

111TH CONGRESS
2D SESSION

H. R. 6543

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

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 17, 2010

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of drugs, 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 Safety Enhance-
5 ment Act of 2011”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents for this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

TITLE I—PREVENTION

Sec. 101. Registration of producers of drugs; applicable fee.

- Sec. 102. Drug supply quality and safety.
- Sec. 103. Inspection of producers of drugs.
- Sec. 104. Prohibition against delaying, limiting, or refusing inspection.
- Sec. 105. Clarification of inspection authority related to BIMO and IRB inspections.
- Sec. 106. Notification, nondistribution, and recall of adulterated or misbranded drug products.
- Sec. 107. Notification.

TITLE II—RESPONSE

- Sec. 201. Administrative detention.
- Sec. 202. Destruction of adulterated, misbranded, or counterfeit drugs offered for import.
- Sec. 203. Criminal penalties.
- Sec. 204. Civil penalties.
- Sec. 205. Seizure.
- Sec. 206. Asset forfeiture.

TITLE III—IMPORTATION AND EXPORTATION

- Sec. 301. Documentation for admissibility of imports.
- Sec. 302. Registration for commercial importers; fee.
- Sec. 303. Registration for customs brokers.
- Sec. 304. Exportation certificate program.
- Sec. 305. Extraterritorial jurisdiction.
- Sec. 306. Dedicated foreign inspectorate.

TITLE IV—MISCELLANEOUS

- Sec. 401. Unique identification number for establishments, importers, and customs brokers.
- Sec. 402. Country of origin labeling.
- Sec. 403. False or misleading reporting to FDA.
- Sec. 404. Subpoena authority.
- Sec. 405. Whistleblower protections.
- Sec. 406. Rule of construction.

1 **TITLE I—PREVENTION**

2 **SEC. 101. REGISTRATION OF PRODUCERS OF DRUGS; AP-** 3 **PLICABLE FEE.**

4 (a) FOREIGN REGISTRANTS.—

5 (1) MISBRANDING.—Section 502(o) of the Fed-
 6 eral, Food, Drug, and Cosmetic Act (21 U.S.C.
 7 352(o)) is amended by inserting “if it is a drug and
 8 was manufactured, prepared, propagated, com-
 9 pounded, or processed in an establishment not duly

1 registered under section 510(i),” after “not duly
2 registered under section 510,”.

3 (2) APPLICATION.—The amendment made by
4 paragraph (1) applies only with respect to registra-
5 tion (including failure to register) under section 510
6 of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 360) occurring on or after the date of the en-
8 actment of this Act.

9 (b) EXCIPIENT MANUFACTURERS.—

10 (1) IN GENERAL.—Not later than 6 months
11 after the date of the enactment of this Act, the Sec-
12 retary of Health and Human Services shall revise
13 section 207.10 of title 21, Code of Federal Regula-
14 tions, and such other regulations as may be nec-
15 essary to require owners and operators of establish-
16 ments that engage in the manufacture, preparation,
17 propagation, compounding, or processing of an ex-
18 cipient of a drug to register such establishments
19 under section 510 of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 360).

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

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

3 (c) DRUG LISTING ELEMENTS AND FREQUENCY.—

4 (1) IN GENERAL.—Sections 510(j) of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C.
6 360(j)) is amended—

7 (A) in paragraph (1), by amending sub-
8 paragraph (C) to read as follows:

9 “(C) in the case of any drug contained in an
10 applicable list which is described in subparagraph
11 (A) or (B), a qualitative and quantitative listing of
12 each of its active and other ingredients, and any
13 other information that the Secretary finds is nec-
14 essary to carry out the purposes of this Act; and”;
15 and

16 (B) in paragraph (2), in the matter pre-
17 ceeding subparagraph (A), by inserting “, unless
18 otherwise specified by the Secretary” after
19 “once during the month of December of each
20 year”.

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

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

3 (d) SUSPENSION AND CANCELLATION OF REGISTRA-
4 TION.—Section 510 of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 360j) is amended by adding at the
6 end the following:

7 “(q) SUSPENSION AND CANCELLATION OF REG-
8 ISTRATION.—With respect to any registration under this
9 section attributable to the manufacture, preparation,
10 propagation, compounding, or processing of a drug:

11 “(1) SUSPENSION OF REGISTRATION.—

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

16 “(i) a violation of this Act; or

17 “(ii) the knowing or repeated making
18 of an inaccurate or incomplete statement
19 or submission of information relating to
20 the manufacture, preparation, propagation,
21 compounding, processing, or importing of a
22 drug.

23 “(B) REQUEST.—Any person or establish-
24 ment whose registration is suspended under
25 subparagraph (A) may request that the Sec-

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

4 “(C) VACATING OF SUSPENSION.—If the
5 Secretary determines that adequate reasons do
6 not exist to continue the suspension of a reg-
7 istration under subparagraph (A), the Secretary
8 shall vacate such suspension.

9 “(2) CANCELLATION OF REGISTRATION.—

10 “(A) IN GENERAL.—Not earlier than 10
11 days after providing the notice under subpara-
12 graph (B), the Secretary may cancel a registra-
13 tion if the Secretary determines that—

14 “(i) such registration was not updated
15 in accordance with this section or contains
16 false, incomplete, or inaccurate informa-
17 tion; or

18 “(ii) the fee required under section
19 736C for such registration has not been
20 paid within 30 days after the date due.

21 “(B) NOTICE OF CANCELLATION.—Before
22 cancelling the registration of a person or estab-
23 lishment under this section, the Secretary shall
24 give notice to the person or establishment of the

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

3 “(C) **TIMELY UPDATE OR CORRECTION.**—
4 If a registration is adequately updated or cor-
5 rected no later than 7 days after notice is pro-
6 vided under subparagraph (B) with respect to
7 the registration, the Secretary shall not cancel
8 such registration.”.

9 (e) **REGISTRATION FEE.**—

10 (1) **ESTABLISHMENT.**—Part 2 of subchapter C
11 of chapter VII of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 379g et seq.) is amended by
13 adding at the end the following:

14 **“SEC. 736C. REGISTRATION FEE.**

15 “(a) **IN GENERAL.**—In the case of any registration
16 under section 510 that is attributable to the manufacture,
17 preparation, propagation, compounding, processing, or im-
18 porting of a drug, the Secretary shall assess and collect
19 an annual fee for such registration to defray the increase
20 in the costs of drug safety activities.

21 “(b) **PAYABLE DATE.**—A fee under this section shall
22 be payable—

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

1 “(2) for any other facility—

2 “(A) for fiscal year 2012, not later than
3 the sooner of 90 days after the date of the en-
4 actment of this section or December 31, 2011;
5 and

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

8 “(c) FEE AMOUNTS.—

9 “(1) TOTAL REVENUE AMOUNT.—

10 “(A) INITIAL YEAR.—For fiscal year 2012,
11 fees under subsection (a) shall, except as pro-
12 vided in subsections (f) and (g), be established
13 to generate a total revenue amount that is
14 equal to the increase in the costs of drug safety
15 activities (as estimated by the Secretary) for
16 such fiscal year.

17 “(B) SUBSEQUENT YEARS.—For each of
18 fiscal years 2013 through 2016, fees under sub-
19 section (a) shall, except as provided in sub-
20 sections (f) and (g), be the total revenue
21 amount for fiscal year 2012, as adjusted under
22 subsection (d).

23 “(2) ANNUAL FEE SETTING.—For fiscal year
24 2012 and each subsequent fiscal year, the Secretary

1 shall establish registration fees under subsection
2 (a)—

3 “(A) based on the total revenue amount
4 applicable under paragraph (1); and

5 “(B) taking into consideration the dif-
6 ference in costs of inspections between foreign
7 and domestic establishments.

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

12 “(A) the total revenue amount for the up-
13 coming fiscal year, as applicable under para-
14 graph (1); and

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

17 “(d) INFLATION ADJUSTMENT.—For fiscal year
18 2013 and subsequent fiscal years, the fee amount under
19 subsection (c) shall be adjusted by the Secretary by notice,
20 published in the Federal Register, for the respective fiscal
21 year to reflect the greater of—

22 “(1) the total percentage change that occurred
23 in the Consumer Price Index for all urban con-
24 sumers (all items; United States city average) for

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

3 “(2) the total percentage change for the pre-
4 vious fiscal year in basic pay under the General
5 Schedule in accordance with section 5332 of title 5,
6 United States Code, as adjusted by any locality-
7 based comparability payment pursuant to section
8 5304 of such title for Federal employees stationed in
9 the District of Columbia; or

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

15 The adjustment made each fiscal year under this sub-
16 section will be added on a compounded basis to the sum
17 of all adjustments made each fiscal year after fiscal year
18 2011 under this subsection.

19 “(e) FEE WAIVER OR REDUCTION.—The Secretary
20 may grant to a person a waiver from, or a reduction of,
21 one or more fees under this section if the Secretary finds
22 that—

23 “(1) such waiver or reduction is necessary to
24 protect the public health; or

1 “(2) the assessment of the fee would impose
2 significant financial hardship because of limited re-
3 sources available to such person or other cir-
4 cumstances.

5 “(f) LIMITATIONS.—

6 “(1) IN GENERAL.—Fees under subsection (a)
7 shall be refunded for a fiscal year beginning after
8 fiscal year 2012 unless appropriations for salaries
9 and expenses of the Food and Drug Administration
10 for such fiscal year (excluding the amount of fees
11 appropriated for such fiscal year) are equal to or
12 greater than the amount of appropriations for the
13 salaries and expenses of the Food and Drug Admin-
14 istration for the fiscal year 2012 (excluding the
15 amount of fees appropriated for such fiscal year) ad-
16 justed in the same manner that fee amounts are ad-
17 justed under subsection (d).

18 “(2) AUTHORITY.—If the Secretary does not
19 assess fees under subsection (a) during any portion
20 of a fiscal year because of paragraph (1) and if at
21 a later date in such fiscal year the Secretary may as-
22 sess such fees, the Secretary may assess and collect
23 such fees, without any modification in the rate, for
24 registration under section 510 at any time in such
25 fiscal year.

1 “(g) CREDITING AND AVAILABILITY OF FEES.—

2 “(1) IN GENERAL.—Fees authorized under sub-
3 section (a) shall be collected and available for obliga-
4 tion only to the extent and in the amount provided
5 in advance in appropriations Acts. Such fees are au-
6 thorized to remain available until expended. Such
7 sums as may be necessary may be transferred from
8 the Food and Drug Administration salaries and ex-
9 penses appropriation account without fiscal year lim-
10 itation to such appropriation account for salaries
11 and expenses with such fiscal year limitation.

12 “(2) COLLECTIONS AND APPROPRIATIONS
13 ACTS.—The fees authorized by this section—

14 “(A) shall be retained in each fiscal year in
15 an amount not to exceed the amount specified
16 in appropriations Acts, or otherwise made avail-
17 able for obligation, for such fiscal year; and

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

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

24 “(h) COLLECTION OF UNPAID FEES.—In any case
25 in which the Secretary does not receive payment of a fee

1 assessed under subsection (a) within 30 days after it is
2 due, such fee shall be treated as a claim of the United
3 States Government subject to subchapter II of chapter 37
4 of title 31, United States Code.

5 “(i) CONSTRUCTION.—This section may not be con-
6 strued to require that the number of full-time equivalent
7 positions in the Department of Health and Human Serv-
8 ices, for officers, employers, and advisory committees not
9 engaged in drug safety activities, be reduced to offset the
10 number of officers, employees, and advisory committees so
11 engaged.

12 “(j) ANNUAL FISCAL REPORTS.—Beginning with fis-
13 cal year 2013, not later than 120 days after the end of
14 each fiscal year for which fees are collected under this sec-
15 tion, the Secretary shall prepare and submit to the Com-
16 mittee on Energy and Commerce of the House of Rep-
17 resentatives and the Committee on Health, Education,
18 Labor, and Pensions of the Senate a report on the imple-
19 mentation of the authority for such fees during such fiscal
20 year and the use, by the Food and Drug Administration,
21 of the fees collected for such fiscal year.

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

1 “(1) DEFINITIONS.—In this section:

2 “(1) The term ‘costs of drug safety activities’
3 means the expenses incurred in connection with drug
4 safety activities for—

5 “(A) officers and employees of the Food
6 and Drug Administration, contractors of the
7 Food and Drug Administration, advisory com-
8 mittees, and costs related to such officers, em-
9 ployees, and committees and to contracts with
10 such contractors;

11 “(B) laboratory space;

12 “(C) management of information, and the
13 acquisition, maintenance, and repair of infor-
14 mation technology resources;

15 “(D) leasing, maintenance, renovation, and
16 repair of facilities and acquisition, maintenance,
17 and repair of fixtures, furniture, scientific
18 equipment, and other necessary materials and
19 supplies; and

20 “(E) collecting fees under this section and
21 accounting for resources allocated for drug
22 safety activities.

23 “(2) The term ‘drug safety activities’ means ac-
24 tivities related to compliance by persons and estab-
25 lishments registered under section 510 with the re-

1 requirements of this Act relating to drugs (including
2 research related to and the development of stand-
3 ards (such as performance standards and preventive
4 controls), risk assessments, hazard analyses, inspec-
5 tion planning and inspections, third-party inspec-
6 tions, compliance review and enforcement, import re-
7 view, information technology support, test develop-
8 ment, product sampling, risk communication, and
9 administrative detention).”.

10 (2) TRANSITIONAL PROVISIONS.—

11 (A) FIRST IMPOSITION OF FEES.—The
12 Secretary of Health and Human Services shall
13 first impose the fee established under section
14 736C of the Federal Food, Drug, and Cosmetic
15 Act, as added by paragraph (1), for fiscal years
16 beginning with fiscal year 2012.

17 (B) SUNSET DATE.—Section 736C of the
18 Federal Food, Drug, and Cosmetic Act, as
19 added by paragraph (1), does not authorize the
20 assessment or collection of a fee for registration
21 under section 510 of such Act (21 U.S.C. 360)
22 occurring after fiscal year 2016.

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

1 shall modify the registration forms under section 510 of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 350d) to comply with the amendments made by this sec-
4 tion.

5 **SEC. 102. DRUG SUPPLY QUALITY AND SAFETY.**

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

9 “(3) In the case of a drug, the term ‘component’ in-
10 cludes—

11 “(A) any active ingredient or bulk drug sub-
12 stance;

13 “(B) any inactive ingredient;

14 “(C) any intermediate of an active ingredient,
15 inactive ingredient, or bulk drug substance, whether
16 or not it appears in the finished product and wheth-
17 er or not derived from any chemical, human, animal,
18 plant, or other material; and

19 “(D) any original source material for compo-
20 nents specified in clauses (A), (B), and (C) whether
21 or not the original source material—

22 “(i) appears in the finished product; and

23 “(ii) is derived from any chemical, human,
24 animal, plant, or other material.”.

25 (b) EFFECTIVE QUALITY SYSTEMS.—

1 (1) PROHIBITED ACTS.—

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

5 (i) by inserting “503C,” after
6 “417(g),”; and

7 (ii) by inserting “503C,” after
8 “417,”.

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

13 “(j) If it is a drug that was manufactured (as defined
14 in section 503C) by a manufacturer that is or was at the
15 time of such manufacture in violation of section 503C be-
16 cause of the failure to have in effect or implement an effec-
17 tive quality system in accordance with such section.”.

18 (2) SYSTEM REQUIREMENTS.—The Federal
19 Food, Drug, and Cosmetic Act is amended by insert-
20 ing after section 503B (21 U.S.C. 353b) the fol-
21 lowing:

1 **“SEC. 503C. EFFECTIVE QUALITY SYSTEM FOR DRUG MANU-**
2 **FACTURERS.**

3 “(a) IN GENERAL.—Each manufacturer of a drug re-
4 quired to be registered under section 510 shall have in
5 effect and implement an effective quality system.

6 “(b) SYSTEM REQUIREMENTS.—An effective quality
7 system applicable to a manufacturer of a drug under sub-
8 section (a) shall require each of the following:

9 “(1) MANAGEMENT RESPONSIBILITY.—The
10 manufacturer shall ensure that—

11 “(A) adequate resources are provided to
12 ensure compliance with current good manufac-
13 turing practice;

14 “(B) procedures are established and main-
15 tained to ensure timely communication of prod-
16 uct quality issues to appropriate levels of man-
17 agement, including executive management;

18 “(C) periodic reviews of process perform-
19 ance, product quality, and other elements of the
20 quality system are conducted;

21 “(D) the periodic reviews under subpara-
22 graph (C) are evaluated by executive manage-
23 ment to determine any appropriate action; and

24 “(E) the integrity of data, records, and
25 regulatory submissions, including with respect

1 to accuracy, veracity, and validity, is main-
2 tained.

3 “(2) QUALITY RESPONSIBILITY.—

4 “(A) INTERNAL, INDEPENDENT UNIT.—

5 The manufacturer shall establish and maintain
6 an internal, independent unit with the authority
7 to ensure that all operations related to manu-
8 facturing drugs, including those performed by
9 another person, are appropriately designed, ap-
10 proved, conducted, monitored, and corrected in
11 compliance with current good manufacturing
12 practice.

13 “(B) PROCEDURES.—The manufacturer
14 shall establish and maintain procedures to en-
15 sure that—

16 “(i) any discrepancy related to manu-
17 facturing a drug (including the
18 discrepancy’s causes) is promptly identi-
19 fied, investigated, and corrected, the recur-
20 rence of the discrepancy is prevented, and
21 any corrective or preventive action is
22 verified or validated to ensure that such
23 action is effective and does not adversely
24 affect the drug; and

1 “(ii) ongoing reviews of all data re-
2 lated to manufacturing a drug are con-
3 ducted to identify trends that might affect
4 product quality and timely actions are per-
5 formed to prevent any adverse effect on
6 product safety, identity, quality, strength,
7 or purity.

8 “(3) RISK MANAGEMENT.—The manufacturer
9 shall establish and maintain risk management proce-
10 dures that ensure effective risk assessment, control,
11 and communication. The risk assessment procedures
12 shall ensure that all factors throughout the supply
13 chain that may reasonably be expected to indicate a
14 risk to the safety, identity, quality, strength, purity,
15 or security of any drug manufactured by that manu-
16 facturer are identified, starting with factors relating
17 to origin of all components including the original
18 source materials; information relating to all such
19 factors is continuously gathered, monitored, and
20 evaluated; and new factors are promptly identified.

21 “(4) SUPPLY CHAIN MANAGEMENT.—

22 “(A) IN GENERAL.—The manufacturer
23 shall establish and maintain procedures that en-
24 sure the safety, identity, quality, strength, pu-
25 rity, and security of all drugs and other mate-

1 rials used by that manufacturer. The supply
2 chain procedures shall address the entire supply
3 chain from original source materials used in the
4 manufacture of the drug to the manufacturer.
5 The supply chain procedures shall ensure that
6 there is adequate followup, which shall include
7 no longer receiving any source materials or
8 drugs from, or using operations conducted by,
9 any person who fails to implement timely cor-
10 rections for supply chain management practices
11 or other applicable requirements under this Act
12 or sections 351 or 361 of the Public Health
13 Service Act.

14 “(B) PROCEDURES.—Supply chain man-
15 agement procedures under subparagraph (A)
16 shall include—

17 “(i) acceptance and rejection criteria
18 for each component that ensures that such
19 component is appropriate for its intended
20 use and that include, unless not feasible
21 using current technology, a sufficient im-
22 purity profile for each component, includ-
23 ing each component that is naturally de-
24 rived, except that the requirements of this
25 clause shall not apply to any component of

1 a licensed biological product unless re-
2 quired under the license issued for such
3 product under section 351 of the Public
4 Health Service Act or under paragraph
5 (5);

6 “(ii) onsite audits, performed by
7 qualified individuals, of each person that
8 supplies a drug or conducts operations re-
9 lated to manufacturing, before such person
10 begins initial supply or operation and at an
11 appropriate frequency to assess the contin-
12 ued compliance of such person with the
13 manufacturer’s supply chain practices and
14 with the applicable requirements under this
15 Act and sections 351 and 361 of the Pub-
16 lic Health Service Act;

17 “(iii) requirements for a quality
18 agreement with any person who supplies a
19 drug or conducts operations related to
20 manufacturing a drug which addresses all
21 applicable current good manufacturing
22 practice requirements;

23 “(iv) the sharing of manufacturing in-
24 formation by any person who supplies a
25 drug or conducts operations related to

1 manufacturing, including timely notifica-
2 tion concerning any change to, discrepancy
3 in, or defect in, materials or operations re-
4 lated to manufacturing, along with ade-
5 quate information about such change, dis-
6 crepancy, or defect;

7 “(v) when supplying any drug to an-
8 other manufacturer, provision of a certifi-
9 cate of analysis for each batch and lot that
10 includes complete source, manufacturing,
11 and test information and results; and

12 “(vi) methods, which shall include ac-
13 ceptance and rejection criteria, adequate—

14 “(I) to detect, or exclude the pos-
15 sibility of, the presence of any sub-
16 stance that may reasonably be ex-
17 pected to indicate a risk to safety,
18 identity, quality, strength, purity, or
19 security; and

20 “(II) to detect, or exclude the
21 possibility of, other risks to safety,
22 identity, quality, strength, purity, or
23 security.

24 “(5) METHODS.—

1 “(A) IN GENERAL.—Each manufacturer
2 shall establish and maintain procedures that en-
3 sure—

4 “(i) periodic evaluation and, where
5 necessary, prompt revision of methods, in-
6 cluding acceptance and rejection criteria,
7 to ensure the safety, identity, quality,
8 strength, purity, and security of each drug
9 manufactured by such manufacturer, or
10 component used in the manufacture of
11 such drug;

12 “(ii) when any new risk is identified—

13 “(I) adoption of appropriate re-
14 vised or new methods; and

15 “(II) evaluation of every batch
16 and lot of drug using such revised
17 methods; and

18 “(iii) if required, an application is
19 submitted for timely approval by the Sec-
20 retary of the revised or new methods under
21 section 505, 506A, 512, or 571 of this Act
22 or section 351 of the Public Health Service
23 Act.

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

4 “(C) NOTIFICATION REGARDING REVISED
5 METHOD.—Each manufacturer of a drug shall
6 promptly notify the Secretary and the appro-
7 priate body charged with revision of an official
8 compendium of any revised method for such
9 drug and its rationale. Such notification shall
10 be made in such form and manner as the Sec-
11 retary shall prescribe by regulation.

12 “(D) ORDERS REGARDING REVISED OR
13 NEW METHODS.—If the Secretary determines
14 that a revised or new method, including accept-
15 ance and rejection criteria, is appropriate for
16 the safety, identity, quality, strength, purity, or
17 security of any drug, the Secretary may by let-
18 ter order any manufacturer of such drug to
19 promptly—

20 “(i) revise any method, or adopt any
21 new method, and any related acceptance
22 and rejection criteria for such drug; and

23 “(ii) implement such revised or new
24 method and any related acceptance and re-
25 jection criteria.

1 “(6) RECORDS.—

2 “(A) IN GENERAL.—Each manufacturer
3 shall maintain adequate, contemporaneous
4 records (which may be electronic) to document
5 conformity with requirements under this sec-
6 tion. Such records shall be accurate, indelible,
7 and legible. Each manufacturer shall establish
8 and maintain a procedure to ensure the identi-
9 fication, storage, protection, retrieval, retention,
10 and disposition of such records.

11 “(B) MAINTENANCE OF RECORDS; INSPEC-
12 TION.—Each manufacturer shall maintain
13 records under subparagraph (A) for at least 2
14 years from the date of the expiration date of
15 the drug involved and make such records read-
16 ily available for inspection by the Secretary.
17 Such records or copies thereof shall be subject
18 to photocopying or other means of reproduction
19 as part of such inspection. Each manufacturer
20 shall provide to the Secretary these records or
21 copies thereof in a timely manner, upon verbal
22 or written request by an officer or employee
23 duly designated by the Secretary.

24 “(7) ADDITIONAL PROVISIONS.—If the Sec-
25 retary determines that provisions in addition to

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

6 “(c) EXEMPTIONS AND VARIANCES.—Any person
7 subject to any requirement prescribed pursuant to this
8 section may petition the Secretary for an exemption or
9 variance from such requirement. Such a petition shall be
10 submitted to the Secretary in such form and manner as
11 the Secretary shall prescribe by regulation. If, when grant-
12 ing a request for exemption or variance under this sub-
13 section, the Secretary determines that it is appropriate to
14 apply the exemption or variance to more than one manu-
15 facturer, the Secretary shall publish a notice of the exemp-
16 tion or variance in the Federal Register.

17 “(d) DEFINITIONS.—In this section:

18 “(1) The term ‘manufacturer’ means any per-
19 son who manufactures a drug.

20 “(2) The terms ‘manufacture’, ‘manufacturing’,
21 or ‘manufactured’ include preparation, processing,
22 packing, or holding.

23 “(3) The term ‘establish and maintain’ means
24 adequately—

1 “(A) define, document (by paper or elec-
2 tronically), implement, and follow; and

3 “(B) review and, as needed, revise on an
4 ongoing basis.”.

5 (3) APPLICATION.—The requirements of section
6 503C of the Federal Food, Drug, and Cosmetic Act,
7 as added by paragraph (2), apply beginning on the
8 date that is 2 years after the date of the enactment
9 of this Act.

10 (c) DOCUMENTATION OF SUPPLY CHAIN.—

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

15 “(r) DOCUMENTATION OF SUPPLY CHAIN.—Each es-
16 tablishment required to be registered under this section
17 for the manufacture, preparation, propagation,
18 compounding, or processing of a drug, shall maintain and
19 provide to the Secretary, upon request, adequate informa-
20 tion, in electronic form, establishing—

21 “(1) where the drug, including its raw mate-
22 rials, was produced, including all preceding pro-
23 ducers, manufacturers, distributors, and shippers;
24 and

1 “(2) that the drug, its ingredients, and its raw
2 materials were manufactured, prepared, propagated,
3 compounded, processed, distributed, shipped,
4 warehoused, brokered, imported, and conveyed under
5 conditions that ensure the identity, strength, quality,
6 and purity of the drug.”.

7 (2) APPLICATION.—The amendment made by
8 paragraph (1) applies beginning on the date that is
9 2 years after the date of the enactment of this Act.

10 **SEC. 103. INSPECTION OF PRODUCERS OF DRUGS.**

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

14 (1) by striking “(h)” and inserting “(h)(1)”;
15 and

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

17 “(2) Notwithstanding paragraph (1), every establish-
18 ment engaged in the manufacture, propagation,
19 compounding, or processing of a drug that is a finished
20 dosage form or an active pharmaceutical ingredient shall
21 be inspected pursuant to section 704 by one or more offi-
22 cers or employees duly designated by the Secretary—

23 “(A) at least once in the 2-year period begin-
24 ning with the date of registration of such establish-

1 ment pursuant to this section and at least once in
2 every successive 2-year period thereafter; or

3 “(B) at least once in the 4-year period begin-
4 ning with the date of registration of such establish-
5 ment pursuant to this section and at least once in
6 every successive 4-year period thereafter, if the Sec-
7 retary determines that sufficient information about
8 the type of product produced in the establishment,
9 inspection history, compliance history, and such ad-
10 ditional factors as the Secretary determines by guid-
11 ance, exists to assess risk and to establish a risk-
12 based inspection schedule.

13 “(3) The Secretary shall conduct an inspection of a
14 drug establishment when the establishment begins to man-
15 ufacture, prepare, propagate, compound, or process a drug
16 that is a finished dosage form or active pharmaceutical
17 ingredient before the drug is introduced into interstate
18 commerce if the active ingredient is new to the drug prod-
19 uct or the drug has undergone a major change requiring
20 prior approval by the Secretary of a supplement to an ap-
21 plication submitted under section 505. Notwithstanding
22 the preceding sentence, the Secretary may opt against con-
23 ducting such an inspection if the Secretary determines,
24 based on the inspection history of the establishment, that
25 such an inspection is not necessary to verify the data con-

1 tained in the application (or supplement to the applica-
2 tion) submitted under section 505, ensure compliance with
3 current good manufacturing practices, or otherwise ensure
4 the safety of the drug or ingredient.

5 “(4) The Secretary may inspect, pursuant to section
6 704, every establishment engaged in the manufacture,
7 propagation, compounding, or processing of an excipient
8 of a drug to the same extent as the Secretary is authorized
9 to inspect an establishment engaged in the manufacture,
10 propagation, compounding, or processing of any other
11 drug.

12 “(5) Nothing in this subsection shall be construed as
13 limiting the authority of the Secretary to conduct inspec-
14 tions of establishments under any other provision of the
15 Act.

16 “(6) With respect to fiscal year 2012 and each subse-
17 quent fiscal year, the Secretary shall submit an annual
18 report to the Congress on—

19 “(A) funding dedicated to inspections under
20 this subsection of establishments engaged in the
21 manufacture, propagation, compounding, or proc-
22 essing of a drug; and

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

1 “(7) For purposes of determining inspection fre-
2 quency under paragraph (2), the Secretary shall establish
3 information systems capacity sufficient to assess risk and
4 shall develop and maintain a risk-based system for con-
5 ducting surveillance of current good manufacturing prac-
6 tices by establishments engaged in the manufacture, prop-
7 agation, compounding, or processing of a drug that is a
8 finished dosage form or an active pharmaceutical ingre-
9 dient. The Secretary shall have such capacity in place and
10 begin implementation of such risk-based system not later
11 than 3 years after the date of the enactment of the Drug
12 Safety Enhancement Act of 2011. Such risk-based system
13 shall include consideration of the class of the establish-
14 ment’s products and associated risks, the date the estab-
15 lishment was last inspected, the establishment’s compli-
16 ance and safety history, the establishment’s shipping vol-
17 ume and history, and such other factors as the Secretary
18 determines relevant to assessing the risk presented by the
19 establishment.”.

20 (b) GAO REPORT.—Not later than 3 years after the
21 date of the enactment of this Act, the Comptroller General
22 of the United States shall submit a report to the Congress
23 on the risk-based process for conducting surveillance of
24 current good manufacturing practices developed and im-
25 plemented under section 510(h)(7) of the Federal Food,

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

3 (c) APPLICATION.—The amendments made by this
4 section shall apply to drugs introduced or delivered for in-
5 troduction into interstate commerce on or after the date
6 of the enactment of this Act.

7 **SEC. 104. PROHIBITION AGAINST DELAYING, LIMITING, OR**
8 **REFUSING INSPECTION.**

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

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

20 **SEC. 105. CLARIFICATION OF INSPECTION AUTHORITY RE-**
21 **LATED TO BIMO AND IRB INSPECTIONS.**

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

1 (1) by inserting after the second sentence the
2 following: “For purposes of enforcement of this Act,
3 officers or employees duly designated by the Sec-
4 retary, upon presenting appropriate credentials and
5 a written notice to the owner, operator, or agent in
6 charge, are also authorized to enter, at reasonable
7 times, any premises of a clinical investigator, spon-
8 sor, monitor, contract research organization, site
9 management organization, institutional review
10 board, or other person that oversees, initiates, or
11 conducts a clinical investigation subject to section
12 505(i), or a postmarket study or clinical trial subject
13 to section 505(k) or 505(o).”; and

14 (2) by inserting “or any establishment associ-
15 ated with a clinical investigation subject to section
16 505(i), or a postmarket study or clinical trial subject
17 to section 505(k) or 505(o) (including the premises
18 of any clinical investigator, sponsor, monitor, con-
19 tract research organization, site management organi-
20 zation, person that oversees or participates in data
21 acquisition, data generation, data archiving, or data
22 analysis, institutional review board, or any other
23 person, other than a subject, that participates in the
24 conduct of a clinical investigation of a drug),” before
25 “inspection shall extend to all things therein”.

1 (b) CONFORMING AMENDMENT.—Section 704(a)(2)
 2 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 3 374(a)(2)) is amended by striking “third sentence” and
 4 inserting “fourth sentence”.

5 **SEC. 106. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
 6 **OF ADULTERATED OR MISBRANDED DRUG**
 7 **PRODUCTS.**

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

11 “(uu)(1) The failure to notify the Secretary in viola-
 12 tion of section 568(a).

13 “(2) The failure to comply with any order issued
 14 under section 568.”.

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

20 **“SEC. 568. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
 21 **OF ADULTERATED OR MISBRANDED DRUGS.**

22 “(a) NOTIFICATION, NONDISTRIBUTION, AND RE-
 23 CALL OF ADULTERATED OR MISBRANDED DRUGS.—

1 “(1) IN GENERAL.—A person required, with re-
2 spect to drugs, to register under section 510, 801(r),
3 or 801(s) that has reason to believe that—

4 “(A) a drug when introduced into or while
5 in interstate commerce, or while held for sale
6 (regardless of whether the first sale) after ship-
7 ment in interstate commerce, is adulterated or
8 misbranded, and

9 “(B) as a result, the use or consumption
10 of, or exposure to, the drug (or an ingredient
11 or component used in any such drug) may re-
12 sult in illness or injury to humans or animals,
13 shall, as soon as practicable, notify the Secretary of
14 the identity and location of the drug.

15 “(2) MANNER OF NOTIFICATION.—Notification
16 under paragraph (1) shall be made in such manner
17 and by such means as the Secretary may require by
18 regulation.

19 “(b) VOLUNTARY RECALL.—The Secretary may re-
20 quest that any person who distributes a drug that the Sec-
21 retary has reason to believe is adulterated, misbranded,
22 or otherwise in violation of this Act voluntarily—

23 “(1) recall such drug; and

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

4 “(c) ORDER TO CEASE DISTRIBUTION.—If the Sec-
5 retary has reason to believe that the use or consumption
6 of, or exposure to, a drug may result in illness or injury
7 to humans or animals, the Secretary shall have the author-
8 ity to issue an order requiring any person who distributes
9 such drug to immediately cease distribution of such drug.

10 “(d) ACTION FOLLOWING ORDER.—Any person who
11 is subject to an order under subsection (c) shall imme-
12 diately cease distribution of such drug and provide notifi-
13 cation as required by such order, and may appeal within
14 24 hours of issuance of such order to the Secretary. Such
15 appeal may include a request for an informal hearing and
16 a description of any efforts to recall such drug undertaken
17 voluntarily by the person, including after a request under
18 subsection (b). Except as provided in subsection (f), an
19 informal hearing shall be held as soon as practicable, but
20 not later than 5 calendar days, or less as determined by
21 the Secretary, after such an appeal is filed, unless the par-
22 ties jointly agree to an extension. After affording an op-
23 portunity for an informal hearing, the Secretary shall de-
24 termine whether the order should be amended to require
25 a recall of such drug. If, after providing an opportunity

1 for such a hearing, the Secretary determines that inad-
2 equate grounds exist to support the actions required by
3 the order, the Secretary shall vacate the order.

4 “(e) ORDER TO RECALL.—

5 “(1) AMENDMENT.—Except as provided under
6 subsection (f), if after providing an opportunity for
7 an informal hearing under subsection (d), the Sec-
8 retary determines that the order should be amended
9 to include a recall of the drug with respect to which
10 the order was issued, the Secretary shall amend the
11 order to require a recall.

12 “(2) CONTENTS.—An amended order under
13 paragraph (1) shall—

14 “(A) specify a timetable in which the recall
15 will occur;

16 “(B) require periodic reports to the Sec-
17 retary describing the progress of the recall; and

18 “(C) provide for notice, including to indi-
19 viduals as appropriate, to persons who may be
20 affected by the recall. In providing for such no-
21 tice, the Secretary may allow for the assistance
22 of health professionals, State or local officials,
23 or other individuals designated by the Sec-
24 retary.

25 “(f) EMERGENCY RECALL ORDER.—

1 “(1) IN GENERAL.—If the Secretary has cred-
2 ible evidence or information that a drug subject to
3 an order under subsection (c) presents an imminent
4 threat of serious adverse health consequences or
5 death to humans or animals, the Secretary may
6 issue an order requiring any person who distributes
7 such drug—

8 “(A) to immediately recall such drug; and

9 “(B) to provide for notice, including to in-
10 dividuals as appropriate, to persons who may be
11 affected by the recall.

12 “(2) ACTION FOLLOWING ORDER.—Any person
13 who is subject to an emergency recall order under
14 this subsection shall immediately recall such drug
15 and provide notification as required by such order,
16 and may appeal within 24 hours after issuance such
17 order to the Secretary. The person subject to an
18 emergency recall order shall conduct the recall not-
19 withstanding the pendency of any such appeal. An
20 informal hearing shall be held as soon as practicable
21 but not later than 5 calendar days, or less as deter-
22 mined by the Secretary, after such an appeal is filed,
23 unless the parties jointly agree to an extension.
24 After affording an opportunity for an informal hear-
25 ing, the Secretary shall determine whether the order

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

6 “(g) NOTICE TO CONSUMERS AND HEALTH OFFI-
7 CIALS.—The Secretary shall, as the Secretary determines
8 to be necessary, provide notice of a recall order under this
9 section to consumers to whom the drug was, or may have
10 been, distributed and to appropriate State and local health
11 officials.

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

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

18 “(2) the ability of the Secretary to request any
19 person to perform a voluntary activity related to any
20 drug subject to this Act or the Public Health Service
21 Act.”.

22 (c) ARTICLES SUBJECT TO REFUSAL.—The third
23 sentence of subsection (a) of section 801 of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amend-
25 ed by inserting “or (4) in the case of a drug, such article

1 is subject to an order under section 568 to cease distribu-
2 tion of or recall the article,” before “then such article shall
3 be refused admission”.

4 (d) APPLICATION.—Sections 301(uu) and 568 of the
5 Federal Food, Drug, and Cosmetic Act, as added by sub-
6 sections (a) and (b), shall apply with respect to a drug
7 as of such date, not later than 1 year after the date of
8 the enactment of this Act, as the Secretary of Health and
9 Human Services shall specify.

10 **SEC. 107. NOTIFICATION.**

11 (a) IN GENERAL.—

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

16 “(vv) The failure to notify the Secretary in violation
17 of section 569.”.

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

22 **“SEC. 569. NOTIFICATION.**

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

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

3 “(2) a significant loss or known theft of such
4 drug;

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

7 “(4) repeated failures by a manufacturer of a
8 component or other material used in the manufac-
9 ture of such drug to ensure compliance with applica-
10 ble quality systems requirements under section
11 501(a)(2)(B) or 503C of this Act or section 351 or
12 361 of the Public Health Service Act;

13 “(5) any incident causing such drug to be mis-
14 taken for, or its labeling applied to, another drug;

15 “(6) any contamination or any significant
16 chemical, physical, or other change or deterioration
17 in such drug after distribution, or any failure of a
18 distributed lot or batch of such drug to meet an es-
19 tablished specification; and

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

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

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

3 “(c) DEFINITION.—In this section, the term ‘regu-
4 lated person’ means a person who is required to register
5 under section 510, 801(r), or 801(s); a wholesale dis-
6 tributor of a drug product; and any other person that dis-
7 tributes drugs except exclusively for retail sale.”.

8 (b) EXCHANGE OF INFORMATION.—

9 (1) PROHIBITED ACTS.—

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

13 (i) by striking “or” before “to the
14 courts when relevant”; and

15 (ii) by inserting “, or as specified in
16 section 708,” before “any information ac-
17 quired”.

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

21 (i) by striking “573.” and inserting
22 “573”; and

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

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

4 (A) by striking “The Secretary” and in-
5 serting “(a) The Secretary”; and

6 (B) by adding at the end the following:

7 “(b)(1)(A) The Secretary may provide to any Federal
8 agency acting within the scope of its jurisdiction any infor-
9 mation respecting a drug that is exempt from disclosure
10 pursuant to subsection (a) of section 552 of title 5, United
11 States Code, by reason of subsection (b)(4) of such sec-
12 tion.

13 “(B) Any such information provided to another Fed-
14 eral agency shall not be disclosed by such agency except
15 in any investigation within the receiving agency’s jurisdic-
16 tion or in an action or proceeding under the laws of the
17 United States in which the receiving agency or the United
18 States is a party.

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

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

4 “(3) Except as provided by section 301(j), in carrying
5 out this Act, the Secretary may provide to any person any
6 information respecting a drug that is exempt from disclo-
7 sure pursuant to section 552(a) of title 5, United States
8 Code, by reason of subsection (b)(4) of such section, if
9 the Secretary determines that providing the information
10 to the person is appropriate under the circumstances and
11 the recipient provides adequate assurances to the Sec-
12 retary that the recipient will preserve the confidentiality
13 of the information.

14 “(4) In carrying out this Act, the Secretary may pro-
15 vide any information respecting a drug that is exempt
16 from disclosure pursuant to section 552(a) of title 5,
17 United States Code, by reason of subsection (b)(4) of such
18 section—

19 “(A) to any foreign government agency; or

20 “(B) any international organization established
21 by law, treaty, or other governmental action and
22 having responsibility—

23 “(i) to facilitate global or regional harmo-
24 nization of standards and requirements in an

1 area of responsibility of the Food and Drug Ad-
2 ministration; or

3 “(ii) to promote and coordinate public
4 health efforts, if the agency or organization pro-
5 vides adequate assurances to the Secretary that
6 the agency or organization will preserve the
7 confidentiality of the information.

8 “(c) Except as provided by section 301(j), the Sec-
9 retary may disclose to the public any information respect-
10 ing a drug that is exempt from disclosure pursuant to sec-
11 tion 552(a) of title 5, United States Code, by reason of
12 subsection (b)(4) of such section, if the Secretary deter-
13 mines that such disclosure is necessary to protect the pub-
14 lic health.

15 “(d) Except as provided in subsection (e), the Sec-
16 retary shall not be required to disclose under section 552
17 of title 5, United States Code, or any other provision of
18 law any information respecting a drug obtained from a
19 Federal, State, or local government agency, or from a for-
20 eign government agency, or from an international organi-
21 zation described in subsection (b)(4), if the agency or or-
22 ganization has requested that the information be kept con-
23 fidential, or has precluded such disclosure under other use
24 limitations, as a condition of providing the information.

1 “(e) Nothing in subsection (d) authorizes the Sec-
2 retary to withhold information from the Congress or pre-
3 vents the Secretary from complying with an order of a
4 court of the United States.

5 “(f) This section shall not affect the authority of the
6 Secretary to provide or disclose information under any
7 other provision of law.”.

8 **TITLE II—RESPONSE**

9 **SEC. 201. ADMINISTRATIVE DETENTION.**

10 (a) ADMINISTRATIVE DETENTION OF DRUGS.—Sec-
11 tion 304 of the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 334) is amended by adding at the end the fol-
13 lowing:

14 “(i) ADMINISTRATIVE DETENTION OF DRUGS.—

15 “(1) DETENTION AUTHORITY.—

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

1 required to institute an action under subsection
2 (a) or section 302, in which case the Secretary
3 may authorize a detention period of not to ex-
4 ceed 60 days.

5 “(B) SECRETARY’S APPROVAL.—Regula-
6 tions of the Secretary prescribed under this
7 paragraph shall require that, before a drug may
8 be ordered detained under this paragraph, the
9 Secretary or an officer or employee designated
10 by the Secretary approve such order.

11 “(C) SECURITY OF DETAINED DRUG.—A
12 detention order under this paragraph may re-
13 quire—

14 “(i) the labeling or marking of a drug
15 during the period of its detention for the
16 purpose of identifying the drug as de-
17 tained; and

18 “(ii) that the drug be removed to a se-
19 cure facility, as appropriate.

20 “(D) APPEAL OF DETENTION ORDER.—

21 “(i) RIGHT TO APPEAL.—Any person
22 who would be entitled to claim a drug if it
23 were seized under subsection (a) may ap-
24 peal to the Secretary a detention of such
25 drug under this paragraph.

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

7 “(2) LIMITATION ON MOVEMENT OF DETAINED
8 DRUGS.—

9 “(A) IN GENERAL.—Except as authorized
10 by subparagraph (B), a drug subject to a deten-
11 tion order issued under paragraph (1) shall not
12 be moved by any person from the place at
13 which it is ordered detained until—

14 “(i) released by the Secretary; or

15 “(ii) the expiration of the detention
16 period applicable to such order,
17 whichever occurs first.

18 “(B) EXCEPTION.—A drug subject to a de-
19 tention order under paragraph (1) may be
20 moved—

21 “(i) in accordance with regulations
22 prescribed by the Secretary; and

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

1 the device for the purpose of completing
2 the work required to put it in such form.”.

3 (b) REGULATIONS.—The Secretary shall issue regula-
4 tions or guidance to implement the amendments made by
5 this section.

6 (c) PROHIBITED ACTS.—Section 301(r) of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331), is
8 amended—

9 (1) by inserting “, drug,” after “device”, each
10 place it appears; and

11 (2) by inserting “or section 304(i)” after “sec-
12 tion 304(g)”.

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

16 **SEC. 202. DESTRUCTION OF ADULTERATED, MISBRANDED,**
17 **OR COUNTERFEIT DRUGS OFFERED FOR IM-**
18 **PORT.**

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

22 “(q)(1) Subject to paragraph (2), the Secretary of the
23 Treasury shall cause the destruction, upon referral from
24 the Secretary of Health and Human Services, of any drug
25 that—

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

4 “(B) is valued at an amount that is \$2,000 or
5 less (or such higher amount as the Secretary of the
6 Treasury may set by regulation pursuant to section
7 498 of the Tariff Act of 1930).

8 “(2) The Secretary of Health and Human Services
9 shall issue regulations providing for notice and an oppor-
10 tunity for an informal hearing for destruction of drugs
11 under paragraph (1). The regulations under this para-
12 graph shall allow the Secretary of Health and Human
13 Services to provide the notice and opportunity for an infor-
14 mal hearing to the owner or consignee after the destruc-
15 tion has occurred.

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

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

1 ing “Except as provided in subsection (q), the Secretary
2 of the Treasury shall”.

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

6 **SEC. 203. CRIMINAL PENALTIES.**

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

9 (1) in subsection (a)—

10 (A) in paragraph (1), by striking “Any”
11 and inserting “Except as provided in paragraph
12 (2) or (3), any”; and

13 (B) by adding at the end the following:

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

19 (2) in subsection (b)(1), by striking “fined not
20 more than \$250,000” and inserting “fined in ac-
21 cordance with title 18, United States Code”.

22 **SEC. 204. CIVIL PENALTIES.**

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

1 amended by striking paragraph (4) and inserting the fol-
2 lowing:

3 “(4)(A) Except as provided in paragraph (3)
4 and subsection (g), any person who violates a re-
5 quirement of this Act that relates to drugs shall be
6 subject to a civil penalty in an amount not to ex-
7 ceed—

8 “(i) \$500,000 for each such violation; and

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

11 “(B) Each violation described in subparagraph
12 (A) and each day during which the violation con-
13 tinues shall be considered to be a separate offense.”.

14 (b) CONFORMING AMENDMENTS.—

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

18 (A) in subparagraph (A), by striking “Any
19 person who” and inserting “Notwithstanding
20 paragraph (4), any person who”; and

21 (B) in subparagraph (B), by striking “If a
22 violation of” and inserting “Notwithstanding
23 paragraph (4), if a violation of”.

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

1 amended by striking “With respect to a person who”
2 and inserting “Notwithstanding subsection (f)(4),
3 with respect to a person who”.

4 **SEC. 205. SEIZURE.**

5 Section 304(b) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 334(b)) is amended—

7 (1) by striking “(b)” and inserting “(b)(1)”;

8 and

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

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

1 mons and arrest warrant shall be issued by the clerk of
2 the court without court review. When libel for condemna-
3 tion proceedings relating to a drug under this section, in-
4 volving the same claimant and the same issues of adultera-
5 tion or misbranding, are pending in two or more jurisdic-
6 tions, such pending proceedings, upon application of the
7 claimant reasonably made to the court of one such juris-
8 diction, shall be consolidated for trial by order of such
9 court, and tried in (1) any district selected by the claimant
10 where one of such proceedings is pending; or (2) a district
11 agreed upon by stipulation between the parties. If no order
12 for consolidation is so made within a reasonable time, the
13 claimant may apply to the court of one such jurisdiction,
14 and such court (after giving the United States attorney
15 for such district reasonable notice and opportunity to be
16 heard) shall by order, unless good cause to the contrary
17 is shown, specify a district of reasonable proximity to the
18 claimant's principal place of business, in which all such
19 pending proceedings shall be consolidated for trial and
20 tried. Such order of consolidation shall not apply so as
21 to require the removal of any case the date for trial of
22 which has been fixed. The court granting such order shall
23 give prompt notification thereof to the other courts having
24 jurisdiction of the cases covered thereby.”.

1 **SEC. 206. ASSET FORFEITURE.**

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

5 “(h) FORFEITURE RELATED TO VIOLATIONS WITH
6 RESPECT TO DRUGS.—

7 “(1) CRIMINAL FORFEITURE.—Any person con-
8 victed of a violation of section 301 with respect to
9 drugs, or a conspiracy to commit such violation,
10 shall forfeit to the United States any property, real
11 or personal, constituting or traceable to the gross
12 proceeds obtained, directly or indirectly, as a result
13 of such violation. Pursuant to section 2461(c) of
14 title 28, United States Code, the provisions of sec-
15 tion 413 of the Controlled Substances Act, except
16 subsections (a), (d), and (q) of such section 413,
17 shall apply to criminal forfeitures under this para-
18 graph.

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

1 upon the customs officer or any other person with
2 respect to the seizure and forfeiture of property
3 under the customs laws as described in section
4 981(d) of title 18, United States Code, shall be per-
5 formed with respect to seizures and forfeitures of
6 property under this section by such officers, agents,
7 or other persons as may be authorized or designated
8 for that purpose by the Secretary.”.

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

12 “(C) section 304 of the Federal Food,
13 Drug, and Cosmetic Act;”.

14 **TITLE III—IMPORTATION AND**
15 **EXPORTATION**

16 **SEC. 301. DOCUMENTATION FOR ADMISSIBILITY OF IM-**
17 **PORTS.**

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

22 “(ww) The submission (with respect to drugs) of in-
23 formation that is required pursuant to section 801 that
24 is inaccurate or incomplete.

1 “(xx) The failure (with respect to drugs) to submit
2 information that is required pursuant to section 801.”.

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

7 “(r) DOCUMENTATION.—

8 “(1) SUBMISSION.—The Secretary may require
9 by regulation the submission of documentation or
10 other information for a drug that is imported or of-
11 fered for import into the United States. When devel-
12 oping any regulation in accordance with this para-
13 graph, to the extent that the collection of docu-
14 mentation or other information involves Customs
15 and Border Protection efforts or resources, the Sec-
16 retary shall consult with Customs and Border Pro-
17 tection.

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

21 “(3) REFUSAL OF ADMISSION.—A drug im-
22 ported or offered for import into the United States
23 shall be refused admission unless all documentation
24 and information the Secretary requires under this

1 Act or the Public Health Service Act for such article
2 is submitted.”.

3 **SEC. 302. REGISTRATION FOR COMMERCIAL IMPORTERS;**

4 **FEE.**

5 (a) REGISTRATION.—

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

10 “(yy) The failure to register in accordance with sec-
11 tion 801(s).”.

12 (2) MISBRANDING.—Section 502(o) of the Fed-
13 eral Food, Drug, and Cosmetic Act (21 U.S.C.
14 352(o)), as amended, is further amended by insert-
15 ing “if it is imported or offered for import by an im-
16 porter not duly registered under section 801(s),” be-
17 fore “or if it does not bear”.

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

21 “(s) REGISTRATION OF IMPORTERS.—

22 “(1) REGISTRATION.—The Secretary shall re-
23 quire an importer of drugs—

1 “(A) to be registered with the Secretary in
2 a form and manner specified by the Secretary;
3 and

4 “(B) consistent with section 1012, to sub-
5 mit appropriate unique identifiers as a condi-
6 tion of registration.

7 “(2) GOOD IMPORTER PRACTICES.—The main-
8 tenance of registration under this subsection is con-
9 ditioned on compliance with good importer practices
10 in accordance with the following:

11 “(A) The Secretary, in consultation with
12 Customs and Border Protection, shall promul-
13 gate regulations to establish good importer
14 practices that specify the measures an importer
15 shall take to ensure imported drugs are in com-
16 pliance with the requirements of this Act and
17 the Public Health Service Act.

18 “(B) The measures under subparagraph
19 (A) shall ensure that the importer—

20 “(i) has adequate information about
21 the article, its hazards, and the require-
22 ments of this Act and the Public Health
23 Service Act applicable to such article;

24 “(ii) has adequate information or pro-
25 cedures in place to verify that both the ar-

1 ticle and each person that produced, manu-
2 factured, processed, packed, transported,
3 or held the article, including components of
4 the article, are in compliance with the re-
5 quirements of this Act and the Public
6 Health Service Act; and

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

14 “(C) In promulgating good importer prac-
15 tice regulations under this subsection, the Sec-
16 retary may, as appropriate, take into account
17 differences among importers and the types of
18 imports, including based on the level of risk
19 posed by the imported drug.

20 “(3) SUSPENSION OF REGISTRATION.—

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

25 “(i) a violation of this Act; or

1 “(ii) the knowing or repeated making
2 of an inaccurate or incomplete statement
3 or submission of information relating to
4 the importation of a drug.

5 “(B) REQUEST.—The importer whose reg-
6 istration is suspended may request that the
7 Secretary vacate the suspension of registration
8 when such importer has corrected the violation
9 that is the basis for such suspension.

10 “(C) VACATING OF SUSPENSION.—If the
11 Secretary determines that adequate reasons do
12 not exist to continue the suspension of a reg-
13 istration, the Secretary shall vacate such sus-
14 pension.

15 “(4) CANCELLATION OF REGISTRATION.—

16 “(A) IN GENERAL.—Not earlier than 10
17 days after providing the notice under subpara-
18 graph (B), the Secretary may cancel a registra-
19 tion if the Secretary determines that—

20 “(i) such registration was not updated
21 in accordance with this section or other-
22 wise contains false, incomplete, or inac-
23 curate information; or

24 “(ii) the registration fee required
25 under section 743 for such registration has

1 not been paid within 30 days after the date
2 due.

3 “(B) NOTICE OF CANCELLATION.—Can-
4 cellation shall be preceded by notice to the im-
5 porter of the intent to cancel the registration
6 and the basis for such cancellation.

7 “(C) TIMELY UPDATE OR CORRECTION.—
8 If the registration for the importer is updated
9 or corrected no later than 7 days after notice
10 is provided under subparagraph (B), the Sec-
11 retary shall not cancel such registration.

12 “(5) EXEMPTIONS.—The Secretary, by notice
13 in the Federal Register—

14 “(A) shall establish an exemption from the
15 requirements of this subsection for importations
16 for personal use; and

17 “(B) may establish other exemptions from
18 the requirements of this subsection.”.

19 (4) REGULATIONS.—Not later than 36 months
20 after the date of the enactment of this Act, the Sec-
21 retary of Health and Human Services in consulta-
22 tion with the Commissioner responsible for Customs
23 and Border Protection shall promulgate the regula-
24 tions required to carry out section 801(s) of the
25 Federal Food, Drug, and Cosmetic Act, as added by

1 paragraph (3). In establishing the effective date of
2 a regulation promulgated under section 801(s), the
3 Secretary shall, in consultation with the Commis-
4 sioner responsible for Customs and Border Protec-
5 tion, as appropriate, provide a reasonable period of
6 time for an importer of a drug to comply with good
7 importer practices, taking into account differences
8 among importers and the types of imports, including
9 based on the level of risk posed by the imported
10 product.

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

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

17 **“PART 6—IMPORTERS OF DRUGS**

18 **“SEC. 743. IMPORTERS OF DRUGS.**

19 “(a) IMPORTERS.—The Secretary shall assess and
20 collect an annual fee for the registration of an importer
21 under section 801(s).

22 “(b) AMOUNT OF FEE.—

23 “(1) BASE AMOUNTS.—The registration fee
24 under subsection (a) shall be—

25 “(A) for fiscal year 2012, \$500; and

1 “(B) for fiscal year 2013 and each subse-
2 quent fiscal year, the fee for fiscal year 2012 as
3 adjusted under paragraph (2).

4 “(2) ADJUSTMENT.—For fiscal year 2013 and
5 subsequent fiscal years, the fees established pursu-
6 ant to paragraph (1) shall be adjusted by the Sec-
7 retary by notice, published in the Federal Register,
8 for a fiscal year to reflect the greater of—

9 “(A) the total percentage change that oc-
10 curred in the Consumer Price Index for all
11 urban consumers (all items; United States city
12 average) for the 12-month period ending June
13 30 preceding the fiscal year for which fees are
14 being established;

15 “(B) the total percentage change for the
16 previous fiscal year in basic pay under the Gen-
17 eral Schedule in accordance with section 5332
18 of title 5, United States Code, as adjusted by
19 any locality-based comparability payment pur-
20 suant to section 5304 of such title for Federal
21 employees stationed in the District of Columbia;
22 or

23 “(C) the average annual change in the
24 cost, per full-time equivalent position of the
25 Food and Drug Administration, of all personnel

1 compensation and benefits paid with respect to
2 such positions for the first 5 years of the pre-
3 ceding 6 fiscal years.

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

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

13 “(A) a fee under section 736C for registra-
14 tion of one or more establishments under sec-
15 tion 510, for drugs; and

16 “(B) a fee under this section for registra-
17 tion as an importer under section 801(s).

18 “(c) CREDITING AND AVAILABILITY OF FEES.—

19 “(1) IN GENERAL.—Fees authorized under sub-
20 section (a) shall be collected and available for obliga-
21 tion only to the extent and in the amount provided
22 in advance in appropriations Acts. Such fees are au-
23 thorized to remain available until expended. Such
24 sums as may be necessary may be transferred from
25 the Food and Drug Administration salaries and ex-

1 penses appropriation account without fiscal year lim-
2 itation to such appropriation account for salaries
3 and expenses with such fiscal year limitation.

4 “(2) COLLECTIONS AND APPROPRIATIONS
5 ACTS.—The fees authorized by this section—

6 “(A) shall be retained in each fiscal year in
7 an amount not to exceed the amount specified
8 in appropriations Acts, or otherwise made avail-
9 able for obligation, for such fiscal year; and

10 “(B) shall only be collected and available
11 to cover the costs associated with registering
12 importers under sections 801(s) and with en-
13 suring compliance with good importer practices.

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

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

21 “(h) IMPORTERS.—Every person engaged in the im-
22 porting of any drug shall, upon request of an officer or
23 employee designated by the Secretary, permit such officer
24 or employee at all reasonable times to inspect the facilities

1 of such person and have access to, and to copy and verify,
2 any related records.”.

3 **SEC. 303. REGISTRATION FOR CUSTOMS BROKERS.**

4 (a) REGISTRATION.—

5 (1) PROHIBITIONS.—Section 301(yy) of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 331), as added by section 302(a)(1), is amended by
8 inserting “or 801(t)” after “801(s)”.

9 (2) MISBRANDING.—Section 502(o) (21 U.S.C.
10 352(o)), as amended by section 302(a)(2), is amend-
11 ed—

12 (A) by inserting “or a customs broker”
13 after “by an importer”; and

14 (B) by inserting “or 801(t)” after
15 “801(s)”.

16 (3) REGISTRATION.—Section 801 of the Fed-
17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 381),
18 as amended, is further amended by adding at the
19 end the following:

20 “(t) REGISTRATION OF CUSTOMS BROKER.—

21 “(1) REGISTRATION.—The Secretary shall re-
22 quire a customs broker, with respect to the importa-
23 tion of drugs—

1 “(A) to be registered with the Secretary in
2 a form and manner specified by the Secretary;
3 and

4 “(B) consistent with section 1012, to sub-
5 mit appropriate unique identifiers as a condi-
6 tion of registration.

7 “(2) CANCELLATION OF REGISTRATION.—

8 “(A) IN GENERAL.—Not earlier than 10
9 days after providing the notice under subpara-
10 graph (B), the Secretary may cancel a registra-
11 tion that the Secretary determines was not up-
12 dated in accordance with this section or other-
13 wise contains false, incomplete, or inaccurate
14 information.

15 “(B) NOTICE OF CANCELLATION.—Can-
16 cellation shall be preceded by notice to the cus-
17 toms broker of the intent to cancel the registra-
18 tion and the basis for such cancellation.

19 “(C) TIMELY UPDATE OR CORRECTION.—
20 If the registration for the customs broker is up-
21 dated or corrected no later than 7 days after
22 notice is provided under subparagraph (B), the
23 Secretary shall not cancel such registration.

24 “(3) NOTIFICATION.—The Secretary shall no-
25 tify the Commissioner responsible for Customs and

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

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

7 “(A) shall establish an exemption from the
8 requirements of this subsection for importations
9 for personal use; and

10 “(B) may establish other exemptions from
11 the requirements of this subsection.

12 “(5) CIVIL PENALTIES.—Notwithstanding any
13 other provision in this Act, a customs broker who
14 violates section 301 because of a violation of sub-
15 section (ww), (xx), or (yy) of such section shall not
16 be subject to a civil penalty under section
17 303(f)(1)(C) of this Act.”.

18 (4) REGULATIONS.—Not later than 24 months
19 after the date of the enactment of this Act, the Sec-
20 retary of Health and Human Services, in consulta-
21 tion with the Commissioner responsible for Customs
22 and Border Protection, shall promulgate the regula-
23 tions required to carry out section 801(t) of the
24 Federal Food, Drug, and Cosmetic Act, as added by
25 paragraph (3).

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

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

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

13 **SEC. 304. EXPORTATION CERTIFICATE PROGRAM.**

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

16 (1) in subparagraph (B), by striking “If the
17 Secretary” and inserting “With respect to a device,
18 if the Secretary”; and

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

20 “(C) With respect to a drug:

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

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

1 “(iii) Any person who exports from a coun-
2 try other than the United States a drug ap-
3 proved in the United States may request that
4 the Secretary certify that the exported drug
5 meets the applicable requirements of this Act.
6 The Secretary shall issue such a certification
7 within 20 days of the receipt of a request for
8 such certification if the request demonstrates
9 that the drug meets the applicable requirements
10 of this Act.

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

16 “(v) If the Secretary, with respect to a
17 drug, issues an export certification within the
18 20 days prescribed by subparagraph (A) or
19 clause (iii) of this subparagraph, a fee for such
20 certification may be charged but such fee shall
21 not exceed such amount as the Secretary deter-
22 mines is reasonably related to the cost of
23 issuing such certificates. The Secretary may ad-
24 just this fee annually to account for inflation
25 and other cost adjustments. Fees collected for

1 a fiscal year pursuant to this subparagraph
2 shall be credited to the appropriation account
3 for salaries and expenses of the Food and Drug
4 Administration and shall be available in accord-
5 ance with appropriations Acts until expended,
6 without fiscal year limitation. Such fees shall be
7 collected in each fiscal year in an amount equal
8 to the amount specified in appropriations Acts
9 for such fiscal year and shall only be collected
10 and available for the costs of the Food and
11 Drug Administration to cover the cost of
12 issuing such certifications. Such sums as nec-
13 essary may be transferred from such appropria-
14 tion account for salaries and expenses of the
15 Food and Drug Administration without fiscal
16 year limitation to such appropriation account
17 for salaries and expenses with fiscal year limita-
18 tion.”.

19 **SEC. 305. EXTRATERRITORIAL JURISDICTION.**

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

23 **“SEC. 311. EXTRATERRITORIAL JURISDICTION.**

24 “There is extraterritorial jurisdiction over any viola-
25 tion of this Act relating to any drug if such drug was in-

1 tended for import into the United States or if any act in
2 furtherance of the violation was committed in the United
3 States.”.

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

7 “(zz) The production, manufacture, processing, prep-
8 aration, packing, holding, or distribution of an adulterated
9 or misbranded drug with the knowledge or intent that
10 such drug will be imported into the United States, or the
11 production, manufacture, processing, preparation, pack-
12 ing, holding, or distribution of a drug with the knowledge
13 or intent that the drug will be imported into the United
14 States in violation of section 505.”.

15 **SEC. 306. DEDICATED FOREIGN INSPECTORATE.**

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

19 “(j) The Secretary shall establish and maintain a
20 corps of inspectors dedicated to inspections of foreign drug
21 facilities and establishments. This corps shall be staffed
22 and funded by the Secretary at a level sufficient to allow
23 it to conduct inspections of foreign drug facilities and es-
24 tablishments at a frequency at least equivalent to the in-

1 spection rate of domestic drug facilities and establish-
2 ments.”.

3 **TITLE IV—MISCELLANEOUS**

4 **SEC. 401. UNIQUE IDENTIFICATION NUMBER FOR ESTAB-** 5 **LISHMENTS, IMPORTERS, AND CUSTOMS BRO-** 6 **KERS.**

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

10 **“SEC. 1012. UNIQUE IDENTIFIER.**

11 “(a) REGISTRATION OF ESTABLISHMENTS.—A per-
12 son required to register a drug establishment pursuant to
13 section 510 shall submit, at the time of registration, a
14 unique identifier for the establishment.

15 “(b) REGISTRATION OF IMPORTERS AND CUSTOMS
16 BROKERS.—A person required to register pursuant to sec-
17 tion 801(s) or 801(t) shall submit, at the time of registra-
18 tion, a unique identifier for the principal place of business
19 for which such person is required to register under section
20 801(s) or 801(t).

21 “(c) GUIDANCE.—The Secretary may, by guidance,
22 and, with respect to importers and customs brokers, in
23 consultation with the Commissioner responsible for Cus-
24 toms and Border Protection, specify the unique numerical
25 identifier system to be used to meet the requirements of

1 subsections (a) and (b) and the form, manner, and timing
2 of a submission under such subsections. Development of
3 such guidance shall take into account the utilization of ex-
4 isting unique identification schemes and compatibility with
5 customs automated systems.

6 “(d) IMPORTATION.—A drug imported or offered for
7 import shall be refused admission unless the appropriate
8 unique identifiers, as specified by the Secretary, are pro-
9 vided for such article.”.

10 **SEC. 402. COUNTRY OF ORIGIN LABELING.**

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

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

16 “(1) the country of origin for each active phar-
17 maceutical ingredient; and

18 “(2) the place of manufacture of the finished
19 dosage form of such drug.”.

20 (b) REGULATIONS.—Not later than 3 years after the
21 date of the enactment of this Act, the Secretary shall pro-
22 mulgate final regulations to carry out section 502(aa) of
23 the Federal Food, Drug, and Cosmetic Act, as added by
24 subsection (a).

1 (c) EFFECTIVE DATE.—The requirement of section
2 502(aa) of the Federal Food, Drug, and Cosmetic Act,
3 as added by subsection (a), takes effect 4 years after the
4 date of the enactment of this Act.

5 **SEC. 403. FALSE OR MISLEADING REPORTING TO FDA.**

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

9 (b) EFFECTIVE DATE.—The amendment made by
10 subsection (a) shall apply to submissions made on or after
11 the date of the enactment of this Act.

12 **SEC. 404. SUBPOENA AUTHORITY.**

13 (a) PROHIBITED ACT.—Section 301(f) of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 331(f)) is
15 amended by inserting before the period “or the failure or
16 refusal to obey a subpoena issued pursuant to section
17 312”.

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

22 **“SEC. 312. EXERCISE OF SUBPOENA AUTHORITY.**

23 “(a) IN GENERAL.—For the purpose of—

24 “(1) any hearing, investigation, or other pro-
25 ceeding respecting a violation of a provision of this

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

3 “(2) any hearing, investigation, or other pro-
4 ceeding to determine if a person is in violation of a
5 specific provision of this Act, the Public Health
6 Service Act, or the Federal Anti-Tampering Act, re-
7 lating to a drug,

8 the Commissioner may issue subpoenas requiring the at-
9 tendance and testimony of witnesses and the production
10 of records and other things.

11 “(b) TIMING OF COMPLIANCE.—When the Commis-
12 sioner deems that immediate compliance with a subpoena
13 issued under this section is necessary to address a threat
14 of serious adverse health consequences or death, the sub-
15 poena may require immediate production.

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

17 “(1) IN GENERAL.—Subpoenas of the Commis-
18 sioner shall be served by a person authorized by the
19 Commissioner by delivering a copy thereof to the
20 person named therein or by certified mail addressed
21 to such person at such person’s last known dwelling
22 place or principal place of business.

23 “(2) CORPORATIONS AND OTHER ENTITIES.—
24 Service on a domestic or foreign corporation, part-
25 nership, unincorporated association, or other entity

1 that is subject to suit under a common name may
2 be made by delivering the subpoena to an officer, a
3 managing or general agent, or any other agent au-
4 thorized by appointment or by law to receive service
5 of process.

6 “(3) PERSON OUTSIDE U.S. JURISDICTION.—
7 Service on any person not found within the terri-
8 torial jurisdiction of any court of the United States
9 may be made in any manner as the Federal Rules
10 of Civil Procedure prescribe for service in a foreign
11 nation.

12 “(4) PROOF OF SERVICE.—A verified return by
13 the person so serving the subpoena setting forth the
14 manner of service, or, in the case of service by cer-
15 tified mail, the return post office receipt therefore
16 signed by the person so served, shall be proof of
17 service.

18 “(d) PAYMENT OF WITNESSES.—Witnesses subpoe-
19 naed under subsection (a) shall be paid the same fees and
20 mileage as are paid witnesses in the district courts of the
21 United States.

22 “(e) ENFORCEMENT.—In the case of a refusal to
23 obey a subpoena duly served upon any person under sub-
24 section (a), any district court of the United States for the
25 judicial district in which such person charged with refusal

1 to obey is found, resides, or transacts business, upon ap-
2 plication by the Commissioner, shall have jurisdiction to
3 issue an order compelling compliance with the subpoena
4 and requiring such person to appear and give testimony
5 or to appear and produce records and other things, or
6 both. The failure to obey such order of the court may be
7 punished by the court as contempt thereof. If the person
8 charged with failure or refusal to obey is not found within
9 the territorial jurisdiction of the United States, the United
10 States District Court for the District of Columbia shall
11 have the same jurisdiction, consistent with due process,
12 to take any action respecting compliance with the sub-
13 poena by such person that such district court would have
14 if such person were personally within the jurisdiction of
15 such district court.

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

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

3 “(1) furtherance of a potential violation under
4 investigation;

5 “(2) endangerment to the life or physical safety
6 of any person;

7 “(3) flight or other action to avoid prosecution
8 or other enforcement remedies;

9 “(4) destruction of or tampering with evidence;
10 or

11 “(5) intimidation of potential witnesses.

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

16 “(g) RELATION TO OTHER PROVISIONS.—The sub-
17 poena authority vested in the Commissioner and the dis-
18 trict courts of the United States by this section is in addi-
19 tion to any such authority vested in the Commissioner or
20 such courts by other provisions of law, or as is otherwise
21 authorized by law.

22 “(h) NONDELEGATION.—The authority to issue a
23 subpoena under this section is limited to the Commis-
24 sioner or an official designated by the Commissioner. An
25 official may not be so designated unless the official is the

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

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

7 “(u)(1) A drug shall be refused admission if any per-
8 son who manufactures, processes, packs, holds, or ships
9 such drug before it is imported or offered for import into
10 the United States fails or refuses to obey a subpoena
11 issued pursuant to section 312 and such subpoena was
12 issued, in whole or in part, for the purpose of determining
13 whether such drug is adulterated, misbranded, or an unap-
14 proved new drug.

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

19 **SEC. 405. WHISTLEBLOWER PROTECTIONS.**

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

1 **“SEC. 1013. PROTECTIONS FOR EMPLOYEES WHO REFUSE**
2 **TO VIOLATE, OR WHO DISCLOSE VIOLATIONS**
3 **OF, THIS ACT.**

4 “(a) IN GENERAL.—No person who submits or is re-
5 quired under this Act or the Public Health Service Act
6 to submit any information related to a drug, or any offi-
7 cer, employee, contractor, subcontractor, or agent of such
8 person, may discharge, demote, suspend, threaten, harass,
9 or in any other manner discriminate against an employee
10 in the terms and conditions of employment because of any
11 lawful act done by the employee (including any lawful act
12 that is within the ordinary course of the job duties of such
13 employee)—

14 “(1) to provide information, cause information
15 to be provided, or otherwise assist in any investiga-
16 tion regarding any conduct which the employee rea-
17 sonably believes constitutes a violation of this Act
18 that is related to a drug, or any other provision of
19 Federal law relating to the safety of a drug, if the
20 information or assistance is provided to, or an inves-
21 tigation stemming from the provided information is
22 conducted by—

23 “(A) a Federal regulatory or law enforce-
24 ment agency;

25 “(B) any Member of Congress or any com-
26 mittee of Congress; or

1 “(C) a person with supervisory authority
2 over the employee (or such other person work-
3 ing for the employer who has the authority to
4 investigate, discover, or terminate the mis-
5 conduct);

6 “(2) to file, cause to be filed, testify, participate
7 in, or otherwise assist in a proceeding filed, or about
8 to be filed (with any knowledge of the employer), in
9 any court or administrative forum relating to any
10 such alleged violation; or

11 “(3) to refuse to commit or assist in any such
12 violation.

13 “(b) ENFORCEMENT ACTION.—

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

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

20 “(B) if the Secretary of Labor has not
21 issued a final decision within 210 days of the
22 filing of the complaint and there is no showing
23 that such delay is due to the bad faith of the
24 claimant, or within 90 days after receiving a
25 final decision or order from the Secretary,

1 bringing an action at law or equity for de novo
2 review in the appropriate district court of the
3 United States, which court shall have jurisdic-
4 tion over such action without regard to the
5 amount in controversy, and which action shall,
6 at the request of either party to such action, be
7 tried by the court with a jury.

8 “(2) PROCEDURE.—

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

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

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

1 “(D) STATUTE OF LIMITATIONS.—An ac-
2 tion under paragraph (1)(A) shall be com-
3 menced not later than 180 days after the date
4 on which 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) ISSUANCE OF ORDER.—If, in response to
10 a complaint filed under subsection (b)(1), the Sec-
11 retary of Labor or the district court, as applicable,
12 determines that a violation of subsection (a) has oc-
13 curred, the Secretary or the court shall order the
14 person who committed such violation—

15 “(A) to take affirmative action to abate
16 the violation;

17 “(B) to—

18 “(i) reinstate the complainant to his
19 or her former position together with com-
20 pensation (including backpay); and

21 “(ii) restore the terms, conditions,
22 and privileges associated with his or her
23 employment; and

24 “(C) to provide compensatory damages to
25 the complainant.

1 If such an order is issued under this paragraph, the
2 Secretary or the court, at the request of the com-
3 plainant, shall assess against the person against
4 whom the order is issued a sum equal to the aggre-
5 gate amount of all costs and expenses (including at-
6 torney and expert witness fees) reasonably incurred,
7 as determined by the Secretary, by the complainant
8 for, or in connection with, the bringing of the com-
9 plaint upon which the order was issued.

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

17 **SEC. 406. RULE OF CONSTRUCTION.**

18 Nothing in this Act or any amendment made by this
19 Act shall be construed as affecting any authority or re-
20 quirement relating to devices (as defined in section 201
21 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 321)).

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