under this section for registration of an establishment under section 510 on the basis of such establishment's manufacture, preparation, propagation, or processing of an excipient of a drug.

"(c) FEE REVENUE AMOUNTS.—

"(1) IN GENERAL.—For each of fiscal years 2010 through 2014, fees under subsection (a) shall, except as provided in subsections (d), (f), and (g), be established to generate a total revenue amount under subsection (a).

''(2) TOTAL REVENUE AMOUNT.—Not later than September 1, 2010, the Secretary shall transmit to the Congress the total revenue amount under paragraph (1) and how such amount was calculated.

''(3) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of each fiscal year that begins after September 30, 2009, establish, for the next fiscal year, registration fees under subsection (a)—

''(A) based on the total revenue amount applicable under paragraph (1); and

''(B) taking into consideration the difference in costs of inspections between foreign and domestic establishments.

''(d) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—For fiscal year 2011 and subsequent fiscal years, the revenues established in subsection (c)(1) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

''(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average) for the 12-month period ending June 30 pre-

ceding the fiscal year for which fees are being established;

"(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia; or

"(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 5 years of the preceding 6 fiscal years.

The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2009 under this subsection.

"(2) WORKLOAD ADJUSTMENT.—For fiscal year 2011 and subsequent fiscal years, after the fee revenues established in subsection (c)(1) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be ad-

justed further for such fiscal year to reflect changes in the workload of the Secretary for inspections described in subsection (a). 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 amount of inspections described in subsection (a). The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

"(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 (c)(1), as adjusted for inflation under paragraph (1). Any adjustment for changes in inspection activities made in setting fees and revenue amounts for fiscal year 2011 may not result in the total workload adjustment being more than 2 percentage points higher than it would have been in the absence of the adjustment for changes in inspection activities.

"(C) The Secretary shall contract with an independent accounting firm to study the ad-

justment for changes in inspection activities applied in setting fees and revenue amounts for fiscal year 2011 and to make recommendations, if warranted, for future changes in the methodology for calculating the adjustment. After review of the recommendations, the Secretary shall, if warranted, make appropriate changes to the methodology, and the changes shall be effective for each of the fiscal years 2012 through 2014. The Secretary shall not make any adjustment for changes in inspection activities for any fiscal year after 2011 unless such study has been completed.

''(3) RENT AND RENT-RELATED COST ADJUSTMENT.—For fiscal year 2012 and each subsequent fiscal year, the Secretary shall, before making adjustments under paragraphs (1) and (2), decrease the fee revenue amount established in subsection (c)(1) if actual costs paid for rent and rent-related expenses for the preceding fiscal year are less than estimates made for such year in fiscal year 2008. Any reduction made under this paragraph shall not exceed the amount by which such costs fall below the estimates made in fiscal year 2008 for such fiscal

year, and shall not exceed $11,721,000 for any fiscal year.

''(4) FINAL YEAR ADJUSTMENT.—For fiscal year 2014, the Secretary may, in addition to adjustments under paragraphs (1), (2), (3), and (5), further increase the fee revenues and fees established in subsection (c) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for inspections described in subsection (a) for the first 3 months of fiscal year 2015. 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 2014. If the Secretary has carryover balances for such inspections in excess of 3 months of such operating reserves, the adjustment under this paragraph shall not be made.

''(5) COST ESTIMATE ADJUSTMENT.—For fiscal year 2011 and subsequent fiscal years, the Secretary by notice, published in the Federal Register, shall—

''(A) provide an estimate of the amount of the total increases described in subsection (a) for such fiscal year; and

''(B) after making adjustments under paragraphs (1), (2), and (3), adjust the reve-

nues established in subsection (c)(1) to be equal to such amount.

''(6) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total increases described in subsection (a) for such fiscal year.

''(e) FEE WAIVER OR REDUCTION..—

''(1) IN GENERAL.—The Secretary may grant to a person a waiver from, or a reduction of, one or more fees under this section if the Secretary finds that—

''(A) such waiver or reduction is necessary to protect the public health; or

''(B) the assessment of the fee would impose significant financial hardship because of limited resources available to such person or other circumstances.

''(2) SPECIAL RULES FOR POSITRON EMISSION TOMOGRAPHY DRUGS.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), each person who is named as the applicant in an approved human drug application for a positron emission tomography drug shall be subject under paragraph (a) to one-sixth of an annual registration fee with re-

spect to each establishment identified in the application as producing positron emission tomography drugs under the approved application.

''(B) EXCEPTION FROM ANNUAL REGISTRATION FEE.—Each person who is named as the applicant in an application described in subparagraph (A) shall be granted a waiver under paragraph (1) from an annual registration fee under subsection (a) for a fiscal year if the person certifies to the Secretary, at a time specified by the Secretary and using procedures specified by the Secretary, that—

''(i) the person is a not-for-profit medical center that has only 1 establishment for the production of positron emission tomography drugs; and

''(ii) at least 95 percent of the total number of doses of each positron emission tomography drug produced by such establishment during such fiscal year will be used within the medical center.

''(3) DESIGNATED ORPHAN DRUG.—An establishment registered under section 510 shall, with respect to the manufacture, preparation, propagation, compounding, or processing of drugs, be granted a

waiver under paragraph (1) from a fee under subsection (a) if all drugs manufactured, prepared, propagated, compounded, or processed by the establishment are designated as a drug for a rare disease or condition pursuant to section 526. The preceding sentence shall not apply if the application approved under section 505 for any such drug includes an indication for a disease or condition other than such a rare disease or condition.

''(f) LIMITATIONS.—

''(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2010 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2010 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at

a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for registration under subsection (b), (c), (d), or (i) of section 510 at any time in such fiscal year.

''(g) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—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. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

''(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 in appropriation Acts, or otherwise made available for obligation, for such fiscal year; and

"(ii) shall only be collected and available to defray increases in the costs of inspecting establishments registered under subsection (b), (c), (d), or (i) of section 510 to ensure compliance by such establishments with the requirements of this Act relating to drugs and devices (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such inspections) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2009 multiplied by the adjustment factor.

"(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 inspections described in subsection (a)—

"(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.—For each of the fiscal years 2010 through 2014, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (c)(1) for the fiscal year, as adjusted or otherwise affected under subsection (d) and paragraph (4) of this subsection.

''(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2010 through 2013 and the amount of fees estimated to be collected under this section for fiscal year 2014 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2010 through 2014, the excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would

otherwise be authorized to be collected under this section for fiscal year 2014.

''(h) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (e), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

''(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in inspections described in subsection (a), be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(k) ANNUAL FISCAL REPORTS.—Beginning with fiscal year 2011, not later than 120 days after the end of each fiscal year for which fees are collected under this sec-

tion, the Secretary 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 for such fiscal year.

''(l) DEFINITION.—The term 'costs of inspecting establishments registered under subsection (b), (c), (d), or (i) of section 510 to ensure compliance by such establishments with the requirements of this Act relating to drugs and devices' means the expenses incurred, in connection with inspecting establishments registered under subsection (b), (c), (d), or (i) of section 510 to ensure compliance by such establishments with the requirements of this Act relating to drugs and devices, for—

''(1) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, and costs related to such officers and employees and to contracts with such contractors;

''(2) management of information, and the acquisition, maintenance, and repair of information technology resources;

''(3) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

''(4) collecting fees under this section and accounting for resources allocated for such inspections.''.

(3) 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 paragraph (2), for fiscal years beginning with fiscal year 2010.

(4) SUNSET DATE.—Section 736C of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (2), does not authorize the assessment or collection of a fee for registration under section 510 of such Act (21 U.S.C. 360) occurring after fiscal year 2014.

SEC. 202. INSPECTION OF PRODUCERS OF DRUGS AND ACTIVE PHARMACEUTICAL INGREDIENTS.

(a) 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)'';

(3) by striking ''704(g), at least once'' and all that follows and inserting the following: ''704(g)—

''(A) at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter; or

''(B) at least once in the 4-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 4-year period thereafter, if the Secretary determines that sufficient information about the type of product produced in the establishment, inspection history, compliance history, and such additional factors as the Secretary determines, by guidance, exists to assess risk and to establish a risk-based inspection schedule.''; and

(4) by adding at the end the following:

''(2)(A) The Secretary shall conduct an inspection of a drug establishment when the establishment begins to manufacture, prepare, propagate, compound, or process a

drug or active pharmaceutical ingredient of a drug before its introduction into interstate commerce if the drug or ingredient is new or has undergone a major change requiring prior approval by the Secretary of a supplement to an application submitted under section 505. Notwithstanding the preceding sentence, the Secretary may opt against conducting such an inspection if the Secretary determines, based on the inspection history of the establishment, that such an inspection is not necessary to verify the data contained in the application (or supplement to the application) submitted under section 505, ensure compliance with current good manufacturing practice, or otherwise ensure the safety of the drug or ingredient.

''(B) The Secretary shall annually submit a report to the Congress on each instance during the preceding year in which the Secretary determined under subparagraph (A) that an inspection was not necessary.

''(3) The Secretary may, by regulation, provide for a risk-based inspection schedule for establishments engaged in the manufacture, propagation, compounding, or processing of an excipient of a drug at a frequency different than the inspection schedule for an establishment under paragraph (1).

''(4) Nothing in this subsection shall be construed as limiting the authority of the Secretary to conduct inspections under any other provision of the Act.

''(5) With respect to fiscal year 2010 and each subsequent fiscal year, the Secretary shall submit an annual report to the Congress on—

''(A) funding dedicated to inspections under this subsection; and

''(B) the number of establishments for which the frequency of such inspections has been modified pursuant to paragraph (1)(B).

''(6) For purposes of determining inspection frequency under subparagraphs (A) and (B) of paragraph (1), the Secretary shall establish information systems capacity sufficient to assess risk and shall develop and maintain a risk-based system for conducting surveillance of current good manufacturing practices by establishments registered with the Secretary pursuant to subsection (b), (c), (d), or (i). The Secretary shall have such capacity in place and begin implementation of such risk-based system not later than 3 years after the date of the enactment of the Food and Drug Administration Globalization Act of 2009. Such risk-based system shall include consideration of the class of the establishment's products and associated risks, the date the establishment was last inspected, the

establishment's compliance and safety history, the establishment's shipping volume and history, and such other factors as the Secretary determines relevant to assessing the risk presented by the establishment.''.

(b) GAO REPORT.—Not later than 3 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit a report to the Congress on the risk-based process for conducting surveillance of current good manufacturing practices developed and implemented under section 510(h)(6) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)(4) of this section.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to drugs introduced or delivered for introduction into interstate commerce on or after the date of the enactment of this Act.

SEC. 203. DOCUMENTATION FOR ADMISSIBILITY OF DRUG IMPORTS.

Section 801 (21 U.S.C. 381), as amended by section 123, is further amended by adding at the end the following:

''(q) Beginning 3 years after the date of the enactment of this subsection, a drug shall not enter the United States unless the party offering the drug for import provides the Secretary, at the time of offering the drug for

import, information demonstrating compliance with applicable requirements pertaining to identity, strength, quality, purity, approval, listing, labeling, registration, and such additional categories as the Secretary, by guidance, determines are necessary for protection of the public health. The Secretary may allow that such compliance be demonstrated through verification by an accredited third party or through such other means as determined, by guidance, by the Secretary.''.

SEC. 204. DRUG SUPPLY QUALITY AND SAFETY.

(a) ADULTERATION.—Section 501 (21 U.S.C. 351) is amended by adding at the end the following:

''(j) If it is drug that was manufactured, prepared, propagated, compounded, or processed by an establishment that is or was at the time of such manufacture, preparation, propagation, compounding, or processing in violation of section 505–2 because of—

''(1) the failure to have in effect and implement a quality risk management plan in accordance with section 505–2; or

''(2) the failure to transmit information in electronic form as requested by the Secretary under section 505–2(f).''.

(b) QUALITY RISK MANAGEMENT PLANS.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 505–1 the following:

"SEC. 505–2. DRUG SUPPLY QUALITY AND SAFETY.

"(a) IMPLEMENTATION OF QUALITY RISK MANAGEMENT PLAN.—An establishment required to be registered with the Secretary pursuant to subsection (b), (c), (d), or (i) of section 510 for the manufacture, preparation, propagation, compounding, or processing of a drug shall have in effect and implement an adequate quality risk management plan that ensures the safety and quality of each such drug, including any ingredients produced, manufactured, processed, packed, or held by another person.

"(b) PLAN PROVISIONS.—A quality risk management plan required by subsection (a) shall address risk assessment, risk control, risk communication, and risk review and shall—

"(1) provide for an assessment, prior to contracting with a person to supply raw materials or ingredients or to undertake any aspect of the manufacturing of the drug, of the suitability and competence of such person to carry out such activity, using audits, material evaluations, or qualification, as appropriate;

''(2) define responsibilities and communication processes for manufacturing, quality control, and quality assurance activities of any person referred to in paragraph (1);

''(3) provide for the monitoring and review through periodic on-site audits of the facility conditions, controls, and practices of any person referred to in paragraph (1) and ensure the implementation of appropriate measures to improve such conditions, controls, and practices;

''(4) provide for the monitoring of incoming materials to ensure they are from a person that meets the requirements in paragraphs (1) through (3);

''(5) provide for implementation of effective systems, including appropriate specifications and test methods and verification of the drug ingredients' identity, quality, strength, and purity, to detect any hazard that has been, or is reasonably likely to be, present in or on the drug during production, manufacturing, processing, packing, holding, or transporting; and

''(6) be periodically reviewed and, as needed, updated.

''(c) ADDITIONAL PROVISIONS.—If the Secretary determines that provisions in addition to those described in subsections (a) and (b) would be appropriate to include in a quality risk management plan for protection of the public health, including provisions for the prevention of intentional adulteration of a drug or class of drugs, the Secretary may by regulation require the inclusion of such provisions in a quality risk management plan.

''(d) APPLICATION OF SPECIFICATIONS OR TEST METHODS BY ORDER OF THE SECRETARY.—Upon a finding that there is a significant threat to public health, the Secretary may order an establishment—

''(1) to promptly revise its quality risk management plan to include new or modified specifications or test methods for a drug; and

''(2) to promptly implement such specifications or test methods.

''(e) INSPECTION OF QUALITY RISK MANAGEMENT PLAN.—The Secretary shall, in the course of an inspection of an establishment subject to this section or upon request by the Secretary, conduct a review of the establishment's quality risk management plan.

''(f) DOCUMENTATION OF SUPPLY CHAIN.—

''(1) IN GENERAL.—Each establishment required to be registered with the Secretary pursuant

to subsection (b), (c), (d), or (i) of Section 510 for the manufacture, preparation, propagation, compounding, or processing of a drug, shall provide to the Secretary, upon request, adequate information transmitted in electronic form, establishing—

''(A) where the drug, including its raw materials, were produced, including all preceding producers, manufacturers, distributors, and shippers; and

''(B) that the drug, its ingredients and raw materials were manufactured, prepared, propagated, compounded, processed, distributed, shipped, warehoused, brokered, imported, and conveyed under conditions that ensure the identity, strength, quality, and purity of the drug.

''(2) REPACKAGERS.—For those establishments that are repackagers, paragraph (1)(A) requires only information regarding the immediately preceding establishment.''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The requirements of sections 501(j) and 505–2 of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b), take effect 2 years after the date of the enactment of this Act.

(2) EXCEPTION.—Notwithstanding the effective date specified in paragraph (1)—

(A) the authority of the Secretary to order an establishment to promptly implement new or modified specifications or test methods for a drug, as described in section 505–2(d)(2) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), shall take effect on the date of the enactment of this Act;

(B) such authority shall apply irrespective of whether the establishment has in effect a quality risk management plan; and

(C) a civil penalty under section 303(f)(5) of the Federal Food, Drug, and Cosmetic Act, as added by section 211 of this Act, shall apply to a violation of an order under this paragraph to the same extent and in the same manner as such a penalty applies to a violation of an order under such section 505–2(d)(2).

SEC. 205. DELAY, LIMITATION, OR DENIAL OF INSPECTION.

(a) REQUIREMENT.—Subsection (h) of section 510 (21 U.S.C. 351), as amended by section 202(a), is further amended by adding at the end the following:

''(7) The person who owns or operates an establishment registered with the Secretary pursuant to subsection

(b), (c), (d), or (i), any agent or employee of such person, and any agent of a governmental authority in the foreign country within which such establishment is located shall not delay or limit an inspection, or refuse to permit entry or inspection, authorized by this subsection.''.

(b) REFERENCE TO PROHIBITED ACT.—For provision making delay, limiting, or denying an inspection under section 510(h) of the Federal Food, Drug, and Cosmetic Act a prohibited act under section 301(f) of such Act, see the amendment made by section 403.

(c) DRUGS OFFERED FOR IMPORT.—The third sentence of subsection (a) of section 801 (21 U.S.C. 381), as amended by section 105(b), is amended by inserting ''or (5) such article has been manufactured, prepared, propagated, compounded, or processed by an establishment required to be registered with the Secretary pursuant to subsection (b), (c), (d), or (i) of section 510 and such establishment is in violation of section 510(h)(7) (prohibiting the delay, limitation, or denial of an inspection under section 510(h)),'' before ''then such article shall be refused admission''.

SEC. 206. COUNTRY OF ORIGIN LABELING.

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

''(aa) If it is a drug and the website of the manufacturer of the drug does not list the country of origin for each active pharmaceutical ingredient and finished dosage form of such drug.''.

(b) REGULATIONS.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall promulgate final regulations to carry out section 502(aa) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(c) EFFECTIVE DATE.—The requirement of section 502(aa) 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. NONDISTRIBUTION AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.

(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331), as amended by sections 102, 104, and 112 of this Act, is amended by adding at the end the following:

''(rr) The failure to comply with—

''(1) an order issued under section 568(a) following any hearing requested under section 568(b); or

''(2) an amended order issued under section 568(c)(1).''.

(b) NONDISTRIBUTION AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.—Subchapter E of chapter V (21 U.S.C. 360bb et seq.) is amended by adding at the end the following:

"SEC. 568. NONDISTRIBUTION AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.

''(a) RECALL AND CONSUMER NOTIFICATION.—

''(1) VOLUNTARY ACTIONS.—On receiving information of a suspected adulteration or misbranding of a drug, if the Secretary finds that there is a reasonable probability that a drug intended for human use would cause serious, adverse health consequences or death, the Secretary shall provide all persons (including the manufacturer, importer, distributor, or retailer of the drug) with an opportunity (as determined by the Secretary)—

''(A) to cease distribution of the drug;

''(B) to notify all entities—

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

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

''(C) to recall the drug;

''(D) in consultation with the Secretary, to provide notice of the finding of the Secretary to all consumers to which the drug 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 a person referred to in paragraph (1) does not carry out the actions described in that paragraph with respect to a drug within the time period and in the manner prescribed by the Secretary, the Secretary shall issue an order requiring such person—

''(A) to immediately cease distribution of the drug; and

''(B) to immediately notify health professionals and drug user facilities of the order and to instruct such professionals and facilities to cease use of such drug.

''(b) HEARINGS ON ORDERS.—The Secretary shall provide a person subject to an order under subsection (a)(2) with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on—

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

''(2) any reasons why the drug that is the subject of the order should not be recalled.

''(c) POST-HEARING RECALL ORDERS.—

''(1) AMENDMENT OF ORDERS.—If, after providing an opportunity for an informal hearing under subsection (b), the Secretary determines that an order under subsection (a)(2) with respect to a drug should be amended to include a recall or other appropriate action, the Secretary shall, except as provided in paragraph (2)—

''(A) amend the order—

''(i) to require recall of the drug or other appropriate action; and

''(ii) to specify a timetable during which any such recall shall occur; and

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

''(2) CONTENTS OF ORDER.—

''(A) INDIVIDUALS AND DRUG USER FACILITIES.—An amended order under paragraph (1) shall not include—

''(i) a recall of a drug from individuals; or

"(ii) a recall of a drug from drug user facilities if the Secretary determines that the risk of recalling such drug from the facilities presents a greater health risk than the health risk of not recalling the drug from use.

"(B) NOTICE TO INDIVIDUALS SUBJECT TO RISKS.—An amended order under paragraph (1) shall provide for notice to individuals subject to the risks associated with the use of such drug. In providing the notice required by this paragraph, the Secretary may use the assistance of health professionals who prescribed or dispensed such a drug for individuals. If a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 705(b).

"(3) VACATION OF ORDERS.—If, after providing an opportunity for an informal hearing under subsection (b), the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary shall vacate the order.

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

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

(a) IN GENERAL.—The fifth sentence of subsection (a) of section 801 (21 U.S.C. 381), as amended by sections 105(b) and 205(c), is further amended by inserting before the period at the end of the following: ", except that any article that is refused admission may, at the discretion of the Secretary, be promptly (subject to the next sentence) destroyed and not exported if it appears to pose a risk of injury or death".

(b) NOTICE.—Subsection (a) of section 801 (21 U.S.C. 381), as amended by sections 105(b) and 205(c) and subsection (a) of this section, is amended by inserting after the fifth sentence the following: "Before causing the destruction of an article with a value greater than $2,000 under the preceding sentence, the Secretary shall provide notice and an opportunity for an informal hearing to the owner or consignee.".

(c) IMPROPER DESTRUCTION.—Section 801 (21 U.S.C. 381), as amended by sections 123 and 203, is amended by adding at the end the following:

"(r) Any person claiming any article which has been destroyed under subsection (a) may, at any time within 3 months after the date of destruction, apply to the Secretary for reimbursement of the value of the article as de-

termined by the Secretary. Upon the production of satisfactory proof that the destruction of the article was not within the authority of the Secretary as provided in this section, the Secretary shall order the value of the article restored to the applicant.''.

(d) SAMPLES OF DESTROYED ARTICLES.—Section 801 (21 U.S.C. 381), as amended by sections 123 and 203 and subsection (c) of this section, is amended by adding at the end the following:

''(s) Where an article is caused to be destroyed under subsection (a) the Secretary shall, upon request, provide a sample of the article to the owner of the article, the owner's attorney or agent, or if applicable any person named on the label of the article, except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as the Secretary finds necessary for the proper administration of the provisions of this Act.''.

(e) EFFECTIVE DATE.—The amendments made by subsections (a), (b), (c), and (d) shall take effect 90 days after the date of the enactment of this Act.

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.

SEC. 210. PENALTIES REGARDING COUNTERFEIT DRUGS.

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

''(3) Notwithstanding paragraph (1) or (2), any person who engages in any conduct described in section 301(i)(2) knowing that the conduct concerns the rendering of a drug as a counterfeit drug, or who engages in conduct described in section 301(i)(3) knowing that the conduct will cause a drug to be a counterfeit drug or knowing that a drug held, sold, or dispensed is a counterfeit drug, shall be fined in accordance with title 18, United States Code,

or imprisoned not more than 20 years, or both, except that if the use of the counterfeit drug by a consumer is the proximate cause of the death of the consumer, the term of imprisonment shall be any term of years or for life.''.

SEC. 211. CIVIL MONEY PENALTIES FOR VIOLATIVE DRUGS AND DEVICES AND IMPROPER IMPORT ENTRY FILINGS.

(a) IN GENERAL.—Section 303(f) (21 U.S.C. 333) is amended—

(1) by redesignating paragraphs (5), (6), and (7) as paragraphs (6), (7), and (8), respectively;

(2) by inserting after paragraph (4) the following:

''(5)(A)(i) Any person that violates a requirement of this Act that relates to drugs for human use (except a requirement referred to in paragraph (4) or subsection (g)) shall be liable to the United States for a civil penalty not to exceed—

''(I) $100,000 for an initial violation of such a requirement; or

''(II) $200,000 for a subsequent violation of the same requirement.

''(ii) In clause (i)(I), the term 'initial violation' means the first violation by a person of a requirement described in clause (i) that occurs on or after

the date of the enactment of the Food and Drug Administration Globalization Act of 2009.

''(iii) Each day during which a violation continues shall be considered a separate violation under clause (i), except that a continuing initial violation shall not be treated as a subsequent violation for purposes of clause (i)(II).

''(B)(i) Any person that knowingly reports or enters false or misleading data on documents related to the importation of a drug shall be liable to the United States for a civil penalty not to exceed $200,000.

''(ii) Each act of reporting or entering false data shall be considered a separate violation under clause (i).

''(C) Any manufacturer, importer, distributer, or retailer who fails to comply with an order or an amended order issued under section 568(a) or 568(c)(1), respectively, shall be liable to the United States for a civil penalty not to exceed $250,000 per day.''.

(3) in paragraph (6), as so redesignated, by striking '', or (4)'' each place it appears and inserting ''(4), or (5)'';

(4) in paragraph (7), as so redesignated, by striking ''(5)(A)'' and inserting ''(6)(A)''; and

(5) in paragraph (8), as so redesignated, by striking ''paragraph (6)'' each place it appears and inserting ''paragraph (7)''.

(b) APPLICABILITY.—Section 303(f)(5) (as amended by subsection (a)), shall apply to violations described in such section that occur after the date of the enactment of this Act.

SEC. 212. HUMAN GENERIC DRUG APPLICATION AND SUPPLEMENT FEES TO COVER PRE-APPROVAL INSPECTION COSTS.

(a) SENSE OF CONGRESS.—It is the sense of the Congress that the amount of additional revenues generated from fees under this section should be used to support pre-approval inspections of generic drug establishments, in accordance with performance goals to be developed by the Secretary of Health and Human Services in consultation with the entities listed in subparagraphs (A) through (F) of section 736B(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2(d)(1)).

(b) FEE.—

(1) MISBRANDING.—Paragraph (o) of section 502 (21 U.S.C. 352), as amended by subsections (a)

and (b) of section 501, is further amended by striking ''736C'' and inserting ''736C or 736D''.

(2) ESTABLISHMENT.—Part 2 of subchapter C of chapter VII (21 U.S.C. 379g et seq.), as amended by section 201(b), is amended by adding at the end the following:

''SEC. 736D. HUMAN GENERIC DRUG APPLICATION AND SUPPLEMENT FEES TO COVER PRE-APPROVAL INSPECTION COSTS.

''(a) IN GENERAL.—The Secretary shall assess and collect a fee upon submission of any human generic drug application or supplement to defray increases (as described in subsection (c)(2)(B)) in the costs of resources allocated for conducting inspections in connection with the review of human generic drug applications and supplements.

''(b) FEE REVENUE AMOUNTS.—For each of fiscal years 2010 through 2014, fees under subsection (a) shall be established, subject to the provisions referred to in subsection (d), to generate a total revenue amount.

''(c) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—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 au-

thorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—The fees authorized by this section—

''(A) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year; and

''(B) shall only be collected and available to defray increases in the costs of resources allocated for conducting inspections in connection with the review of human generic drug applications and supplements (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such review) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2009 multiplied by the adjustment factor.

''(d) APPLICABILITY OF CERTAIN PROVISIONS.—To the extent determined by the Secretary to be consistent with this section, the provisions of section 736 apply with respect to human generic drug application fees and supplement fees under this section to the same extent and in the same manner as such provisions apply with respect to human drug application fees and supplement fees under section 736.

''(e) DEFINITIONS.—In this section:

''(1) The term 'costs of resources allocated for conducting inspections in connection with the review of human generic drug applications and supplements' means the expenses that are—

''(A) incurred in connection with inspections undertaken as part of the Secretary's review of pending human generic drug applications and supplements; and

''(B) described in subparagraphs (A) through (D) of section 735(7), except that the reference in section 735(7)(D) to section 736 is deemed to be a reference to this section, and the reference is section 735(7)(D) to human drug applications and supplements (as defined in section 735(2)) is deemed to be a reference

to human generic drug applications and supplements (as defined in this section).

''(2) The term 'human generic drug application' means an application for approval of a new drug submitted under section 505(j). Such term does not include an application or a supplement to an application described in section 735(1).

''(3) Notwithstanding section 735(2), the term 'supplement' means a request to the Secretary to approve a change in a human generic drug application which has been approved.''.

(3) EFFECTIVE DATE.—The Secretary of Health and Human Services shall first impose the fee established under section 736D of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (2), for fiscal years beginning with fiscal year 2010.

(4) SUNSET DATE.—Section 736D, as added by paragraph (2), does not authorize the assessment or collection of a fee for submission of an application or supplement under section 505(j) of such Act (21 U.S.C. 355(j)) occurring after fiscal year 2014.

TITLE III—COSMETIC SAFETY

SEC. 301. REGISTRATION OF COSMETIC ESTABLISHMENTS.

(a) MISBRANDING.—Section 602 is amended by adding at the end the following:

''(g) If it was manufactured or packaged in an establishment that is not duly registered under section 604.''.

(b) ANNUAL REGISTRATION.—Chapter VI is amended by adding at the end the following:

''SEC. 604. REGISTRATION OF COSMETIC ESTABLISHMENTS.

''(a) REGISTRATION.—

''(1) IN GENERAL.—The Secretary shall by regulation require that any establishment engaged in manufacturing or packaging cosmetics for use in the United States be registered annually with the Secretary. To be registered—

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

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

''(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 establishment at which, and all trade names under which, the registrant manufactures or packages cosmetics. The registrant shall notify the Secretary in a timely manner of changes to such information. The registrant shall notify the Secretary of any change in the products, function, or legal status of each such establishment (including cessation of business activities) not later than 30 days after the date of such change.

''(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 establishment.

''(4) LIST.—The Secretary shall compile and maintain an up-to-date list of establishments that are registered under this section. The Secretary shall remove from such list the name of any establishment that fails to reregister in accordance with this section and shall treat such removal as a suspension of the establishment's registration. Such list and any

registration documents submitted pursuant 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 such information discloses the identity or location of a specific registered person.

''(b) ESTABLISHMENT.—For purposes of this section:

''(1) The term 'domestic establishment' means an establishment located in any State (as defined in section 201).

''(2)(A) The term 'foreign establishment' means an establishment that manufactures or packages cosmetics that are exported to the United States without further processing or packaging outside the United States.

''(B) A cosmetic 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 cosmetic.''.

SEC. 302. COSMETIC AND INGREDIENT STATEMENTS.

(a) MISBRANDING.—Section 602, as amended by section 301 of this Act, is amended by adding at the end the following:

''(h) If its manufacturer is in violation of section 605 for failure to submit a cosmetic and ingredient statement with respect to the cosmetic.''.

(b) STATEMENTS.—Chapter VI, as amended by section 301 of this Act, is amended by adding at the end the following:

''SEC. 605. COSMETIC AND INGREDIENT STATEMENTS.

''(a) IN GENERAL.—The Secretary shall require by regulation that every establishment engaged in the manufacture of a cosmetic intended to be marketed in the United States submit to the Secretary for each cosmetic manufactured in the establishment, within 60 days after beginning manufacture of the product, a cosmetic and ingredient statement containing—

''(1) the registration number of the manufacturing establishment where the cosmetic is manufactured or, if the same cosmetic is manufactured in more than one establishment, the registration number of each establishment where it is manufactured;

''(2) the brand name or names for the cosmetic;

''(3) the applicable cosmetic category or categories for the cosmetic;

''(4) the ingredients in the cosmetic in descending order of predominance by weight, except that—

''(A) flavors and fragrances may be designated as such; and

''(B) all variations in color, flavor, or fragrance may be included in one statement; and

''(5) the title and full contact information for the individual or individuals responsible for submitting and maintaining the statement.

The registrant shall notify the Secretary in a timely manner of any change to the information required to be in such statement.

''(b) PROCEDURE.—Upon receipt of a completed cosmetic and ingredient statement described in paragraph (a), the Secretary shall notify the registrant of the receipt of such statement and assign a cosmetic and ingredient statement number.

''(c) LIST.—The Secretary shall compile and maintain an up-to-date list of cosmetics and ingredients for which statements are submitted under this section.''.

SEC. 303. SERIOUS AND UNEXPECTED ADVERSE EVENT REPORTS FOR COSMETICS.

(a) PROHIBITED ACTS.—Section 301 is amended—

(1) in paragraph (e), by striking ''or 761'' each place it appears and inserting ''761, or 762''; and

(2) in paragraph (ii)—

(A) by striking ''or the'' and inserting '', the''; and

(B) by striking the period at the end and inserting '', or the falsification of a report submitted under section 762 to the Secretary.''.

(b) ADVERSE EVENT REPORTING.—Subchapter H of chapter VII is amended by adding at the end the following:

''SEC. 762. SERIOUS AND UNEXPECTED ADVERSE EVENT REPORTS FOR COSMETICS.

''(a) IN GENERAL.—The Secretary shall require by regulation that the manufacturer, packager, or distributor whose name appears on the label of a cosmetic marketed in the United States pursuant to section 602(b)(1) submit to the Secretary under subsection (b) a report containing information received concerning any serious and unexpected adverse event in the United States associated with the use of the cosmetic.

''(b) SUBMISSION OF REPORTS.—

''(1) IN GENERAL.—A report under subsection (a) shall be submitted to the Secretary no later than 15 business days after information concerning the adverse event is received at the place of business labeled on the cosmetic under section 602(b)(1).

''(2) CONTENTS.—A report under subsection (a) shall include the following information, to the extent to which the person submitting the report has been able to verify the information—

''(A) an identifiable patient;

''(B) an identifiable reporter;

''(C) a suspect cosmetic; and

''(D) a serious and unexpected adverse event.

''(3) ADDITIONAL INFORMATION.—The person submitting a report under subsection (a) may include in the submission any additional pertinent information and may supplement the report with additional information at a later time.

''(c) RELATION TO OTHER PROVISIONS.—A report under subsection (a) (including all information submitted in the initial report or added later) shall be considered to be—

''(1) a safety report under section 756;

''(2) a record about an individual under section 552a of title 5, United States Code; and

''(3) a medical or similar file the disclosure of which would constitute a violation of section 552(b)(6) of such title 5, United States Codes, and shall not be disclosed under section 552 of such title.

''(d) DEFINITIONS.—In this section:

''(1) The term 'serious', with respect to an adverse event, means—

''(A) resulting in—

''(i) death;

''(ii) a life-threatening experience;

''(iii) inpatient hospitalization;

''(iv) a persistent and significant disability or incapacity; or

''(v) a congenital anomaly or birth defect; or

''(B) requiring, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described in subparagraph (A).

''(2) The term 'unexpected', with respect to an adverse event, means not identified in the current labeling for the cosmetic.''.

SEC. 304. GOOD MANUFACTURING PRACTICES FOR COSMETICS.

Section 601 is amended by adding at the end the following:

''(f) If the methods used in, or the facilities or controls used for, its manufacture, processing, packaging, storage, or holding do not conform to current good manu-

facturing practice, as prescribed by the Secretary in regulations, to ensure that the cosmetic is safe and otherwise in compliance with this Act.''.

SEC. 305. AUTHORIZATION OF APPROPRIATIONS.

Chapter VI, as amended by sections 301 and 302, is amended by adding at the end the following:

''SEC. 606. AUTHORIZATION OF APPROPRIATIONS.

''To carry out this chapter and section 762, there is authorized to be appropriated $10,000,000 for each of fiscal years 2010 through 2014.''.

SEC. 306. EFFECTIVE DATE.

The amendments made by sections 301, 302, 303, and 304 shall take effect 18 months after the date of the enactment of this Act.

TITLE IV—MISCELLANEOUS

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

(a) PROHIBITIONS.—Section 301 (21 U.S.C. 331), as amended by sections 102, 104, 112, and 207, is amended by adding at the end the following:

''(ss) 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, re-

spectively, unless the importer is registered under section 801(t).''.

(b) REGISTRATION.—Section 801, as amended by sections 123, 203, and 208, is amended by adding at the end the following:

''(t) The Secretary shall by regulation require that an importer of food, drugs, devices, or cosmetics, other than only for personal use, that is not required to be 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 (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

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

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

''(a) IN GENERAL.—The Secretary shall assess and collect an annual fee for the registration of an importer of food, drugs, or devices under section 801(t).

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

''(c) RULE OF CONSTRUCTION.—This section shall not be construed to authorize the assessment or collection of any fee from an importer of food, drugs, or devices if, with respect to such food, drugs, or devices, the importer is registered under section 415 or 510 and required to pay a fee under section 736C or 741.''.

(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(t) 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 inserting ''unique'' before ''registration number''.

(b) DRUGS AND DEVICES.—Section 510(e) (21 U.S.C. 360(e)) is amended by adding after the first sentence the following: ''The registration number shall be the

unique identification number for each such establishment.''.

(c) 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. PROHIBITION AGAINST DELAYING OR LIMITING INSPECTION.

Section 301(f) (21 U.S.C. 331(e)) is amended to read as follows:

''(f) The delay or limitation of an inspection, or the refusal to permit entry or inspection, as authorized by section 510(h) or 704, including any such delay, limitation, or refusal by an agent of a governmental authority in a foreign country.''.

SEC. 404. DEDICATED FOREIGN INSPECTORATE.

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

''(i) 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. 405. 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 subsection (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. 406. 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. 407. SUBPOENA AUTHORITY.

Chapter III (21 U.S.C. 331 et seq.) is amended by adding at the end the following:

''SEC. 311. EXERCISE OF SUBPOENA AUTHORITY.

''(a) IN GENERAL.—For the purpose of—

''(1) any hearing, investigation, or other proceeding respecting a violation of the Act, or

''(2) any hearing, investigation, or other proceeding to determine if a person is in violation of a specific provision of the Act,

the Commissioner may issue subpoenas requiring the attendance and testimony of witnesses and the production of documentary evidence. Such attendance of witnesses and production of evidence at the designated place of such hearing, investigation, or other proceeding may be required from any place in the United States or in any territory or possession of the United States. Subpoenas of the Commissioner shall be served by a person authorized by the Commissioner by delivering a copy thereof to the person named therein or by certified mail addressed to such person at such person's last known dwelling place or principal place of business. A verified return by the person so serving the subpoena setting forth the manner of service, or, in the case of service by certified mail, the return post office receipt therefor signed by the person so served, shall be proof of service. Witnesses so subpoenaed shall be paid the same fees and mileage as are paid witnesses in the district courts of the United States.

''(b) ENFORCEMENT.—In the case of a refusal to obey a subpoena duly served upon any person under subsection (a), any district court of the United States for the judicial district in which such person charged with refusal

to obey is found, resides, or transacts business, upon application by the Commissioner, shall have jurisdiction to issue an order requiring such person to appear and give testimony or to appear and produce evidence, or both. The failure to obey such order of the court may be punished by the court as contempt thereof. Furthermore, the failure or refusal to obey such a subpoena shall be treated as a prohibited act under section 301(a).

''(c) RELATION TO OTHER PROVISIONS.—The subpoena authority vested in the Commissioner and the district courts of the United States by this section is in addition to any such authority vested in the Commissioner or such courts by other provisions of law.''.

SEC. 408. WHISTLEBLOWER PROTECTIONS.

Chapter IX (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

''SEC. 911. PROTECTIONS FOR EMPLOYEES WHO REFUSE TO VIOLATE, OR WHO DISCLOSE VIOLATIONS OF, THIS ACT OR SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT.

''(a) IN GENERAL.—No person that submits or is required to submit to the Secretary, a registration under section 415, 510, or 604, a new drug application under section 505(b), an abbreviated new drug application under section 505(j), a biologics license application under section

351 of the Public Health Service Act, an application for an investigational new drug exemption under section 505(i), a new animal drug application under section 512(b), an abbreviated new animal drug application under section 512(b), an application under section 571, a request under section 572, an application or report for premarket approval under section 515, an application for an investigational device exemption under section 520(g), a report under section 510(k), an application for a humanitarian device exemption under section 520(m), an amendment, supplement, or other submission with respect to any such registration, application, or report, or a record or report related to an adverse event, a postapproval study, a postapproval clinical trial, a report, or postmarket surveillance under section 505(k), 505(o), 519, 522, or 760, or any officer, employee, contractor, subcontractor, or agent of such a person, may discharge, demote, suspend, threaten, harass, or in any other manner discriminate against an employee in the terms and conditions of employment because of any lawful act done by the employee, including within the ordinary course of the job duties of such employee—

"(1) to provide information, cause information to be provided, or otherwise assist in any investigation regarding any conduct which the employee rea-

sonably believes constitutes a violation of this Act or section 351 of the Public Health Service Act, any other provision of Federal law relating to the safety or effectiveness of a drug, biological product, or device or to the safety of a food or cosmetic, or any provision of Federal law prohibiting fraud against the Food and Drug Administration, if the information or assistance is provided to, or an investigation stemming from the provided information is conducted by—

''(A) a Federal regulatory or law enforcement agency;

''(B) any Member of Congress or any committee of Congress; or

''(C) a person with supervisory authority over the employee (or such other person working for the employer who has the authority to investigate, discover, or terminate the misconduct);

''(2) to file, cause to be filed, testify, participate in, or otherwise assist in a proceeding filed or about to be filed (with any knowledge of the employer) relating to any such alleged violation; or

''(3) to refuse to commit or assist in any such violation.

''(b) ENFORCEMENT ACTION.—

''(1) IN GENERAL.—An employee who alleges discharge, or other discrimination in violation of subsection (a), may seek relief in accordance with the provisions of subsection (c), by—

''(A) filing a complaint with the Secretary of Labor; or

''(B) if the Secretary of Labor has not issued a final decision within 210 days of the filing of the complaint, or within 90 days after receiving a final decision or order from the Secretary, and there is no showing that such delay is due to the bad faith of the claimant, bringing an action at law or equity for de novo review in the appropriate district court of the United States, which court shall have jurisdiction over such action without regard to the amount in controversy, and which action shall, at the request of either party to such action, be tried by the court with a jury.

''(2) PROCEDURE.—

''(A) IN GENERAL.—Any action under paragraph (1) shall be governed under the rules and procedures set forth in section 42121(b) of title 49, United States Code.

"(B) EXCEPTION.—Notification in an action under paragraph (1) shall be made in accordance with section 42121(b)(1) of title 49, United States Code, except that such notification shall be made to the person named in the complaint and to the employer.

"(C) BURDENS OF PROOF.—An action brought under paragraph (1)(B) shall be governed by the legal burdens of proof set forth in section 42121(b) of title 49, United States Code.

"(D) STATUTE OF LIMITATIONS.—An action under paragraph (1) shall be commenced not later than 180 days after the date on which the violation occurs.

"(c) REMEDIES.—

"(1) IN GENERAL.—An employee prevailing in any action under subsection (b)(1) shall be entitled to all relief necessary to make the employee whole.

"(2) ISSUANCE OF ORDER.—If, in response to a complaint filed under paragraph (b)(1), the Secretary of Labor or the district court, as applicable, determines that a violation of subsection (a) has occurred, the Secretary or the court shall order the person who committed such violation—

"(A) to take affirmative action to abate the violation;

"(B) to reinstate the complainant to his or her former position together with compensation (including back pay) and restore the terms, conditions, and privileges associated with his or her employment; and

"(C) to provide compensatory damages to the complainant.

If such an order is issued under this paragraph, the Secretary or the court, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney and expert witness fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

"(d) RIGHTS RETAINED BY EMPLOYEE.—Nothing in this section shall be deemed to diminish the rights, privileges, or remedies of any employee under any Federal or State law or under any collective bargaining agreement. The rights and remedies in this section may not be waived

by any agreement, policy, form, or condition of employment.''.

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