[111H6543]

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(Original Signature of Member)

112TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. DINGELL introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of drugs, 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.

This Act may be cited as the "Drug Safety Enhancement Act of 2011".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—PREVENTION

SEC. 101. REGISTRATION OF PRODUCERS OF DRUGS; APPLICABLE FEE.

(a) FOREIGN REGISTRANTS.—

(1) MISBRANDING.—Section 502(o) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 352(o)) is amended by inserting ''if it is a drug and was manufactured, prepared, propagated, com-

pounded, or processed in an establishment not duly registered under section 510(i),'' after ''not duly registered under section 510,''.

(2) APPLICATION.—The amendment made by paragraph (1) applies only with respect to registration (including failure to register) 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) EXCIPIENT MANUFACTURERS.—

(1) IN GENERAL.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall revise section 207.10 of title 21, Code of Federal Regulations, and such other regulations as may be necessary to require owners and operators of establishments that engage in the manufacture, preparation, propagation, compounding, or processing of an excipient of a drug to register such establishments under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360).

(2) APPLICATION.—The revisions to regulations under paragraph (1) shall apply with respect to the manufacture, preparation, propagation, compounding, or processing of an excipient of a drug

on or after the date that is 18 months after the date of the enactment of this Act.

(c) DRUG LISTING ELEMENTS AND FREQUENCY.—

(1) IN GENERAL.—Sections 510(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)) is amended—

(A) in paragraph (1), by amending subparagraph (C) to read as follows:

''(C) in the case of any drug contained in an applicable list which is described in subparagraph (A) or (B), a qualitative and quantitative listing of each of its active and other ingredients, and any other information that the Secretary finds is necessary to carry out the purposes of this Act; and''; and

(B) in paragraph (2), in the matter preceding subparagraph (A), by inserting '', unless otherwise specified by the Secretary'' after ''once during the month of December of each year''.

(2) APPLICATION.—The amendments made by paragraph (1) apply with respect to the filing of a list under section 510(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)) that occurs on

or after the date that is 6 months after the date of the enactment of this Act.

(d) SUSPENSION AND CANCELLATION OF REGISTRATION.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following:

''(q) SUSPENSION AND CANCELLATION OF REGISTRATION.—With respect to any registration under this section attributable to the manufacture, preparation, propagation, compounding, or processing of a drug:

''(1) SUSPENSION OF REGISTRATION.—

''(A) IN GENERAL.—Registration under this section is subject to suspension upon a finding by the Secretary, after notice and an opportunity for an informal hearing, of—

''(i) a violation of this Act; or

''(ii) the knowing or repeated making of an inaccurate or incomplete statement or submission of information relating to the manufacture, preparation, propagation, compounding, processing, or importing of a drug.

''(B) REQUEST.—Any person or establishment whose registration is suspended under subparagraph (A) may request that the Sec-

retary vacate the suspension when such person or establishment has corrected the violation that is the basis for such suspension.

''(C) VACATING OF SUSPENSION.—If the Secretary determines that adequate reasons do not exist to continue the suspension of a registration under subparagraph (A), the Secretary shall vacate such suspension.

''(2) CANCELLATION OF REGISTRATION.—

''(A) IN GENERAL.—Not earlier than 10 days after providing the notice under subparagraph (B), the Secretary may cancel a registration if the Secretary determines that—

''(i) such registration was not updated in accordance with this section or contains false, incomplete, or inaccurate information; or

''(ii) the fee required under section 736C for such registration has not been paid within 30 days after the date due.

''(B) NOTICE OF CANCELLATION.—Before cancelling the registration of a person or establishment under this section, the Secretary shall give notice to the person or establishment of the

Secretary's intent to cancel the registration and the basis for such cancellation.

''(C) TIMELY UPDATE OR CORRECTION.—If a registration is adequately updated or corrected no later than 7 days after notice is provided under subparagraph (B) with respect to the registration, the Secretary shall not cancel such registration.''.

(e) REGISTRATION FEE.—

(1) ESTABLISHMENT.—Part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.) is amended by adding at the end the following:

''SEC. 736C. REGISTRATION FEE.

''(a) IN GENERAL.—In the case of any registration under section 510 that is attributable to the manufacture, preparation, propagation, compounding, processing, or importing of a drug, the Secretary shall assess and collect an annual fee for such registration to defray the increase in the costs of drug safety activities.

''(b) PAYABLE DATE.—A fee under this section shall be payable—

''(1) for a facility that was not registered under section 510 for the preceding fiscal year, on the date of registration; and

''(2) for any other facility—

''(A) for fiscal year 2012, not later than the sooner of 90 days after the date of the enactment of this section or December 31, 2011; and

''(B) for a subsequent fiscal year, not later than December 31 of such fiscal year.

''(c) FEE AMOUNTS.—

''(1) TOTAL REVENUE AMOUNT.—

''(A) INITIAL YEAR.—For fiscal year 2012, fees under subsection (a) shall, except as provided in subsections (f) and (g), be established to generate a total revenue amount that is equal to the increase in the costs of drug safety activities (as estimated by the Secretary) for such fiscal year.

''(B) SUBSEQUENT YEARS.—For each of fiscal years 2013 through 2016, fees under subsection (a) shall, except as provided in subsections (f) and (g), be the total revenue amount for fiscal year 2012, as adjusted under subsection (d).

''(2) ANNUAL FEE SETTING.—For fiscal year 2012 and each subsequent fiscal year, the Secretary

shall establish 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.

''(3) TRANSMISSION TO CONGRESS.—Not later than 60 days before the start of fiscal year 2012 and each subsequent fiscal year, the Secretary shall transmit to the Congress—

''(A) the total revenue amount for the upcoming fiscal year, as applicable under paragraph (1); and

''(B) the registration fees for such year, as established under paragraph (2).

''(d) INFLATION ADJUSTMENT.—For fiscal year 2013 and subsequent fiscal years, the fee amount under subsection (c) shall be adjusted by the Secretary by notice, published in the Federal Register, for the respective fiscal year to reflect the greater of—

''(1) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for

the 12-month period ending June 30 preceding the fiscal year for which fees are being established;

''(2) 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

''(3) 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 will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2011 under this subsection.

''(e) FEE WAIVER OR REDUCTION.—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—

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

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

''(f) LIMITATIONS.—

''(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2012 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 2012 (excluding the amount of fees appropriated for such fiscal year) adjusted in the same manner that fee amounts are adjusted under subsection (d).

''(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 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 APPROPRIATIONS 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 appropriations Acts, or otherwise made available for obligation, for such fiscal year; and

''(B) shall only be collected and available to defray the costs of drug safety activities.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2012 through 2016, there are authorized to be appropriated for fees under this section such sums as may be necessary.

''(h) COLLECTION OF UNPAID FEES.—In any case in which 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) 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 drug safety activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(j) ANNUAL FISCAL REPORTS.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this section, 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.

''(k) RELATION TO OTHER FEES.—Fees assessed and collected under this section are in addition to other fees assessed and collected under this Act with respect to the same person or establishment.

''(l) DEFINITIONS.—In this section:

''(1) The term 'costs of drug safety activities' means the expenses incurred in connection with drug safety activities for—

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

''(B) laboratory space;

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

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

''(E) collecting fees under this section and accounting for resources allocated for drug safety activities.

''(2) The term 'drug safety activities' means activities related to compliance by persons and establishments registered under section 510 with the re-

quirements of this Act relating to drugs (including research related to and the development of standards (such as performance standards and preventive controls), risk assessments, hazard analyses, inspection planning and inspections, third-party inspections, compliance review and enforcement, import review, information technology support, test development, product sampling, risk communication, and administrative detention).''.

(2) TRANSITIONAL PROVISIONS.—

(A) FIRST IMPOSITION OF FEES.—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 (1), for fiscal years beginning with fiscal year 2012.

(B) SUNSET DATE.—Section 736C of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1), 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 2016.

(f) MODIFICATION OF REGISTRATION FORM.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services

shall modify the registration forms under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) to comply with the amendments made by this section.

SEC. 102. DRUG SUPPLY QUALITY AND SAFETY.

(a) DEFINITIONS.—Section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) is amended by adding at the end the following:

''(3) In the case of a drug, the term 'component' includes—

''(A) any active ingredient or bulk drug substance;

''(B) any inactive ingredient;

''(C) any intermediate of an active ingredient, inactive ingredient, or bulk drug substance, whether or not it appears in the finished product and whether or not derived from any chemical, human, animal, plant, or other material; and

''(D) any original source material for components specified in clauses (A), (B), and (C) whether or not the original source material—

''(i) appears in the finished product; and

''(ii) is derived from any chemical, human, animal, plant, or other material.''.

(b) EFFECTIVE QUALITY SYSTEMS.—

(1) PROHIBITED ACTS.—

(A) RECORDKEEPING.—Section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is amended—

(i) by inserting ''503C,'' after ''417(j),''; and

(ii) by inserting ''503C,'' after ''417,''.

(B) ADULTERATION.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended by adding at the end the following:

''(j) If it is a drug that was manufactured (as defined in section 503C) by a manufacturer that is or was at the time of such manufacture in violation of section 503C because of the failure to have in effect or implement an effective quality system in accordance with such section.''.

(2) SYSTEM REQUIREMENTS.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 503B (21 U.S.C. 353b) the following:

"SEC. 503C. EFFECTIVE QUALITY SYSTEM FOR DRUG MANUFACTURERS.

"(a) IN GENERAL.—Each manufacturer of a drug required to be registered under section 510 shall have in effect and implement an effective quality system.

"(b) SYSTEM REQUIREMENTS.—An effective quality system applicable to a manufacturer of a drug under subsection (a) shall require each of the following:

"(1) MANAGEMENT RESPONSIBILITY.—The manufacturer shall ensure that—

"(A) adequate resources are provided to ensure compliance with current good manufacturing practice;

"(B) procedures are established and maintained to ensure timely communication of product quality issues to appropriate levels of management, including executive management;

"(C) periodic reviews of process performance, product quality, and other elements of the quality system are conducted;

"(D) the periodic reviews under subparagraph (C) are evaluated by executive management to determine any appropriate action; and

"(E) the integrity of data, records, and regulatory submissions, including with respect

to accuracy, veracity, and validity, is maintained.

''(2) QUALITY RESPONSIBILITY.—

''(A) INTERNAL, INDEPENDENT UNIT.—The manufacturer shall establish and maintain an internal, independent unit with the authority to ensure that all operations related to manufacturing drugs, including those performed by another person, are appropriately designed, approved, conducted, monitored, and corrected in compliance with current good manufacturing practice.

''(B) PROCEDURES.—The manufacturer shall establish and maintain procedures to ensure that—

''(i) any discrepancy related to manufacturing a drug (including the discrepancy's causes) is promptly identified, investigated, and corrected, the recurrence of the discrepancy is prevented, and any corrective or preventive action is verified or validated to ensure that such action is effective and does not adversely affect the drug; and

''(ii) ongoing reviews of all data related to manufacturing a drug are conducted to identify trends that might affect product quality and timely actions are performed to prevent any adverse effect on product safety, identity, quality, strength, or purity.

''(3) RISK MANAGEMENT.—The manufacturer shall establish and maintain risk management procedures that ensure effective risk assessment, control, and communication. The risk assessment procedures shall ensure that all factors throughout the supply chain that may reasonably be expected to indicate a risk to the safety, identity, quality, strength, purity, or security of any drug manufactured by that manufacturer are identified, starting with factors relating to origin of all components including the original source materials; information relating to all such factors is continuously gathered, monitored, and evaluated; and new factors are promptly identified.

''(4) SUPPLY CHAIN MANAGEMENT.—

''(A) IN GENERAL.—The manufacturer shall establish and maintain procedures that ensure the safety, identity, quality, strength, purity, and security of all drugs and other mate-

rials used by that manufacturer. The supply chain procedures shall address the entire supply chain from original source materials used in the manufacture of the drug to the manufacturer. The supply chain procedures shall ensure that there is adequate followup, which shall include no longer receiving any source materials or drugs from, or using operations conducted by, any person who fails to implement timely corrections for supply chain management practices or other applicable requirements under this Act or sections 351 or 361 of the Public Health Service Act.

''(B) PROCEDURES.—Supply chain management procedures under subparagraph (A) shall include—

''(i) acceptance and rejection criteria for each component that ensures that such component is appropriate for its intended use and that include, unless not feasible using current technology, a sufficient impurity profile for each component, including each component that is naturally derived, except that the requirements of this clause shall not apply to any component of

a licensed biological product unless required under the license issued for such product under section 351 of the Public Health Service Act or under paragraph (5);

''(ii) onsite audits, performed by qualified individuals, of each person that supplies a drug or conducts operations related to manufacturing, before such person begins initial supply or operation and at an appropriate frequency to assess the continued compliance of such person with the manufacturer's supply chain practices and with the applicable requirements under this Act and sections 351 and 361 of the Public Health Service Act;

''(iii) requirements for a quality agreement with any person who supplies a drug or conducts operations related to manufacturing a drug which addresses all applicable current good manufacturing practice requirements;

''(iv) the sharing of manufacturing information by any person who supplies a drug or conducts operations related to

manufacturing, including timely notification concerning any change to, discrepancy in, or defect in, materials or operations related to manufacturing, along with adequate information about such change, discrepancy, or defect;

''(v) when supplying any drug to another manufacturer, provision of a certificate of analysis for each batch and lot that includes complete source, manufacturing, and test information and results; and

''(vi) methods, which shall include acceptance and rejection criteria, adequate—

''(I) to detect, or exclude the possibility of, the presence of any substance that may reasonably be expected to indicate a risk to safety, identity, quality, strength, purity, or security; and

''(II) to detect, or exclude the possibility of, other risks to safety, identity, quality, strength, purity, or security.

''(5) METHODS.—

''(A) IN GENERAL.—Each manufacturer shall establish and maintain procedures that ensure—

''(i) periodic evaluation and, where necessary, prompt revision of methods, including acceptance and rejection criteria, to ensure the safety, identity, quality, strength, purity, and security of each drug manufactured by such manufacturer, or component used in the manufacture of such drug;

''(ii) when any new risk is identified—

''(I) adoption of appropriate revised or new methods; and

''(II) evaluation of every batch and lot of drug using such revised methods; and

''(iii) if required, an application is submitted for timely approval by the Secretary of the revised or new methods under section 505, 506A, 512, or 571 of this Act or section 351 of the Public Health Service Act.

''(B) DETERMINATION OF RISK.—Each evaluation and revision under subparagraph (A)(i) shall be based on a determination of risk.

''(C) NOTIFICATION REGARDING REVISED METHOD.—Each manufacturer of a drug shall promptly notify the Secretary and the appropriate body charged with revision of an official compendium of any revised method for such drug and its rationale. Such notification shall be made in such form and manner as the Secretary shall prescribe by regulation.

''(D) ORDERS REGARDING REVISED OR NEW METHODS.—If the Secretary determines that a revised or new method, including acceptance and rejection criteria, is appropriate for the safety, identity, quality, strength, purity, or security of any drug, the Secretary may by letter order any manufacturer of such drug to promptly—

''(i) revise any method, or adopt any new method, and any related acceptance and rejection criteria for such drug; and

''(ii) implement such revised or new method and any related acceptance and rejection criteria.

''(6) RECORDS.—

''(A) IN GENERAL.—Each manufacturer shall maintain adequate, contemporaneous records (which may be electronic) to document conformity with requirements under this section. Such records shall be accurate, indelible, and legible. Each manufacturer shall establish and maintain a procedure to ensure the identification, storage, protection, retrieval, retention, and disposition of such records.

''(B) MAINTENANCE OF RECORDS; INSPECTION.—Each manufacturer shall maintain records under subparagraph (A) for at least 2 years from the date of the expiration date of the drug involved and make such records readily available for inspection by the Secretary. Such records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection. Each manufacturer shall provide to the Secretary these records or copies thereof in a timely manner, upon verbal or written request by an officer or employee duly designated by the Secretary.

''(7) ADDITIONAL PROVISIONS.—If the Secretary determines that provisions in addition to

those described in paragraphs (1) through (6) would be appropriate to provide additional assurance of the safety, identity, quality, strength, purity, or security of any drug, the Secretary may promulgate such provisions by regulation.

''(e) EXEMPTIONS AND VARIANCES.—Any person subject to any requirement prescribed pursuant to this section may petition the Secretary for an exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as the Secretary shall prescribe by regulation. If, when granting a request for exemption or variance under this subsection, the Secretary determines that it is appropriate to apply the exemption or variance to more than one manufacturer, the Secretary shall publish a notice of the exemption or variance in the Federal Register.

''(d) DEFINITIONS.—In this section:

''(1) The term 'manufacturer' means any person who manufactures a drug.

''(2) The terms 'manufacture', 'manufacturing', or 'manufactured' include preparation, processing, packing, or holding.

''(3) The term 'establish and maintain' means adequately—

''(A) define, document (by paper or electronically), implement, and follow; and

''(B) review and, as needed, revise on an ongoing basis.''.

(3) APPLICATION.—The requirements of section 503C of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (2), apply beginning on the date that is 2 years after the date of the enactment of this Act.

(c) DOCUMENTATION OF SUPPLY CHAIN.—

(1) IN GENERAL.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j), as amended, is further amended by adding at the end the following:

''(r) DOCUMENTATION OF SUPPLY CHAIN.—Each establishment required to be registered under this section for the manufacture, preparation, propagation, compounding, or processing of a drug, shall maintain and provide to the Secretary, upon request, adequate information, in electronic form, establishing—

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

''(2) that the drug, its ingredients, and its 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) APPLICATION.—The amendment made by paragraph (1) applies beginning on the date that is 2 years after the date of the enactment of this Act.

SEC. 103. INSPECTION OF PRODUCERS OF DRUGS.

(a) INSPECTION.—Subsection (h) of section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended—

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

(2) by adding at the end the following:

''(2) Notwithstanding paragraph (1), every establishment engaged in the manufacture, propagation, compounding, or processing of a drug that is a finished dosage form or an active pharmaceutical ingredient shall be inspected pursuant to section 704 by one or more officers or employees duly designated by the Secretary—

''(A) at least once in the 2-year period beginning with the date of registration of such establish-

ment 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.

''(3) The Secretary shall conduct an inspection of a drug establishment when the establishment begins to manufacture, prepare, propagate, compound, or process a drug that is a finished dosage form or active pharmaceutical ingredient before the drug is introduced into interstate commerce if the active ingredient is new to the drug product or the drug 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 con-

tained in the application (or supplement to the application) submitted under section 505, ensure compliance with current good manufacturing practices, or otherwise ensure the safety of the drug or ingredient.

''(4) The Secretary may inspect, pursuant to section 704, every establishment engaged in the manufacture, propagation, compounding, or processing of an excipient of a drug to the same extent as the Secretary is authorized to inspect an establishment engaged in the manufacture, propagation, compounding, or processing of any other drug.

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

''(6) With respect to fiscal year 2012 and each subsequent fiscal year, the Secretary shall submit an annual report to the Congress on—

''(A) funding dedicated to inspections under this subsection of establishments engaged in the manufacture, propagation, compounding, or processing of a drug; and

''(B) the number of such establishments for which the frequency of such inspections has been modified pursuant to paragraph (2).

''(7) For purposes of determining inspection frequency under paragraph (2), 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 engaged in the manufacture, propagation, compounding, or processing of a drug that is a finished dosage form or an active pharmaceutical ingredient. 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 Drug Safety Enhancement Act of 2011. 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)(7) of the Federal Food,

Drug, and Cosmetic Act, as added by subsection (a)(2) of this section.

(c) APPLICATION.—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. 104. PROHIBITION AGAINST DELAYING, LIMITING, OR REFUSING INSPECTION.

Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351), as amended, is further amended by adding at the end the following:

''(k) If it is a drug and it has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment, or any agent of a governmental authority in the foreign country within which such factory, warehouse, or establishment is located, delays or limits an inspection, or refuses to permit entry or inspection, under section 510(h) or 704.''.

SEC. 105. CLARIFICATION OF INSPECTION AUTHORITY RELATED TO BIMO AND IRB INSPECTIONS.

(a) IN GENERAL.—Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)), is amended—

(1) by inserting after the second sentence the following: ''For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are also authorized to enter, at reasonable times, any premises of a clinical investigator, sponsor, monitor, contract research organization, site management organization, institutional review board, or other person that oversees, initiates, or conducts a clinical investigation subject to section 505(i), or a postmarket study or clinical trial subject to section 505(k) or 505(o).''; and

(2) by inserting ''or any establishment associated with a clinical investigation subject to section 505(i), or a postmarket study or clinical trial subject to section 505(k) or 505(o) (including the premises of any clinical investigator, sponsor, monitor, contract research organization, site management organization, person that oversees or participates in data acquisition, data generation, data archiving, or data analysis, institutional review board, or any other person, other than a subject, that participates in the conduct of a clinical investigation of a drug),'' before ''inspection shall extend to all things therein''.

(b) CONFORMING AMENDMENT.—Section 704(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(2)) is amended by striking ''third sentence'' and inserting ''fourth sentence''.

SEC. 106. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUG PRODUCTS.

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

''(aaa)(1) The failure to notify the Secretary in violation of section 568(a).

''(2) The failure to comply with any order issued under section 568.''.

(b) NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.—Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

''SEC. 568. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.

''(a) NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.—

''(1) IN GENERAL.—A person required, with respect to drugs, to register under section 510, 801(t), or 801(u) that has reason to believe that—

''(A) a drug 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, and

''(B) as a result, the use or consumption of, or exposure to, the drug (or an ingredient or component used in any such drug) may result in illness or injury to humans or animals,

shall, as soon as practicable, notify the Secretary of the identity and location of the drug.

''(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) VOLUNTARY RECALL.—The Secretary may request that any person who distributes a drug that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of this Act voluntarily—

''(1) recall such drug; and

''(2) provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

''(c) ORDER TO CEASE DISTRIBUTION.—If the Secretary has reason to believe that the use or consumption of, or exposure to, a drug may result in illness or injury to humans or animals, the Secretary shall have the authority to issue an order requiring any person who distributes such drug to immediately cease distribution of such drug.

''(d) ACTION FOLLOWING ORDER.—Any person who is subject to an order under subsection (c) shall immediately cease distribution of such drug and provide notification as required by such order, and may appeal within 24 hours of issuance of such order to the Secretary. Such appeal may include a request for an informal hearing and a description of any efforts to recall such drug undertaken voluntarily by the person, including after a request under subsection (b). Except as provided in subsection (f), an informal hearing shall be held as soon as practicable, but not later than 5 calendar days, or less as determined by the Secretary, after such an appeal is filed, unless the parties jointly agree to an extension. After affording an opportunity for an informal hearing, the Secretary shall determine whether the order should be amended to require a recall of such drug. If, after providing an opportunity

for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

''(e) ORDER TO RECALL.—

''(1) AMENDMENT.—Except as provided under subsection (f), if after providing an opportunity for an informal hearing under subsection (d), the Secretary determines that the order should be amended to include a recall of the drug with respect to which the order was issued, the Secretary shall amend the order to require a recall.

''(2) CONTENTS.—An amended order under paragraph (1) shall—

''(A) specify a timetable in which the recall will occur;

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

''(C) provide for notice, including to individuals as appropriate, to persons who may be affected by the recall. In providing for such notice, the Secretary may allow for the assistance of health professionals, State or local officials, or other individuals designated by the Secretary.

''(f) EMERGENCY RECALL ORDER.—

''(1) IN GENERAL.—If the Secretary has credible evidence or information that a drug subject to an order under subsection (c) presents an imminent threat of serious adverse health consequences or death to humans or animals, the Secretary may issue an order requiring any person who distributes such drug—

''(A) to immediately recall such drug; and

''(B) to provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

''(2) ACTION FOLLOWING ORDER.—Any person who is subject to an emergency recall order under this subsection shall immediately recall such drug and provide notification as required by such order, and may appeal within 24 hours after issuance such order to the Secretary. The person subject to an emergency recall order shall conduct the recall notwithstanding the pendency of any such appeal. An informal hearing shall be held as soon as practicable but not later than 5 calendar days, or less as determined by the Secretary, after such an appeal is filed, unless the parties jointly agree to an extension. After affording an opportunity for an informal hearing, the Secretary shall determine whether the order

should be amended pursuant to subsection (e)(1). If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

''(g) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—The Secretary shall, as the Secretary determines to be necessary, provide notice of a recall order under this section to consumers to whom the drug was, or may have been, distributed and to appropriate State and local health officials.

''(h) SAVINGS CLAUSE.—Nothing contained in this section shall be construed as limiting—

''(1) the authority of the Secretary to issue an order to cease distribution of, or to recall, a drug under any other provision of this Act or the Public Health Service Act; or

''(2) the ability of the Secretary to request any person to perform a voluntary activity related to any drug subject to this Act or the Public Health Service Act.''.

(c) ARTICLES SUBJECT TO REFUSAL.—The third sentence of subsection (a) of section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by inserting ''or (5) in the case of a drug, such article

is subject to an order under section 568 to cease distribution of or recall the article,'' before ''then such article shall be refused admission''.

(d) APPLICATION.—Sections 301(aaa) and 568 of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b), shall apply with respect to a drug 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.

SEC. 107. NOTIFICATION.

(a) IN GENERAL.—

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

''(bbb) The failure to notify the Secretary in violation of section 569.''.

(2) NOTIFICATION.—Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.), as amended, is further amended by adding at the end the following:

''SEC. 569. NOTIFICATION.

''(a) NOTIFICATION TO SECRETARY.—With respect to a drug, the Secretary may require notification to the Secretary by a regulated person of—

''(1) the use of, or exposure to, such drug which may result in illness or injury to humans or animals;

''(2) a significant loss or known theft of such drug;

''(3) a reasonable probability that such drug has been or is being counterfeited;

''(4) repeated failures by a manufacturer of a component or other material used in the manufacture of such drug to ensure compliance with applicable quality systems requirements under section 501(a)(2)(B) or 503C of this Act or section 351 or 361 of the Public Health Service Act;

''(5) any incident causing such drug to be mistaken for, or its labeling applied to, another drug;

''(6) any contamination or any significant chemical, physical, or other change or deterioration in such drug after distribution, or any failure of a distributed lot or batch of such drug to meet an established specification; and

''(7) any other type of information regarding such drug that the Secretary deems necessary for protection of the public health.

''(b) MANNER OF NOTIFICATION.—Notification under this section shall be made in such manner and by

such means as the Secretary may require by regulation or guidance.

''(c) DEFINITION.—In this section, the term 'regulated person' means a person who is required to register under section 510, 801(t), or 801(u); a wholesale distributor of a drug product; and any other person that distributes drugs except exclusively for retail sale.''.

(b) EXCHANGE OF INFORMATION.—

(1) PROHIBITED ACTS.—

(A) IN GENERAL.—The first sentence of section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)) is amended—

(i) by striking ''or'' before ''to the courts when relevant''; and

(ii) by inserting '', or as specified in section 708,'' before ''any information acquired''.

(B) TECHNICAL CORRECTIONS.—The first sentence of such section 301(j) is further amended—

(i) by striking ''573.'' and inserting ''573''; and

(ii) by striking the second of the two consecutive periods at the end.

(2) AMENDMENT.—Section 708 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379) is amended—

(A) by striking ''The Secretary'' and inserting ''(a) The Secretary''; and

(B) by adding at the end the following:

''(b)(1)(A) The Secretary may provide to any Federal agency acting within the scope of its jurisdiction any information respecting a drug that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section.

''(B) Any such information provided to another Federal agency shall not be disclosed by such agency except in any investigation within the receiving agency's jurisdiction or in an action or proceeding under the laws of the United States in which the receiving agency or the United States is a party.

''(2)(A) In carrying out this Act, the Secretary may provide to a State or local government agency any information respecting a drug that is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section.

''(B) Any such information provided to a State or local government agency shall not be disclosed by such agency.

''(3) Except as provided by section 301(j), in carrying out this Act, the Secretary may provide to any person any information respecting a drug that is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section, if the Secretary determines that providing the information to the person is appropriate under the circumstances and the recipient provides adequate assurances to the Secretary that the recipient will preserve the confidentiality of the information.

''(4) In carrying out this Act, the Secretary may provide any information respecting a drug that is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section—

''(A) to any foreign government agency; or

''(B) any international organization established by law, treaty, or other governmental action and having responsibility—

''(i) to facilitate global or regional harmonization of standards and requirements in an

area of responsibility of the Food and Drug Administration; or

''(ii) to promote and coordinate public health efforts, if the agency or organization provides adequate assurances to the Secretary that the agency or organization will preserve the confidentiality of the information.

''(c) Except as provided by section 301(j), the Secretary may disclose to the public any information respecting a drug that is exempt from disclosure pursuant to section 552(a) of title 5, United States Code, by reason of subsection (b)(4) of such section, if the Secretary determines that such disclosure is necessary to protect the public health.

''(d) Except as provided in subsection (e), the Secretary shall not be required to disclose under section 552 of title 5, United States Code, or any other provision of law any information respecting a drug obtained from a Federal, State, or local government agency, or from a foreign government agency, or from an international organization described in subsection (b)(4), if the agency or organization has requested that the information be kept confidential, or has precluded such disclosure under other use limitations, as a condition of providing the information.

''(e) Nothing in subsection (d) authorizes the Secretary to withhold information from the Congress or prevents the Secretary from complying with an order of a court of the United States.

''(f) This section shall not affect the authority of the Secretary to provide or disclose information under any other provision of law.''.

TITLE II—RESPONSE

SEC. 201. ADMINISTRATIVE DETENTION.

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

''(i) ADMINISTRATIVE DETENTION OF DRUGS.—

''(1) DETENTION AUTHORITY.—

''(A) IN GENERAL.—If during any lawful activity conducted by an officer or employee, a drug which such officer or employee has reason to believe is in violation of any provision of this Act is found, such officer or employee may order the drug detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed 20 days unless the Secretary determines that a period of detention greater than 20 days is re-

quired to institute an action under subsection (a) or section 302, in which case the Secretary may authorize a detention period of not to exceed 60 days.

''(B) SECRETARY'S APPROVAL.—Regulations of the Secretary prescribed under this paragraph shall require that, before a drug may be ordered detained under this paragraph, the Secretary or an officer or employee designated by the Secretary approve such order.

''(C) SECURITY OF DETAINED DRUG.—A detention order under this paragraph may require—

''(i) the labeling or marking of a drug during the period of its detention for the purpose of identifying the drug as detained; and

''(ii) that the drug be removed to a secure facility, as appropriate.

''(D) APPEAL OF DETENTION ORDER.—

''(i) RIGHT TO APPEAL.—Any person who would be entitled to claim a drug if it were seized under subsection (a) may appeal to the Secretary a detention of such drug under this paragraph.

''(ii) HEARING AND RESPONSE.—Within 15 days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

''(2) LIMITATION ON MOVEMENT OF DETAINED DRUGS.—

''(A) IN GENERAL.—Except as authorized by subparagraph (B), a drug subject to a detention order issued under paragraph (1) shall not be moved by any person from the place at which it is ordered detained until—

''(i) released by the Secretary; or

''(ii) the expiration of the detention period applicable to such order,

whichever occurs first.

''(B) EXCEPTION.—A drug subject to a detention order under paragraph (1) may be moved—

''(i) in accordance with regulations prescribed by the Secretary; and

''(ii) if not in final form for shipment, at the discretion of the manufacturer of

the device for the purpose of completing the work required to put it in such form.''.

(b) REGULATIONS.—The Secretary shall issue regulations or guidance to implement the amendments made by this section.

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

(1) by inserting '', drug,'' after ''device'', each place it appears; and

(2) by inserting ''or section 304(i)'' after ''section 304(g)''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply beginning on the day that is 180 days after the date of enactment of this Act.

SEC. 202. DESTRUCTION OF ADULTERATED, MISBRANDED, OR COUNTERFEIT DRUGS OFFERED FOR IMPORT.

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

''(r)(1) Subject to paragraph (2), the Secretary of the Treasury shall cause the destruction, upon referral from the Secretary of Health and Human Services, of any drug that—

''(A) poses a reasonable probability of causing a significant adverse health effect, as determined by the Secretary of Health and Human Services; or

''(B) is valued at an amount that is $2,000 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498 of the Tariff Act of 1930).

''(2) The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity for an informal hearing for destruction of drugs under paragraph (1). The regulations under this paragraph shall allow the Secretary of Health and Human Services to provide the notice and opportunity for an informal hearing to the owner or consignee after the destruction has occurred.

''(3) For a drug not described in paragraph (1), the Secretary of Health and Human Services shall provide for notice and an opportunity for an informal hearing to the owner or consignee before the destruction of the drug under the fifth sentence of subsection (a).''.

(b) CONFORMING AMENDMENT.—The fifth sentence of subsection (a) of section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by striking ''The Secretary of the Treasury shall'' and insert-

ing ''Except as provided in subsection (r), the Secretary of the Treasury shall''.

(c) APPLICATION.—The amendments made by subsections (a) and (b) shall apply beginning on the day that is 90 days after the date of the enactment of this Act.

SEC. 203. CRIMINAL PENALTIES.

Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended—

(1) in subsection (a)—

(A) in paragraph (1), by striking ''Any'' and inserting ''Except as provided in paragraph (2) or (3), any''; and

(B) by adding at the end the following:

''(3) Notwithstanding paragraph (1), any person who, with respect to a drug, knowingly violates paragraph (a), (b), (c), (d), (f), (g), (i), (k), or (jj)(3) of section 301 shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.''; and

(2) in subsection (b)(1), by striking ''fined not more than $250,000'' and inserting ''fined in accordance with title 18, United States Code''.

SEC. 204. CIVIL PENALTIES.

(a) IN GENERAL.—Section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(f)) is

amended by striking paragraph (4) and inserting the following:

''(4)(A) Except as provided in paragraph (3) and subsection (g), any person who violates a requirement of this Act that relates to drugs shall be subject to a civil penalty in an amount not to exceed—

''(i) $500,000 for each such violation; and

''(ii) for all such violations adjudicated in a single proceeding, $10,000,000.

''(B) Each violation described in subparagraph (A) and each day during which the violation continues shall be considered to be a separate offense.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 303(f)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(f)(3)) is amended—

(A) in subparagraph (A), by striking ''Any person who'' and inserting ''Notwithstanding paragraph (4), any person who''; and

(B) in subparagraph (B), by striking ''If a violation of'' and inserting ''Notwithstanding paragraph (4), if a violation of''.

(2) Section 303(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(g)(1)) is

amended by striking ''With respect to a person who'' and inserting ''Notwithstanding subsection (f)(4), with respect to a person who''.

SEC. 205. SEIZURE.

Section 304(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(b)) is amended—

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

(2) by adding at the end the following:

''(2) PROCEDURE WITH RESPECT TO DRUGS; MULTIPLICITY OF PENDING PROCEEDINGS.—In the case of a violation relating to a drug, the article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty rather than the procedure used for civil asset forfeiture proceedings set forth in section 983 of title 18, United States Code. On demand of either party, any issue of fact joined in any such case brought under this section shall be tried by jury. Any such seizure brought under this section is not governed by Rule G of the Supplemental Rules of Admiralty or Maritime Claims and Asset Forfeiture Actions. In addition, exigent circumstances shall be deemed to exist for all such seizures brought under this section, and in such cases, the sum-

mons and arrest warrant shall be issued by the clerk of the court without court review. When libel for condemnation proceedings relating to a drug under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant reasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.''.

SEC. 206. ASSET FORFEITURE.

(a) IN GENERAL.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(h) FORFEITURE RELATED TO VIOLATIONS WITH RESPECT TO DRUGS.—

''(1) CRIMINAL FORFEITURE.—Any person convicted of a violation of section 301 with respect to drugs, or a conspiracy to commit such violation, shall forfeit to the United States any property, real or personal, constituting or traceable to the gross proceeds obtained, directly or indirectly, as a result of such violation. Pursuant to section 2461(c) of title 28, United States Code, the provisions of section 413 of the Controlled Substances Act, except subsections (a), (d), and (q) of such section 413, shall apply to criminal forfeitures under this paragraph.

''(2) CIVIL FORFEITURE.—Any property, real or personal, constituting or traceable to the gross proceeds obtained, directly or indirectly, as a result of a violation of section 301 with respect to drugs, or a conspiracy to commit such violation, is subject to forfeiture to the United States in accordance with the provisions of chapter 46 of title 18, United States Code, except that such duties as are imposed

upon the customs officer or any other person with respect to the seizure and forfeiture of property under the customs laws as described in section 981(d) of title 18, United States Code, shall be performed with respect to seizures and forfeitures of property under this section by such officers, agents, or other persons as may be authorized or designated for that purpose by the Secretary.''.

(b) CIVIL FORFEITURE STATUTE DEFINITION.—Subparagraph (C) of section 983(i)(2) of title 18, United States Code, is amended to read as follows:

''(C) section 304 of the Federal Food, Drug, and Cosmetic Act;''.

TITLE III—IMPORTATION AND EXPORTATION

SEC. 301. DOCUMENTATION FOR ADMISSIBILITY OF IMPORTS.

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

''(ccc) The submission (with respect to drugs) of information that is required pursuant to section 801 that is inaccurate or incomplete.

''(ddd) The failure (with respect to drugs) to submit information that is required pursuant to section 801.''.

(b) DOCUMENTATION FOR IMPORTS.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), as amended, is further amended by adding at the end the following:

''(s) DOCUMENTATION.—

''(1) SUBMISSION.—The Secretary may require by regulation the submission of documentation or other information for a drug that is imported or offered for import into the United States. When developing any regulation in accordance with this paragraph, to the extent that the collection of documentation or other information involves Customs and Border Protection efforts or resources, the Secretary shall consult with Customs and Border Protection.

''(2) FORMAT.—A regulation under paragraph (1) may specify the format for submission of the documentation or other information.

''(3) REFUSAL OF ADMISSION.—A drug imported or offered for import into the United States shall be refused admission unless all documentation and information the Secretary requires under this

Act or the Public Health Service Act for such article is submitted.''.

SEC. 302. REGISTRATION FOR COMMERCIAL IMPORTERS; FEE.

(a) REGISTRATION.—

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

''(eee) The failure to register in accordance with section 801(t).''.

(2) MISBRANDING.—Section 502(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(o)), as amended, is further amended by inserting ''if it is imported or offered for import by an importer not duly registered under section 801(t),'' before ''or if it does not bear''.

(3) REGISTRATION.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following:

''(t) REGISTRATION OF IMPORTERS.—

''(1) REGISTRATION.—The Secretary shall require an importer of drugs—

''(A) to be registered with the Secretary in a form and manner specified by the Secretary; and

''(B) consistent with section 1013, to submit appropriate unique identifiers as a condition of registration.

''(2) GOOD IMPORTER PRACTICES.—The maintenance of registration under this subsection is conditioned on compliance with good importer practices in accordance with the following:

''(A) The Secretary, in consultation with Customs and Border Protection, shall promulgate regulations to establish good importer practices that specify the measures an importer shall take to ensure imported drugs are in compliance with the requirements of this Act and the Public Health Service Act.

''(B) The measures under subparagraph (A) shall ensure that the importer—

''(i) has adequate information about the article, its hazards, and the requirements of this Act and the Public Health Service Act applicable to such article;

''(ii) has adequate information or procedures in place to verify that both the ar-

ticle and each person that produced, manufactured, processed, packed, transported, or held the article, including components of the article, are in compliance with the requirements of this Act and the Public Health Service Act; and

''(iii) has adequate procedures in place to take corrective action, such as the ability to appropriately trace, withhold, and recall articles, if an article imported by the importer is not in compliance with the requirements of this Act or the Public Health Service Act.

''(C) In promulgating good importer practice regulations under this subsection, the Secretary may, as appropriate, take into account differences among importers and the types of imports, including based on the level of risk posed by the imported drug.

''(3) SUSPENSION OF REGISTRATION.—

''(A) IN GENERAL.—Registration under this subsection is subject to suspension upon a finding by the Secretary, after notice and an opportunity for an informal hearing, of—

''(i) a violation of this Act; or

''(ii) the knowing or repeated making of an inaccurate or incomplete statement or submission of information relating to the importation of a drug.

''(B) REQUEST.—The importer whose registration is suspended may request that the Secretary vacate the suspension of registration when such importer has corrected the violation that is the basis for such suspension.

''(C) VACATING OF SUSPENSION.—If the Secretary determines that adequate reasons do not exist to continue the suspension of a registration, the Secretary shall vacate such suspension.

''(4) CANCELLATION OF REGISTRATION.—

''(A) IN GENERAL.—Not earlier than 10 days after providing the notice under subparagraph (B), the Secretary may cancel a registration if the Secretary determines that—

''(i) such registration was not updated in accordance with this section or otherwise contains false, incomplete, or inaccurate information; or

''(ii) the registration fee required under section 744 for such registration has

not been paid within 30 days after the date due.

''(B) NOTICE OF CANCELLATION.—Cancellation shall be preceded by notice to the importer of the intent to cancel the registration and the basis for such cancellation.

''(C) TIMELY UPDATE OR CORRECTION.—If the registration for the importer is updated or corrected no later than 7 days after notice is provided under subparagraph (B), the Secretary shall not cancel such registration.

''(5) EXEMPTIONS.—The Secretary, by notice in the Federal Register—

''(A) shall establish an exemption from the requirements of this subsection for importations for personal use; and

''(B) may establish other exemptions from the requirements of this subsection.''.

(4) REGULATIONS.—Not later than 36 months after the date of the enactment of this Act, the Secretary of Health and Human Services in consultation with the Commissioner responsible for Customs and Border Protection shall promulgate the regulations required to carry out section 801(t) of the Federal Food, Drug, and Cosmetic Act, as added by

paragraph (3). In establishing the effective date of a regulation promulgated under section 801(t), the Secretary shall, in consultation with the Commissioner responsible for Customs and Border Protection, as appropriate, provide a reasonable period of time for an importer of a drug to comply with good importer practices, taking into account differences among importers and the types of imports, including based on the level of risk posed by the imported product.

(5) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date that is 24 months after the date of enactment of this Act.

(b) FEE.—Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

"PART 7—IMPORTERS OF DRUGS

"SEC. 744. IMPORTERS OF DRUGS.

''(a) IMPORTERS.—The Secretary shall assess and collect an annual fee for the registration of an importer under section 801(t).

''(b) AMOUNT OF FEE.—

''(1) BASE AMOUNTS.—The registration fee under subsection (a) shall be—

''(A) for fiscal year 2012, $500; and

''(B) for fiscal year 2013 and each subsequent fiscal year, the fee for fiscal year 2012 as adjusted under paragraph (2).

''(2) ADJUSTMENT.—For fiscal year 2013 and subsequent fiscal years, the fees established pursuant to paragraph (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; United States 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.

''(3) COMPOUNDED BASIS.—The adjustment made each fiscal year pursuant to this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2012 under this subsection.

''(4) WAIVER FOR IMPORTERS REQUIRED TO PAY REGISTRATION FEE.—The Secretary shall waive the fee applicable to a person under this section if such person is required to pay both—

''(A) a fee under section 736C for registration of one or more establishments under section 510, for drugs; and

''(B) a fee under this section for registration as an importer under section 801(t).

''(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 authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and ex-

penses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

''(2) COLLECTIONS AND APPROPRIATIONS 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 appropriations Acts, or otherwise made available for obligation, for such fiscal year; and

''(B) shall only be collected and available to cover the costs associated with registering importers under sections 801(t) and with ensuring compliance with good importer practices.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2012 through 2016, there are authorized to be appropriated for fees under this section such sums as may be necessary.''.

(c) INSPECTION.—Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) is amended by adding at the end the following:

''(h) IMPORTERS.—Every person engaged in the importing of any drug shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to inspect the facilities

of such person and have access to, and to copy and verify, any related records.''.

SEC. 303. REGISTRATION FOR CUSTOMS BROKERS.

(a) REGISTRATION.—

(1) PROHIBITIONS.—Section 301(eee) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as added by section 302(a)(1), is amended by inserting ''or 801(u)'' after ''801(t)''.

(2) MISBRANDING.—Section 502(o) (21 U.S.C. 352(o)), as amended by section 302(a)(2), is amended—

(A) by inserting ''or a customs broker'' after ''by an importer''; and

(B) by inserting ''or 801(u)'' after ''801(t)''.

(3) REGISTRATION.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), as amended, is further amended by adding at the end the following:

''(u) REGISTRATION OF CUSTOMS BROKER.—

''(1) REGISTRATION.—The Secretary shall require a customs broker, with respect to the importation of drugs—

''(A) to be registered with the Secretary in a form and manner specified by the Secretary; and

''(B) consistent with section 1013, to submit appropriate unique identifiers as a condition of registration.

''(2) CANCELLATION OF REGISTRATION.—

''(A) IN GENERAL.—Not earlier than 10 days after providing the notice under subparagraph (B), the Secretary may cancel a registration that the Secretary determines was not updated in accordance with this section or otherwise contains false, incomplete, or inaccurate information.

''(B) NOTICE OF CANCELLATION.—Cancellation shall be preceded by notice to the customs broker of the intent to cancel the registration and the basis for such cancellation.

''(C) TIMELY UPDATE OR CORRECTION.—If the registration for the customs broker is updated or corrected no later than 7 days after notice is provided under subparagraph (B), the Secretary shall not cancel such registration.

''(3) NOTIFICATION.—The Secretary shall notify the Commissioner responsible for Customs and

Border Protection whenever the Secretary cancels a registration under this subsection.

''(4) EXEMPTIONS.—In consultation with the Commissioner responsible for Customs and Border Protection, the Secretary, by notice published in the Federal Register—

''(A) shall establish an exemption from the requirements of this subsection for importations for personal use; and

''(B) may establish other exemptions from the requirements of this subsection.

''(5) CIVIL PENALTIES.—Notwithstanding any other provision in this Act, a customs broker who violates section 301 because of a violation of subsection (ccc), (ddd), or (eee) of such section shall not be subject to a civil penalty under section 303(f)(1)(C) of this Act.''.

(4) REGULATIONS.—Not later than 24 months after the date of the enactment of this Act, the Secretary of Health and Human Services, in consultation with the Commissioner responsible for Customs and Border Protection, shall promulgate the regulations required to carry out section 801(u) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (3).

(5) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date that is 24 months after the date of enactment of this Act.

(b) INSPECTION.—Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374), as amended, is further amended by adding at the end the following:

''(i) BROKERS.—Every customs broker required to be registered with the Secretary shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to inspect the facilities of such person and have access to, and to copy and verify, any related records.''.

SEC. 304. EXPORTATION CERTIFICATE PROGRAM.

Section 801(e)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)) is amended—

(1) in subparagraph (B), by striking ''If the Secretary'' and inserting ''With respect to a device, if the Secretary''; and

(2) by adding at the end the following:

''(E) With respect to a drug:

''(i) A certification by the Secretary under subparagraph (A) need not be in writing.

''(ii) Subparagraph (A) applies only with respect to exportation from the United States.

''(iii) Any person who exports from a country other than the United States a drug approved in the United States may request that the Secretary certify that the exported drug meets the applicable requirements of this Act. The Secretary shall issue such a certification within 20 days of the receipt of a request for such certification if the request demonstrates that the drug meets the applicable requirements of this Act.

''(iv) For purposes of this subparagraph, a certification by the Secretary shall be made on such basis and in such form (such as a publicly available listing) as the Secretary determines appropriate.

''(v) If the Secretary, with respect to a drug, issues an export certification within the 20 days prescribed by subparagraph (A) or clause (iii) of this subparagraph, a fee for such certification may be charged but such fee shall not exceed such amount as the Secretary determines is reasonably related to the cost of issuing such certificates. The Secretary may adjust this fee annually to account for inflation and other cost adjustments. Fees collected for

a fiscal year pursuant to this subparagraph shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriations Acts until expended, without fiscal year limitation. Such fees shall be collected in each fiscal year in an amount equal to the amount specified in appropriations Acts for such fiscal year and shall only be collected and available for the costs of the Food and Drug Administration to cover the cost of issuing such certifications. Such sums as necessary may be transferred from such appropriation account for salaries and expenses of the Food and Drug Administration without fiscal year limitation to such appropriation account for salaries and expenses with fiscal year limitation.''.

SEC. 305. EXTRATERRITORIAL JURISDICTION.

(a) IN GENERAL.—Chapter III of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331 et seq.) is amended by adding at the end the following:

''SEC. 311. EXTRATERRITORIAL JURISDICTION.

''There is extraterritorial jurisdiction over any violation of this Act relating to any drug if such drug was in-

tended for import into the United States or if any act in furtherance of the violation was committed in the United States.''.

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

''(fff) The production, manufacture, processing, preparation, packing, holding, or distribution of an adulterated or misbranded drug with the knowledge or intent that such drug will be imported into the United States, or the production, manufacture, processing, preparation, packing, holding, or distribution of a drug with the knowledge or intent that the drug will be imported into the United States in violation of section 505.''.

SEC. 306. DEDICATED FOREIGN INSPECTORATE.

Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374), as amended, is further amended by adding at the end the following:

''(j) The Secretary shall establish and maintain a corps of inspectors dedicated to inspections of foreign drug 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 drug facilities and establishments at a frequency at least equivalent to the in-

spection rate of domestic drug facilities and establishments.''.

TITLE IV—MISCELLANEOUS

SEC. 401. UNIQUE IDENTIFICATION NUMBER FOR ESTABLISHMENTS, IMPORTERS, AND CUSTOMS BROKERS.

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

''SEC. 1013. UNIQUE IDENTIFIER.

''(a) REGISTRATION OF ESTABLISHMENTS.—A person required to register a drug establishment pursuant to section 510 shall submit, at the time of registration, a unique identifier for the establishment.

''(b) REGISTRATION OF IMPORTERS AND CUSTOMS BROKERS.—A person required to register pursuant to section 801(t) or 801(u) shall submit, at the time of registration, a unique identifier for the principal place of business for which such person is required to register under section 801(t) or 801(u).

''(c) GUIDANCE.—The Secretary may, by guidance, and, with respect to importers and customs brokers, in consultation with the Commissioner responsible for Customs and Border Protection, specify the unique numerical identifier system to be used to meet the requirements of

subsections (a) and (b) and the form, manner, and timing of a submission under such subsections. Development of such guidance shall take into account the utilization of existing unique identification schemes and compatibility with customs automated systems.

''(d) IMPORTATION.—A drug imported or offered for import shall be refused admission unless the appropriate unique identifiers, as specified by the Secretary, are provided for such article.''.

SEC. 402. COUNTRY OF ORIGIN LABELING.

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(aa) If it is a finished dosage form drug and the Web site of the manufacturer of such drug does not list—

''(1) the country of origin for each active pharmaceutical ingredient; and

''(2) the place of manufacture of the finished dosage form of such drug.''.

(b) REGULATIONS.—Not later than 3 years 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 4 years after the date of the enactment of this Act.

SEC. 403. FALSE OR MISLEADING REPORTING TO FDA.

(a) IN GENERAL.—Section 301(q)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(q)(2)) is amended by inserting ‘‘, drug,’’ after ‘‘device’’.

(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. 404. SUBPOENA AUTHORITY.

(a) PROHIBITED ACT.—Section 301(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(f)) is amended by inserting before the period ‘‘or the failure or refusal to obey a subpoena issued pursuant to section 312’’.

(b) EXERCISE OF SUBPOENA AUTHORITY.—Chapter III of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331 et seq.), as amended, is further amended by adding at the end the following new section:

‘‘SEC. 312. EXERCISE OF SUBPOENA AUTHORITY.

‘‘(a) IN GENERAL.—For the purpose of—

‘‘(1) any hearing, investigation, or other proceeding respecting a violation of a provision of this

Act, the Public Health Service Act, or the Federal Anti-Tampering Act, relating to a drug; or

''(2) any hearing, investigation, or other proceeding to determine if a person is in violation of a specific provision of this Act, the Public Health Service Act, or the Federal Anti-Tampering Act, relating to a drug,

the Commissioner may issue subpoenas requiring the attendance and testimony of witnesses and the production of records and other things.

''(b) TIMING OF COMPLIANCE.—When the Commissioner deems that immediate compliance with a subpoena issued under this section is necessary to address a threat of serious adverse health consequences or death, the subpoena may require immediate production.

''(c) SERVICE OF SUBPOENA.—Under this section:

''(1) IN GENERAL.—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.

''(2) CORPORATIONS AND OTHER ENTITIES.—Service on a domestic or foreign corporation, partnership, unincorporated association, or other entity

that is subject to suit under a common name may be made by delivering the subpoena to an officer, a managing or general agent, or any other agent authorized by appointment or by law to receive service of process.

''(3) PERSON OUTSIDE U.S. JURISDICTION.—Service on any person not found within the territorial jurisdiction of any court of the United States may be made in any manner as the Federal Rules of Civil Procedure prescribe for service in a foreign nation.

''(4) PROOF OF SERVICE.—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 therefore signed by the person so served, shall be proof of service.

''(d) PAYMENT OF WITNESSES.—Witnesses subpoenaed under subsection (a) shall be paid the same fees and mileage as are paid witnesses in the district courts of the United States.

''(e) 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 compelling compliance with the subpoena and requiring such person to appear and give testimony or to appear and produce records and other things, or both. The failure to obey such order of the court may be punished by the court as contempt thereof. If the person charged with failure or refusal to obey is not found within the territorial jurisdiction of the United States, the United States District Court for the District of Columbia shall have the same jurisdiction, consistent with due process, to take any action respecting compliance with the subpoena by such person that such district court would have if such person were personally within the jurisdiction of such district court.

''(f) NONDISCLOSURE.—A United States district court for the district in which the subpoena is or will be served, upon application of the Commissioner, may issue an ex parte order that no person or entity disclose to any other person or entity (other than to an attorney to obtain legal advice) the existence of such subpoena for a period of up to 90 days. Such order may be issued on a showing that the records or things being sought may be relevant to the hearing, investigation, proceeding, or other matter

and that there is reason to believe that such disclosure may result in—

''(1) furtherance of a potential violation under investigation;

''(2) endangerment to the life or physical safety of any person;

''(3) flight or other action to avoid prosecution or other enforcement remedies;

''(4) destruction of or tampering with evidence; or

''(5) intimidation of potential witnesses.

An order under this subsection may be renewed for additional periods of up to 90 days upon a showing that any of the circumstances described in paragraphs (1) through (5) continue to exist.

''(g) 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, or as is otherwise authorized by law.

''(h) NONDELEGATION.—The authority to issue a subpoena under this section is limited to the Commissioner or an official designated by the Commissioner. An official may not be so designated unless the official is the

director of the district under this Act in which the drug is located, or is an official senior to such director.''.

(c) FAILURE TO OBEY SUBPOENA.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), as amended, is further amended by adding at the end the following new subsection:

''(v)(1) A drug shall be refused admission if any person who manufactures, processes, packs, holds, or ships such drug before it is imported or offered for import into the United States fails or refuses to obey a subpoena issued pursuant to section 312 and such subpoena was issued, in whole or in part, for the purpose of determining whether such drug is adulterated, misbranded, or an unapproved new drug.

''(2) No drug shall be refused admission under this section based on the failure or refusal to obey a subpoena that has been withdrawn by the Commissioner or quashed by a United States district court.''.

SEC. 405. WHISTLEBLOWER PROTECTIONS.

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

"SEC. 1014. PROTECTIONS FOR EMPLOYEES WHO REFUSE TO VIOLATE, OR WHO DISCLOSE VIOLATIONS OF, THIS ACT.

''(a) IN GENERAL.—No person who submits or is required under this Act or the Public Health Service Act to submit any information related to a drug, or any officer, employee, contractor, subcontractor, or agent of such 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 any lawful act that is 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 reasonably believes constitutes a violation of this Act that is related to a drug, or any other provision of Federal law relating to the safety of a drug, 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), in any court or administrative forum 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 and there is no showing that such delay is due to the bad faith of the claimant, or within 90 days after receiving a final decision or order from the Secretary,

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, the employer, and the Commissioner of Food and Drugs.

''(C) BURDENS OF PROOF.—An action brought under paragraph (1)(A) or (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)(A) 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 subsection (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—

''(i) reinstate the complainant to his or her former position together with compensation (including backpay); and

''(ii) 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.''.

SEC. 406. RULE OF CONSTRUCTION.

Nothing in this Act or any amendment made by this Act shall be construed as affecting any authority or requirement relating to devices (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)).