

110TH CONGRESS
2^D SESSION

S. 3409

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

JULY 31, 2008

Mr. REID (for Mr. KENNEDY (for himself and Mr. GRASSLEY)) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Drug and Device Ac-
5 countability Act of 2008”.

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

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

- Sec. 1. Short title.
 Sec. 2. Table of contents; references in Act.

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.
 Sec. 102. Registration and licensing of drug importers.
 Sec. 103. Inspection of drug and device establishments.
 Sec. 104. Listing of drugs and devices; enhanced information technology system
 for registration and listing.
 Sec. 105. Registration and inspection fees for drug and device establishments.
 Sec. 106. Technical and conforming amendments.
 Sec. 107. Effective date.

Subtitle B—Ensuring Identity and Sourcing of Drug Ingredients

- Sec. 111. Testing of drug purity and identity.
 Sec. 112. Manufacturer responsibility for source and quality of drug ingredi-
 ents.
 Sec. 113. Current manufacturing science.
 Sec. 114. Electronic pedigree for drug ingredients.
 Sec. 115. Country of origin labeling.
 Sec. 116. Effective date.

Subtitle C—Ensuring Standards for Imported Drugs

- Sec. 121. Good distribution and import practices.
 Sec. 122. Standards for admission of imported drugs and drug ingredients.
 Sec. 123. Prohibition on use of drugs and drug ingredients not declared as
 drugs on importation.
 Sec. 124. Destruction of unsafe products refused admission.
 Sec. 125. Effective date.

Subtitle D—Enhanced Response to Unsafe Drugs

- Sec. 131. Administrative detention of drugs.
 Sec. 132. Mandatory recall authority for drugs.
 Sec. 133. Records and reports of drug defects and destruction of defective
 drugs that cannot be reconditioned.
 Sec. 134. Civil money penalties.

Subtitle E—Additional Provisions Related to Medical Products

- Sec. 141. Certification of information.
 Sec. 142. Whistleblower protections.

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

- Sec. 201. Dedicated foreign inspectorate.
 Sec. 202. Authority to exchange confidential information with foreign govern-
 ment officials.

Sec. 203. Subpoena authority.
Sec. 204. Information reporting.

1 (b) REFERENCES IN ACT.—Except as otherwise spec-
2 ified, amendments made by this Act to a section or other
3 provision of law are amendments to such section or other
4 provision of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 301 et seq.).

6 **TITLE I—ENSURING THE SAFETY**
7 **AND QUALITY OF MEDICAL**
8 **PRODUCTS AND THEIR COM-**
9 **PONENTS**

10 **Subtitle A—Enhanced Registration**
11 **and Inspection of Drug and De-**
12 **vice Establishments**

13 **SEC. 101. REGISTRATION OF DRUG AND DEVICE ESTAB-**
14 **LISHMENTS.**

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

18 (b) REGISTRATION OF ESTABLISHMENTS FOR DRUG
19 PRECURSOR AND INACTIVE INGREDIENTS.—

20 (1) REGISTRATION.—Section 510(a) (21 U.S.C.
21 360(a)) is amended—

22 (A) in the matter preceding paragraph (1),
23 by striking “As used” and inserting “DEFINI-
24 TIONS.—As used”;

1 (B) by redesignating paragraphs (1) and
2 (2) as paragraphs (2) and (3), respectively; and
3 (C) by inserting after “this section—” the
4 following:

5 “(1) DRUG.—The term ‘drug’ includes a pre-
6 cursor ingredient.”.

7 (2) PRECURSOR INGREDIENT.—Section 201 (21
8 U.S.C. 321) is amended by adding at the end the
9 following:

10 “(rr) The term ‘precursor ingredient’, with respect to
11 a component of a drug, means an article that is a mate-
12 rial—

13 “(1) of animal origin from which such compo-
14 nent is derived; or

15 “(2) used in the final stage of synthesis or puri-
16 fication of such component.”.

17 (3) TERMINATION OF EFFECT OF REGULA-
18 TION.—On the date that is 180 days after the date
19 of enactment of this Act, the exemption from reg-
20 istration in subsection (e) of section 207.10 of title
21 21, Code of Federal Regulations, shall cease to have
22 force or effect.

23 (e) REGISTRATION OF DOMESTIC ESTABLISH-
24 MENTS.—Section 510 (21 U.S.C. 360) is amended—

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

3 “(b) REGISTRATION OF DOMESTIC ESTABLISH-
4 MENTS.—Any person who owns or operates any establish-
5 ment in any State engaged in the manufacture, prepara-
6 tion, propagation, compounding, or processing of a drug
7 or device shall—

8 “(1) upon first engaging in any such activity,
9 immediately submit a registration to the Secretary
10 that includes the name of such person, places of
11 business of such person, all such establishments, the
12 D-U-N-S number of each such establishment, an e-
13 mail address for use in an emergency, and payment
14 of any registration and inspection fee for each such
15 establishment required under section 741;

16 “(2) thereafter immediately submit a registra-
17 tion that includes the information and fee described
18 in paragraph (1) for any additional establishment
19 owned or operated by such person in any State in
20 which such person begins the manufacture, prepara-
21 tion, propagation, compounding, or processing of a
22 drug or device; and

23 “(3) thereafter—

24 “(A) with respect to such drugs, submit a
25 registration described in paragraph (1) to the

1 Secretary on or before December 31 of each
2 year; and

3 “(B) with respect to such devices, submit
4 a registration described in paragraph (1) to the
5 Secretary during the period beginning on Octo-
6 ber 1 and ending on December 31 of each
7 year.”; and

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

9 (d) REGISTRATION OF FOREIGN ESTABLISH-
10 MENTS.—Section 510 (U.S.C. 360) is amended—

11 (1) by transferring subsection (i) so as to ap-
12 pear after subsection (b) (as amended by subsection
13 (c)); and

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

15 (A) by striking “(i) (1)” and all that fol-
16 lows through “of each year.” and inserting the
17 following:

18 “(c) REGISTRATION OF FOREIGN ESTABLISH-
19 MENTS.—

20 “(1) IN GENERAL.—Any person who owns or
21 operates any establishment within any foreign coun-
22 try engaged in the manufacture, preparation, propa-
23 gation, compounding, or processing of a drug or de-
24 vice that is imported or offered for import into the
25 United States shall—

1 “(A) upon first engaging in any such activ-
2 ity, immediately submit a registration to the
3 Secretary that includes the name and place of
4 business of such person, all such establish-
5 ments, the D-U-N-S number of each such es-
6 tablishment, an e-mail address for use in an
7 emergency, payment of any registration and in-
8 spection fee for each such establishment re-
9 quired under section 741, the name of the
10 United States agent of each such establishment,
11 the name of each importer of such drug or de-
12 vice in the United States that is known to each
13 such establishment, and the name of each per-
14 son who imports or offers for import such drug
15 or device to the United States for purposes of
16 importation;

17 “(B) thereafter immediately submit a reg-
18 istration that includes the information and fee
19 described in paragraph (1) for any additional
20 establishment owned or operated by such per-
21 son within any foreign country in which such
22 person begins the manufacture, preparation,
23 propagation, compounding, or processing of
24 such a drug or device; and

25 “(C) thereafter—

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

5 “(ii) with respect to devices, submit a
6 registration described in subparagraph (A)
7 to the Secretary during the period begin-
8 ning on October 1 and ending on Decem-
9 ber 31 of each year.”;

10 (B) by striking paragraph (2);

11 (C) in paragraph (3), by striking “(3)
12 The” and inserting “(2) COOPERATIVE AR-
13 RANGEMENTS.—”; and

14 (D) by moving the indentation of para-
15 graph (2), as amended, 2 ems to the right.

16 **SEC. 102. REGISTRATION AND LICENSING OF DRUG IM-**
17 **PORTERS.**

18 Section 510 (21 U.S.C. 360), as amended by section
19 101, is further amended by inserting after subsection (c)
20 the following:

21 “(d) REGISTRATION AND LICENSING OF DRUG IM-
22 PORTERS.—

23 “(1) IN GENERAL.—Any person who owns or
24 operates any establishment engaged in the importa-

1 tion, filing for importation, or brokering for importa-
2 tion of drugs into the United States shall—

3 “(A) upon first engaging in any such activ-
4 ity, immediately submit a registration to the
5 Secretary that includes the name of such per-
6 son, places of business of such person, all such
7 establishments, the D-U-N-S number of each
8 such establishment, and an e-mail address for
9 use in an emergency;

10 “(B) thereafter immediately submit a reg-
11 istration that includes the information described
12 in subparagraph (A) for any additional estab-
13 lishment owned or operated by such person in
14 which such person begins any such activity; and

15 “(C) thereafter submit a registration de-
16 scribed in subparagraph (A) to the Secretary
17 during the period beginning on October 1 and
18 ending on December 31 of each year.

19 “(2) LICENSING.—

20 “(A) IN GENERAL.—The Secretary may re-
21 quire any person engaged in the importation,
22 filing for importation, or brokering for importa-
23 tion of a drug into the United States, before en-
24 gaging in those activities, to obtain a license to
25 be issued by the Secretary.

1 “(B) BOND.—The Secretary may require
2 as a condition of a license for a person under
3 subparagraph (A) that the person post a bond
4 subject to forfeiture if the person has, in con-
5 nection with the importation, filing for importa-
6 tion, or brokering for importation of a drug into
7 the United States—

8 “(i) violated, or caused the violation,
9 of this Act; or

10 “(ii) made, or caused to be made, a
11 false or misleading statement.

12 “(C) AMOUNT OF BOND.—The Secretary
13 shall ensure that the amount of any bond re-
14 quired under subparagraph (B) for a person is
15 sufficient to deter such person from, in connec-
16 tion with the importation, filing for importa-
17 tion, or brokering for importation of a drug into
18 the United States—

19 “(i) violating, or causing the violation
20 of, this Act; or

21 “(ii) making, or causing to be made,
22 a false or misleading statement.

23 “(D) REVOCATION.—The Secretary may
24 revoke the license for a person under subpara-
25 graph (A) if the Secretary finds that, in connec-

1 tion with the importation, filing for importa-
 2 tion, or brokering for importation of a drug into
 3 the United States, such person has—

4 “(i) violated, or caused the violation
 5 of, this Act; or

6 “(ii) made, or caused to be made, a
 7 false or misleading statement.”.

8 **SEC. 103. INSPECTION OF DRUG AND DEVICE ESTABLISH-**
 9 **MENTS.**

10 (a) REQUIRING EQUAL TREATMENT OF DOMESTIC
 11 AND FOREIGN ESTABLISHMENTS.—Section 510(h) (21
 12 U.S.C. 360(h)) is amended by—

13 (1) striking “Every” and inserting: “INSPEC-
 14 TIONS.—

15 “(1) IN GENERAL.—Every”;

16 (2) striking “in any State”;

17 (3) striking “section shall” and inserting: “sec-
 18 tion—

19 “(A) shall”;

20 (4) striking “704 and every such” and inserting
 21 “704;

22 “(B) except as provided in paragraph (2),
 23 and for establishments that manufacture, pre-
 24 pare, propagate, compound, or process only in-
 25 active ingredients, every”; and

1 (5) striking “thereafter.” and inserting “there-
2 after; and

3 “(C) shall not be considered duly reg-
4 istered under this section if an inspection of
5 such establishment by the Secretary is refused,
6 delayed, or limited by—

7 “(i) the person who owns or operates
8 such establishment, or any agent or em-
9 ployee of such person; or

10 “(ii) any agent of a governmental au-
11 thority in the foreign country within which
12 such establishment is located.”.

13 (b) PROVIDING FOR RISK-BASED INSPECTIONS OF
14 ESTABLISHMENTS.—Section 510(h) (21 U.S.C. 360(h)),
15 as amended by subsection (a), is further amended by add-
16 ing at the end the following:

17 “(2) RISK-BASED INSPECTION SCHEDULE.—

18 “(A) IN GENERAL.—The Secretary may by
19 regulation provide for an inspection schedule
20 for establishments described in paragraph (1)
21 (including those establishments that manufac-
22 ture, prepare, propagate, compound, or process
23 only inactive ingredients) different from that re-
24 quired by such paragraph.

1 “(B) INSPECTION FREQUENCY AND RISK-
2 BASED FACTORS.—In providing for an inspec-
3 tion schedule under subparagraph (A), the Sec-
4 retary—

5 “(i) may require inspections of an es-
6 tablishment more frequently than once in
7 every successive 2-year period;

8 “(ii) shall require inspections of an es-
9 tablishment at least once in every succes-
10 sive 5-year period; and

11 “(iii) shall consider—

12 “(I) the risks of the drug or
13 drugs, or the device or devices, manu-
14 factured, prepared, propagated, com-
15 pounded, or processed by an establish-
16 ment (including whether the drug is a
17 finished dosage form, an active ingre-
18 dient, a precursor ingredient, or an
19 inactive ingredient; the route of ad-
20 ministration of the drug; whether the
21 device is intended to be implanted,
22 permanently implantable, life sus-
23 taining, or life supporting; and the
24 use or uses for which the drug or de-
25 vice is approved or cleared under this

1 Act or licensed under section 351 of
2 the Public Health Service Act);

3 “(II) whether or not an establish-
4 ment is within a foreign country with
5 a governmental authority responsible
6 for drugs or devices, as applicable,
7 deemed adequate by the Secretary;

8 “(III) whether or not, and the
9 frequency with which, an establish-
10 ment is subject to inspection by a gov-
11 ernmental authority responsible for
12 drugs or devices, as applicable,
13 deemed adequate by the Secretary;
14 and

15 “(IV) such other factors as the
16 Secretary determines are relevant to
17 determining an inspection schedule for
18 establishments.

19 “(C) RISK-BASED FACTORS FOR MODI-
20 FYING FREQUENCY OF INSPECTIONS OF AN ES-
21 TABLISHMENT.—The Secretary may inspect an
22 establishment at a frequency different than that
23 required by the inspection schedule under sub-
24 paragraph (A) by considering—

1 “(i) the history of any safety problems
2 with drugs or devices manufactured, pre-
3 pared, propagated, compounded, or proc-
4 essed by the establishment;

5 “(ii) the record of inspections by the
6 Secretary of the establishment;

7 “(iii) with respect to a drug that is
8 not a finished dosage form, the record of
9 inspections by a governmental authority re-
10 sponsible for drugs deemed adequate by
11 the Secretary;

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

16 “(v) such other factors as the Sec-
17 retary determines are relevant to assessing
18 the risk presented by the establishment.”.

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

23 “(3) ANNUAL REPORT ON INSPECTIONS OF ES-
24 TABLISHMENTS.—Not later than February 1 of each

1 year, the Secretary shall submit a report to the Con-
2 gress about—

3 “(A) the appropriations used to inspect es-
4 tablishments registered pursuant to this section
5 in the previous fiscal year;

6 “(B)(i) the number and identities of do-
7 mestic and foreign establishments registered
8 pursuant to this section that the Secretary in-
9 spected in the previous fiscal year; and

10 “(ii) if the Secretary has provided for a
11 schedule under paragraph (2)(A) with different
12 frequencies of inspection for different classes of
13 establishments, the numbers and identities for
14 each such class;

15 “(C)(i) the number of domestic and foreign
16 establishments registered pursuant to this sec-
17 tion that the Secretary did not inspect in the
18 previous fiscal year; and

19 “(ii) if the Secretary has provided for a
20 schedule under paragraph (2)(A) with expected
21 frequencies of inspection for different classes of
22 establishments, the numbers for each such
23 class;

24 “(D) information on the performance in
25 the previous fiscal year of the foreign

1 inspectorate established under section 704(h)
2 including—

3 “(i) the number of inspections con-
4 ducted with and without personnel who are
5 fluent in the language used in the estab-
6 lishment under inspection;

7 “(ii) the number of personnel in such
8 inspectorate;

9 “(iii) the countries in which such per-
10 sonnel conduct inspections;

11 “(iv) the offices in foreign countries
12 where such personnel are permanently sta-
13 tioned;

14 “(v) the number of personnel con-
15 ducting inspections in each country who
16 are fluent in the language or languages
17 used in the establishments of that country;
18 and

19 “(vi) the number of personnel who are
20 permanently stationed in each in-country
21 office who are fluent in the language or
22 languages used in the establishments of
23 that country;

24 “(E) the number of domestic and foreign
25 establishments registered with the Secretary

1 under this section during the previous calendar
2 year; and

3 “(F) other information deemed relevant by
4 the Secretary.

5 “(4) PUBLIC AVAILABILITY OF ANNUAL RE-
6 PORTS.—The Secretary shall make the report re-
7 quired under paragraph (3) available to the public
8 on the Internet Web site of the Food and Drug Ad-
9 ministration.”.

10 **SEC. 104. LISTING OF DRUGS AND DEVICES; ENHANCED IN-**
11 **FORMATION TECHNOLOGY SYSTEM FOR REG-**
12 **ISTRATION AND LISTING.**

13 (a) IN GENERAL.—Section 510 (21 U.S.C. 360) is
14 amended—

15 (1) in subsection (j)—

16 (A) by striking “(j)(1) Every person who
17 registers with the Secretary under subsection
18 (b), (c), (d), or (i)” and inserting the following:

19 “(i) SUBMISSION OF LIST OF DRUGS AND DE-
20 VICES.—

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

23 (B) in paragraph (1)—

1 (i) by moving the indentation of sub-
2 paragraphs (A) through (D) 2 ems to the
3 right; and

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

7 (C) in paragraph (2)—

8 (i) by striking “(2) Each person who
9 registers with the Secretary under this sec-
10 tion” and inserting the following:

11 “(2) REPORT TO SECRETARY.—Every person
12 who registers with the Secretary under subsection
13 (b) or (c)”; and

14 (ii) by moving the indentation of sub-
15 paragraphs (A) through (D) 2 ems to the
16 right;

17 (D) in paragraph (3), by striking “(3) The
18 Secretary” and inserting the following:

19 “(3) ADDITIONAL LIST.—The Secretary”; and

20 (E) by adding at the end the following:

21 “(4) SUBMISSION FOR FINISHED DOSAGE
22 FORM.—Every person who files a list under para-
23 graph (1) or reports a list under paragraph (2) shall
24 submit with such list, for any drug that is a finished
25 dosage form, the identity of each establishment en-

1 gaged in the manufacture, preparation, propagation,
2 compounding, or processing of—

3 “(A) the finished dosage form;

4 “(B) any active ingredient of the drug;

5 “(C) any inactive ingredient of the drug;

6 or

7 “(D) any precursor ingredient of any such
8 active or inactive ingredient.

9 “(5) ELECTRONIC SUBMISSION AND MAINTENANCE OF INFORMATION.—The Secretary shall establish and maintain—

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

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

21 “(i) includes appropriate links be-
22 tween registered establishments and be-
23 tween such establishments and listed drugs
24 and devices sufficient to enable the Sec-
25 retary to track and assess the establish-

1 ments and articles involved in the manu-
2 facture, preparation, propagation,
3 compounding, or processing of each drug
4 that is a finished dosage form or an active
5 ingredient and each device;

6 “(ii) includes the date of each inspec-
7 tion by the Secretary (with the Secretary’s
8 report on and assessment of the inspec-
9 tion) for each such establishment and such
10 other information on the inspectional
11 record and compliance history of the estab-
12 lishment as the Secretary deems necessary
13 and appropriate to assess the compliance
14 history of the establishment and, if appli-
15 cable, apply the inspection schedule under
16 subsection (h)(2) to such establishment;
17 and

18 “(iii) is interoperable and commu-
19 nicates with other relevant databases with-
20 in the Food and Drug Administration.”.

21 **SEC. 105. REGISTRATION AND INSPECTION FEES FOR DRUG**
22 **AND DEVICE ESTABLISHMENTS.**

23 (a) REDESIGNATION.—Chapter VII (21 U.S.C. 371
24 et seq.) is amended by redesignating sections 741, 742,
25 and 746 as sections 746, 747, and 749, respectively.

1 (b) FEES RELATED TO ESTABLISHMENT INSPEC-
2 TIONS.—Subchapter C of chapter VII (21 U.S.C. 379f et
3 seq.) is amended by adding at the end the following:

4 **“PART 5—FEES RELATED TO ESTABLISHMENT**
5 **INSPECTIONS**

6 **“SEC. 741. AUTHORITY TO ASSESS AND USE FEES.**

7 “(a) TYPES OF FEES.—

8 “(1) DRUG REGISTRATION AND INSPECTION
9 FEES.—Beginning in fiscal year 2009, the Secretary
10 shall collect drug registration and inspection fees in
11 accordance with this section as follows:

12 “(A) IN GENERAL.—Except as provided
13 under subparagraphs (B), (C), and (D), each
14 person that during a fiscal year registers a drug
15 establishment under subsection (b) or (c) of
16 section 510 shall be subject to a drug registra-
17 tion and inspection fee established under sub-
18 section (b)(1).

19 “(B) REDUCTION FOR POSITRON EMISSION
20 TOMOGRAPHY DRUGS.—The drug registration
21 and inspection fee for a drug establishment en-
22 gaged solely in the manufacture, preparation,
23 propagation, compounding, or processing of 1
24 or more drugs to which section 736(a)(2)(C)(i)
25 applies shall be one-sixth of the drug registra-

1 tion and inspection fee otherwise applicable to
2 such establishment under subsection (b)(1).

3 “(C) EXEMPTION FOR CERTAIN POSITRON
4 EMISSION TOMOGRAPHY DRUGS AND CERTAIN
5 ORPHAN DRUGS.—A drug establishment en-
6 gaged solely in the manufacture, preparation,
7 propagation, compounding, or processing of 1
8 or more drugs to which section 736(a)(2)(C)(ii)
9 or section 736(k) applies shall not be assessed
10 a drug registration and inspection fee.

11 “(D) WAIVER OR REDUCTION.—The Sec-
12 retary shall grant a waiver from or reduction of
13 the drug registration and inspection fee as pro-
14 vided for under section 736(d).

15 “(2) DEVICE REGISTRATION AND INSPECTION
16 FEES.—Beginning in fiscal year 2009, the Secretary
17 shall collect device registration and inspection fees in
18 accordance with this section as follows:

19 “(A) IN GENERAL.—Except as provided
20 under subparagraphs (B) and (C), each person
21 that during a fiscal year registers a device es-
22 tablishment under subsection (b) or (c) of sec-
23 tion 510 shall pay a device registration and in-
24 spection fee established under subsection (b)(2).

1 “(B) REDUCTION FOR SMALL BUSI-
2 NESSES.—The device registration and inspec-
3 tion fee for a device establishment owned or op-
4 erated by an entity that qualifies as a small
5 business under section 738(d)(2) shall be one-
6 fourth of the device registration and inspection
7 fee otherwise applicable to such establishment
8 under subsection (b)(2).

9 “(C) EXEMPTION FOR CERTAIN STATE OR
10 FEDERAL GOVERNMENT ESTABLISHMENTS.—A
11 device establishment operated by a State or
12 Federal government entity shall not be assessed
13 a device registration and inspection fee unless a
14 device classified in class II or class III manu-
15 factured by the establishment is to be distrib-
16 uted commercially.

17 “(b) FEE AMOUNTS.—

18 “(1) DRUG REGISTRATION AND INSPECTION
19 FEE AMOUNTS.—

20 “(A) IN GENERAL.—Beginning with fiscal
21 year 2009, the Secretary shall, not later than
22 30 days after the amount has been appro-
23 priated for a fiscal year in an appropriations
24 Act as described in subsection (d), establish for
25 such fiscal year, and publish in the Federal

1 Register, drug registration and inspection fees,
2 based on the amount provided for in advance in
3 appropriations Acts for such fees as described
4 in subsection (d), considering—

5 “(i)(I) the registration and inspection
6 fee for a drug establishment that under the
7 inspection schedule provided for under sec-
8 tion 510(h)(2)(A) is to be inspected more
9 frequently than once in every 2-year period
10 shall be more than the registration and in-
11 spection fee for a drug establishment that
12 under such schedule is to be inspected once
13 in every 2-year period, in proportion to the
14 factor by which such drug establishment to
15 be is inspected more frequently than once
16 in every 2-year period; and

17 “(II) the registration and inspection
18 fee for a drug establishment that under the
19 inspection schedule provided for under sec-
20 tion 510(h)(2)(A) is to be inspected less
21 frequently than once in every 2-year period
22 shall be less than the registration and in-
23 spection fee for a drug establishment that
24 under such schedule is to be inspected once
25 in every 2-year period, in proportion to the

1 factor by which such establishment is to be
2 inspected less frequently than once in every
3 2-year period;

4 “(ii) the reductions required under
5 subparagraphs (B) and (D) of subsection
6 (a)(1); and

7 “(iii) the number of drug establish-
8 ments subject to such a fee, considering
9 subparagraphs (C) and (D) of subsection
10 (a)(1).

11 “(B) FOREIGN DRUG ESTABLISHMENT.—
12 For a foreign drug establishment, the drug reg-
13 istration and inspection fee shall be—

14 “(i) the applicable drug registration
15 and inspection fee under subparagraph
16 (A), plus

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

18 “(I) travel to and within, and
19 lodging in, the country in which the
20 establishment is located for the indi-
21 vidual or individuals who conduct the
22 inspection of the establishment; and

23 “(II) a translator for the inspec-
24 tion of the establishment.

1 “(2) DEVICE REGISTRATION AND INSPECTION
2 FEE AMOUNTS.—

3 “(A) IN GENERAL.—Beginning with fiscal
4 year 2009, the Secretary shall, not later than
5 30 days after the amount has been appro-
6 priated for a fiscal year in an appropriations
7 Act as described in subsection (d) establish for
8 such fiscal year, and publish in the Federal
9 Register device registration and inspection fees,
10 based on the amount provided for in advance in
11 appropriations Acts for such fees and consid-
12 ering—

13 “(i)(I) the registration and inspection
14 fee for a device establishment that under
15 the inspection schedule provided for under
16 section 510(h)(2)(A) is to be inspected
17 more frequently than once in every 2-year
18 period shall be more than the registration
19 and inspection fee for a device establish-
20 ment that under such schedule is to be in-
21 spected once in every 2-year period, in pro-
22 portion to the factor by which such device
23 establishment is to be inspected more fre-
24 quently than once in every 2-year period;
25 and

1 “(II) the registration and inspection
2 fee for a device establishment that under
3 the inspection schedule provided for under
4 section 510(h)(2)(A) is to be inspected less
5 frequently than once in every 2-year period
6 shall be less than the registration and in-
7 spection fee for a device establishment that
8 under such schedule is to be inspected once
9 in every 2-year period, in proportion to the
10 factor by which such establishment is to be
11 inspected less frequently than once in every
12 2-year period;

13 “(ii) the reduction required under
14 subsection (a)(2)(B); and

15 “(iii) the number of device establish-
16 ments subject to such a fee, considering
17 subsection (a)(2)(C).

18 “(B) FOREIGN DEVICE ESTABLISHMENT.—
19 For a foreign device establishment, the device
20 registration and inspection fee shall be—

21 “(i) the applicable device registration
22 and inspection fee under subparagraph
23 (A), plus

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

1 “(I) travel to and within, and
2 lodging in, the country in which the
3 establishment is located for the indi-
4 vidual or individuals who conduct the
5 inspection of the establishment; and

6 “(II) a translator for the inspec-
7 tion of the establishment.

8 “(c) EFFECT OF FAILURE TO PAY FEES.—

9 “(1) DRUG REGISTRATION AND INSPECTION
10 FEE.—An establishment subject to a drug registra-
11 tion and inspection fee under subsection (a) shall be
12 considered not to be registered under section 510
13 until all registration and inspection fees under this
14 section owed by the person required to register such
15 establishment have been paid.

16 “(2) DEVICE REGISTRATION AND INSPECTION
17 FEE.—An establishment subject to a device registra-
18 tion and inspection fee under subsection (a) shall be
19 considered not to be registered under section 510
20 until all registration and inspection fees under this
21 section owed by the person required to register such
22 establishment have been paid.

23 “(d) CREDITING AND AVAILABILITY OF FEES.—

24 “(1) DRUG REGISTRATION AND INSPECTION
25 FEES.—Drug registration and inspection fees au-

1 thorized under subsection (a) shall be collected and
2 available for obligation only to the extent and in the
3 amount provided in advance in appropriations Acts.
4 Such fees are authorized to remain available until
5 expended. Such sums as may be necessary may be
6 transferred from the Food and Drug Administration
7 salaries and expenses appropriation account without
8 fiscal year limitation to such appropriation account
9 for salaries and expenses with such fiscal year limi-
10 tation. The sums transferred shall be available solely
11 for drug registration and inspection activities.

12 “(2) DEVICE REGISTRATION AND INSPECTION
13 FEES.—Device registration and inspection fees au-
14 thorized under subsection (a) shall be collected and
15 available for obligation only to the extent and in the
16 amount provided in advance in appropriations Acts.
17 Such fees are authorized to remain available until
18 expended. Such sums as may be necessary may be
19 transferred from the Food and Drug Administration
20 salaries and expenses appropriation account without
21 fiscal year limitation to such appropriation account
22 for salaries and expenses with such fiscal year limi-
23 tation. The sums transferred shall be available solely
24 for device registration and inspection activities.

25 “(3) AUTHORIZATION OF APPROPRIATIONS.—

1 “(A) DRUG REGISTRATION AND INSPEC-
2 TION FEES.—Beginning in fiscal year 2009,
3 there is authorized to be appropriated for each
4 fiscal year for drug registration and inspection
5 fees under this section such sums as may be
6 necessary to carry out drug registration and in-
7 spection activities for such fiscal year, except
8 that such sums may be no greater than the
9 lesser of—

10 “(i) the amount appropriated (exclud-
11 ing fees) for such activities for such fiscal
12 year; or

13 “(ii) one-half of the amount necessary
14 to carry out such activities for such fiscal
15 year.

16 “(B) DEVICE REGISTRATION AND INSPEC-
17 TION FEES.—Beginning in fiscal year 2009,
18 there is authorized to be appropriated for each
19 fiscal year for device registration and inspection
20 fees under this section such sums as may be
21 necessary to carry out device registration and
22 inspection activities for such fiscal year, except
23 that such sums may be no greater than the
24 lesser of—

1 “(i) the amount appropriated (exclud-
2 ing fees) for such activities for such fiscal
3 year; or

4 “(ii) one-half of the amount necessary
5 to carry out such activities for such fiscal
6 year.

7 “(e) AUTHORITY.—If the Secretary does not assess
8 fees under subsection (a) during any portion of a fiscal
9 year and if at a later date in such fiscal year the Secretary
10 may assess such fees, the Secretary may assess and collect
11 such fees, without any modification in the rate, at any
12 time in such fiscal year notwithstanding the provisions of
13 subsections (b) and (c) of section 510 relating to the date
14 fees are to be paid.

15 “(f) COLLECTION OF UNPAID FEES.—In any case
16 where the Secretary does not receive payment of a reg-
17 istration and inspection fee required to be paid under sub-
18 section (a) within 30 days after it is due, such fee shall
19 be treated as a claim of the United States Government
20 subject to subchapter II of chapter 37 of title 31, United
21 States Code.

22 “(g) REPORTS.—

23 “(1) PERFORMANCE REPORT.—Beginning for
24 fiscal year 2009, not later than 120 days after the
25 end of each fiscal year for which drug registration

1 and inspection fees and device registration and in-
2 spection fees are collected under this section, the
3 Secretary shall prepare and submit to the Com-
4 mittee on Health, Education, Labor, and Pensions
5 and the Committee on Appropriations of the Senate
6 and the Committee on Energy and Commerce and
7 the Committee on Appropriations of the House of
8 Representatives a report concerning the performance
9 of the Food and Drug Administration with respect
10 to—

11 “(A) drug registration and inspection ac-
12 tivities during such fiscal year; and

13 “(B) device registration and inspection ac-
14 tivities during such fiscal year.

15 “(2) FISCAL REPORT.—Beginning for fiscal
16 year 2009, not later than 120 days after the end of
17 each fiscal year for which drug registration and in-
18 spection fees and device registration and inspection
19 fees are collected under this section, the Secretary
20 shall prepare and submit to the Committee on
21 Health, Education, Labor, and Pensions and the
22 Committee on Appropriations of the Senate and the
23 Committee on Energy and Commerce and the Com-
24 mittee on Appropriations of the House of Represent-
25 atives a report on the implementation of the author-

1 ity for such fees during such fiscal year and the use,
2 by the Food and Drug Administration, of the fees
3 collected for such fiscal year.

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

8 “(h) DEFINITIONS.—In this section:

9 “(1) AFFILIATE.—The term ‘affiliate’ means a
10 business entity that has a relationship with a second
11 business entity if, directly or indirectly—

12 “(A) one business entity controls, or has
13 the power to control, the other business entity;
14 or

15 “(B) a third business entity controls, or
16 has the power to control, both of the business
17 entities.

18 “(2) DEVICE ESTABLISHMENT.—The term ‘de-
19 vice establishment’ means—

20 “(A) an establishment in any State that is
21 engaged in the manufacture, preparation, prop-
22 agation, compounding, or processing of a device
23 classified in class II or class III; or

24 “(B) an establishment within any foreign
25 country that is engaged in the manufacture,

1 preparation, propagation, compounding, or
2 processing of a device classified in class II or
3 class III that is imported or offered for import
4 into the United States.

5 “(3) DEVICE REGISTRATION AND INSPECTION
6 ACTIVITIES.—The term ‘device registration and in-
7 spection activities’ means the following activities of
8 the Secretary:

9 “(A) The registration of device establish-
10 ments under subsections (b) and (c) of section
11 510.

12 “(B) The listing of devices under section
13 510(i), including the activities for devices de-
14 scribed in section 510(i)(5).

15 “(C) The inspection of device establish-
16 ments under section 510(h)(1)(B) or, if applica-
17 ble, section 510(h)(2).

18 “(D) The review of inspection reports from
19 such inspections.

20 “(E) Any action under this Act pursuant
21 to such registration, listing, inspections, and re-
22 views.

23 “(4) DRUG ESTABLISHMENT.—The term ‘drug
24 establishment’ means—

1 “(A) an establishment in any State that
2 is—

3 “(i) engaged in the manufacture,
4 preparation, propagation, compounding, or
5 processing of a drug; and

6 “(ii) subject to inspection under sub-
7 section (h)(1)(B) or (h)(2) of section 510,
8 as applicable; or

9 “(B) an establishment within any foreign
10 country that is—

11 “(i) engaged in the manufacture,
12 preparation, propagation, compounding, or
13 processing of a drug; and

14 “(ii) subject to inspection under sub-
15 section (h)(1)(B) or (h)(2) of section 510,
16 as applicable.

17 “(5) DRUG REGISTRATION AND INSPECTION AC-
18 TIVITIES.—The term ‘drug registration and inspec-
19 tion activities’ means the following activities of the
20 Secretary:

21 “(A) The registration of drug establish-
22 ments under subsections (b) and (c) of section
23 510.

1 “(B) The listing of drugs under section
2 510(i), including the activities for drugs de-
3 scribed in section 510(i)(5).

4 “(C) The inspection of drug establishments
5 under section 510(h)(1)(B) or, if applicable,
6 section 510(h)(2).

7 “(D) The review of inspection reports from
8 such inspections.

9 “(E) Any action under this Act pursuant
10 to such registration, listing, inspections, and re-
11 views.

12 “(6) PERSON.—The term ‘person’ includes an
13 affiliate thereof.”.

14 **SEC. 106. TECHNICAL AND CONFORMING AMENDMENTS.**

15 (a) SECTION 510.—

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

18 (A) by striking “(e) The Secretary” and all
19 that follows through “Any number” and insert-
20 ing the following:

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

24 (B) by striking “subsection (j)” and insert-
25 ing “subsection (i)”.

1 (2) INSPECTION BY PUBLIC OF REGISTRA-
2 TION.—Section 510(f) (21 U.S.C. 360(f)) is amend-
3 ed—

4 (A) by striking “(f) The Secretary” and in-
5 serting the following:

6 “(f) INSPECTION BY PUBLIC OF REGISTRATION.—”;

7 and

8 (B) by striking “subsection (j)” and insert-
9 ing “subsection (i)”.

10 (3) EXEMPTIONS.—Section 510(g) (21 U.S.C.
11 360(g)) is amended—

12 (A) by striking “(g) The foregoing” and
13 inserting the following:

14 “(g) EXEMPTIONS.—The foregoing”; and

15 (B) by moving the indentation of para-
16 graphs (1) through (5) 2 ems to the right.

17 (4) ELECTRONIC SUBMISSION.—Section 510
18 (21 U.S.C. 360) is amended by inserting after sub-
19 section (i) (as redesignated by section 104) the fol-
20 lowing:

21 “(j) ELECTRONIC SUBMISSION.—Registrations and
22 listings under this section (including the submission of up-
23 dated information) shall be submitted to the Secretary by
24 electronic means unless the Secretary grants a request for
25 waiver of such requirement because use of electronic

1 means is not reasonable for the person requesting such
2 waiver.”.

3 (5) DEVICE REPORTS.—Section 510(k) (21
4 U.S.C. 360(k)) is amended—

5 (A) by striking “(k) Each person” and in-
6 serting the following:

7 “(k) DEVICE REPORTS.—Each person”; and

8 (B) by moving the indentation of para-
9 graphs (1) and (2) 2 ems to the right.

10 (6) NO REPORT REQUIRED.—Section 510(l) (21
11 U.S.C. 360(l)) is amended by striking “(l) A report”
12 and inserting the following:

13 “(l) NO REPORT REQUIRED.—A report”.

14 (7) EXEMPTIONS FOR CLASS II DEVICES.—Sec-
15 tion 510(m) (21 U.S.C. 360(m)) is amended—

16 (A) by striking “(m)(1) Not later than”
17 and inserting the following:

18 “(m) EXEMPTIONS FOR CLASS II DEVICES.—

19 “(1) LIST OF EXEMPTED DEVICES.—Not later
20 than”; and

21 (B) by striking “(2) Beginning” and in-
22 serting the following:

23 “(2) OTHER EXEMPTED DEVICES.—Begin-
24 ning”.

1 (8) REVIEW OF REPORT.—Section 510(n) (21
2 U.S.C. 360(n)) is amended by striking “(n) The
3 Secretary” and inserting the following:

4 “(n) REVIEW OF REPORT.—The Secretary”.

5 (9) REPROCESSED SINGLE-USE DEVICES.—Sec-
6 tion 510(o) (21 U.S.C. 360(o)) is amended—

7 (A) by striking “(o)(1) With respect to”
8 and inserting the following:

9 “(o) REPROCESSED SINGLE-USE DEVICES.—

10 “(1) REPROCESSED SINGLE-USE DEVICES FOR
11 WHICH REPORTS ARE REQUIRED.—With respect to”;

12 (B) in paragraph (1), by moving the inden-
13 tation of subparagraphs (A) through (D) 2 ems
14 to the right;

15 (C) by striking “(2) With respect to” and
16 inserting the following:

17 “(2) CRITICAL AND SEMICRITICAL REPROC-
18 ESSED SINGLE-USE DEVICES.—With respect to”; and

19 (D) in paragraph (2), by moving the in-
20 dentation of subparagraphs (A) through (E) 2
21 ems to the right.

22 (10) ELECTRONIC SUBMISSION.—Section 510
23 (21 U.S.C. 360) is amended by striking subsection
24 (p).

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

3 (1) by striking “510(i)” each place it appears
4 and inserting “510(c)”;

5 (2) in section 301—

6 (A) in subsection (p)—

7 (i) by striking “510(j),” and inserting
8 “510(i),”; and

9 (ii) by striking “510(j)(2)” and in-
10 sserting “510(i)(2)”;

11 (B) in subsection (o), by striking “510(j)”
12 and inserting “510(i)”;

13 (3) in section 801(a), by striking “subsection
14 (i) of section 510” and inserting “subsection (e) of
15 section 510”.

16 **SEC. 107. EFFECTIVE DATE.**

17 This subtitle, and the amendments made by this sub-
18 title, shall take effect on October 1, 2008.

19 **Subtitle B—Ensuring Identity and**
20 **Sourcing of Drug Ingredients**

21 **SEC. 111. TESTING OF DRUG PURITY AND IDENTITY.**

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

24 “(j) If it is a drug—

1 “(1) and it bears or contains an article, unless
2 the manufacturer of such drug verifies the purity
3 and identity of such article using scientifically sound
4 and appropriate methods of sufficient analytical pre-
5 cision and specificity to detect and quantify the arti-
6 cle separate from—

7 “(A) impurities; and

8 “(B) contaminants and adulterants reason-
9 ably likely to be present in or on such article;

10 “(2) unless the manufacturer of such drug peri-
11 odically evaluates the impurity profile of each active
12 ingredient of such drug to verify that such profile is
13 substantially similar to the profile of the lot or lots
14 of such ingredient used in the clinical investigations
15 or toxicological evaluations of such drug submitted
16 to the Secretary under section 505 or section 351 of
17 the Public Health Service Act; and

18 “(3) unless the manufacturer of such drug re-
19 ports to the Secretary—

20 “(A) any deviation from purity and iden-
21 tity identified under paragraph (1) or (2); and

22 “(B) any necessary actions in response to
23 such a deviation to assure the safety and effec-
24 tiveness of the drug.”.

1 (b) COMPENDIAL MODERNIZATION.—Section 501(b)
2 (21 U.S.C. 351(b)) is amended by—

3 (1) inserting “or of the appropriate body
4 charged with the revision of such compendium” after
5 “in the judgment of the Secretary”;

6 (2) inserting “(1)” after “insufficient for the
7 making of such determination,”;

8 (3) striking “attention of the appropriate body
9 charged with the revision of such compendium” and
10 inserting “attention of such body”; and

11 (4) inserting “, or (2) such body shall bring
12 such fact to the attention of the Secretary, and the
13 Secretary shall work with such body to develop ap-
14 proaches that will allow such body to establish suffi-
15 cient standards” after “purity shall be made”.

16 (c) RULEMAKING.—Section 701(e)(1) (21 U.S.C.
17 371(e)(1)) is amended in the first sentence by deleting
18 “501(b),”.

19 (d) ASSESSMENT.—The Secretary of Health and
20 Human Services, in consultation with the United States
21 Pharmacopeia, other drug regulatory agencies, academic
22 experts, and industry, shall periodically assess the tests
23 and methods of assay for drugs found in official com-
24 pendia to determine whether, considering current scientific
25 methods, such tests and methods of assay remain scientif-

1 ically sound and appropriate and of sufficient analytical
2 precision and specificity for their purpose.

3 **SEC. 112. MANUFACTURER RESPONSIBILITY FOR SOURCE**
4 **AND QUALITY OF DRUG INGREDIENTS.**

5 Section 501 (21 U.S.C. 351), as amended by section
6 111, is further amended by adding at the end the fol-
7 lowing:

8 “(k) If it is a drug and the manufacturer or importer
9 fails to establish and maintain for a period of time deter-
10 mined by the Secretary documentation adequate to—

11 “(1) identify each establishment that manufac-
12 tured, processed, packed, or held each article that is
13 a component of the drug or a precursor ingredient
14 of such a component; and

15 “(2) establish, including through appropriate
16 and periodic audits of the establishments described
17 in paragraph (1), that the drug and each such arti-
18 cle is not adulterated under this section or mis-
19 branded under section 502.”.

20 **SEC. 113. CURRENT MANUFACTURING SCIENCE.**

21 Section 501(a) (21 U.S.C. 351(a)) is amended by
22 striking “; or (3)” and inserting the following: “or (D)
23 if it is manufactured in a manner that is inconsistent with
24 current manufacturing technologies, including quality
25 risk-management practices, in-process controls, and rela-

1 tion of quality standards to clinical performance of the
2 drug or device, as determined by the Secretary; or (3)”.

3 **SEC. 114. ELECTRONIC PEDIGREE FOR DRUG INGREDI-**
4 **ENTS.**

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

7 “(d) If it is a drug and any article that is a compo-
8 nent of the drug or a precursor ingredient of such a com-
9 ponent was distributed by a person, unless such person
10 distributed with the article an electronic statement (in
11 such form and containing such information as the Sec-
12 retary may require by guidance or regulation) identifying
13 each prior sale, purchase, or trade of the article (including
14 the date of the transaction and the names and addresses
15 of all parties to the transaction).”.

16 **SEC. 115. COUNTRY OF ORIGIN LABELING.**

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

19 “(aa) If it is a drug in final dosage form or device
20 for use on or by patients unless its label bears, and the
21 Internet Web site of the manufacturer of the drug or de-
22 vice lists, the identity of—

23 “(1) the country of manufacture of the drug or
24 device; and

1 “(2) if it is a drug, the country of manufacture
2 of each active ingredient in the drug.”.

3 **SEC. 116. EFFECTIVE DATE.**

4 This subtitle, and the amendments made by this sub-
5 title, shall take effect on the date that is 180 days after
6 the date of enactment of this Act.

7 **Subtitle C—Ensuring Standards for**
8 **Imported Drugs**

9 **SEC. 121. GOOD DISTRIBUTION AND IMPORT PRACTICES.**

10 (a) GOOD DISTRIBUTION AND IMPORT PRACTICES.—
11 Section 501(a) (21 U.S.C. 351(a)), as amended by section
12 113, is further amended by striking “; or (3)” and insert-
13 ing “or (E) if it is a drug and it is not distributed,
14 shipped, warehoused, brokered, imported, or conveyed in
15 conformity with current good distribution and import
16 practices to assure the identity, strength, quality, and pu-
17 rity of the drug; or (3)”.

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

20 (1) in subsection (a)—

21 (A) in paragraph (1)(A), by inserting
22 “(and in the case of drugs, distributed, shipped,
23 warehoused, or conveyed)” after “or held,”; and

24 (B) in the third sentence—

1 (i) by inserting “(and in the case of
2 drugs, distributed, shipped, warehoused, or
3 conveyed)” after “packed, or held,”; and

4 (ii) by inserting “, (and in the case of
5 drugs, distributed, shipped, warehoused, or
6 conveyed)” after “transported, or held”;
7 and

8 (2) in subsection (e), by striking “519 or” and
9 inserting “502(a)(2)(E), 519, or”.

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

12 Section 801 (21 U.S.C. 381) is amended—

13 (1) in subsection (o), by striking “drug or”;
14 and

15 (2) by adding at the end the following:

16 “(p) Except as provided in subsection (g), a drug,
17 or an article that appears to be a drug, in finished dosage
18 form, an article that is intended to be a component of a
19 drug, or an article that is intended to be a precursor ingre-
20 dient of such a component that is being imported or of-
21 fered for import into the United States shall be refused
22 admission unless the person importing or offering for im-
23 port such drug or article provides to the Secretary, at the
24 time of being imported or offered for import—

1 “(1) all information submitted to U.S. Customs
2 and Border Protection in the entry declaration for
3 such drug or such article;

4 “(2) for a drug, or an article that appears to
5 be a drug, in finished dosage form—

6 “(A) the listing number under section
7 510(e) of such drug;

8 “(B) the D-U-N-S number of each estab-
9 lishment in which such drug was manufactured,
10 prepared, propagated, compounded, or proc-
11 essed;

12 “(C) the new drug application number, the
13 abbreviated new drug application number, or
14 the drug monograph number, as applicable;

15 “(D) the label required by the new drug
16 application, abbreviated new drug application,
17 or drug monograph, as applicable; and

18 “(E) the record of inspections by the Sec-
19 retary;

20 “(3) for an article that is an active ingredient
21 of a drug, or an article that is a precursor ingredient
22 of an active ingredient—

23 “(A) the listing number under section
24 510(e) of such article;

1 “(B) the D-U-N-S number of each estab-
2 lishment in which such article was manufac-
3 tured, prepared, propagated, compounded, or
4 processed;

5 “(C) the new drug application number, the
6 abbreviated new drug application number, or
7 the drug monograph number, as applicable, of
8 the finished dosage form for which such article
9 is intended;

10 “(D) the label under a regulatory exemp-
11 tion from section 502(f)(1); and

12 “(E) the record of inspections by the Sec-
13 retary or by a governmental authority respon-
14 sible for drugs deemed adequate by the Sec-
15 retary; and

16 “(4) for an article (other than an active ingre-
17 dient) that is intended to be a component of a drug,
18 or an article that is a precursor ingredient of any
19 such component—

20 “(A) the listing number under section
21 510(e) of such article;

22 “(B) the D-U-N-S number of each estab-
23 lishment in which such article was manufac-
24 tured, prepared, propagated, compounded, or
25 processed;

1 **Subtitle D—Enhanced Response to**
2 **Unsafe Drugs**

3 **SEC. 131. ADMINISTRATIVE DETENTION OF DRUGS.**

4 (a) IN GENERAL.—Section 304(g) (21 U.S.C.
5 334(g)) is amended—

6 (1) in paragraph (1)—

7 (A) by inserting “drug or” before “device”
8 each place it appears; and

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

13 (2) in paragraph (2), by inserting “drug or” be-
14 fore “device” each place it appears.

15 (b) TECHNICAL AMENDMENTS.—Section 304(g)(1)
16 (21 U.S.C. 334(g)(1)), as amended by subsection (a), is
17 further amended by—

18 (1) striking “(1) If” and inserting “(1)(A) If”;

19 (2) striking “thirty days. Regulations” and in-
20 serting the following: “thirty days.

21 “(B) Regulations”;

22 (3) striking “such order. A detention” and in-
23 serting the following: “such order.

24 “(C) A detention”; and

1 (4) striking “as detained. Any person” and in-
2 serting the following: “as detained.

3 “(D) Any person”.

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

12 **SEC. 132. MANDATORY RECALL AUTHORITY FOR DRUGS.**

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

15 **“SEC. 507. MANDATORY RECALL AUTHORITY FOR DRUGS.**

16 “(a) ORDER TO CEASE DISTRIBUTION; NOTIFICA-
17 TION; PROCESS.—

18 “(1) ORDER TO CEASE DISTRIBUTION; NOTIFI-
19 CATION.—If the Secretary finds that there is a rea-
20 sonable probability that a drug intended for human
21 use would cause serious, adverse health con-
22 sequences or death, the Secretary shall issue an
23 order requiring the appropriate person (including
24 the manufacturers, importers, distributors, or retail-
25 ers of the drug)—

1 “(A) to immediately cease distribution of
2 such drug; and

3 “(B) to immediately notify health profes-
4 sionals and hospitals and other health care fa-
5 cilities of the order and to instruct such profes-
6 sionals and facilities to cease use of such drug.

7 “(2) PROCESS.—The order under paragraph
8 (1) shall provide the person subject to the order with
9 an opportunity for an informal hearing, to be held
10 not later than 10 days after the date of the issuance
11 of the order, on the actions required by the order
12 and on whether the order should be amended to re-
13 quire a recall of such drug. If, after providing an op-
14 portunity for such a hearing, the Secretary deter-
15 mines that inadequate grounds exist to support the
16 actions required by the order, the Secretary shall va-
17 cate the order.

18 “(b) ORDER TO RECALL.—

19 “(1) IN GENERAL.—If, after providing an op-
20 portunity for an informal hearing under subsection
21 (a), the Secretary determines that the order should
22 be amended to include a recall of the drug with re-
23 spect to which the order was issued, the Secretary
24 shall, except as provided in paragraph (2), amend
25 the order to require a recall. The Secretary shall

1 specify a timetable in which the drug recall will
2 occur and shall require periodic reports to the Sec-
3 retary describing the progress of the recall.

4 “(2) AMENDED ORDER.—An amended order
5 under paragraph (1)—

6 “(A) shall—

7 “(i) not include recall of a drug from
8 individuals; and

9 “(ii) not include recall of a drug from
10 hospitals and other health care facilities if
11 the Secretary determines that the risk of
12 recalling such drug from the facilities pre-
13 sents a greater health risk than the health
14 risk of not recalling the drug from use;
15 and

16 “(B) shall provide for notice to individuals
17 subject to the risks associated with the use of
18 such drug.

19 “(3) ASSISTANCE.—In providing the notice re-
20 quired by paragraph (2), the Secretary may use the
21 assistance of health professionals who prescribed or
22 used such a drug for individuals. If a significant
23 number of such individuals cannot be identified, the
24 Secretary shall notify such individuals pursuant to
25 section 705(b).”.

1 (b) REGULATIONS.—Until the date that the Sec-
2 retary of Health and Human Services issues a final regu-
3 lation to implement section 507 of the Federal Food,
4 Drug, and Cosmetic Act (as added by subsection (a)), the
5 regulations on medical device recall authority in part 810
6 of title 21, Code of Federal Regulations, shall apply to
7 any recall of a drug under such section 507.

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

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

13 “(h) DRUG DEFECTS.—

14 “(1) RECORDS AND REPORTS.—The manufac-
15 turer of a drug shall make and maintain records,
16 and promptly submit reports to the Secretary, about
17 any defect of the drug.

18 “(2) INVESTIGATION AND CORRECTIVE AC-
19 TION.—The manufacturer of a drug shall—

20 “(A) investigate the cause of any defect of
21 the drug; and

22 “(B) take appropriate corrective action.

23 “(3) DESTRUCTION.—If a drug may cause in-
24 jury or death because of a defect, the manufacturer
25 shall, after the investigation of the defect required

1 under paragraph (2), destroy the drug and shall not
2 recondition the drug.

3 “(4) DEFECT.—For purposes of this sub-
4 section, a drug shall be considered to have a defect
5 if the manufacturer rejects the drug for manufac-
6 turing or distribution because of—

7 “(A) microbiological or other contamina-
8 tion;

9 “(B) significant chemical, physical, or
10 other change or deterioration; or

11 “(C) any failure of 1 or more batches of
12 the drug to meet a specification established for
13 it.”.

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

16 (1) in subsection (d), by striking “505” and in-
17 serting “503(h), 505”; and

18 (2) in subsection (e), by striking “504” and in-
19 serting “503(h), 504”.

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

23 **SEC. 134. CIVIL MONEY PENALTIES.**

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

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

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

6 (3) by inserting after paragraph (4) the fol-
7 lowing:

8 “(5)(A)(i) Any manufacturer, distributor, im-
9 porter, broker, or filer that violates a requirement of
10 this Act that relates to drugs for human use (except
11 a requirement referred to in paragraph (4) or sub-
12 section (g)) shall be liable to the United States for
13 a civil penalty not to exceed \$100,000 per violation.

14 “(ii) Each day during which a violation con-
15 tinues shall be considered a separate violation under
16 clause (i).

17 “(B)(i) Any manufacturer, distributor, im-
18 porter, broker, or filer that knowingly reports or en-
19 ters false or misleading data on documents related
20 to the importation of a drug shall be liable to the
21 United States for a civil penalty not to exceed
22 \$150,000.

23 “(ii) Each act of reporting or entering false
24 data shall be considered a separate violation under
25 clause (i).”;

1 (4) in paragraph (6), as so redesignated, by
2 striking “, or (4)” each place it appears and insert-
3 ing “(4), or (5)”;

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

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

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

13 **Subtitle E—Additional Provisions** 14 **Related to Medical Products**

15 **SEC. 141. CERTIFICATION OF INFORMATION.**

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

18 **“SEC. 505E. CERTIFICATION OF DRUG INFORMATION.**

19 “(a) CERTIFICATION.—

20 “(1) IN GENERAL.—A new drug application
21 under section 505(b), an abbreviated new drug ap-
22 plication under section 505(j), a biologics license ap-
23 plication under section 351 of the Public Health
24 Service Act, an application for an investigational
25 new drug exemption under section 505(i), a new ani-

1 mal drug application under section 512(b), an abbrevi-
2 viated new animal drug application under section
3 512(b), an application under section 571, a request
4 under section 572, an amendment, supplement, or
5 other information submitted to the Secretary with
6 respect to any such application or request, or a
7 record or report related to the safety or effectiveness
8 of a drug subject to section 505 or such section 351,
9 to an adverse event under section 505(k) or 760, or
10 to a postapproval study or postapproval clinical trial
11 under section 505(o), when submitted to the Sec-
12 retary, shall include a certification, in writing and
13 under penalty of perjury, by the responsible person
14 that—

15 “(A) such person has actual knowledge of
16 the requirements under this Act and, if applica-
17 ble, such section 351, with respect to the drug
18 that is the subject of such submission;

19 “(B) such person has actual knowledge of
20 the information related to such drug;

21 “(C) such person has actual knowledge of
22 the information in such submission;

23 “(D) the information in such submission
24 complies with such requirements;

1 “(E) the information in such submission is
2 not false or misleading; and

3 “(F) full reports of all clinical trials and
4 postmarket studies (whether conducted within
5 or outside the United States) related to the
6 safety or effectiveness of the drug under review
7 that were funded by the sponsor of such sub-
8 mission, or the full reports of which the sponsor
9 of such submission had access, have been sub-
10 mitted to the Food and Drug Administration.

11 “(2) RESPONSIBLE PERSON.—A responsible
12 person under this section is, with respect to a sub-
13 mission described under paragraph (1), a senior offi-
14 cer or director of the sponsor of such submission
15 with knowledge of, and management responsibility
16 for, such submission.

17 “(b) INSPECTIONS.—

18 “(1) IN GENERAL.—If the Secretary deter-
19 mines, after notice and opportunity for an informal
20 hearing, that a sponsor described in paragraph
21 (2)(A) knew or should have known that the informa-
22 tion in a submission described in subsection (a)(1)
23 did not comply with the requirements of this Act or
24 was false or misleading, the Secretary may provide
25 that any factory, warehouse, establishment, or con-

1 sulting laboratory related to such noncompliance or
2 such false or misleading information shall be in-
3 spected periodically by officers or employees duly
4 designated by the Secretary for a period of time de-
5 termined by the Secretary, not to exceed 5 years.

6 “(2) COSTS.—The Secretary shall assess the
7 costs of such inspections to such sponsor.”.

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

10 **“SEC. 523A. CERTIFICATION OF DEVICE INFORMATION.**

11 “(a) CERTIFICATION.—

12 “(1) CERTIFICATION BY SPONSOR.—An applica-
13 tion or report for premarket approval under section
14 515, an application for an investigational device ex-
15 emption under section 520(g), a report under section
16 510(k), an application for a humanitarian device ex-
17 emption under section 520(m), an amendment, sup-
18 plement, or other information submitted to the Sec-
19 retary with respect to any such application or report,
20 or a record or report related to an adverse event, a
21 report, or postmarket surveillance under section 519
22 or 522, when submitted to the Secretary, shall in-
23 clude a certification, in writing and under penalty of
24 perjury, by the responsible person that—

1 “(A) such person has actual knowledge of
2 the requirements under this Act with respect to
3 the device that is the subject of such submis-
4 sion;

5 “(B) such person has actual knowledge of
6 the information related to such device;

7 “(C) such person has actual knowledge of
8 the information in such submission;

9 “(D) the information in such submission
10 complies with such requirements;

11 “(E) the information in such submission is
12 not false or misleading; and

13 “(F) full reports of all clinical trials and
14 postmarket studies (whether conducted within
15 or outside the United States) related to the
16 safety or effectiveness of the device under re-
17 view that were funded by the sponsor of such
18 submission, or the full reports of which the
19 sponsor of such submission had access, have
20 been submitted to the Food and Drug Adminis-
21 tration.

22 “(2) RESPONSIBLE PERSON.—A responsible
23 person under this section is, with respect to a sub-
24 mission described under paragraph (1), a senior offi-
25 cer or director of the sponsor of such submission

1 with knowledge of, and management responsibility
2 for, such submission.

3 “(b) INSPECTIONS.—

4 “(1) IN GENERAL.—If the Secretary deter-
5 mines, after notice and opportunity for an informal
6 hearing, that a sponsor described in paragraph
7 (a)(2) knew or should have known that the informa-
8 tion in a submission described in subsection (a)(1)
9 did not comply with the requirements of this Act or
10 was false or misleading, the Secretary may provide
11 that any factory, warehouse, establishment, or con-
12 sulting laboratory related to such noncompliance or
13 such false or misleading information shall be in-
14 spected periodically by officers or employees duly
15 designated by the Secretary for a period of time de-
16 termined by the Secretary, not to exceed 5 years.

17 “(2) COSTS.—The Secretary shall assess the
18 costs of such inspections to such sponsor.”.

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

22 “§ 1041. **Certifications related to drug and device in-**
23 **formation**

24 “(a) If a responsible person—

1 “(1) certifies any submission as set forth in sec-
2 tion 505E or 523A of the Federal Food, Drug, and
3 Cosmetic Act knowing that a component of such cer-
4 tification is false or misleading, then—

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

7 “(B) such responsible person shall be fined
8 not more than \$1,000,000, imprisoned for not
9 more than 10 years, or both; or

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

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

16 “(B) such responsible person shall be fined
17 not more than \$5,000,000, imprisoned not more
18 than 20 years, or both.

19 “(b) In this section:

20 “(1) The term ‘responsible person’—

21 “(A) with respect to a submission related
22 to a drug, has the meaning given that term in
23 section 505E(a)(2) of the Federal Food, Drug,
24 and Cosmetic Act; and

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

4 “(2) The term ‘submission’ means—

5 “(A) with respect to a drug—

6 “(i) a new drug application under sec-
7 tion 505(b) of the Federal Food, Drug,
8 and Cosmetic Act;

9 “(ii) an abbreviated new drug applica-
10 tion under section 505(j) of such Act;

11 “(iii) a biologics license application
12 under section 351 of the Public Health
13 Service Act;

14 “(iv) an application for an investiga-
15 tional new drug exemption under section
16 505(i) of the Federal Food, Drug, and
17 Cosmetic Act;

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

21 “(vi) an abbreviated new animal drug
22 application under section 512(b) of such
23 Act;

24 “(vii) an application under section
25 571 of such Act;

1 “(viii) a request under section 572 of
2 such Act;

3 “(ix) an amendment, supplement, or
4 other information submitted to the Sec-
5 retary with respect to any application or
6 request described in clauses (i) through
7 (viii); or

8 “(x) a record or report related to the
9 safety or effectiveness of a drug subject to
10 section 505 of such Act or section 351 of
11 the Public Health Service Act, to an ad-
12 verse event under section 505(k) or 760 of
13 the Federal Food, Drug, and Cosmetic
14 Act, or to a postapproval study or post-
15 approval clinical trial under section 505(o)
16 of such Act; and

17 “(B) with respect to a device—

18 “(i) an application or report for pre-
19 market approval under section 515 of the
20 Federal Food, Drug, and Cosmetic Act;

21 “(ii) an application for an investiga-
22 tional device exemption under section
23 520(g) of such Act;

24 “(iii) a report under section 510(k) of
25 such Act;

1 “(iv) an application for a humani-
2 tarian device exemption under section
3 520(m) of such Act;

4 “(v) an amendment, supplement, or
5 other information submitted to the Sec-
6 retary with respect to any application or
7 report described in clauses (i) through (iv);
8 or

9 “(vi) a record or report related to an
10 adverse event, a report, or postmarket sur-
11 veillance under section 519 or 522 of such
12 Act.”.

13 (d) CONFORMING AMENDMENT.—The table of sec-
14 tions for chapter 47 of title 18, United States Code, is
15 amended by inserting after the item relating to section
16 1040 the following:

 “1041. Certification of drug and device information.”.

17 **SEC. 142. WHISTLEBLOWER PROTECTIONS.**

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

20 **“SEC. 911. PROTECTIONS FOR EMPLOYEES WHO REFUSE TO**
21 **VIOLATE, OR WHO DISCLOSE VIOLATIONS OF,**
22 **THIS ACT OR SECTION 351 OF THE PUBLIC**
23 **HEALTH SERVICE ACT.**

24 “(a) IN GENERAL.—No person that submits or is re-
25 quired to submit to the Secretary, a new drug application

1 under section 505(b), an abbreviated new drug application
2 under section 505(j), a biologics license application under
3 section 351 of the Public Health Service Act, an applica-
4 tion for an investigational new drug exemption under sec-
5 tion 505(i), a new animal drug application under section
6 512(b), an abbreviated new animal drug application under
7 section 512(b), an application under section 571, a request
8 under section 572, an application or report for premarket
9 approval under section 515, an application for an inves-
10 tigational device exemption under section 520(g), a report
11 under section 510(k), an application for a humanitarian
12 device exemption under section 520(m), an amendment,
13 supplement, or other submission with respect to any such
14 application or report, or a record or report related to an
15 adverse event, a postapproval study, a postapproval clin-
16 ical trial, a report, or postmarket surveillance under sec-
17 tion 505(k), 505(o), 519, 522, or 760, or any officer, em-
18 ployee, contractor, subcontractor, or agent of such a per-
19 son, may discharge, demote, suspend, threaten, harass, or
20 in any other manner discriminate against an employee in
21 the terms and conditions of employment because of any
22 lawful act done by the employee, including within the ordi-
23 nary course of the job duties of such employee—

24 “(1) to provide information, cause information
25 to be provided, or otherwise assist in any investiga-

1 tion regarding any conduct which the employee rea-
2 sonably believes constitutes a violation of any such
3 section of this Act or such section 351 of the Public
4 Health Service Act, any other provision of Federal
5 law relating to the safety or effectiveness of a drug,
6 biological product, or device, or any provision of
7 Federal law prohibiting fraud against the Food and
8 Drug Administration, if the information or assist-
9 ance is provided to, or an investigation stemming
10 from the provided information is conducted by—

11 “(A) a Federal regulatory or law enforce-
12 ment agency;

13 “(B) any Member of Congress or any com-
14 mittee of Congress; or

15 “(C) a person with supervisory authority
16 over the employee (or such other person work-
17 ing for the employer who has the authority to
18 investigate, discover, or terminate the mis-
19 conduct);

20 “(2) to file, cause to be filed, testify, participate
21 in, or otherwise assist in a proceeding filed or about
22 to be filed (with any knowledge of the employer) re-
23 lating to an alleged violation of any such section of
24 this Act or such section 351 of the Public Health
25 Service Act, any other provision of Federal law re-

1 lating to the safety or effectiveness of a drug, bio-
2 logical product, or device, or any provision of Fed-
3 eral law prohibiting fraud against the Food and
4 Drug Administration; or

5 “(3) to refuse to violate or assist in the viola-
6 tion of any such section of this Act or such section
7 351 of the Public Health Service Act, any other pro-
8 vision of Federal law relating to the safety or effec-
9 tiveness of a drug, biological product, or device, or
10 any provision of Federal law prohibiting fraud
11 against the Food and Drug Administration.

12 “(b) ENFORCEMENT ACTION.—

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

17 “(A) filing a complaint with the Secretary
18 of Labor; or

19 “(B) if the Secretary of Labor has not
20 issued a final decision within 210 days of the
21 filing of the complaint and there is no showing
22 that such delay is due to the bad faith of the
23 claimant, bringing an action at law or equity
24 for de novo review in the appropriate district
25 court of the United States, which shall have ju-

1 jurisdiction over such an action without regard to
2 the amount in controversy.

3 “(2) PROCEDURE.—

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

8 “(B) EXCEPTION.—Notification in an ac-
9 tion under paragraph (1) shall be made in ac-
10 cordance with section 42121(b)(1) of title 49,
11 United States Code, except that such notifica-
12 tion shall be made to the person named in the
13 complaint and to the employer.

14 “(C) BURDENS OF PROOF.—An action
15 brought under paragraph (1)(B) shall be gov-
16 erned by the legal burdens of proof set forth in
17 section 42121(b) of title 49, United States
18 Code.

19 “(D) STATUTE OF LIMITATIONS.—An ac-
20 tion under paragraph (1) shall be commenced
21 not later than 180 days after the date on which
22 the violation occurs.

23 “(c) REMEDIES.—

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

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

6 “(A) reinstatement with the same seniority
7 status that the employee would have had, but
8 for the discrimination;

9 “(B) the amount of backpay owed to the
10 employee, with interest; and

11 “(C) compensation for any special damages
12 sustained as a result of the discrimination, in-
13 cluding litigation costs, expert witness fees, and
14 reasonable attorney fees.

15 “(d) RIGHTS RETAINED BY EMPLOYEE.—Nothing in
16 this section shall be deemed to diminish the rights, privi-
17 leges, or remedies of any employee under any Federal or
18 State law or under any collective bargaining agreement.
19 The rights and remedies in this section may not be waived
20 by any agreement, policy, form, or condition of employ-
21 ment.”.

1 **TITLE II—GENERAL AUTHORITIES TO ENHANCE FOOD AND**
2 **DRUG ADMINISTRATION**
3 **OVERSIGHT OF PRODUCTS**
4 **FROM A GLOBAL MARKET**

6 **SEC. 201. DEDICATED FOREIGN INSPECTORATE.**

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

9 “(h) FOREIGN INSPECTORATE.—

10 “(1) IN GENERAL.—The Secretary shall estab-
11 lish and maintain a corps of inspectors dedicated to
12 inspections of foreign establishments registered
13 under section 510 and foreign facilities registered
14 under section 415. Such corps shall include per-
15 sonnel, in numbers sufficient to act as inspectors or
16 translators for inspectors on each inspection by such
17 corps, who are able to understand and speak the
18 language used in the establishment or facility under
19 inspection.

20 “(2) ORGANIZATION.—The corps established
21 under paragraph (1) shall be organized into the fol-
22 lowing 4 units:

23 “(A) A unit with expertise in inspections of
24 food facilities.

1 “(B) A unit with expertise in inspections
2 of human drug establishments.

3 “(C) A unit with expertise in inspections of
4 animal drug establishments.

5 “(D) A unit with expertise in inspections
6 of medical device establishments.

7 “(3) STAFFING AND FUNDING.—Each unit
8 shall be staffed and funded by the Secretary at a
9 level sufficient to allow the unit to conduct inspec-
10 tions, as applicable—

11 “(A) of foreign establishments registered
12 under section 510 at a frequency, considering
13 risk, that is comparable to the inspection rate
14 of domestic establishments registered under sec-
15 tion 510; or

16 “(B) of foreign facilities registered under
17 section 415 at a frequency, considering risk,
18 that is comparable to the inspection rate of do-
19 mestic facilities registered under section 415.

20 “(4) DISTRIBUTION.—The Secretary shall dis-
21 tribute the staff of each unit described in paragraph
22 (2) in countries, and may modify such distribution
23 over time, considering—

24 “(A) the volume of product exported from
25 such country to the United States;

1 “(2) DISCLOSURE TO SECRETARY.—The Sec-
2 retary may receive information from officials of for-
3 eign governments under conditions of confidentiality.
4 Such information shall be exempt from disclosure
5 under section 552 of title 5, United States Code.”.

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

10 **SEC. 203. SUBPOENA AUTHORITY.**

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

13 “(f)(1) The Secretary may conduct investigations as
14 the Secretary deems necessary—

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

18 “(B) to determine whether any person has en-
19 gaged or is about to engage in any act that con-
20 stitutes or will constitute a violation of this Act or
21 such section 351.

22 “(2) For the purpose of any investigation conducted
23 under paragraph (1), the Secretary may administer oaths
24 and affirmations, subpoena witnesses, compel the attend-
25 ance of such witnesses, take evidence, and require the pro-

1 duction of any books, papers, documents, or other mate-
2 rials that are relevant to the investigation.

3 “(3)(A) In case of contumacy or refusal to obey a
4 subpoena issued under paragraph (2), the district court
5 of the United States for the judicial district in which such
6 investigation or proceeding is conducted, or in which the
7 subpoenaed person resides or conducts business, may issue
8 an order requiring such person to appear before the Sec-
9 retary, testify, or produce books, papers, documents, or
10 other materials that are relevant to the investigation. All
11 process in any such case may be served in the judicial dis-
12 trict in which such person resides or may be found.

13 “(B) Any failure to obey an order issued under sub-
14 paragraph (A) may be punished by the court as contempt
15 of court.”.

16 **SEC. 204. INFORMATION REPORTING.**

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

19 **“SEC. 757. INFORMATION REPORTING.**

20 “(a) NOTIFICATION OF SETTLEMENTS OR JUDG-
21 MENTS.—If a particular product regulated by the Sec-
22 retary under this Act or section 351 of the Public Health
23 Service Act is the subject of at least 3 civil actions that
24 have been filed in Federal or State court alleging death,
25 serious injury, or serious illness caused in whole or in part

1 by such product which, in any 24-month period, result in
2 either a final settlement involving the manufacturer or a
3 court judgment in favor of the plaintiff, the manufacturer
4 of such product shall, in accordance with subsection (b),
5 report to the Secretary each such civil action not later
6 than 30 days after the final settlement or court judgment
7 in the third of such civil actions, and report to the Sec-
8 retary any other such action not later than 30 days after
9 any subsequent such settlement or judgment that—

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

12 “(2) has not been previously reported to the
13 Secretary under this section.

14 “(b) INFORMATION TO BE REPORTED.—

15 “(1) REQUIRED INFORMATION.—The informa-
16 tion required by subsection (a) to be reported to the
17 Secretary, with respect to each civil action described
18 in such subsection, shall include and, in addition to
19 any voluntary information provided under paragraph
20 (2), shall be limited to the following:

21 “(A) The name and address of the manu-
22 facturer.

23 “(B) The name or model of the product
24 subject to the civil action.

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

5 “(D) A statement as to whether the civil
6 action resulted in a final settlement or a judg-
7 ment in favor of the plaintiff.

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

12 “(2) VOLUNTARY INFORMATION.—A manufac-
13 turer furnishing the report required by paragraph
14 (1) may include—

15 “(A) a statement as to whether any judg-
16 ment in favor of the plaintiff is under appeal or
17 is expected to be appealed; or

18 “(B) any other information which the
19 manufacturer chooses to provide.

20 “(c) SAFETY REPORT.—A report of a civil action de-
21 scribed in subsection (a) shall be considered a safety re-
22 port under section 756 and may be accompanied by a
23 statement, which shall be part of any report released for
24 public disclosure, that denies that the report constitutes

1 an admission that the product involved caused or contrib-
2 uted to a death, serious injury, or serious illness.

3 “(d) ADMISSION.—A report of a civil action described
4 in subsection (a) shall not be considered an admission that
5 the product involved is adulterated or caused or contrib-
6 uted to a death, serious injury, or serious illness.

7 “(e) DEFINITIONS.—The terms ‘serious illness’ and
8 ‘serious injury’ mean illness or injury, respectively, that—

9 “(1) is life threatening,

10 “(2) results in permanent impairment of a body
11 function or permanent damage to a body structure,
12 or

13 “(3) necessitates medical or surgical interven-
14 tion to preclude permanent impairment of a body
15 function or permanent damage to a body struc-
16 ture.”.

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