

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.

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 2009”.

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 of foreign drug and device establishments.
- Sec. 103. Registration of establishments for drug precursor ingredients.
- Sec. 104. Registration and licensing of drug importers.
- Sec. 105. Inspection of drug and device establishments.
- Sec. 106. Listing of drugs and devices; enhanced information technology system for registration and listing; inactive ingredients.
- Sec. 107. Fees related to establishment inspections.
- Sec. 108. Electronic submission and certification of registrations and listings.
- Sec. 109. Technical and conforming amendments.
- Sec. 110. Effective date.

Subtitle B—Ensuring Identity and Sourcing of Drug Ingredients

- Sec. 111. Compendial modernization.
- Sec. 112. Testing of drug purity and identity.
- Sec. 113. Manufacturer responsibility for source and quality of drug ingredients.
- Sec. 114. Current manufacturing science.
- Sec. 115. Country of origin labeling.
- Sec. 116. Effective date; implementation.

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.

Sec. 143. Study by the Institute of Medicine regarding the review of medical devices.

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

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

18 “(b) REGISTRATION OF DOMESTIC ESTABLISH-
19 MENTS.—Any person who owns or operates any establish-
20 ment in any State engaged in the manufacture, prepara-

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

3 “(1) upon first engaging in any such activity,
4 immediately submit a registration to the Secretary
5 that includes the name of such person, places of
6 business of such person, all such establishments, the
7 D-U-N-S number of each such establishment, an e-
8 mail address for use in an emergency, and payment
9 of any inspection fee for each such establishment re-
10 quired under section 743;

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

18 “(3) thereafter—

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

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

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

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

4 **SEC. 102. REGISTRATION OF FOREIGN DRUG AND DEVICE**
5 **ESTABLISHMENTS.**

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

9 (b) REGISTRATION OF FOREIGN ESTABLISH-
10 MENTS.—Section 510 (U.S.C. 360), as amended by sec-
11 tion 101, is further amended—

12 (1) by transferring subsection (i) so as to ap-
13 pear after subsection (b); 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 inspection fee for
8 each such establishment required under section
9 743, the name of the United States agent of
10 each such establishment, the name of each im-
11 porter of such drug or device in the United
12 States that is known to each such establish-
13 ment, and the name of each person who imports
14 or offers for import such drug or device to the
15 United States for purposes of importation;

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

24 “(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) The
12 Secretary” and inserting “(2) COOPERATIVE
13 ARRANGEMENTS.—The Secretary”; and

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

16 **SEC. 103. REGISTRATION OF ESTABLISHMENTS FOR DRUG**
17 **PRECURSOR INGREDIENTS.**

18 (a) REGISTRATION OF ESTABLISHMENTS THAT MAN-
19 UFACTURE DRUG PRECURSOR INGREDIENTS.—Section
20 510(a) (21 U.S.C. 360(a)) is amended—

21 (1) in the matter preceding paragraph (1), by
22 striking “As used” and inserting “DEFINITIONS.—
23 As used”;

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

1 “(1) IN GENERAL.—Any person who owns or
2 operates any establishment engaged in the importa-
3 tion, filing for importation, or brokering for importa-
4 tion of a drug into the United States shall—

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

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

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

21 “(2) LICENSING.—

22 “(A) IN GENERAL.—The Secretary may re-
23 quire any person engaged in the importation,
24 filing for importation, or brokering for importa-
25 tion of a drug into the United States, before en-

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

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

10 “(i) violated, or caused the violation,
11 of this Act; or

12 “(ii) made, or caused to be made, a
13 false or misleading statement.

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

21 “(i) violating, or causing the violation
22 of, this Act; or

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

1 “(D) REVOCATION.—The Secretary may
2 revoke the license for a person under subpara-
3 graph (A) if the Secretary finds that, in connec-
4 tion with the importation, filing for importa-
5 tion, or brokering for importation of a drug into
6 the United States, such person has—

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

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

11 **SEC. 105. INSPECTION OF DRUG AND DEVICE ESTABLISH-**
12 **MENTS.**

13 (a) EQUAL INSPECTION AUTHORITY FOR DOMESTIC
14 AND FOREIGN ESTABLISHMENTS; REFUSED INSPEC-
15 TIONS.—Section 510(h) (21 U.S.C. 360(h)) is amended
16 by—

17 (1) striking “Every” and inserting: “INSPEC-
18 TIONS.—

19 “(1) IN GENERAL.—Every”;

20 (2) striking “in any State”; and

21 (3) striking “704 and every such establish-
22 ment” and inserting “704.

23 “(2) REFUSED INSPECTION.—Any establish-
24 ment described in paragraph (1) shall not be consid-
25 ered duly registered under this section if an inspec-

1 tion of such establishment by the Secretary is re-
2 fused, delayed, or limited by—

3 “(A) the person who owns or operates such
4 establishment, or any agent or employee of such
5 person; or

6 “(B) any agent of a governmental author-
7 ity in the foreign country within which such es-
8 tablishment is located.

9 “(3) BIENNIAL INSPECTION SCHEDULE.—Ex-
10 cept as provided in paragraph (4), and except for es-
11 tablishments that manufacture, prepare, propagate,
12 compound, or process only inactive ingredients, every
13 establishment described in paragraph (1)”.

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

16 (1) IN GENERAL.—Section 510(h) (21 U.S.C.
17 360(h)), as amended by subsection (a), is further
18 amended by adding at the end the following:

19 “(4) RISK-BASED INSPECTION SCHEDULE.—

20 “(A) IN GENERAL.—The Secretary may by
21 regulation provide for an inspection schedule
22 for establishments described in paragraph (3)
23 (including those establishments that manufac-
24 ture, prepare, propagate, compound, or process

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

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

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

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

21 “(C) RISK-BASED FACTORS FOR MODI-
22 FYING FREQUENCY OF INSPECTIONS OF AN ES-
23 TABLISHMENT.—The Secretary may inspect an
24 establishment at a frequency different than that

1 required by the inspection schedule under sub-
2 paragraph (A) by considering—

3 “(i) the history of any safety problems
4 with any drug or device manufactured,
5 prepared, propagated, compounded, or
6 processed by the establishment;

7 “(ii) the record of inspections by the
8 Secretary of the establishment;

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

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

18 “(v) such other factors as the Sec-
19 retary determines are relevant to assessing
20 the risk presented by the drug or drugs, or
21 the device or devices, manufactured, pre-
22 pared, propagated, compounded, or proc-
23 essed by the establishment.”.

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

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

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

9 “(5) ANNUAL REPORT ON INSPECTIONS OF ES-
10 TABLISHMENTS.—Not later than February 1 of each
11 year, the Secretary shall submit a report to the Con-
12 gress about—

13 “(A) the appropriations used to inspect es-
14 tablishments registered pursuant to this section
15 in the previous fiscal year;

16 “(B) the number of domestic and foreign
17 establishments registered with the Secretary
18 under this section during the previous calendar
19 year;

20 “(C)(i) the number of domestic and foreign
21 establishments registered pursuant to this sec-
22 tion that the Secretary inspected in the pre-
23 vious fiscal year; and

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

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

4 “(D)(i) the number of domestic and for-
5 eign establishments registered pursuant to this
6 section that the Secretary did not inspect in the
7 previous fiscal year; and

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

13 “(E) information on the performance in
14 the previous fiscal year of the foreign
15 inspectorate established under section 704(h)
16 including—

17 “(i) the number of inspections con-
18 ducted with and without personnel who are
19 fluent in the language used in the estab-
20 lishment under inspection;

21 “(ii) the number of personnel in such
22 inspectorate;

23 “(iii) the countries in which such per-
24 sonnel conduct inspections;

1 “(iv) the offices in foreign countries
2 where such personnel are permanently sta-
3 tioned;

4 “(v) the number of personnel con-
5 ducting inspections in each country who
6 are fluent in the language or languages
7 used in the establishments of that country;
8 and

9 “(vi) the number of personnel who are
10 permanently stationed in each in-country
11 office who are fluent in the language or
12 languages used in the establishments of
13 that country; and

14 “(F) other information deemed relevant by
15 the Secretary.

16 “(6) PUBLIC AVAILABILITY OF ANNUAL RE-
17 PORTS.—The Secretary shall make the report re-
18 quired under paragraph (5) available to the public
19 on the Internet Web site of the Food and Drug Ad-
20 ministration.”.

1 **SEC. 106. LISTING OF DRUGS AND DEVICES; ENHANCED IN-**
2 **FORMATION TECHNOLOGY SYSTEM FOR REG-**
3 **ISTRATION AND LISTING; INACTIVE INGREDI-**
4 **ENTS.**

5 (a) LISTING OF DRUGS AND DEVICES.—Section
6 510(j) (21 U.S.C. 360(j)) is amended—

7 (1) by striking “(j)(1) Every person who reg-
8 isters with the Secretary under subsection (b), (c),
9 (d), or (i)” and inserting the following:

10 “(i) SUBMISSION OF LIST OF DRUGS AND DE-
11 VICES.—

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

14 (2) in paragraph (1)—

15 (A) in subparagraph (B)(i), by inserting
16 “in the case of a drug, the authority under this
17 Act that does not require such drug to be sub-
18 ject to section 505 and section 512,” after “la-
19 beling for such drug or device”;

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

25 (C) by moving the indentation of subpara-
26 graphs (A) through (D) 2 ems to the right; and

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

4 (3) in paragraph (2)—

5 (A) by striking “(2) Each person who reg-
6 isters with the Secretary under this section”
7 and inserting the following:

8 “(2) REPORT TO SECRETARY.—Every person
9 who registers with the Secretary under subsection
10 (b) or (c)”;

11 (B) by moving the indentation of subpara-
12 graphs (A) through (D) 2 ems to the right;

13 (4) in paragraph (3), by striking “(3) The Sec-
14 retary” and inserting the following:

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

16 (5) by adding at the end the following:

17 “(4) SUBMISSION FOR FINISHED DOSAGE
18 FORM.—Every person who files a list under para-
19 graph (1) or reports a list under paragraph (2) shall
20 submit with such list, for any drug that is a finished
21 dosage form, the identity of each establishment en-
22 gaged in the manufacture, preparation, propagation,
23 compounding, or processing of—

24 “(A) the finished dosage form;

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

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

2 or

3 “(D) any precursor ingredient of any such
4 active ingredient.”.

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

9 “(5) ELECTRONIC SUBMISSION AND MAINTEN-
10 NANCE OF INFORMATION.—Not later than October
11 1, 2010, the Secretary shall establish and main-
12 tain—

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

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

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

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

7 “(ii) includes the date of each inspec-
8 tion by the Secretary (with the Secretary’s
9 report on and assessment of the inspec-
10 tion) for each such establishment and such
11 other information on the inspectional
12 record and compliance history of the estab-
13 lishment as the Secretary deems necessary
14 and appropriate to assess the compliance
15 history of the establishment and, if appli-
16 cable, apply the inspection schedule under
17 subsection (h)(4) to such establishment;
18 and

19 “(iii) is interoperable and commu-
20 nicates with other relevant databases with-
21 in the Food and Drug Administration (in-
22 cluding a database for submission of infor-
23 mation under section 801(p)).”.

1 (c) DRUGS THAT ARE NOT APPROVED UNDER SEC-
2 TION 505 OR 512.—Section 510(f) (21 U.S.C. 360(f)) is
3 amended—

4 (1) by striking “(f) The Secretary” and insert-
5 ing the following:

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

7 “(1) IN GENERAL.—The Secretary”;

8 (2) by striking “subsection (j)” and inserting
9 “subsection (i)”; and

10 (3) by inserting at the end the following:

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

17 “(A) the drug;

18 “(B) the person who listed such drug; and

19 “(C) the authority under this Act that
20 does not require such drug to be subject to sec-
21 tion 505 and section 512, as provided by such
22 person in such list.”.

23 (d) INACTIVE INGREDIENTS.—

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

1 later than March 31, 2011, the Secretary of Health
2 and Human Services (referred to in this subsection
3 as the “Secretary”) shall—

4 (A) use the information populating the
5 electronic database referred to in section
6 510(j)(5) of the Federal, Food, Drug, and Cos-
7 metic Act, as added by subsection (b), to iden-
8 tify the establishments that manufacture, pre-
9 pare, propagate, compound, or process an active
10 ingredient of any drug listed in such database;
11 and

12 (B) complete an assessment as to whether
13 the exemption from registration in subsection
14 (e) of section 207.10 of title 21, Code of Fed-
15 eral Regulations, should be eliminated or modi-
16 fied.

17 (2) REGULATION TO ELIMINATE OR MODIFY
18 THE EXEMPTION FROM REGISTRATION FOR ESTAB-
19 LISHMENTS THAT MANUFACTURE DRUG INACTIVE
20 INGREDIENTS.—In the regulation provided for under
21 section 105(b)(2), the Secretary may propose to
22 eliminate or modify the exemption referred to in
23 paragraph (1)(B), as the Secretary deems appro-
24 priate, after having completed the assessment under
25 such paragraph.

1 **SEC. 107. FEES RELATED TO ESTABLISHMENT INSPEC-**
2 **TIONS.**

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

5 **“PART 6—FEES RELATED TO ESTABLISHMENT**
6 **INSPECTIONS**

7 **“SEC. 743. AUTHORITY TO ASSESS AND USE FEES.**

8 “(a) 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
21 is—

22 “(i) engaged in the manufacture,
23 preparation, propagation, compounding, or
24 processing of a device classified in class II
25 or class III; and

1 “(ii) subject to inspection under sub-
2 section (h)(3) or (h)(4) of section 510, as
3 applicable; or

4 “(B) an establishment within any foreign
5 country that is—

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

11 “(ii) subject to inspection under sub-
12 section (h)(3) or (h)(4) of section 510, as
13 applicable.

14 “(3) DEVICE REGISTRATION AND INSPECTION
15 ACTIVITIES.—The term ‘device registration and in-
16 spection activities’ means the following activities of
17 the Secretary:

18 “(A) The registration of device establish-
19 ments under subsections (b) and (c) of section
20 510.

21 “(B) The listing of devices under section
22 510(i), including the activities for devices de-
23 scribed in section 510(i)(5).

1 “(C) The inspection of device establish-
2 ments under section 510(h)(3) or, if applicable,
3 section 510(h)(4).

4 “(D) The review of inspection reports from
5 such inspections.

6 “(E) Any action under this Act pursuant
7 to such registration, listing, inspections, or re-
8 views.

9 “(4) DRUG ESTABLISHMENT.—The term ‘drug
10 establishment’ means—

11 “(A) an establishment in any State that
12 is—

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

16 “(ii) subject to inspection under sub-
17 section (h)(3) or (h)(4) of section 510, as
18 applicable; or

19 “(B) an establishment within any foreign
20 country that is—

21 “(i) engaged in the manufacture,
22 preparation, propagation, compounding, or
23 processing of a drug; and

1 “(ii) subject to inspection under sub-
2 section (h)(3) or (h)(4) of section 510, as
3 applicable.

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

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

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

14 “(C) The inspection of drug establishments
15 under section 510(h)(3) or, if applicable, sec-
16 tion 510(h)(4).

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

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

22 “(6) PERSON.—The term ‘person’ includes an
23 affiliate thereof.

24 “(b) TYPES OF FEES.—

1 “(1) DRUG INSPECTION FEES.—Beginning in
2 fiscal year 2010, the Secretary shall collect drug in-
3 spection fees in accordance with this section as fol-
4 lows:

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

11 “(B) REDUCTION FOR POSITRON EMISSION
12 TOMOGRAPHY DRUGS.—The drug inspection fee
13 for a drug establishment engaged solely in the
14 manufacture, preparation, propagation,
15 compounding, or processing of 1 or more drugs
16 to which section 736(a)(2)(C)(i) applies shall be
17 one-sixth of the drug inspection fee otherwise
18 applicable to such establishment under sub-
19 section (c)(1).

20 “(C) EXEMPTION FOR CERTAIN POSITRON
21 EMISSION TOMOGRAPHY DRUGS AND CERTAIN
22 ORPHAN DRUGS.—A drug establishment en-
23 gaged solely in the manufacture, preparation,
24 propagation, compounding, or processing of 1
25 or more drugs to which section 736(a)(2)(C)(ii)

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

3 “(D) WAIVER OR REDUCTION.—The Sec-
4 retary shall grant a waiver from or reduction of
5 the drug inspection fee as provided for under
6 section 736(d).

7 “(2) DEVICE INSPECTION FEES.—Beginning in
8 fiscal year 2010, the Secretary shall collect device
9 inspection fees in accordance with this section as fol-
10 lows:

11 “(A) IN GENERAL.—Except as provided
12 under subparagraphs (B) and (C), each person
13 that during a fiscal year registers a device es-
14 tablishment under subsection (b) or (c) of sec-
15 tion 510 shall pay a device inspection fee estab-
16 lished under subsection (c)(2).

17 “(B) REDUCTION FOR SMALL BUSI-
18 NESSES.—The device inspection fee for a device
19 establishment owned or operated by an entity
20 that qualifies as a small business under section
21 738(d)(2) shall be one-fourth of the device in-
22 spection fee otherwise applicable to such estab-
23 lishment under subsection (c)(2).

24 “(C) EXEMPTION FOR CERTAIN STATE OR
25 FEDERAL GOVERNMENT ESTABLISHMENTS.—A

1 device establishment operated by a State or
2 Federal government entity shall not be assessed
3 a device inspection fee unless a device classified
4 in class II or class III manufactured by the es-
5 tablishment is to be distributed commercially.

6 “(c) FEE AMOUNTS.—

7 “(1) DRUG INSPECTION FEE AMOUNTS.—

8 “(A) IN GENERAL.—Beginning with fiscal
9 year 2010, the Secretary shall, not later than
10 30 days after the amount has been appro-
11 priated for a fiscal year in an appropriations
12 Act as described in subsection (e)(1), establish
13 for such fiscal year, and publish in the Federal
14 Register, drug inspection fees, based on the
15 amount provided for in advance in appropria-
16 tions Acts for such fees as described in sub-
17 section (e)(1), considering—

18 “(i) the requirement described under
19 subparagraph (C);

20 “(ii) the reductions required under
21 subparagraphs (B) and (D) of subsection
22 (b)(1); and

23 “(iii) the number of drug establish-
24 ments subject to such a fee, considering

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

3 “(B) FOREIGN DRUG ESTABLISHMENT.—
4 For a foreign drug establishment, the drug in-
5 spection fee shall be—

6 “ (i) the applicable drug inspection fee
7 under subparagraph (A), plus

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

9 “ (I) travel to and within, and
10 lodging in, the country in which the
11 establishment is located for the indi-
12 vidual or individuals who conduct the
13 inspection of the establishment; and

14 “ (II) a translator for the inspec-
15 tion of the establishment.

16 “(C) PROPORTIONAL FEES.—

17 “ (i) INSPECTIONS MORE FREQUENT
18 THAN EVERY 2 YEARS.—The drug inspec-
19 tion fee for a drug establishment that
20 under the inspection schedule provided for
21 under section 510(h)(4) is to be inspected
22 more frequently than once in every 2-year
23 period shall be more than the drug inspec-
24 tion fee for a drug establishment that
25 under such schedule is to be inspected once

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

5 “(ii) INSPECTIONS LESS FREQUENT
6 THAN EVERY 2 YEARS.—The drug inspec-
7 tion fee for a drug establishment that
8 under the inspection schedule provided for
9 under section 510(h)(4) is to be inspected
10 less frequently than once in every 2-year
11 period shall be less than the drug inspec-
12 tion fee for a drug establishment that
13 under such schedule is to be inspected once
14 in every 2-year period, in proportion to the
15 factor by which such establishment is to be
16 inspected less frequently than once in every
17 2-year period.

18 “(2) DEVICE INSPECTION FEE AMOUNTS.—

19 “(A) IN GENERAL.—Beginning with fiscal
20 year 2010, the Secretary shall, not later than
21 30 days after the amount has been appro-
22 priated for a fiscal year in an appropriations
23 Act as described in subsection (e)(2) establish
24 for such fiscal year, and publish in the Federal
25 Register device inspection fees, based on the

1 amount provided for in advance in appropria-
2 tions Acts for such fees as described in sub-
3 section (e)(2) and considering—

4 “(i) the requirement described under
5 subparagraph (C);

6 “(ii) the reduction required under
7 subsection (b)(2)(B); and

8 “(iii) the number of device establish-
9 ments subject to such a fee, considering
10 subsection (b)(2)(C).

11 “(B) FOREIGN DEVICE ESTABLISHMENT.—
12 For a foreign device establishment, the device
13 inspection fee shall be—

14 “(i) the applicable device inspection
15 fee under subparagraph (A), plus

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

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

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

24 “(C) PROPORTIONAL FEES.—

1 “(i) INSPECTIONS MORE FREQUENT
2 THAN EVERY 2 YEARS.—The device inspec-
3 tion fee for a device establishment that
4 under the inspection schedule provided for
5 under section 510(h)(4) is to be inspected
6 more frequently than once in every 2-year
7 period shall be more than the device in-
8 spection fee for a device establishment that
9 under such schedule is to be inspected once
10 in every 2-year period, in proportion to the
11 factor by which such device establishment
12 is to be inspected more frequently than
13 once in every 2-year period.

14 “(ii) INSPECTIONS LESS FREQUENT
15 THAN EVERY 2 YEARS.—The device inspec-
16 tion fee for a device establishment that
17 under the inspection schedule provided for
18 under section 510(h)(4) is to be inspected
19 less frequently than once in every 2-year
20 period shall be less than the device inspec-
21 tion fee for a device establishment that
22 under such schedule is to be inspected once
23 in every 2-year period, in proportion to the
24 factor by which such establishment is to be

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

3 “(d) EFFECT OF FAILURE TO PAY FEES.—

4 “(1) DRUG INSPECTION FEE.—An establish-
5 ment subject to a drug inspection fee under sub-
6 section (b) shall be considered not to be registered
7 under section 510 until all fees under this section
8 owed by the person required to register such estab-
9 lishment have been paid.

10 “(2) DEVICE INSPECTION FEE.—An establish-
11 ment subject to a device inspection fee under sub-
12 section (b) shall be considered not to be registered
13 under section 510 until all fees under this section
14 owed by the person required to register such estab-
15 lishment have been paid.

16 “(e) CREDITING AND AVAILABILITY OF FEES.—

17 “(1) DRUG INSPECTION FEES.—Drug inspec-
18 tion fees authorized under subsection (b) shall be
19 collected and available for obligation only to the ex-
20 tent and in the amount provided in advance in ap-
21 propriations Acts. Such fees are authorized to re-
22 main available until expended. Such sums as may be
23 necessary may be transferred from the Food and
24 Drug Administration salaries and expenses appro-
25 priation account without fiscal year limitation to

1 such appropriation account for salaries and expenses
2 with such fiscal year limitation. The sums trans-
3 ferred shall be available solely for drug registration
4 and inspection activities.

5 “(2) DEVICE INSPECTION FEES.—Device in-
6 spection fees authorized under subsection (b) shall
7 be collected and available for obligation only to the
8 extent and in the amount provided in advance in ap-
9 propriations Acts. Such fees are authorized to re-
10 main available until expended. Such sums as may be
11 necessary may be transferred from the Food and
12 Drug Administration salaries and expenses appro-
13 priation account without fiscal year limitation to
14 such appropriation account for salaries and expenses
15 with such fiscal year limitation. The sums trans-
16 ferred shall be available solely for device registration
17 and inspection activities.

18 “(3) AUTHORIZATION OF APPROPRIATIONS.—

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

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

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

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

18 “(h) REPORTS.—

19 “(1) PERFORMANCE REPORTS.—Beginning for
20 fiscal year 2010, not later than 120 days after the
21 end of each fiscal year for which fees are collected
22 under this section, the Secretary shall prepare and
23 submit to the Committee on Health, Education,
24 Labor, and Pensions and the Committee on Appro-
25 priations of the Senate and the Committee on En-

1 energy and Commerce and the Committee on Appro-
2 priations of the House of Representatives—

3 “(A) a report concerning the performance
4 of the Food and Drug Administration with re-
5 spect to drug registration and inspection activi-
6 ties during such fiscal year; and

7 “(B) a report concerning the performance
8 of the Food and Drug Administration with re-
9 spect to device registration and inspection ac-
10 tivities during such fiscal year.

11 “(2) FISCAL REPORT.—Beginning for fiscal
12 year 2010, not later than 120 days after the end of
13 each fiscal year for which fees are collected under
14 this section, the Secretary shall prepare and submit
15 to the Committee on Health, Education, Labor, and
16 Pensions and the Committee on Appropriations of
17 the Senate and the Committee on Energy and Com-
18 merce and the Committee on Appropriations of the
19 House of Representatives—

20 “(A) a report on—

21 “(i) the implementation of the author-
22 ity for drug establishment fees during such
23 fiscal year;

1 “(ii) the use, by the Food and Drug
2 Administration, of such fees collected for
3 such fiscal year; and

4 “(iii) the amount necessary to carry
5 out drug registration and inspection activi-
6 ties for the subsequent fiscal year (with a
7 detailed explanation of the methodology
8 used to determine such amount); and

9 “(B) a report on—

10 “(i) the implementation of the author-
11 ity for device establishment fees during
12 such fiscal year;

13 “(ii) the use, by the Food and Drug
14 Administration, of such fees collected for
15 such fiscal year; and

16 “(iii) the amount necessary to carry
17 out device registration and inspection ac-
18 tivities for the subsequent fiscal year (with
19 a detailed explanation of the methodology
20 used to determine such amount).

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

1 **SEC. 108. ELECTRONIC SUBMISSION AND CERTIFICATION**
2 **OF REGISTRATIONS AND LISTINGS.**

3 Section 510 (21 U.S.C. 360), as amended by section
4 106, is further amended by—

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

6 “(j) **ELECTRONIC SUBMISSION AND CERTIFI-**
7 **CATION.**—Registrations and listings under this section (in-
8 cluding the submission of updated information) shall be
9 submitted and certified to the Secretary through the elec-
10 tronic portal described in subsection (i)(5)(A) (or by other
11 electronic means until the Secretary establishes such por-
12 tal) unless the Secretary grants a request for waiver of
13 such requirement because use of electronic means is not
14 reasonable for the person requesting such waiver.”; and

15 (2) striking subsection (p).

16 **SEC. 109. TECHNICAL AND CONFORMING AMENDMENTS.**

17 (a) **SECTION 510.**—

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

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

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

1 (B) by striking “subsection (j)” and insert-
2 ing “subsection (i)”.

3 (2) EXEMPTIONS.—Section 510(g) (21 U.S.C.
4 360(g)) is amended by striking “(g) The foregoing”
5 and inserting the following:

6 “(g) EXEMPTIONS.—The foregoing”.

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

10 “(k) DEVICE REPORTS.—Each person”.

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

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

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

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

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

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

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

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

1 (6) 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 (7) 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 (b) OTHER PROVISIONS.—The Federal Food, Drug,
23 and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

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

1 (2) in section 301(p)—

2 (A) by striking “510(j)” and inserting
3 “510(i)”; and

4 (B) by striking “510(j)(2)” and inserting
5 “510(i)(2)”;

6 (3) in section 502(o), by striking “510(j)” and
7 inserting “510(i)”; and

8 (4) in section 801(a), by striking “subsection
9 (i) of section 510” and inserting “subsection (c) of
10 section 510”.

11 **SEC. 110. EFFECTIVE DATE.**

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

15 **Subtitle B—Ensuring Identity and**
16 **Sourcing of Drug Ingredients**

17 **SEC. 111. COMPENDIAL MODERNIZATION.**

18 (a) IN GENERAL.—Section 501(b) (21 U.S.C.
19 351(b)) is amended by—

20 (1) inserting “or of the appropriate body
21 charged with the revision of such compendium” after
22 “are, in the judgment of the Secretary”;

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

1 (3) striking “attention of the appropriate body
2 charged with the revision of such compendium” and
3 inserting “attention of such body”; and

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

9 (b) RULEMAKING.—Section 701(e)(1) (21 U.S.C.
10 371(e)(1)) is amended in the first sentence by deleting
11 “501(b),”.

12 (c) ASSESSMENT.—The Secretary of Health and
13 Human Services, in consultation with the United States
14 Pharmacopeia, other drug regulatory agencies, academic
15 experts, and industry, shall periodically assess the tests
16 and methods of assay for drugs found in official com-
17 pendia to—

18 (1) identify, considering current scientific meth-
19 ods, which tests and methods of assay are no longer
20 scientifically sound and appropriate and of sufficient
21 analytical precision and specificity for their purpose;
22 and

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

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

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

9 **SEC. 112. TESTING OF DRUG PURITY AND IDENTITY.**

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

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

18 “(1) impurities; and

19 “(2) contaminants and adulterants reasonably
20 likely to be present in or on such article.”.

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

23 Section 501 (21 U.S.C. 351), as amended by section
24 112, is further amended by adding at the end the fol-
25 lowing:

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

4 “(1) identify each establishment that manufac-
5 tured, processed, packed, or held each article that is
6 a component of the drug or a precursor ingredient
7 of such a component; and

8 “(2) establish, including through appropriate
9 and periodic audits of the establishments described
10 in paragraph (1), that the drug and each such arti-
11 cle is not adulterated under this section or mis-
12 branded under section 502.”.

13 **SEC. 114. CURRENT MANUFACTURING SCIENCE.**

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

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

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

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

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

4 “(1) the country of manufacture of the drug or
5 device; and

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

8 **SEC. 116. EFFECTIVE DATE; IMPLEMENTATION.**

9 (a) EFFECTIVE DATE.—Sections 112, 113, 114, and
10 115, and the amendments made by such sections, shall
11 take effect on the date that is 2 years after the date of
12 enactment of this Act.

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

21 **Subtitle C—Ensuring Standards for**
22 **Imported Drugs**

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

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

1 114, is further amended by striking “; or (3)” and insert-
2 ing “or (E) if it is a drug and it is not distributed,
3 shipped, warehoused, brokered, imported, or conveyed in
4 conformity with current good distribution and import
5 practices to assure the identity, strength, quality, and pu-
6 rity of the drug; or (3)”.

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

9 (1) in subsection (a)—

10 (A) in paragraph (1)(A), by inserting
11 “(and in the case of drugs, distributed, shipped,
12 warehoused, or conveyed),” after “or held,”;
13 and

14 (B) in the third sentence—

15 (i) by inserting “(and in the case of
16 drugs, distributed, shipped, warehoused, or
17 conveyed),” after “packed, or held,”; and

18 (ii) by inserting “, (and in the case of
19 drugs, distributed, shipped, warehoused, or
20 conveyed),” after “transported, or held”;
21 and

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

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

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

5 (1) in subsection (o), by striking “drug or”;
6 and

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

8 “(p)(1) Except as provided in paragraph (2), a drug,
9 or an article that appears to be a drug, in finished dosage
10 form, an article that is intended to be a component of a
11 drug, or an article that is intended to be a precursor ingre-
12 dient of such a component that is being imported or of-
13 fered for import into the United States shall be refused
14 admission unless the person importing or offering for im-
15 port such drug or article provides to the Secretary, at the
16 time of being imported or offered for import (and through
17 an electronic portal as provided by the Secretary)—

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

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

23 “(i) the listing number under section
24 510(e) of such drug;

25 “(ii) the D-U-N-S number of each estab-
26 lishment in which such drug was manufactured,

1 prepared, propagated, compounded, or proc-
2 essed;

3 “(iii) the new drug application number, the
4 biologics license application number, the abbrev-
5 viated new drug application number, the num-
6 ber of the investigational new drug exemption
7 for the drug, or the drug monograph number,
8 as applicable;

9 “(iv) the label required by the new drug
10 application, the biologics license application
11 number, abbreviated new drug application, in-
12 vestigational new drug exemption, or drug
13 monograph, as applicable; and

14 “(v) the record of inspections by the Sec-
15 retary;

16 “(C) for an article that is an active ingredient
17 of a drug, or an article that is a precursor ingredient
18 of an active ingredient—

19 “(i) the listing number under section
20 510(e) of such article;

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

1 “(iii) the new drug application number, the
2 biologics license application number, the abbrevi-
3 ated new drug application number, the num-
4 ber of the investigational new drug exemption
5 for the drug, or the drug monograph number,
6 as applicable, of the finished dosage form for
7 which such article is intended;

8 “(iv) the label under a regulatory exemp-
9 tion from section 502(f)(1); and

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

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

18 “(i) the listing number under section
19 510(e) of such article;

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

24 “(iii) the new drug application number, the
25 biologics license application number, the abbrevi-

1 viated new drug application number, the num-
2 ber of the investigational new drug exemption
3 for the drug, or the drug monograph number,
4 as applicable, of the finished dosage form for
5 which such article is intended; and

6 “(iv)(I) the record of inspections by the
7 Secretary or by a governmental authority re-
8 sponsible for drugs deemed adequate by the
9 Secretary;

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

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

15 “(2) Paragraph (1) shall not apply to—

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

17 “(B) an article that—

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

21 “(ii) is not deemed to be adulterated or
22 misbranded under subsection (e)(1).”.

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

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

7 **SEC. 125. EFFECTIVE DATE.**

8 This subtitle, and the amendments made by this sub-
9 title, shall take effect on the date that is 30 days after
10 the date of enactment of this Act.

11 **Subtitle D—Enhanced Response to**
12 **Unsafe Drugs**

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

14 (a) IN GENERAL.—Section 304(g) (21 U.S.C.
15 334(g)) is amended—

16 (1) in paragraph (1)—

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

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

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

1 (b) TECHNICAL AMENDMENTS.—Section 304(g)(1)
2 (21 U.S.C. 334(g)(1)), as amended by subsection (a), is
3 further amended by—

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

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

7 “(B) Regulations”;

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

10 “(C) A detention”; and

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

13 “(D) Any person”.

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

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

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

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

2 “(a) ORDER TO CEASE DISTRIBUTION; NOTIFICA-
3 TION; PROCESS.—

4 “(1) ORDER TO CEASE DISTRIBUTION; NOTIFI-
5 CATION.—If the Secretary finds that there is a rea-
6 sonable probability that a drug intended for human
7 use would cause serious, adverse health con-
8 sequences or death, the Secretary shall issue an
9 order requiring the appropriate person (including
10 the manufacturers, importers, distributors, or retail-
11 ers of the drug)—

12 “(A) to immediately cease distribution of
13 such drug; and

14 “(B) to immediately notify health profes-
15 sionals and hospitals and other health care fa-
16 cilities of the order and to instruct such profes-
17 sionals and facilities to cease use of such drug.

18 “(2) PROCESS.—The order under paragraph
19 (1) shall provide the person subject to the order with
20 an opportunity for an informal hearing, to be held
21 not later than 10 days after the date of the issuance
22 of the order, on the actions required by the order
23 and on whether the order should be amended to re-
24 quire a recall of such drug. If, after providing an op-
25 portunity for such a hearing, the Secretary deter-
26 mines that inadequate grounds exist to support the

1 actions required by the order, the Secretary shall va-
2 cate the order.

3 “(b) ORDER TO RECALL.—

4 “(1) IN GENERAL.—If, after providing an op-
5 portunity for an informal hearing under subsection
6 (a), the Secretary determines that the order should
7 be amended to include a recall of the drug with re-
8 spect to which the order was issued, the Secretary
9 shall, except as provided in paragraph (2), amend
10 the order to require a recall. The Secretary shall
11 specify a timetable in which the drug recall will
12 occur and shall require periodic reports to the Sec-
13 retary describing the progress of the recall.

14 “(2) AMENDED ORDER.—An amended order
15 under paragraph (1)—

16 “(A) shall—

17 “(i) not include recall of a drug from
18 individuals; and

19 “(ii) not include recall of a drug from
20 hospitals and other health care facilities if
21 the Secretary determines that the risk of
22 recalling such drug from the facilities pre-
23 sents a greater health risk than the health
24 risk of not recalling the drug from use;
25 and

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

4 “(2) REPORTS.—The manufacturer of a drug
5 shall submit reports to the Secretary about any de-
6 fect of the drug that the Secretary specifies in guid-
7 ance in accordance with a schedule specified by the
8 Secretary in such guidance.

9 “(3) INVESTIGATION AND CORRECTIVE AC-
10 TION.—The manufacturer of a drug shall—

11 “(A) investigate the cause of any defect of
12 the drug; and

13 “(B) take appropriate corrective action.

14 “(4) DESTRUCTION.—If a drug may cause in-
15 jury or death because of a defect, the manufacturer
16 shall, after the investigation of the defect required
17 under paragraph (3), destroy the drug and shall not
18 recondition the drug.

19 “(5) DEFECT.—For purposes of this sub-
20 section, a defect of a drug shall include—

21 “(A) microbiological or other contamina-
22 tion;

23 “(B) significant chemical, physical, or
24 other change or deterioration;

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

3 “(D) any failure of 1 or more batches of
4 the drug to meet a specification established for
5 it.”.

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

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

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

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

15 **SEC. 134. CIVIL MONEY PENALTIES.**

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

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

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

23 (3) by inserting after paragraph (4) the fol-
24 lowing:

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

7 “(ii) Each day during which a violation con-
8 tinues shall be considered a separate violation under
9 clause (i).

10 “(B)(i) Any manufacturer, distributor, im-
11 porter, broker, or filer that knowingly reports or en-
12 ters false or misleading data on documents related
13 to the importation of a drug shall be liable to the
14 United States for a civil penalty not to exceed
15 \$150,000.

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

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

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

1 “(C) such person has actual knowledge of
2 the information in such submission (and, if
3 such submission is an annual report, in any
4 submission of any other information with re-
5 spect to such application or report for which a
6 certification under this paragraph is not other-
7 wise required);

8 “(D) the information in such submission
9 (and, if such submission is an annual report, in
10 any submission of any other information with
11 respect to such application or report for which
12 a certification under this paragraph is not oth-
13 erwise required) complies with such require-
14 ments;

15 “(E) the information in such submission
16 (and, if such submission is an annual report, in
17 any submission of any other information with
18 respect to such application or report for which
19 a certification under this paragraph is not oth-
20 erwise required) is not false or misleading; and

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

1 mission, or the full reports of which the sponsor
2 of such submission had access, have been sub-
3 mitted to the Food and Drug Administration.

4 “(2) DEFINITIONS.—In this section:

5 “(A) RESPONSIBLE PERSON.—The term
6 ‘responsible person’ means, with respect to a
7 submission, a senior officer or director of the
8 sponsor of such submission with knowledge of,
9 and management responsibility for, such sub-
10 mission.

11 “(B) SUBMISSION.—The term ‘submission’
12 means—

13 “(i) new drug application under sec-
14 tion 505(b);

15 “(ii) an abbreviated new drug applica-
16 tion under section 505(j);

17 “(iii) a biologics license application
18 under section 351 of the Public Health
19 Service Act;

20 “(iv) an application for an investiga-
21 tional new drug exemption under section
22 505(i);

23 “(v) a new animal drug application
24 under section 512(b);

1 “(vi) an abbreviated new animal drug
2 application under section 512(b);

3 “(vii) an application under section
4 571;

5 “(viii) a request under section 572;

6 “(ix) or a major amendment, supple-
7 ment, or an annual report submitted to the
8 Secretary with respect to any application
9 or request described in clauses (i) through
10 (viii);

11 “(x) a record or report related to the
12 safety or effectiveness of a drug subject to
13 section 505 or such section 351, to an ad-
14 verse event under section 505(k) or 760, or
15 to a postapproval study or postapproval
16 clinical trial under section 505(o); or

17 “(xi) a list under section 510(i) in-
18 cluding a drug.

19 “(b) INSPECTIONS.—

20 “(1) IN GENERAL.—If the Secretary deter-
21 mines, after notice and opportunity for an informal
22 hearing, that a sponsor described in subsection
23 (a)(2) knew or should have known that the informa-
24 tion in a submission described in subsection (a)(1)
25 did not comply with the requirements of this Act or

1 was false or misleading, the Secretary may provide
2 that any factory, warehouse, establishment, or con-
3 sulting laboratory related to such noncompliance or
4 such false or misleading information shall be in-
5 spected periodically by officers or employees duly
6 designated by the Secretary for a period of time de-
7 termined by the Secretary, not to exceed 5 years.

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

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

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

13 “(a) CERTIFICATION.—

14 “(1) CERTIFICATION BY SPONSOR.—A submis-
15 sion, when submitted to the Secretary, shall include
16 a certification, in writing and under penalty of per-
17 jury, by the responsible person that—

18 “(A) such person has actual knowledge of
19 the requirements under this Act with respect to
20 the device that is the subject of such submis-
21 sion;

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

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

1 such submission is an annual report, in any
2 submission of any other information with re-
3 spect to such application or report for which a
4 certification under this paragraph is not other-
5 wise required);

6 “(D) the information in such submission
7 (and, if such submission is an annual report, in
8 any submission of any other information with
9 respect to such application or report for which
10 a certification under this paragraph is not oth-
11 erwise required) complies with such require-
12 ments;

13 “(E) the information in such submission
14 (and, if such submission is an annual report, in
15 any submission of any other information with
16 respect to such application or report for which
17 a certification under this paragraph is not oth-
18 erwise required) is not false or misleading; and

19 “(F) full reports of all clinical trials and
20 postmarket studies (whether conducted within
21 or outside the United States) related to the
22 safety or effectiveness of the device under re-
23 view that were funded by the sponsor of such
24 submission, or the full reports of which the
25 sponsor of such submission had access, have

1 been submitted to the Food and Drug Adminis-
2 tration.

3 “(2) DEFINITIONS.—In this section:

4 “(A) RESPONSIBLE PERSON.—The term
5 ‘responsible person’ means, with respect to a
6 submission, a senior officer or director of the
7 sponsor of such submission with knowledge of,
8 and management responsibility for, such sub-
9 mission.

10 “(B) SUBMISSION.—The term ‘submission’
11 means—

12 “(i) an application or report for pre-
13 market approval under section 515;

14 “(ii) an application for an investiga-
15 tional device exemption under section
16 520(g);

17 “(iii) a report under section 510(k);

18 “(iv) an application for a humani-
19 tarian device exemption under section
20 520(m);

21 “(v) a major amendment, supplement,
22 or an annual report submitted to the Sec-
23 retary with respect to any application or
24 report described in clauses (i) through (iv);

1 “(vi) a record or report related to an
2 adverse event, a report, or postmarket sur-
3 veillance under section 519 or 522; or

4 “(vii) a list under section 510(i) in-
5 cluding a device,

6 “(b) INSPECTIONS.—

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

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

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

1 **“§ 1041. Certifications related to drug and device in-**
2 **formation**

3 “(a) If a responsible person—

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

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

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

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

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

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

22 “(b) In this section:

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

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

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

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

6 “(2) The term ‘submission’ means—

7 “(A) with respect to a drug—

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

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

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

16 “(iv) an application for an investiga-
17 tional new drug exemption under section
18 505(i) of the Federal Food, Drug, and
19 Cosmetic Act;

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

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

1 “(vii) an application under section
2 571 of such Act;

3 “(viii) a request under section 572 of
4 such Act;

5 “(ix) a major amendment, supple-
6 ment, or other information submitted to
7 the Secretary with respect to any applica-
8 tion or request described in clauses (i)
9 through (viii);

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

19 “(xi) a list under section 510(i) in-
20 cluding the drug; and

21 “(B) with respect to a device—

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

1 “(ii) an application for an investiga-
2 tional device exemption under section
3 520(g) of such Act;

4 “(iii) a report under section 510(k) of
5 such Act;

6 “(iv) an application for a humani-
7 tarian device exemption under section
8 520(m) of such Act;

9 “(v) a major amendment, supplement,
10 or other information submitted to the Sec-
11 retary with respect to any application or
12 report described in clauses (i) through (iv);
13 or

14 “(vi) a record or report related to an
15 adverse event, a report, or postmarket sur-
16 veillance under section 519 or 522 of such
17 Act; or

18 “(vii) a list under section 510(i) in-
19 cluding the device.”.

20 (d) CONFORMING AMENDMENT.—The table of sec-
21 tions for chapter 47 of title 18, United States Code, is
22 amended by inserting after the item relating to section
23 1040 the following:

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

1 **SEC. 142. WHISTLEBLOWER PROTECTIONS.**

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

4 **“SEC. 911. PROTECTIONS FOR EMPLOYEES WHO REFUSE TO**
5 **VIOLATE, OR WHO DISCLOSE VIOLATIONS OF,**
6 **THIS ACT OR SECTION 351 OF THE PUBLIC**
7 **HEALTH SERVICE ACT.**

8 “(a) IN GENERAL.—

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

19 “(A) to provide information, cause infor-
20 mation to be provided, or otherwise assist in
21 any investigation regarding any conduct which
22 the employee reasonably believes constitutes a
23 violation of any section of this Act or the Public
24 Health Service Act described under paragraph
25 (2), any other provision of Federal law relating
26 to the safety or effectiveness of a drug, biologi-

1 cal product, or device, or any provision of Fed-
2 eral law prohibiting fraud against the Food and
3 Drug Administration, if the information or as-
4 sistance is provided to, or an investigation
5 stemming from the provided information is con-
6 ducted by—

7 “(i) a Federal regulatory or law en-
8 forcement agency;

9 “(ii) any Member of Congress or any
10 committee of Congress; or

11 “(iii) a person with supervisory au-
12 thority over the employee (or such other
13 person working for the employer who has
14 the authority to investigate, discover, or
15 terminate the misconduct);

16 “(B) to file, cause to be filed, testify, par-
17 ticipate in, or otherwise assist in a proceeding
18 filed or about to be filed (with any knowledge
19 of the employer) relating to an alleged violation
20 of any section of this Act or the Public Health
21 Service Act described under paragraph (2), any
22 other provision of Federal law relating to the
23 safety or effectiveness of a drug, biological
24 product, or device, or any provision of Federal

1 law prohibiting fraud against the Food and
2 Drug Administration; or

3 “(C) to refuse to violate or assist in the
4 violation of any section of this Act or the Public
5 Health Service Act listed described paragraph
6 (2), any other provision of Federal law relating
7 to the safety or effectiveness of a drug, biologi-
8 cal product, or device, or any provision of Fed-
9 eral law prohibiting fraud against the Food and
10 Drug Administration.

11 “(2) SUBMISSION.—A submission described in
12 this paragraph is—

13 “(A) a new drug application under section
14 505(b);

15 “(B) an abbreviated new drug application
16 under section 505(j);

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

19 “(D) an application for an investigational
20 new drug exemption under section 505(i);

21 “(E) a new animal drug application under
22 section 512(b);

23 “(F) an abbreviated new animal drug ap-
24 plication under section 512(b);

25 “(G) an application under section 571;

1 “(H) a request under section 572;

2 “(I) an application or report for premarket
3 approval under section 515;

4 “(J) an application for an investigational
5 device exemption under section 520(g);

6 “(K) a report under section 510(k);

7 “(L) an application for a humanitarian de-
8 vice exemption under section 520(m);

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

13 “(N) or a record or report related to an
14 adverse event, a postapproval study, a post-
15 approval clinical trial, a report, or postmarket
16 surveillance under section 505(k), 505(o), 519,
17 522, or 760.

18 “(b) ENFORCEMENT ACTION.—

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

23 “(A) filing a complaint with the Secretary
24 of Labor; or

1 “(B) if the Secretary of Labor has not
2 issued a final decision within 210 days of the
3 filing of the complaint and there is no showing
4 that such delay is due to the bad faith of the
5 claimant, bringing an action at law or equity
6 for de novo review in the appropriate district
7 court of the United States, which shall have ju-
8 risdiction over such an action without regard to
9 the amount in controversy.

10 “(2) PROCEDURE.—

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

15 “(B) EXCEPTION.—Notification in an ac-
16 tion under paragraph (1) shall be made in ac-
17 cordance with section 42121(b)(1) of title 49,
18 United States Code, except that such notifica-
19 tion shall be made to the person named in the
20 complaint and to the employer.

21 “(C) BURDENS OF PROOF.—An action
22 brought under paragraph (1)(B) shall be gov-
23 erned by the legal burdens of proof set forth in
24 section 42121(b) of title 49, United States
25 Code.

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

5 “(c) REMEDIES.—

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

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

11 “(A) reinstatement with the same seniority
12 status that the employee would have had, but
13 for the discrimination;

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

16 “(C) compensation for any special damages
17 sustained as a result of the discrimination, in-
18 cluding litigation costs, expert witness fees, and
19 reasonable attorney fees.

20 “(d) RIGHTS RETAINED BY EMPLOYEE.—Nothing in
21 this section shall be deemed to diminish the rights, privi-
22 leges, or remedies of any employee under any Federal or
23 State law or under any collective bargaining agreement.
24 The rights and remedies in this section may not be waived

1 by any agreement, policy, form, or condition of employ-
2 ment.”.

3 **SEC. 143. STUDY BY THE INSTITUTE OF MEDICINE REGARD-**
4 **ING THE REVIEW OF MEDICAL DEVICES.**

5 (a) IN GENERAL.—The Secretary of Health and
6 Human Services shall enter into a contract with the Insti-
7 tute of Medicine to conduct a study to—

8 (1) evaluate the organizational structure and
9 operations of the Food and Drug Administration
10 with respect to the review of medical devices for
11 clearance under section 510(k) of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 360(k)) and for
13 premarket approval under section 515 of such Act
14 (21 U.S.C. 360e);

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

18 (3) identify strengths, weaknesses, and limita-
19 tions of the system used by such Administration to
20 conduct such reviews.

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

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

4 (1) describes the findings of such study; and

5 (2) makes recommendations regarding the orga-
6 nization structure and operations of the Food and
7 Drug Administration, legislation, and regulation to
8 improve or enhance the review of medical devices by
9 such Administration.

10 **TITLE II—GENERAL AUTHORI-**
11 **TIES TO ENHANCE FOOD AND**
12 **DRUG ADMINISTRATION**
13 **OVERSIGHT OF PRODUCTS**
14 **FROM A GLOBAL MARKET**

15 **SEC. 201. DEDICATED FOREIGN INSPECTORATE.**

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

18 “(h) FOREIGN INSPECTORATE.—

19 “(1) IN GENERAL.—The Secretary shall estab-
20 lish and maintain a corps of inspectors dedicated to
21 inspections of foreign establishments registered
22 under section 510 and foreign facilities registered
23 under section 415. Such corps shall include per-
24 sonnel, in numbers sufficient to act as inspectors or
25 translators for inspectors on each inspection by such

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

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

7 “(A) A unit with expertise in inspections of
8 food facilities.

9 “(B) A unit with expertise in inspections
10 of human drug establishments.

11 “(C) A unit with expertise in inspections of
12 animal drug establishments.

13 “(D) A unit with expertise in inspections
14 of medical device establishments.

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

19 “(A) of foreign establishments registered
20 under section 510 at a frequency, considering
21 risk, that is comparable to the inspection rate
22 of domestic establishments registered under sec-
23 tion 510; or

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

1 that is comparable to the inspection rate of do-
2 mestic facilities registered under section 415.

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

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

9 “(B) an assessment of the effectiveness of
10 the regulatory oversight provided by such coun-
11 try for such products;

12 “(C) an assessment of the risk posed by
13 such products; and

14 “(D) such other factors as the Secretary
15 determines are relevant to such distribution.”.

16 **SEC. 202. AUTHORITY TO EXCHANGE CONFIDENTIAL IN-**
17 **FORMATION WITH FOREIGN GOVERNMENT**
18 **OFFICIALS.**

19 (a) AUTHORITY TO EXCHANGE CONFIDENTIAL IN-
20 FORMATION WITH FOREIGN GOVERNMENT OFFICIALS.—

21 Section 803 (21 U.S.C. 383) is amended by adding the
22 following:

23 “(d) EXCHANGE OF CONFIDENTIAL INFORMATION.—

24 “(1) DISCLOSURE BY SECRETARY.—The Sec-
25 retary may disclose information about food, drugs,

1 devices, and cosmetics to officials of a foreign gov-
2 ernment if—

3 “(A) such government is able, and agrees,
4 to guard the confidentiality and guarantee non-
5 disclosure of such information; and

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

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

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

18 **SEC. 203. SUBPOENA AUTHORITY.**

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

21 “(f)(1) The Secretary may conduct investigations as
22 the Secretary deems necessary—

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

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

5 “(2) For the purpose of any investigation conducted
6 under paragraph (1), the Secretary may administer oaths
7 and affirmations, subpoena witnesses, compel the attend-
8 ance of such witnesses, take evidence, and require the pro-
9 duction of any books, papers, documents, or other mate-
10 rials that are relevant to the investigation.

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

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

1 **SEC. 204. INFORMATION REPORTING.**

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

4 **“SEC. 757. INFORMATION REPORTING.**

5 “(a) NOTIFICATION OF SETTLEMENTS OR JUDG-
6 MENTS.—If a particular product regulated by the Sec-
7 retary under this Act or section 351 of the Public Health
8 Service Act is the subject of at least 3 civil actions that
9 have been filed in Federal or State court alleging death,
10 serious injury, or serious illness caused in whole or in part
11 by such product which, in any 24-month period, result in
12 either a final settlement involving the manufacturer or a
13 court judgment in favor of the plaintiff, the manufacturer
14 of such product shall, in accordance with subsection (b),
15 report to the Secretary each such civil action not later
16 than 30 days after the final settlement or court judgment
17 in the third of such civil actions, and report to the Sec-
18 retary any other such action not later than 30 days after
19 any subsequent such settlement or judgment that—

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

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

24 “(b) INFORMATION TO BE REPORTED.—

25 “(1) REQUIRED INFORMATION.—The informa-
26 tion required by subsection (a) to be reported to the

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

5 “(A) The name and address of the manu-
6 facturer.

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

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

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

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

20 “(2) VOLUNTARY INFORMATION.—A manufac-
21 turer furnishing the report required by paragraph
22 (1) may include—

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

1 “(B) any other information which the
2 manufacturer chooses to provide.

3 “(c) SAFETY REPORT.—A report of a civil action de-
4 scribed in subsection (a) shall be considered a safety re-
5 port under section 756 and may be accompanied by a
6 statement, which shall be part of any report released for
7 public disclosure, that denies that the report constitutes
8 an admission that the product involved caused or contrib-
9 uted to a death, serious injury, or serious illness.

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

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

16 “(1) is life threatening,

17 “(2) results in permanent impairment of a body
18 function or permanent damage to a body structure,
19 or

20 “(3) necessitates medical or surgical interven-
21 tion to preclude permanent impairment of a body
22 function or permanent damage to a body struc-
23 ture.”.