111TH CONGRESS
1ST SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to ensure the safety and quality of medical products and enhance the authorities of the Food and Drug Administration, and for other purposes.

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure the safety and quality of medical products and enhance the authorities of the Food and Drug Administration, 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 and Device Accountability Act of 2009''.

SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.

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

(b) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

TITLE I—ENSURING THE SAFETY AND QUALITY OF MEDICAL PRODUCTS AND THEIR COMPONENTS

Subtitle A—Enhanced Registration and Inspection of Drug and Device Establishments

SEC. 101. REGISTRATION OF DRUG AND DEVICE ESTABLISHMENTS.

Section 510 (21 U.S.C. 360) is amended—

(1) by striking subsection (b) and inserting the following:

''(b) REGISTRATION OF DOMESTIC ESTABLISHMENTS.—Any person who owns or operates any establishment in any State engaged in the manufacture, prepara-

tion, propagation, compounding, or processing of a drug or device shall—

''(1) upon first engaging in any such activity, immediately submit a registration to the Secretary that includes the name of such person, places of business of such person, all such establishments, the D-U-N-S number of each such establishment, an e-mail address for use in an emergency, and payment of any inspection fee for each such establishment required under section 743;

''(2) thereafter immediately submit a registration that includes the information and fee described in paragraph (1) for any additional establishment owned or operated by such person in any State in which such person begins the manufacture, preparation, propagation, compounding, or processing of a drug or device; and

''(3) thereafter—

''(A) with respect to such drugs, submit a registration described in paragraph (1) to the Secretary on or before December 31 of each year; and

''(B) with respect to such devices, submit a registration described in paragraph (1) to the Secretary during the period beginning on Octo-

ber 1 and ending on December 31 of each year.''; and

(2) by striking subsections (c) and (d).

SEC. 102. REGISTRATION OF FOREIGN DRUG AND DEVICE ESTABLISHMENTS.

(a) ENFORCEMENT OF REGISTRATION OF FOREIGN ESTABLISHMENTS.—Section 502(o) (21 U.S.C. 352(o)) is amended by striking ''in any State''.

(b) REGISTRATION OF FOREIGN ESTABLISHMENTS.—Section 510 (U.S.C. 360), as amended by section 101, is further amended—

(1) by transferring subsection (i) so as to appear after subsection (b); and

(2) in subsection (i) (as so transferred)—

(A) by striking ''(i) (1)'' and all that follows through ''of each year.'' and inserting the following:

''(c) REGISTRATION OF FOREIGN ESTABLISHMENTS.—

''(1) IN GENERAL.—Any person who owns or operates any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall—

''(A) upon first engaging in any such activity, immediately submit a registration to the Secretary that includes the name and place of business of such person, all such establishments, the D-U-N-S number of each such establishment, an e-mail address for use in an emergency, payment of any inspection fee for each such establishment required under section 743, the name of the United States agent of each such establishment, the name of each importer of such drug or device in the United States that is known to each such establishment, and the name of each person who imports or offers for import such drug or device to the United States for purposes of importation;

''(B) thereafter immediately submit a registration that includes the information and fee described in paragraph (1) for any additional establishment owned or operated by such person within any foreign country in which such person begins the manufacture, preparation, propagation, compounding, or processing of such a drug or device; and

''(C) thereafter—

''(i) with respect to drugs, submit a registration described in subparagraph (A) to the Secretary on or before December 31 of each year; and

''(ii) with respect to devices, submit a registration described in subparagraph (A) to the Secretary during the period beginning on October 1 and ending on December 31 of each year.'';

(B) by striking paragraph (2);

(C) in paragraph (3), by striking ''(3) The Secretary'' and inserting ''(2) COOPERATIVE ARRANGEMENTS.—The Secretary''; and

(D) by moving the indentation of paragraph (2), as amended, 2 ems to the right.

SEC. 103. REGISTRATION OF ESTABLISHMENTS FOR DRUG PRECURSOR INGREDIENTS.

(a) REGISTRATION OF ESTABLISHMENTS THAT MANUFACTURE DRUG PRECURSOR INGREDIENTS.—Section 510(a) (21 U.S.C. 360(a)) is amended—

(1) in the matter preceding paragraph (1), by striking ''As used'' and inserting ''DEFINITIONS.—As used'';

(2) by redesignating paragraphs (1) and (2) as paragraphs (2) and (3), respectively; and

(3) by inserting after ''this section—'' the following:

''(1) the term 'drug' includes a precursor ingredient;''.

(b) DEFINITION OF PRECURSOR INGREDIENT.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

''(rr) The term 'precursor ingredient', with respect to an active ingredient of a drug, means an article that is a material—

''(1) of animal origin from which such active ingredient is derived; or

''(2) used in the final stage of synthesis or purification of such active ingredient, if so specified by the Secretary by regulation or in an order approving a drug that bears or contains such active ingredient.''.

SEC. 104. REGISTRATION AND LICENSING OF DRUG IMPORTERS.

Section 510 (21 U.S.C. 360), as amended by section 102, is further amended by inserting after subsection (c) the following:

''(d) REGISTRATION AND LICENSING OF DRUG IMPORTERS.—

''(1) IN GENERAL.—Any person who owns or operates any establishment engaged in the importation, filing for importation, or brokering for importation of a drug into the United States shall—

''(A) upon first engaging in any such activity, immediately submit a registration to the Secretary that includes the name of such person, places of business of such person, all such establishments, the D-U-N-S number of each such establishment, and an e-mail address for use in an emergency;

''(B) thereafter immediately submit a registration that includes the information described in subparagraph (A) for any additional establishment owned or operated by such person in which such person begins any such activity; and

''(C) thereafter submit a registration described in subparagraph (A) to the Secretary during the period beginning on October 1 and ending on December 31 of each year.

''(2) LICENSING.—

''(A) IN GENERAL.—The Secretary may require any person engaged in the importation, filing for importation, or brokering for importation of a drug into the United States, before en-

gaging in those activities, to obtain a license to be issued by the Secretary.

''(B) BOND.—The Secretary may require as a condition of a license for a person under subparagraph (A) that the person post a bond subject to forfeiture if the person has, in connection with the importation, filing for importation, or brokering for importation of a drug into the United States—

''(i) violated, or caused the violation, of this Act; or

''(ii) made, or caused to be made, a false or misleading statement.

''(C) AMOUNT OF BOND.—The Secretary shall ensure that the amount of any bond required under subparagraph (B) for a person is sufficient to deter such person from, in connection with the importation, filing for importation, or brokering for importation of a drug into the United States—

''(i) violating, or causing the violation of, this Act; or

''(ii) making, or causing to be made, a false or misleading statement.

''(D) REVOCATION.—The Secretary may revoke the license for a person under subparagraph (A) if the Secretary finds that, in connection with the importation, filing for importation, or brokering for importation of a drug into the United States, such person has—

''(i) violated, or caused the violation of, this Act; or

''(ii) made, or caused to be made, a false or misleading statement.''.

SEC. 105. INSPECTION OF DRUG AND DEVICE ESTABLISHMENTS.

(a) EQUAL INSPECTION AUTHORITY FOR DOMESTIC AND FOREIGN ESTABLISHMENTS; REFUSED INSPECTIONS.—Section 510(h) (21 U.S.C. 360(h)) is amended by—

(1) striking ''Every'' and inserting: ''INSPECTIONS.—

''(1) IN GENERAL.—Every'';

(2) striking ''in any State''; and

(3) striking ''704 and every such establishment'' and inserting ''704.

''(2) REFUSED INSPECTION.—Any establishment described in paragraph (1) shall not be considered duly registered under this section if an inspec-

tion of such establishment by the Secretary is refused, delayed, or limited by—

"(A) the person who owns or operates such establishment, or any agent or employee of such person; or

"(B) any agent of a governmental authority in the foreign country within which such establishment is located.

"(3) BIENNIAL INSPECTION SCHEDULE.—Except as provided in paragraph (4), and except for establishments that manufacture, prepare, propagate, compound, or process only inactive ingredients, every establishment described in paragraph (1)".

(b) PROVIDING FOR RISK-BASED INSPECTIONS OF ESTABLISHMENTS.—

(1) IN GENERAL.—Section 510(h) (21 U.S.C. 360(h)), as amended by subsection (a), is further amended by adding at the end the following:

"(4) RISK-BASED INSPECTION SCHEDULE.—

"(A) IN GENERAL.—The Secretary may by regulation provide for an inspection schedule for establishments described in paragraph (3) (including those establishments that manufacture, prepare, propagate, compound, or process

only inactive ingredients) different from that required by such paragraph.

''(B) INSPECTION FREQUENCY AND RISK-BASED FACTORS.—In providing for an inspection schedule under subparagraph (A), the Secretary—

''(i) may require inspections of an establishment more frequently than once in every successive 2-year period;

''(ii) shall require inspections of an establishment at least once in every successive 5-year period; and

''(iii) shall consider—

''(I) the risks presented by the drug or drugs, or the device or devices, manufactured, prepared, propagated, compounded, or processed by an establishment (including whether the drug is a finished dosage form, an active ingredient, a precursor ingredient, or an inactive ingredient; the route of administration of the drug; whether the device is intended to be implanted, permanently implantable, life sustaining, or life supporting; and

the use or uses for which the drug or device is approved or cleared under this Act or licensed under section 351 of the Public Health Service Act);

''(II) whether or not an establishment is within a foreign country with a governmental authority responsible for drugs or devices, as applicable, deemed adequate by the Secretary;

''(III) whether or not, and the frequency with which, an establishment is subject to inspection by a governmental authority responsible for drugs or devices, as applicable, deemed adequate by the Secretary; and

''(IV) such other factors as the Secretary determines are relevant to determining an inspection schedule for establishments.

''(C) RISK-BASED FACTORS FOR MODIFYING FREQUENCY OF INSPECTIONS OF AN ESTABLISHMENT.—The Secretary may inspect an establishment at a frequency different than that

required by the inspection schedule under subparagraph (A) by considering—

''(i) the history of any safety problems with any drug or device manufactured, prepared, propagated, compounded, or processed by the establishment;

''(ii) the record of inspections by the Secretary of the establishment;

''(iii) with respect to a drug that is not a finished dosage form, the record of inspections by a governmental authority responsible for drugs deemed adequate by the Secretary;

''(iv) with respect to a drug that is an inactive ingredient, a quality certification by a private entity, if the Secretary has agreed to accept such a certification; and

''(v) such other factors as the Secretary determines are relevant to assessing the risk presented by the drug or drugs, or the device or devices, manufactured, prepared, propagated, compounded, or processed by the establishment.''.

(2) IMPLEMENTATION.—The Secretary of Health and Human Services may issue a proposed

rule to provide for a risk-based inspection schedule as described in section 510(h)(4) of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, no earlier than March 31, 2011.

(c) ANNUAL REPORT ON INSPECTIONS OF ESTABLISHMENTS.—Section 510(h) (21 U.S.C. 360(h)), as amended by subsection (b), is further amended by adding at the end the following:

"(5) ANNUAL REPORT ON INSPECTIONS OF ESTABLISHMENTS.—Not later than February 1 of each year, the Secretary shall submit a report to the Congress about—

"(A) the appropriations used to inspect establishments registered pursuant to this section in the previous fiscal year;

"(B) the number of domestic and foreign establishments registered with the Secretary under this section during the previous calendar year;

"(C)(i) the number of domestic and foreign establishments registered pursuant to this section that the Secretary inspected in the previous fiscal year; and

"(ii) if the Secretary has provided for a schedule under paragraph (4)(A) with different

frequencies of inspection for different classes of establishments, the numbers and identities for each such class;

"(D)(i) the number of domestic and foreign establishments registered pursuant to this section that the Secretary did not inspect in the previous fiscal year; and

"(ii) if the Secretary has provided for a schedule under paragraph (4)(A) with expected frequencies of inspection for different classes of establishments, the numbers for each such class;

"(E) information on the performance in the previous fiscal year of the foreign inspectorate established under section 704(h) including—

"(i) the number of inspections conducted with and without personnel who are fluent in the language used in the establishment under inspection;

"(ii) the number of personnel in such inspectorate;

"(iii) the countries in which such personnel conduct inspections;

''(iv) the offices in foreign countries where such personnel are permanently stationed;

''(v) the number of personnel conducting inspections in each country who are fluent in the language or languages used in the establishments of that country; and

''(vi) the number of personnel who are permanently stationed in each in-country office who are fluent in the language or languages used in the establishments of that country; and

''(F) other information deemed relevant by the Secretary.

''(6) PUBLIC AVAILABILITY OF ANNUAL REPORTS.—The Secretary shall make the report required under paragraph (5) available to the public on the Internet Web site of the Food and Drug Administration.''.

SEC. 106. LISTING OF DRUGS AND DEVICES; ENHANCED INFORMATION TECHNOLOGY SYSTEM FOR REGISTRATION AND LISTING; INACTIVE INGREDIENTS.

(a) LISTING OF DRUGS AND DEVICES.—Section 510(j) (21 U.S.C. 360(j)) is amended—

(1) by striking ''(j)(1) Every person who registers with the Secretary under subsection (b), (c), (d), or (i)'' and inserting the following:

''(i) SUBMISSION OF LIST OF DRUGS AND DEVICES.—

''(1) IN GENERAL.—Every person who registers with the Secretary under subsection (b) or (c)'';

(2) in paragraph (1)—

(A) in subparagraph (B)(i), by inserting ''in the case of a drug, the authority under this Act that does not require such drug to be subject to section 505 and section 512,'' after ''labeling for such drug or device,'';

(B) in subparagraph (B)(ii), by inserting '', in the case of a drug, the authority under this Act that does not require such drug to be subject to section 505 and section 512,'' after ''insert for such drug or device'';

(C) by moving the indentation of subparagraphs (A) through (D) 2 ems to the right; and

(D) in subparagraph (B), by moving the indentation of clauses (i) and (ii) 2 ems to the right;

(3) in paragraph (2)—

(A) by striking ''(2) Each person who registers with the Secretary under this section'' and inserting the following:

''(2) REPORT TO SECRETARY.—Every person who registers with the Secretary under subsection (b) or (c)''; and

(B) by moving the indentation of subparagraphs (A) through (D) 2 ems to the right;

(4) in paragraph (3), by striking ''(3) The Secretary'' and inserting the following:

''(3) ADDITIONAL LIST.—The Secretary''; and

(5) by adding at the end the following:

''(4) SUBMISSION FOR FINISHED DOSAGE FORM.—Every person who files a list under paragraph (1) or reports a list under paragraph (2) shall submit with such list, for any drug that is a finished dosage form, the identity of each establishment engaged in the manufacture, preparation, propagation, compounding, or processing of—

''(A) the finished dosage form;

''(B) any active ingredient of the drug;

"(C) any inactive ingredient of the drug; or

"(D) any precursor ingredient of any such active ingredient.".

(b) ENHANCED INFORMATION TECHNOLOGY SYSTEM FOR REGISTRATION AND LISTING.—Section 510(j) (21 U.S.C. 360(j)), as amended by subsection (a), is further amended by adding at the end the following:

"(5) ELECTRONIC SUBMISSION AND MAINTENANCE OF INFORMATION.—Not later than October 1, 2010, the Secretary shall establish and maintain—

"(A) an Internet-based portal through which information to register establishments under subsection (b), (c), and (d) and to list drugs and devices under this subsection shall be submitted to the Secretary; and

"(B) an electronic database (which shall not be subject to inspection under subsection (f)) populated with the information submitted under subparagraph (A) that—

"(i) includes appropriate links between registered establishments and between such establishments and listed drugs and devices sufficient to enable the Sec-

retary to track and assess the establishments and articles involved in the manufacture, preparation, propagation, compounding, or processing of each drug that is a finished dosage form or an active ingredient and each device;

"(ii) includes the date of each inspection by the Secretary (with the Secretary's report on and assessment of the inspection) for each such establishment and such other information on the inspectional record and compliance history of the establishment as the Secretary deems necessary and appropriate to assess the compliance history of the establishment and, if applicable, apply the inspection schedule under subsection (h)(4) to such establishment; and

"(iii) is interoperable and communicates with other relevant databases within the Food and Drug Administration (including a database for submission of information under section 801(p)).".

(c) DRUGS THAT ARE NOT APPROVED UNDER SECTION 505 OR 512.—Section 510(f) (21 U.S.C. 360(f)) is amended—

(1) by striking ''(f) The Secretary'' and inserting the following:

''(f) INSPECTION BY PUBLIC OF REGISTRATION.—

''(1) IN GENERAL.—The Secretary'';

(2) by striking ''subsection (j)'' and inserting ''subsection (i)''; and

(3) by inserting at the end the following:

''(2) LIST OF DRUGS THAT ARE NOT APPROVED UNDER SECTION 505 OR 512.—The Secretary shall make available to the public on the Internet Web site of the Food and Drug Administration a list that includes, for each drug described in subsection (i)(1)(B)—

''(A) the drug;

''(B) the person who listed such drug; and

''(C) the authority under this Act that does not require such drug to be subject to section 505 and section 512, as provided by such person in such list.''.

(d) INACTIVE INGREDIENTS.—

(1) ASSESSMENT OF ESTABLISHMENTS THAT MANUFACTURE DRUG INACTIVE INGREDIENTS.—Not

later than March 31, 2011, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall—

(A) use the information populating the electronic database referred to in section 510(j)(5) of the Federal, Food, Drug, and Cosmetic Act, as added by subsection (b), to identify the establishments that manufacture, prepare, propagate, compound, or process an active ingredient of any drug listed in such database; and

(B) complete an assessment as to whether the exemption from registration in subsection (e) of section 207.10 of title 21, Code of Federal Regulations, should be eliminated or modified.

(2) REGULATION TO ELIMINATE OR MODIFY THE EXEMPTION FROM REGISTRATION FOR ESTABLISHMENTS THAT MANUFACTURE DRUG INACTIVE INGREDIENTS.—In the regulation provided for under section 105(b)(2), the Secretary may propose to eliminate or modify the exemption referred to in paragraph (1)(B), as the Secretary deems appropriate, after having completed the assessment under such paragraph.

SEC. 107. FEES RELATED TO ESTABLISHMENT INSPECTIONS.

Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

"PART 6—FEES RELATED TO ESTABLISHMENT INSPECTIONS

"SEC. 743. AUTHORITY TO ASSESS AND USE FEES.

''(a) DEFINITIONS.—In this section:

''(1) AFFILIATE.—The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has the power to control, the other business entity; or

''(B) a third business entity controls, or has the power to control, both of the business entities.

''(2) DEVICE ESTABLISHMENT.—The term 'device establishment' means—

''(A) an establishment in any State that is—

''(i) engaged in the manufacture, preparation, propagation, compounding, or processing of a device classified in class II or class III; and

"(ii) subject to inspection under subsection (h)(3) or (h)(4) of section 510, as applicable; or

"(B) an establishment within any foreign country that is—

"(i) engaged in the manufacture, preparation, propagation, compounding, or processing of a device classified in class II or class III that is imported or offered for import into the United States; and

"(ii) subject to inspection under subsection (h)(3) or (h)(4) of section 510, as applicable.

"(3) DEVICE REGISTRATION AND INSPECTION ACTIVITIES.—The term 'device registration and inspection activities' means the following activities of the Secretary:

"(A) The registration of device establishments under subsections (b) and (c) of section 510.

"(B) The listing of devices under section 510(i), including the activities for devices described in section 510(i)(5).

"(C) The inspection of device establishments under section 510(h)(3) or, if applicable, section 510(h)(4).

"(D) The review of inspection reports from such inspections.

"(E) Any action under this Act pursuant to such registration, listing, inspections, or reviews.

"(4) DRUG ESTABLISHMENT.—The term 'drug establishment' means—

"(A) an establishment in any State that is—

"(i) engaged in the manufacture, preparation, propagation, compounding, or processing of a drug; and

"(ii) subject to inspection under subsection (h)(3) or (h)(4) of section 510, as applicable; or

"(B) an establishment within any foreign country that is—

"(i) engaged in the manufacture, preparation, propagation, compounding, or processing of a drug; and

''(ii) subject to inspection under subsection (h)(3) or (h)(4) of section 510, as applicable.

''(5) DRUG REGISTRATION AND INSPECTION ACTIVITIES.—The term 'drug registration and inspection activities' means the following activities of the Secretary:

''(A) The registration of drug establishments under subsections (b) and (c) of section 510.

''(B) The listing of drugs under section 510(i), including the activities for drugs described in section 510(i)(5).

''(C) The inspection of drug establishments under section 510(h)(3) or, if applicable, section 510(h)(4).

''(D) The review of inspection reports from such inspections.

''(E) Any action under this Act pursuant to such registration, listing, inspections, or reviews.

''(6) PERSON.—The term 'person' includes an affiliate thereof.

''(b) TYPES OF FEES.—

''(1) DRUG INSPECTION FEES.—Beginning in fiscal year 2010, the Secretary shall collect drug inspection fees in accordance with this section as follows:

''(A) IN GENERAL.—Except as provided under subparagraphs (B), (C), and (D), each person that during a fiscal year registers a drug establishment under subsection (b) or (c) of section 510 shall be subject to a drug inspection fee established under subsection (c)(1).

''(B) REDUCTION FOR POSITRON EMISSION TOMOGRAPHY DRUGS.—The drug inspection fee for a drug establishment engaged solely in the manufacture, preparation, propagation, compounding, or processing of 1 or more drugs to which section 736(a)(2)(C)(i) applies shall be one-sixth of the drug inspection fee otherwise applicable to such establishment under subsection (c)(1).

''(C) EXEMPTION FOR CERTAIN POSITRON EMISSION TOMOGRAPHY DRUGS AND CERTAIN ORPHAN DRUGS.—A drug establishment engaged solely in the manufacture, preparation, propagation, compounding, or processing of 1 or more drugs to which section 736(a)(2)(C)(ii)

or section 736(k) applies shall not be assessed a drug inspection fee.

''(D) WAIVER OR REDUCTION.—The Secretary shall grant a waiver from or reduction of the drug inspection fee as provided for under section 736(d).

''(2) DEVICE INSPECTION FEES.—Beginning in fiscal year 2010, the Secretary shall collect device inspection fees in accordance with this section as follows:

''(A) IN GENERAL.—Except as provided under subparagraphs (B) and (C), each person that during a fiscal year registers a device establishment under subsection (b) or (c) of section 510 shall pay a device inspection fee established under subsection (c)(2).

''(B) REDUCTION FOR SMALL BUSINESSES.—The device inspection fee for a device establishment owned or operated by an entity that qualifies as a small business under section 738(d)(2) shall be one-fourth of the device inspection fee otherwise applicable to such establishment under subsection (c)(2).

''(C) EXEMPTION FOR CERTAIN STATE OR FEDERAL GOVERNMENT ESTABLISHMENTS.—A

device establishment operated by a State or Federal government entity shall not be assessed a device inspection fee unless a device classified in class II or class III manufactured by the establishment is to be distributed commercially.

''(c) FEE AMOUNTS.—

''(1) DRUG INSPECTION FEE AMOUNTS.—

''(A) IN GENERAL.—Beginning with fiscal year 2010, the Secretary shall, not later than 30 days after the amount has been appropriated for a fiscal year in an appropriations Act as described in subsection (e)(1), establish for such fiscal year, and publish in the Federal Register, drug inspection fees, based on the amount provided for in advance in appropriations Acts for such fees as described in subsection (e)(1), considering—

''(i) the requirement described under subparagraph (C);

''(ii) the reductions required under subparagraphs (B) and (D) of subsection (b)(1); and

''(iii) the number of drug establishments subject to such a fee, considering

subparagraphs (C) and (D) of subsection (b)(1).

''(B) FOREIGN DRUG ESTABLISHMENT.—For a foreign drug establishment, the drug inspection fee shall be—

''(i) the applicable drug inspection fee under subparagraph (A), plus

''(ii) the pro rata costs, if any, of—

''(I) travel to and within, and lodging in, the country in which the establishment is located for the individual or individuals who conduct the inspection of the establishment; and

''(II) a translator for the inspection of the establishment.

''(C) PROPORTIONAL FEES.—

''(i) INSPECTIONS MORE FREQUENT THAN EVERY 2 YEARS.—The drug inspection fee for a drug establishment that under the inspection schedule provided for under section 510(h)(4) is to be inspected more frequently than once in every 2-year period shall be more than the drug inspection fee for a drug establishment that under such schedule is to be inspected once

in every 2-year period, in proportion to the factor by which such drug establishment to be is inspected more frequently than once in every 2-year period.

"(ii) INSPECTIONS LESS FREQUENT THAN EVERY 2 YEARS.—The drug inspection fee for a drug establishment that under the inspection schedule provided for under section 510(h)(4) is to be inspected less frequently than once in every 2-year period shall be less than the drug inspection fee for a drug establishment that under such schedule is to be inspected once in every 2-year period, in proportion to the factor by which such establishment is to be inspected less frequently than once in every 2-year period.

"(2) DEVICE INSPECTION FEE AMOUNTS.—

"(A) IN GENERAL.—Beginning with fiscal year 2010, the Secretary shall, not later than 30 days after the amount has been appropriated for a fiscal year in an appropriations Act as described in subsection (e)(2) establish for such fiscal year, and publish in the Federal Register device inspection fees, based on the

amount provided for in advance in appropriations Acts for such fees as described in subsection (e)(2) and considering—

"(i) the requirement described under subparagraph (C);

"(ii) the reduction required under subsection (b)(2)(B); and

"(iii) the number of device establishments subject to such a fee, considering subsection (b)(2)(C).

"(B) FOREIGN DEVICE ESTABLISHMENT.—For a foreign device establishment, the device inspection fee shall be—

"(i) the applicable device inspection fee under subparagraph (A), plus

"(ii) the pro rata costs, if any, of—

"(I) travel to and within, and lodging in, the country in which the establishment is located for the individual or individuals who conduct the inspection of the establishment; and

"(II) a translator for the inspection of the establishment.

"(C) PROPORTIONAL FEES.—

"(i) INSPECTIONS MORE FREQUENT THAN EVERY 2 YEARS.—The device inspection fee for a device establishment that under the inspection schedule provided for under section 510(h)(4) is to be inspected more frequently than once in every 2-year period shall be more than the device inspection fee for a device establishment that under such schedule is to be inspected once in every 2-year period, in proportion to the factor by which such device establishment is to be inspected more frequently than once in every 2-year period.

"(ii) INSPECTIONS LESS FREQUENT THAN EVERY 2 YEARS.—The device inspection fee for a device establishment that under the inspection schedule provided for under section 510(h)(4) is to be inspected less frequently than once in every 2-year period shall be less than the device inspection fee for a device establishment that under such schedule is to be inspected once in every 2-year period, in proportion to the factor by which such establishment is to be

inspected less frequently than once in every 2-year period.

''(d) EFFECT OF FAILURE TO PAY FEES.—

''(1) DRUG INSPECTION FEE.—An establishment subject to a drug inspection fee under subsection (b) shall be considered not to be registered under section 510 until all fees under this section owed by the person required to register such establishment have been paid.

''(2) DEVICE INSPECTION FEE.—An establishment subject to a device inspection fee under subsection (b) shall be considered not to be registered under section 510 until all fees under this section owed by the person required to register such establishment have been paid.

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

''(1) DRUG INSPECTION FEES.—Drug inspection fees authorized under subsection (b) 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. The sums transferred shall be available solely for drug registration and inspection activities.

''(2) DEVICE INSPECTION FEES.—Device inspection fees authorized under subsection (b) 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. The sums transferred shall be available solely for device registration and inspection activities.

''(3) AUTHORIZATION OF APPROPRIATIONS.—

''(A) DRUG INSPECTION FEES.—Beginning in fiscal year 2010, there is authorized to be appropriated for each fiscal year for drug inspection fees under this section such sums as may be necessary to carry out drug inspection activities for such fiscal year, except that such sums may be no greater than the lesser of—

''(i) the amount appropriated (excluding fees) for such activities for such fiscal year; or

''(ii) the difference between the amount necessary to carry out such activities for such fiscal year (as provided in the report required by subsection (h)(2)(A)) and the amount appropriated (excluding fees) for such activities for such fiscal year.

''(B) DEVICE INSPECTION FEES.—Beginning in fiscal year 2010, there is authorized to be appropriated for each fiscal year for device inspection fees under this section such sums as may be necessary to carry out device registration and inspection activities for such fiscal year, except that such sums may be no greater than the lesser of—

''(i) the amount appropriated (excluding fees) for such activities for such fiscal year; or

''(ii) the difference between the amount necessary to carry out such activities for such fiscal year (as provided in the report required by subsection (h)(2)(B))

and the amount appropriated (excluding fees) for such activities for such fiscal year.

''(f) AUTHORITY.—If the Secretary does not assess fees under subsection (b) during any portion of a fiscal year 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, at any time in such fiscal year notwithstanding the provisions of subsections (b) and (c) of section 510 relating to the date fees are to be paid.

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

''(h) REPORTS.—

''(1) PERFORMANCE REPORTS.—Beginning for fiscal year 2010, 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 Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on En-

ergy and Commerce and the Committee on Appropriations of the House of Representatives—

"(A) a report concerning the performance of the Food and Drug Administration with respect to drug registration and inspection activities during such fiscal year; and

"(B) a report concerning the performance of the Food and Drug Administration with respect to device registration and inspection activities during such fiscal year.

"(2) FISCAL REPORT.—Beginning for fiscal year 2010, 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 Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives—

"(A) a report on—

"(i) the implementation of the authority for drug establishment fees during such fiscal year;

''(ii) the use, by the Food and Drug Administration, of such fees collected for such fiscal year; and

''(iii) the amount necessary to carry out drug registration and inspection activities for the subsequent fiscal year (with a detailed explanation of the methodology used to determine such amount); and

''(B) a report on—

''(i) the implementation of the authority for device establishment fees during such fiscal year;

''(ii) the use, by the Food and Drug Administration, of such fees collected for such fiscal year; and

''(iii) the amount necessary to carry out device registration and inspection activities for the subsequent fiscal year (with a detailed explanation of the methodology used to determine such amount).

''(3) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet Web site of the Food and Drug Administration.''.

SEC. 108. ELECTRONIC SUBMISSION AND CERTIFICATION OF REGISTRATIONS AND LISTINGS.

Section 510 (21 U.S.C. 360), as amended by section 106, is further amended by—

(1) inserting after subsection (i) the following:

''(j) ELECTRONIC SUBMISSION AND CERTIFICATION.—Registrations and listings under this section (including the submission of updated information) shall be submitted and certified to the Secretary through the electronic portal described in subsection (i)(5)(A) (or by other electronic means until the Secretary establishes such portal) unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.''; and

(2) striking subsection (p).

SEC. 109. TECHNICAL AND CONFORMING AMENDMENTS.

(a) SECTION 510.—

(1) LISTING NUMBERS.—Section 510(e) (21 U.S.C. 360(e)) is amended—

(A) by striking ''(e) The Secretary'' and all that follows through ''Any number'' and inserting the following:

''(e) LISTING NUMBER.—The Secretary may assign a listing number to each drug or class of drugs listed under subsection (i). Any number''; and

(B) by striking ''subsection (j)'' and inserting ''subsection (i)''.

(2) EXEMPTIONS.—Section 510(g) (21 U.S.C. 360(g)) is amended by striking ''(g) The foregoing'' and inserting the following:

''(g) EXEMPTIONS.—The foregoing''.

(3) DEVICE REPORTS.—Section 510(k) (21 U.S.C. 360(k)) is amended by striking ''(k) Each person'' and inserting the following:

''(k) DEVICE REPORTS.—Each person''.

(4) NO REPORT REQUIRED.—Section 510(l) (21 U.S.C. 360(l)) is amended by striking ''(l) A report'' and inserting the following:

''(l) NO REPORT REQUIRED.—A report''.

(5) EXEMPTIONS FOR CLASS II DEVICES.—Section 510(m) (21 U.S.C. 360(m)) is amended—

(A) by striking ''(m)(1) Not later than'' and inserting the following:

''(m) EXEMPTIONS FOR CLASS II DEVICES.—

''(1) LIST OF EXEMPTED DEVICES.—Not later than''; and

(B) by striking ''(2) Beginning'' and inserting the following:

''(2) OTHER EXEMPTED DEVICES.—Beginning''.

(6) REVIEW OF REPORT.—Section 510(n) (21 U.S.C. 360(n)) is amended by striking ''(n) The Secretary'' and inserting the following:

''(n) REVIEW OF REPORT.—The Secretary''.

(7) REPROCESSED SINGLE-USE DEVICES.—Section 510(o) (21 U.S.C. 360(o)) is amended—

(A) by striking ''(o)(1) With respect to'' and inserting the following:

''(o) REPROCESSED SINGLE-USE DEVICES.—

''(1) REPROCESSED SINGLE-USE DEVICES FOR WHICH REPORTS ARE REQUIRED.—With respect to'';

(B) in paragraph (1), by moving the indentation of subparagraphs (A) through (D) 2 ems to the right;

(C) by striking ''(2) With respect to'' and inserting the following:

''(2) CRITICAL AND SEMICRITICAL REPROCESSED SINGLE-USE DEVICES.—With respect to''; and

(D) in paragraph (2), by moving the indentation of subparagraphs (A) through (E) 2 ems to the right.

(b) OTHER PROVISIONS.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) by striking ''510(i)'' each place it appears and inserting ''510(c)'';

(2) in section 301(p)—

(A) by striking ''510(j)'' and inserting ''510(i)''; and

(B) by striking ''510(j)(2)'' and inserting ''510(i)(2)'';

(3) in section 502(o), by striking ''510(j)'' and inserting ''510(i)''; and

(4) in section 801(a), by striking ''subsection (i) of section 510'' and inserting ''subsection (c) of section 510''.

SEC. 110. EFFECTIVE DATE.

Except as otherwise provided in this subtitle, this subtitle, and the amendments made by this subtitle, shall take effect on October 1, 2009.

Subtitle B—Ensuring Identity and Sourcing of Drug Ingredients

SEC. 111. COMPENDIAL MODERNIZATION.

(a) IN GENERAL.—Section 501(b) (21 U.S.C. 351(b)) is amended by—

(1) inserting ''or of the appropriate body charged with the revision of such compendium'' after ''are, in the judgment of the Secretary'';

(2) inserting ''(1)'' after ''insufficient for the making of such determination,'';

(3) striking ''attention of the appropriate body charged with the revision of such compendium'' and inserting ''attention of such body''; and

(4) inserting '', or (2) such body shall bring such fact to the attention of the Secretary, and the Secretary shall work with such body to develop approaches that will allow such body to establish sufficient standards'' after ''purity shall be made''.

(b) RULEMAKING.—Section 701(e)(1) (21 U.S.C. 371(e)(1)) is amended in the first sentence by deleting ''501(b),''.

(c) ASSESSMENT.—The Secretary of Health and Human Services, in consultation with the United States Pharmacopeia, other drug regulatory agencies, academic experts, and industry, shall periodically assess the tests and methods of assay for drugs found in official compendia to—

(1) identify, considering current scientific methods, which tests and methods of assay are no longer scientifically sound and appropriate and of sufficient analytical precision and specificity for their purpose; and

(2) prioritize which such tests and methods of assay should be revised, considering—

(A) the risks posed by a drug if its strength differs, or its quality or purity falls below, the compendia standards for such drug; and

(B) whether such tests and methods of assay are sufficient to distinguish such drug from contaminants or adulterants reasonably likely to be present in or on such drug.

SEC. 112. TESTING OF DRUG PURITY AND IDENTITY.

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

''(j) If it is a drug and it bears or contains an article, unless the manufacturer of such drug verifies the purity and identity of such article using scientifically sound and appropriate methods of sufficient analytical precision and specificity to detect and quantify the article separate from—

''(1) impurities; and

''(2) contaminants and adulterants reasonably likely to be present in or on such article.''.

SEC. 113. MANUFACTURER RESPONSIBILITY FOR SOURCE AND QUALITY OF DRUG INGREDIENTS.

Section 501 (21 U.S.C. 351), as amended by section 112, is further amended by adding at the end the following:

''(k) If it is a drug and the manufacturer or importer fails to establish and maintain for a period of time determined by the Secretary documentation adequate to—

''(1) identify each establishment that manufactured, processed, packed, or held each article that is a component of the drug or a precursor ingredient of such a component; and

''(2) establish, including through appropriate and periodic audits of the establishments described in paragraph (1), that the drug and each such article is not adulterated under this section or misbranded under section 502.''.

SEC. 114. CURRENT MANUFACTURING SCIENCE.

Section 501(a) (21 U.S.C. 351(a)) is amended by striking ''; or (3)'' and inserting the following: ''or (D) if it is manufactured in a manner that is inconsistent with current manufacturing technologies, including quality risk-management practices, in-process controls, and relation of quality standards to clinical performance of the drug or device, as determined by the Secretary; or (3)''.

SEC. 115. COUNTRY OF ORIGIN LABELING.

Section 502 (21 U.S.C. 352) is amended by inserting after subsection (c) the following:

''(d) If it is a drug in final dosage form or device for use on or by patients unless the Internet Web site of

the manufacturer or distributor of the drug or device (whichever is identified on the label of the drug or device) lists, for each lot of such drug or device, the identity of—

''(1) the country of manufacture of the drug or device; and

''(2) if it is a drug, the country of manufacture of each active ingredient of the drug.''.

SEC. 116. EFFECTIVE DATE; IMPLEMENTATION.

(a) EFFECTIVE DATE.—Sections 112, 113, 114, and 115, and the amendments made by such sections, shall take effect on the date that is 2 years after the date of enactment of this Act.

(b) IMPLEMENTATION.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue a guidance for industry about how a drug may comply with the requirements of subsections (a)(2)(D), (j), and (k) of section 501 of the Federal Food, Drug, and Cosmetic Act (as added by this subtitle) and section 501(a)(2)(B) of such Act (21 U.S.C. 351(a)(2)(B)).

Subtitle C—Ensuring Standards for Imported Drugs

SEC. 121. GOOD DISTRIBUTION AND IMPORT PRACTICES.

(a) GOOD DISTRIBUTION AND IMPORT PRACTICES.—Section 501(a) (21 U.S.C. 351(a)), as amended by section

114, is further amended by striking ''; or (3)'' and inserting ''or (E) if it is a drug and it is not distributed, shipped, warehoused, brokered, imported, or conveyed in conformity with current good distribution and import practices to assure the identity, strength, quality, and purity of the drug; or (3)''.

(b) INSPECTION OF IMPORTERS AND DISTRIBUTORS OF DRUGS.—Section 704 (21 U.S.C. 374) is amended—

(1) in subsection (a)—

(A) in paragraph (1)(A), by inserting ''(and in the case of drugs, distributed, shipped, warehoused, or conveyed),'' after ''or held,''; and

(B) in the third sentence—

(i) by inserting ''(and in the case of drugs, distributed, shipped, warehoused, or conveyed),'' after ''packed, or held,''; and

(ii) by inserting '', (and in the case of drugs, distributed, shipped, warehoused, or conveyed),'' after ''transported, or held''; and

(2) in subsection (e), by striking ''519 or'' and inserting ''502(a)(2)(E), 519, or''.

SEC. 122. STANDARDS FOR ADMISSION OF IMPORTED DRUGS AND DRUG INGREDIENTS.

(a) IN GENERAL.—Section 801 (21 U.S.C. 381) is amended—

(1) in subsection (o), by striking ''drug or''; and

(2) by adding at the end the following:

''(p)(1) Except as provided in paragraph (2), a drug, or an article that appears to be a drug, in finished dosage form, an article that is intended to be a component of a drug, or an article that is intended to be a precursor ingredient of such a component that is being imported or offered for import into the United States shall be refused admission unless the person importing or offering for import such drug or article provides to the Secretary, at the time of being imported or offered for import (and through an electronic portal as provided by the Secretary)—

''(A) all information submitted to U.S. Customs and Border Protection in the entry declaration for such drug or such article;

''(B) for a drug, or an article that appears to be a drug, in finished dosage form—

''(i) the listing number under section 510(e) of such drug;

''(ii) the D-U-N-S number of each establishment in which such drug was manufactured,

prepared, propagated, compounded, or processed;

''(iii) the new drug application number, the biologics license application number, the abbreviated new drug application number, the number of the investigational new drug exemption for the drug, or the drug monograph number, as applicable;

''(iv) the label required by the new drug application, the biologics license application number, abbreviated new drug application, investigational new drug exemption, or drug monograph, as applicable; and

''(v) the record of inspections by the Secretary;

''(C) for an article that is an active ingredient of a drug, or an article that is a precursor ingredient of an active ingredient—

''(i) the listing number under section 510(e) of such article;

''(ii) the D-U-N-S number of each establishment in which such article was manufactured, prepared, propagated, compounded, or processed;

''(iii) the new drug application number, the biologics license application number, the abbreviated new drug application number, the number of the investigational new drug exemption for the drug, or the drug monograph number, as applicable, of the finished dosage form for which such article is intended;

''(iv) the label under a regulatory exemption from section 502(f)(1); and

''(v) the record of inspections by the Secretary or by a governmental authority responsible for drugs deemed adequate by the Secretary; and

''(D) for an article (other than an active ingredient) that is intended to be a component of a drug, or an article that is a precursor ingredient of any such component—

''(i) the listing number under section 510(e) of such article;

''(ii) the D-U-N-S number of each establishment in which such article was manufactured, prepared, propagated, compounded, or processed;

''(iii) the new drug application number, the biologics license application number, the abbre-

viated new drug application number, the number of the investigational new drug exemption for the drug, or the drug monograph number, as applicable, of the finished dosage form for which such article is intended; and

''(iv)(I) the record of inspections by the Secretary or by a governmental authority responsible for drugs deemed adequate by the Secretary;

''(II) a quality certification by a private entity, if the Secretary has agreed to accept such a certification; and

''(III) other evidence of quality that the Secretary has deemed acceptable by regulation.

''(2) Paragraph (1) shall not apply to—

''(A) a drug to which subsection (g) applies; or

''(B) an article that—

''(i) is intended to be subject to further manufacturing for export as a drug, a device, or a component of a drug or a device; and

''(ii) is not deemed to be adulterated or misbranded under subsection (e)(1).''.

(b) IMPLEMENTATION.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall provide for an electronic portal

for submission of the information required to be submitted under section 801(p) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

SEC. 123. PROHIBITION ON USE OF DRUGS AND DRUG INGREDIENTS NOT DECLARED AS DRUGS ON IMPORTATION.

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

''(aa) If it is a drug and it is, bears, or contains an article that, when imported or offered for import into the United States is intended to be a drug or a component of a drug, unless—

''(1) the label of such article, when so imported or offered for import, contains the statement 'for drug use'; and

''(2) the article is declared when so imported or offered for import as 'for drug use'.''.

SEC. 124. DESTRUCTION OF UNSAFE PRODUCTS REFUSED ADMISSION.

Section 801(a) (21 U.S.C. 381(a)) is amended by striking the sixth sentence and inserting the following: ''The Secretary of the Treasury shall cause the destruction of any such article refused admission (1) if the Secretary of Health and Human Services informs the Secretary of the Treasury that such article appears to pose a risk of

injury or death; or (2) if such article is not exported, under regulations prescribed by the Secretary of the Treasury, within 90 days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. The preceding sentence shall not apply to drugs to which subsection (g) applies.''.

SEC. 125. EFFECTIVE DATE.

This subtitle, and the amendments made by this subtitle, shall take effect on the date that is 30 days after the date of enactment of this Act.

Subtitle D—Enhanced Response to Unsafe Drugs

SEC. 131. ADMINISTRATIVE DETENTION OF DRUGS.

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

(1) in paragraph (1)—

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

(B) by inserting '', or, in the case of a drug, which the officer or employee making the inspection has reason to believe is in violation of section 505,'' after ''or misbranded''; and

(2) in paragraph (2), by inserting ''drug or'' before ''device'' each place it appears.

(b) TECHNICAL AMENDMENTS.—Section 304(g)(1) (21 U.S.C. 334(g)(1)), as amended by subsection (a), is further amended by—

(1) striking ''(1) If'' and inserting ''(1)(A) If'';

(2) striking ''thirty days. Regulations'' and inserting the following: ''thirty days.

''(B) Regulations'';

(3) striking ''such order. A detention'' and inserting the following: ''such order.

''(C) A detention''; and

(4) striking ''as detained. Any person'' and inserting the following: ''as detained.

''(D) Any person''.

(c) REGULATIONS.—Until the date that the Secretary of Health and Human Services issues a final regulation to implement the amendments to section 304(g) of the Federal Food, Drug, and Cosmetic Act (as made by subsection (a)), the regulations on administrative detention in section 800.55 of title 21, Code of Federal Regulations, shall apply to any administrative detention of a drug under such section 304(g).

SEC. 132. MANDATORY RECALL AUTHORITY FOR DRUGS.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 506C the following:

"SEC. 507. MANDATORY RECALL AUTHORITY FOR DRUGS.

"(a) ORDER TO CEASE DISTRIBUTION; NOTIFICATION; PROCESS.—

"(1) ORDER TO CEASE DISTRIBUTION; NOTIFICATION.—If the Secretary finds that there is a reasonable probability that a drug intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the drug)—

"(A) to immediately cease distribution of such drug; and

"(B) to immediately notify health professionals and hospitals and other health care facilities of the order and to instruct such professionals and facilities to cease use of such drug.

"(2) PROCESS.—The order under paragraph (1) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on 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.

''(b) ORDER TO RECALL.—

''(1) IN GENERAL.—If, after providing an opportunity for an informal hearing under subsection (a), 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, except as provided in paragraph (2), amend the order to require a recall. The Secretary shall specify a timetable in which the drug recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

''(2) AMENDED ORDER.—An amended order under paragraph (1)—

''(A) shall—

''(i) not include recall of a drug from individuals; and

''(ii) not include recall of a drug from hospitals and other health care facilities if the Secretary determines that the risk of recalling such drug from the facilities presents a greater health risk than the health risk of not recalling the drug from use; and

''(B) shall provide for notice to individuals subject to the risks associated with the use of such drug.

''(3) ASSISTANCE.—In providing the notice required by paragraph (2), the Secretary may use the assistance of health professionals who prescribed or used such a drug for individuals. If a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 705(b).''.

(b) REGULATIONS.—Until the date that the Secretary of Health and Human Services issues a final regulation to implement section 507 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), the regulations on medical device recall authority in part 810 of title 21, Code of Federal Regulations, shall apply to any recall of a drug under such section 507.

SEC. 133. RECORDS AND REPORTS OF DRUG DEFECTS AND DESTRUCTION OF DEFECTIVE DRUGS THAT CANNOT BE RECONDITIONED.

(a) IN GENERAL.—Section 503 (21 U.S.C. 353) is amended by adding at the end the following:

''(h) DRUG DEFECTS.—

''(1) RECORDS.—The manufacturer of a drug shall make and maintain records about any defect of the drug.

''(2) REPORTS.—The manufacturer of a drug shall submit reports to the Secretary about any defect of the drug that the Secretary specifies in guidance in accordance with a schedule specified by the Secretary in such guidance.

''(3) INVESTIGATION AND CORRECTIVE ACTION.—The manufacturer of a drug shall—

''(A) investigate the cause of any defect of the drug; and

''(B) take appropriate corrective action.

''(4) DESTRUCTION.—If a drug may cause injury or death because of a defect, the manufacturer shall, after the investigation of the defect required under paragraph (3), destroy the drug and shall not recondition the drug.

''(5) DEFECT.—For purposes of this subsection, a defect of a drug shall include—

''(A) microbiological or other contamination;

''(B) significant chemical, physical, or other change or deterioration;

"(C) any deviation from purity or identity identified under section 501(j); and

"(D) any failure of 1 or more batches of the drug to meet a specification established for it.".

(b) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331) is amended—

(1) in subsection (d), by striking "505" and inserting "503(h), 505"; and

(2) in subsection (e), by striking "504" and inserting "503(h), 504".

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

SEC. 134. CIVIL MONEY PENALTIES.

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

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

(2) in paragraph (4), by striking "or 505–1" each place it appears and inserting "505–1, 505A, or 523A";

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

''(5)(A)(i) Any manufacturer, distributor, importer, broker, or filer that violates a requirement of this Act that relates to drugs for human use (except a requirement referred to in paragraph (4) or subsection (g)) shall be liable to the United States for a civil penalty not to exceed $100,000 per violation.

''(ii) Each day during which a violation continues shall be considered a separate violation under clause (i).

''(B)(i) Any manufacturer, distributor, importer, broker, or filer that knowingly reports or enters false or misleading data on documents related to the importation of a drug shall be liable to the United States for a civil penalty not to exceed $150,000.

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

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

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

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

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

Subtitle E—Additional Provisions Related to Medical Products

SEC. 141. CERTIFICATION OF INFORMATION.

(a) DRUGS.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 505D the following:

''SEC. 505E. CERTIFICATION OF DRUG INFORMATION.

''(a) CERTIFICATION.—

''(1) IN GENERAL.—A submission, when submitted to the Secretary, shall include a certification, in writing (which may be in electronic form) and under penalty of perjury, by the responsible person that—

''(A) such person has actual knowledge of the requirements under this Act and, if applicable, such section 351, with respect to the drug that is the subject of such submission;

''(B) such person has actual knowledge of the information related to such drug;

''(C) such person has actual knowledge of the information in such submission (and, if such submission is an annual report, in any submission of any other information with respect to such application or report for which a certification under this paragraph is not otherwise required);

''(D) the information in such submission (and, if such submission is an annual report, in any submission of any other information with respect to such application or report for which a certification under this paragraph is not otherwise required) complies with such requirements;

''(E) the information in such submission (and, if such submission is an annual report, in any submission of any other information with respect to such application or report for which a certification under this paragraph is not otherwise required) is not false or misleading; and

''(F) full reports of all clinical trials and postmarket studies (whether conducted within or outside the United States) related to the safety or effectiveness of the drug under review that were funded by the sponsor of such sub-

mission, or the full reports of which the sponsor of such submission had access, have been submitted to the Food and Drug Administration.

''(2) DEFINITIONS.—In this section:

''(A) RESPONSIBLE PERSON.—The term 'responsible person' means, with respect to a submission, a senior officer or director of the sponsor of such submission with knowledge of, and management responsibility for, such submission.

''(B) SUBMISSION.—The term 'submission' means—

''(i) new drug application under section 505(b);

''(ii) an abbreviated new drug application under section 505(j);

''(iii) a biologics license application under section 351 of the Public Health Service Act;

''(iv) an application for an investigational new drug exemption under section 505(i);

''(v) a new animal drug application under section 512(b);

"(vi) an abbreviated new animal drug application under section 512(b);

"(vii) an application under section 571;

"(viii) a request under section 572;

"(ix) or a major amendment, supplement, or an annual report submitted to the Secretary with respect to any application or request described in clauses (i) through (viii);

"(x) a record or report related to the safety or effectiveness of a drug subject to section 505 or such section 351, to an adverse event under section 505(k) or 760, or to a postapproval study or postapproval clinical trial under section 505(o); or

"(xi) a list under section 510(i) including a drug.

"(b) INSPECTIONS.—

"(1) IN GENERAL.—If the Secretary determines, after notice and opportunity for an informal hearing, that a sponsor described in subsection (a)(2) knew or should have known that the information in a submission described in subsection (a)(1) did not comply with the requirements of this Act or

was false or misleading, the Secretary may provide that any factory, warehouse, establishment, or consulting laboratory related to such noncompliance or such false or misleading information shall be inspected periodically by officers or employees duly designated by the Secretary for a period of time determined by the Secretary, not to exceed 5 years.

''(2) COSTS.—The Secretary shall assess the costs of such inspections to such sponsor.''.

(b) DEVICES.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 523 the following:

''SEC. 523A. CERTIFICATION OF DEVICE INFORMATION.

''(a) CERTIFICATION.—

''(1) CERTIFICATION BY SPONSOR.—A submission, when submitted to the Secretary, shall include a certification, in writing and under penalty of perjury, by the responsible person that—

''(A) such person has actual knowledge of the requirements under this Act with respect to the device that is the subject of such submission;

''(B) such person has actual knowledge of the information related to such device;

''(C) such person has actual knowledge of the information in such submission (and, if

such submission is an annual report, in any submission of any other information with respect to such application or report for which a certification under this paragraph is not otherwise required);

''(D) the information in such submission (and, if such submission is an annual report, in any submission of any other information with respect to such application or report for which a certification under this paragraph is not otherwise required) complies with such requirements;

''(E) the information in such submission (and, if such submission is an annual report, in any submission of any other information with respect to such application or report for which a certification under this paragraph is not otherwise required) is not false or misleading; and

''(F) full reports of all clinical trials and postmarket studies (whether conducted within or outside the United States) related to the safety or effectiveness of the device under review that were funded by the sponsor of such submission, or the full reports of which the sponsor of such submission had access, have

been submitted to the Food and Drug Administration.

''(2) DEFINITIONS.—In this section:

''(A) RESPONSIBLE PERSON.—The term 'responsible person' means, with respect to a submission, a senior officer or director of the sponsor of such submission with knowledge of, and management responsibility for, such submission.

''(B) SUBMISSION.—The term 'submission' means—

''(i) an application or report for premarket approval under section 515;

''(ii) an application for an investigational device exemption under section 520(g);

''(iii) a report under section 510(k);

''(iv) an application for a humanitarian device exemption under section 520(m);

''(v) a major amendment, supplement, or an annual report submitted to the Secretary with respect to any application or report described in clauses (i) through (iv);

"(vi) a record or report related to an adverse event, a report, or postmarket surveillance under section 519 or 522; or

"(vii) a list under section 510(i) including a device,

"(b) INSPECTIONS.—

"(1) IN GENERAL.—If the Secretary determines, after notice and opportunity for an informal hearing, that a sponsor described in subsection (a)(2) knew or should have known that the information in a submission described in subsection (a)(1) did not comply with the requirements of this Act or was false or misleading, the Secretary may provide that any factory, warehouse, establishment, or consulting laboratory related to such noncompliance or such false or misleading information shall be inspected periodically by officers or employees duly designated by the Secretary for a period of time determined by the Secretary, not to exceed 5 years.

"(2) COSTS.—The Secretary shall assess the costs of such inspections to such sponsor.".

(c) CRIMINAL PENALTIES.—Chapter 47 of title 18, United States Code, is amended by adding at the end the following:

"§ 1041. Certifications related to drug and device information

''(a) If a responsible person—

''(1) certifies any submission as set forth in section 505E or 523A of the Federal Food, Drug, and Cosmetic Act knowing that a component of such certification is false or misleading, then—

''(A) the sponsor of such submission shall be fined not more than $1,000,000; and

''(B) such responsible person shall be fined not more than $1,000,000, imprisoned for not more than 10 years, or both; or

''(2) willfully certifies any submission as set forth in section 505E or 523A of the Federal Food, Drug, and Cosmetic Act knowing that a component of such certification is false or misleading, then—

''(A) the sponsor of such submission shall be fined not more than $5,000,000; and

''(B) such responsible person shall be fined not more than $5,000,000, imprisoned not more than 20 years, or both.

''(b) In this section:

''(1) The term 'responsible person'—

''(A) with respect to a submission related to a drug, has the meaning given that term in

section 505E(a)(2) of the Federal Food, Drug, and Cosmetic Act; and

''(B) with respect to a submission related to device, has the meaning given that term in section 523A(a)(2) of such Act.

''(2) The term 'submission' means—

''(A) with respect to a drug—

''(i) a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act;

''(ii) an abbreviated new drug application under section 505(j) of such Act;

''(iii) a biologics license application under section 351 of the Public Health Service Act;

''(iv) an application for an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act;

''(v) a new animal drug application under section 512(b) of the Federal Food, Drug, and Cosmetic Act;

''(vi) an abbreviated new animal drug application under section 512(b) of such Act;

"(vii) an application under section 571 of such Act;

"(viii) a request under section 572 of such Act;

"(ix) a major amendment, supplement, or other information submitted to the Secretary with respect to any application or request described in clauses (i) through (viii);

"(x) a record or report related to the safety or effectiveness of a drug subject to section 505 of such Act or section 351 of the Public Health Service Act, to an adverse event under section 505(k) or 760 of the Federal Food, Drug, and Cosmetic Act, or to a postapproval study or postapproval clinical trial under section 505(o) of such Act; or

"(xi) a list under section 510(i) including the drug; and

"(B) with respect to a device—

"(i) an application or report for premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act;

''(ii) an application for an investigational device exemption under section 520(g) of such Act;

''(iii) a report under section 510(k) of such Act;

''(iv) an application for a humanitarian device exemption under section 520(m) of such Act;

''(v) a major amendment, supplement, or other information submitted to the Secretary with respect to any application or report described in clauses (i) through (iv); or

''(vi) a record or report related to an adverse event, a report, or postmarket surveillance under section 519 or 522 of such Act; or

''(vii) a list under section 510(i) including the device.''.

(d) CONFORMING AMENDMENT.—The table of sections for chapter 47 of title 18, United States Code, is amended by inserting after the item relating to section 1040 the following:

''1041. Certification of drug and device information.''.

SEC. 142. WHISTLEBLOWER PROTECTIONS.

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

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

''(a) IN GENERAL.—

''(1) PROTECTIONS FOR EMPLOYEES.—No person that submits, or is required to submit to the Secretary a submission described in paragraph (2), or any officer, employee, contractor, subcontractor, or agent of such a person, may discharge, demote, suspend, threaten, harass, or in any other manner discriminate against an employee in the terms and conditions of employment because of any lawful act done by the employee, including within the ordinary course of the job duties of such employee—

''(A) 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 any section of this Act or the Public Health Service Act described under paragraph (2), any other provision of Federal law relating to the safety or effectiveness of a drug, biologi-

cal product, or device, or any provision of Federal law prohibiting fraud against the Food and Drug Administration, if the information or assistance is provided to, or an investigation stemming from the provided information is conducted by—

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

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

''(iii) 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);

''(B) to file, cause to be filed, testify, participate in, or otherwise assist in a proceeding filed or about to be filed (with any knowledge of the employer) relating to an alleged violation of any section of this Act or the Public Health Service Act described under paragraph (2), any other provision of Federal law relating to the safety or effectiveness of a drug, biological product, or device, or any provision of Federal

law prohibiting fraud against the Food and Drug Administration; or

''(C) to refuse to violate or assist in the violation of any section of this Act or the Public Health Service Act listed described paragraph (2), any other provision of Federal law relating to the safety or effectiveness of a drug, biological product, or device, or any provision of Federal law prohibiting fraud against the Food and Drug Administration.

''(2) SUBMISSION.—A submission described in this paragraph is—

''(A) a new drug application under section 505(b);

''(B) an abbreviated new drug application under section 505(j);

''(C) a biologics license application under section 351 of the Public Health Service Act;

''(D) an application for an investigational new drug exemption under section 505(i);

''(E) a new animal drug application under section 512(b);

''(F) an abbreviated new animal drug application under section 512(b);

''(G) an application under section 571;

"(H) a request under section 572;

"(I) an application or report for premarket approval under section 515;

"(J) an application for an investigational device exemption under section 520(g);

"(K) a report under section 510(k);

"(L) an application for a humanitarian device exemption under section 520(m);

"(M) an amendment, supplement, or other submission with respect to any such application or report described in subparagraphs (A) through (L);

"(N) or a record or report related to an adverse event, a postapproval study, a postapproval clinical trial, a report, or postmarket surveillance under section 505(k), 505(o), 519, 522, or 760.

"(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, bringing an action at law or equity for de novo review in the appropriate district court of the United States, which shall have jurisdiction over such an action without regard to the amount in controversy.

"(2) PROCEDURE.—

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

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

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

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

"(c) REMEDIES.—

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

"(2) COMPENSATORY DAMAGES.—Relief in an action under subsection (b) shall include—

"(A) reinstatement with the same seniority status that the employee would have had, but for the discrimination;

"(B) the amount of backpay owed to the employee, with interest; and

"(C) compensation for any special damages sustained as a result of the discrimination, including litigation costs, expert witness fees, and reasonable attorney fees.

"(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. 143. STUDY BY THE INSTITUTE OF MEDICINE REGARDING THE REVIEW OF MEDICAL DEVICES.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine to conduct a study to—

(1) evaluate the organizational structure and operations of the Food and Drug Administration with respect to the review of medical devices for clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) and for premarket approval under section 515 of such Act (21 U.S.C. 360e);

(2) evaluate the analytical and methodological tools used by such Administration to conduct such reviews; and

(3) identify strengths, weaknesses, and limitations of the system used by such Administration to conduct such reviews.

(b) REPORT.—Not later than September 31, 2010, the Institute of Medicine shall complete the study described under subsection (a) and submit to the Secretary of Health and Human Services, the Committee on Health, Education, Labor, and Pensions and the Committee on Fi-

nance of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that—

(1) describes the findings of such study; and

(2) makes recommendations regarding the organization structure and operations of the Food and Drug Administration, legislation, and regulation to improve or enhance the review of medical devices by such Administration.

TITLE II—GENERAL AUTHORITIES TO ENHANCE FOOD AND DRUG ADMINISTRATION OVERSIGHT OF PRODUCTS FROM A GLOBAL MARKET

SEC. 201. DEDICATED FOREIGN INSPECTORATE.

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

''(h) FOREIGN INSPECTORATE.—

''(1) IN GENERAL.—The Secretary shall establish and maintain a corps of inspectors dedicated to inspections of foreign establishments registered under section 510 and foreign facilities registered under section 415. Such corps shall include personnel, in numbers sufficient to act as inspectors or translators for inspectors on each inspection by such

corps, who are able to understand and speak the language used in the establishment or facility under inspection.

''(2) ORGANIZATION.—The corps established under paragraph (1) shall be organized into the following 4 units:

''(A) A unit with expertise in inspections of food facilities.

''(B) A unit with expertise in inspections of human drug establishments.

''(C) A unit with expertise in inspections of animal drug establishments.

''(D) A unit with expertise in inspections of medical device establishments.

''(3) STAFFING AND FUNDING.—Each unit shall be staffed and funded by the Secretary at a level sufficient to allow the unit to conduct inspections, as applicable—

''(A) of foreign establishments registered under section 510 at a frequency, considering risk, that is comparable to the inspection rate of domestic establishments registered under section 510; or

''(B) of foreign facilities registered under section 415 at a frequency, considering risk,

that is comparable to the inspection rate of domestic facilities registered under section 415.

''(4) DISTRIBUTION.—The Secretary shall distribute the staff of each unit described in paragraph (2) in countries, and may modify such distribution over time, considering—

''(A) the volume of product exported from such country to the United States;

''(B) an assessment of the effectiveness of the regulatory oversight provided by such country for such products;

''(C) an assessment of the risk posed by such products; and

''(D) such other factors as the Secretary determines are relevant to such distribution.''.

SEC. 202. AUTHORITY TO EXCHANGE CONFIDENTIAL INFORMATION WITH FOREIGN GOVERNMENT OFFICIALS.

(a) AUTHORITY TO EXCHANGE CONFIDENTIAL INFORMATION WITH FOREIGN GOVERNMENT OFFICIALS.—Section 803 (21 U.S.C. 383) is amended by adding the following:

''(d) EXCHANGE OF CONFIDENTIAL INFORMATION.—

''(1) DISCLOSURE BY SECRETARY.—The Secretary may disclose information about food, drugs,

devices, and cosmetics to officials of a foreign government if—

''(A) such government is able, and agrees, to guard the confidentiality and guarantee nondisclosure of such information; and

''(B) the Secretary determines that such disclosure is necessary to promote a regulatory, enforcement, or other public health function.

''(2) DISCLOSURE TO SECRETARY.—The Secretary may receive information from officials of foreign governments under conditions of confidentiality. Such information shall be exempt from disclosure under section 552 of title 5, United States Code.''.

(b) CONFORMING AMENDMENT.—Section 301(j) (21 U.S.C. 331(j)) is amended by inserting ''or pursuant to section 803(d),'' after ''judicial proceeding under this Act,''.

SEC. 203. SUBPOENA AUTHORITY.

Section 702 (21 U.S.C. 372) is amended by adding at the end the following:

''(f)(1) The Secretary may conduct investigations as the Secretary deems necessary—

''(A) to carry out the authority of the Secretary under this Act or section 351 of the Public Health Service Act; or

"(B) to determine whether any person has engaged or is about to engage in any act that constitutes or will constitute a violation of this Act or such section 351.

"(2) For the purpose of any investigation conducted under paragraph (1), the Secretary may administer oaths and affirmations, subpoena witnesses, compel the attendance of such witnesses, take evidence, and require the production of any books, papers, documents, or other materials that are relevant to the investigation.

"(3)(A) In case of contumacy or refusal to obey a subpoena issued under paragraph (2), the district court of the United States for the judicial district in which such investigation or proceeding is conducted, or in which the subpoenaed person resides or conducts business, may issue an order requiring such person to appear before the Secretary, testify, or produce books, papers, documents, or other materials that are relevant to the investigation. All process in any such case may be served in the judicial district in which such person resides or may be found.

"(B) Any failure to obey an order issued under subparagraph (A) may be punished by the court as contempt of court.".

SEC. 204. INFORMATION REPORTING.

Subchapter G of chapter VII (21 U.S.C. 379v et seq.) is amended by adding at the end the following:

"SEC. 757. INFORMATION REPORTING.

"(a) NOTIFICATION OF SETTLEMENTS OR JUDGMENTS.—If a particular product regulated by the Secretary under this Act or section 351 of the Public Health Service Act is the subject of at least 3 civil actions that have been filed in Federal or State court alleging death, serious injury, or serious illness caused in whole or in part by such product which, in any 24-month period, result in either a final settlement involving the manufacturer or a court judgment in favor of the plaintiff, the manufacturer of such product shall, in accordance with subsection (b), report to the Secretary each such civil action not later than 30 days after the final settlement or court judgment in the third of such civil actions, and report to the Secretary any other such action not later than 30 days after any subsequent such settlement or judgment that—

"(1) occurs within 24 months of any other 2 such settlements or judgments; and

"(2) has not been previously reported to the Secretary under this section.

"(b) INFORMATION TO BE REPORTED.—

"(1) REQUIRED INFORMATION.—The information required by subsection (a) to be reported to the

Secretary, with respect to each civil action described in such subsection, shall include and, in addition to any voluntary information provided under paragraph (2), shall be limited to the following:

''(A) The name and address of the manufacturer.

''(B) The name or model of the product subject to the civil action.

''(C) A statement as to whether the civil action alleged death, injury, or illness and in the case of an allegation of injury, a statement of the category of such injury.

''(D) A statement as to whether the civil action resulted in a final settlement or a judgment in favor of the plaintiff.

''(E) In the case of a judgment in favor of the plaintiff, the name of the civil action, the number assigned the civil action, and the court in which the civil action was filed.

''(2) VOLUNTARY INFORMATION.—A manufacturer furnishing the report required by paragraph (1) may include—

''(A) a statement as to whether any judgment in favor of the plaintiff is under appeal or is expected to be appealed; or

''(B) any other information which the manufacturer chooses to provide.

''(c) SAFETY REPORT.—A report of a civil action described in subsection (a) shall be considered a safety report under section 756 and may be accompanied by a statement, which shall be part of any report released for public disclosure, that denies that the report constitutes an admission that the product involved caused or contributed to a death, serious injury, or serious illness.

''(d) ADMISSION.—A report of a civil action described in subsection (a) shall not be considered an admission that the product involved is adulterated or caused or contributed to a death, serious injury, or serious illness.

''(e) DEFINITIONS.—The terms 'serious illness' and 'serious injury' mean illness or injury, respectively, that—

''(1) is life threatening,

''(2) results in permanent impairment of a body function or permanent damage to a body structure, or

''(3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.''.