

[DISCUSSION DRAFT]111TH CONGRESS
2^D SESSION**H. R.** _____

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

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

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

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 “_____ Act of
5 2010”.

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 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 custom 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-

1 pounded, or processed in an establishment not duly
2 registered under section 510(i),” after “not duly
3 registered under section 510,”.

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

10 (b) EXCIPIENT MANUFACTURERS.—

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

22 (2) APPLICATION.—The revisions to regulations
23 under paragraph (1) shall apply with respect to the
24 manufacture, preparation, propagation,
25 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 ceding 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 736A 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 costs of
20 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 2011, not later than
3 the sooner of 90 days after the date of the en-
4 actment of this section or December 31, 2010;
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) IN GENERAL.—The registration fee under
10 subsection (a) shall be—

11 “(A) for fiscal year 2011, \$____; and

12 “(B) for fiscal year 2012 and each subse-
13 quent fiscal year, the fee for fiscal year 2011 as
14 adjusted under subsection (d).

15 “(2) ANNUAL FEE SETTING.—The Secretary
16 shall, not later than 60 days before the start of fis-
17 cal year 2012 and each subsequent fiscal year, es-
18 tablish, for the next fiscal year, registration fees
19 under subsection (a), as described in paragraph (1).

20 “(d) INFLATION ADJUSTMENT.—For fiscal year
21 2012 and subsequent fiscal years, the fee amount under
22 subsection (c) shall be adjusted by the Secretary by notice,
23 published in the Federal Register, for the respective fiscal
24 year to reflect the greater of—

1 “(1) the total percentage change that occurred
2 in the Consumer Price Index for all urban con-
3 sumers (all items; U.S. city average) for the 12-
4 month period ending June 30 preceding the fiscal
5 year for which fees are being established;

6 “(2) the total percentage change for the pre-
7 vious fiscal year in basic pay under the General
8 Schedule in accordance with section 5332 of title 5,
9 United States Code, as adjusted by any locality-
10 based comparability payment pursuant to section
11 5304 of such title for Federal employees stationed in
12 the District of Columbia; or

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

18 The adjustment made each fiscal year under this sub-
19 section will be added on a compounded basis to the sum
20 of all adjustments made each fiscal year after fiscal year
21 2010 under this subsection.

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

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

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

7 “(f) LIMITATIONS.—

8 “(1) IN GENERAL.—Fees under subsection (a)
9 shall be refunded for a fiscal year beginning after
10 fiscal year 2011 unless appropriations for salaries
11 and expenses of the Food and Drug Administration
12 for such fiscal year (excluding the amount of fees
13 appropriated for such fiscal year) are equal to or
14 greater than the amount of appropriations for the
15 salaries and expenses of the Food and Drug Admin-
16 istration for the fiscal year 2011 (excluding the
17 amount of fees appropriated for such fiscal year) ad-
18 justed in the same manner that fee amounts are ad-
19 justed under subsection (d).

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

1 registration under section 510 at any time in such
2 fiscal year.

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

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

14 “(2) COLLECTIONS AND APPROPRIATION
15 ACTS.—The fees authorized by this section—

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

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

22 “(3) AUTHORIZATION OF APPROPRIATIONS.—
23 For each of the fiscal years 2011 through 2015,
24 there are authorized to be appropriated for fees
25 under this section such sums as may be necessary.

1 “(h) COLLECTION OF UNPAID FEES.—In any case
2 in which the Secretary does not receive payment of a fee
3 assessed under subsection (a) within 30 days after it is
4 due, such fee shall be treated as a claim of the United
5 States Government subject to subchapter II of chapter 37
6 of title 31, United States Code.

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

14 “(j) ANNUAL FISCAL REPORTS.—Beginning with fis-
15 cal year 2012, not later than 120 days after the end of
16 each fiscal year for which fees are collected under this sec-
17 tion, the Secretary shall prepare and submit to the Com-
18 mittee on Energy and Commerce of the House of Rep-
19 resentatives and the Committee on Health, Education,
20 Labor, and Pensions of the Senate a report on the imple-
21 mentation of the authority for such fees during such fiscal
22 year and the use, by the Food and Drug Administration,
23 of the fees collected for such fiscal year.

24 “(k) RELATION TO OTHER FEES.—Fees assessed
25 and collected under this section are in addition to other

1 fees assessed and collected under this Act with respect to
2 the same person or establishment.

3 “(l) DEFINITIONS.—In this section:

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

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

13 “(B) laboratory space;

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

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

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

1 “(2) The term ‘drug safety activities’ means ac-
2 tivities related to compliance by persons and estab-
3 lishments registered under section 510 with the re-
4 quirements of this Act relating to drugs (including
5 research related to and the development of stand-
6 ards (such as performance standards and preventive
7 controls), risk assessments, hazard analyses, inspec-
8 tion planning and inspections, third-party inspec-
9 tions, compliance review and enforcement, import re-
10 view, information technology support, test develop-
11 ment, product sampling, risk communication, and
12 administrative detention).”.

13 (2) TRANSITIONAL PROVISIONS.—

14 (A) FIRST IMPOSITION OF FEES.—The
15 Secretary of Health and Human Services shall
16 first impose the fee established under section
17 736C of the Federal Food, Drug, and Cosmetic
18 Act, as added by paragraph (1), for fiscal years
19 beginning with fiscal year 2011.

20 (B) SUNSET DATE.—Section 736C of the
21 Federal Food, Drug, and Cosmetic Act, as
22 added by paragraph (1), does not authorize the
23 assessment or collection of a fee for registration
24 under section 510 of such Act (21 U.S.C. 360)
25 occurring after fiscal year 2015.

1 (f) MODIFICATION OF REGISTRATION FORM.—Not
2 later than 180 days after the date of the enactment of
3 this Act, the Secretary of Health and Human Services
4 shall modify the registration forms under section 510 of
5 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 350d) to comply with the amendments made by this sec-
7 tion.

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

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

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

14 “(A) any active ingredient or bulk drug sub-
15 stance;

16 “(B) any inactive ingredient;

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

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

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

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

3 (b) EFFECTIVE QUALITY SYSTEMS.—

4 (1) PROHIBITED ACTS.—

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

8 (i) by inserting “503C,” after
9 “417(g),”; and

10 (ii) by inserting “503C,” after
11 “417,”.

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

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

21 (2) SYSTEM REQUIREMENTS.—The Federal
22 Food, Drug, and Cosmetic Act is amended by insert-
23 ing after section 503B (21 U.S.C. 353b) the fol-
24 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 follow up, 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) on site 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; and

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) Each evaluation and revision under
2 subparagraph (A)(i) shall be based on a deter-
3 mination of risk.

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

11 “(D) If the Secretary determines that a re-
12 vised or new method, including acceptance and
13 rejection criteria, is appropriate for the safety,
14 identity, quality, strength, purity, or security of
15 any drug, the Secretary may by letter order any
16 manufacturer of such drug to promptly—

17 “(i) revise any method, or adopt any
18 new method, and any related acceptance
19 and rejection criteria for such drug; and

20 “(ii) implement such revised or new
21 method and any related acceptance and re-
22 jection criteria.

23 “(6) RECORDS.—

24 “(A) IN GENERAL.—Each manufacturer
25 shall maintain adequate, contemporaneous

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

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

21 “(7) ADDITIONAL PROVISIONS.—If the Sec-
22 retary determines that provisions in addition to
23 those described in paragraphs (1) through (6) would
24 be appropriate to provide additional assurance of the
25 safety, identity, quality, strength, purity, or security

1 of any drug, the Secretary may promulgate such
2 provisions by regulation.

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

14 “(d) DEFINITIONS.—In this section:

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

17 “(2) The terms ‘manufacture’, ‘manufacturing’,
18 or ‘manufactured’ include preparation, processing,
19 packing, or holding.

20 “(3) The term ‘establish and maintain’ means
21 adequately—

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

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

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

6 (c) DOCUMENTATION OF SUPPLY CHAIN.—

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

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

17 “(1) where the drug, including its raw mate-
18 rials, were produced, including all preceding pro-
19 ducers, manufacturers, distributors, and shippers;
20 and

21 “(2) that the drug, its ingredients, and its raw
22 materials were manufactured, prepared, propagated,
23 compounded, processed, distributed, shipped,
24 warehoused, brokered, imported, and conveyed under

1 conditions that ensure the identity, strength, quality,
2 and purity of the drug.”.

3 (2) APPLICATION.—The amendment made by
4 paragraph (1) applies beginning on the date that is
5 2 years after the date of the enactment of this Act.

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

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

10 (1) by striking “(h)” and inserting “(h)(1)”;
11 and

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

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

19 “(A) at least once in the 2-year period begin-
20 ning with the date of registration of such establish-
21 ment pursuant to this section and at least once in
22 every successive 2-year period thereafter; or

23 “(B) at least once in the 4-year period begin-
24 ning with the date of registration of such establish-
25 ment pursuant to this section and at least once in

1 every successive 4-year period thereafter, if the Sec-
2 retary determines that sufficient information about
3 the type of product produced in the establishment,
4 inspection history, compliance history, and such ad-
5 ditional factors as the Secretary determines by guid-
6 ance, exists to assess risk and to establish a risk-
7 based inspection schedule.

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

1 “(4) The Secretary may inspect, pursuant to section
2 704, every establishment engaged in the manufacture,
3 propagation, compounding, or processing of an excipient
4 of a drug to the same extent as the Secretary is authorized
5 to inspect an establishment engaged in the manufacture,
6 propagation, compounding, or processing of any other
7 drug.

8 “(5) Nothing in this subsection shall be construed as
9 limiting the authority of the Secretary to conduct inspec-
10 tions of establishments under any other provision of the
11 Act.

12 “(6) With respect to fiscal year 2011 and each subse-
13 quent fiscal year, the Secretary shall submit an annual
14 report to the Congress on—

15 “(A) funding dedicated to inspections under
16 this subsection of establishments engaged in the
17 manufacture, propagation, compounding, or proc-
18 essing of a drug; and

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

22 “(7) For purposes of determining inspection fre-
23 quency under paragraph (2), the Secretary shall establish
24 information systems capacity sufficient to assess risk and
25 shall develop and maintain a risk-based system for con-

ducting surveillance of current good manufacturing practices by establishments engaged in the manufacture, propagation, compounding, or processing of a drug that is a finished dosage form or an active pharmaceutical ingredient. The Secretary shall have such capacity in place and begin implementation of such risk-based system not later than 3 years after the date of the enactment of the _____ Act of 2010. Such risk-based system shall include consideration of the class of the establishment's products and associated risks, the date the establishment was last inspected, the establishment's compliance and safety history, the establishment's shipping volume and history, and such other factors as the Secretary determines relevant to assessing the risk presented by the establishment.”.

(b) GAO REPORT.—Not later than 3 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit a report to the Congress on the risk-based process for conducting surveillance of current good manufacturing practices developed and implemented under section 510(h)(7) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)(2) of this section.

(c) APPLICATION.—The amendments made by this section shall apply to drugs introduced or delivered for in-

1 introduction into interstate commerce on or after the date
2 of the enactment of this Act.

3 **SEC. 104. PROHIBITION AGAINST DELAYING, LIMITING, OR**
4 **REFUSING INSPECTION.**

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

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

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

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

21 (1) by inserting after the second sentence the
22 following: “For purposes of enforcement of this Act,
23 officers or employees duly designated by the Sec-
24 retary, upon presenting appropriate credentials and
25 a written notice to the owner, operator, or agent in

1 charge, are also authorized to enter, at reasonable
2 times, any premises of a clinical investigator, spon-
3 sor, monitor, contract research organization, site
4 management organization, institutional review
5 board, or other person that oversees, initiates, or
6 conducts a clinical investigation subject to section
7 505(i), or a postmarket study or clinical trial subject
8 to section 505(k) or 505(o).”; and

9 (2) by inserting “or any establishment associ-
10 ated with a clinical investigation subject to section
11 505(i), or a postmarket study or clinical trial subject
12 to section 505(k) or 505(o) (including the premises
13 of any clinical investigator, sponsor, monitor, con-
14 tract research organization, site management organi-
15 zation, person that oversees or participates in data
16 acquisition, data generation, data archiving, or data
17 analysis, institutional review board, or any other
18 person, other than a subject, that participates in the
19 conduct of a clinical investigation of a drug),” before
20 “inspection shall extend to all things therein”.

21 (b) CONFORMING AMENDMENT.—Section 704(a)(2)
22 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 374(a)(2)) is amended by striking “third sentence” and
24 inserting “fourth sentence”.

1 **SEC. 106. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
2 **OF ADULTERATED OR DRUG PRODUCTS.**

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

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

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

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

15 **“SEC. 568. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
16 **OF ADULTERATED OR MISBRANDED DRUGS.**

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

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

22 “(A) a drug when introduced into or while
23 in interstate commerce, or while held for sale
24 (regardless of whether the first sale) after ship-
25 ment in interstate commerce, is adulterated or
26 misbranded, and

1 “(B) as a result, the use or consumption
2 of, or exposure to, the drug (or an ingredient
3 or component used in any such drug) may re-
4 sult in illness or injury to humans or animals,
5 shall, as soon as practicable, notify the Secretary of
6 the identity and location of the drug.

7 “(2) MANNER OF NOTIFICATION.—Notification
8 under paragraph (1) shall be made in such manner
9 and by such means as the Secretary may require by
10 regulation.

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

15 “(1) recall such drug; and

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

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

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

20 “(e) ORDER TO RECALL.—

21 “(1) AMENDMENT.—Except as provided under
22 subsection (f), if after providing an opportunity for
23 an informal hearing under subsection (d), the Sec-
24 retary determines that the order should be amended
25 to include a recall of the drug with respect to which

1 the order was issued, the Secretary shall amend the
2 order to require a recall.

3 “(2) CONTENTS.—An amended order under
4 paragraph (1) shall—

5 “(A) specify a timetable in which the recall
6 will occur;

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

9 “(C) provide for notice, including to indi-
10 viduals as appropriate, to persons who may be
11 affected by the recall. In providing for such no-
12 tice, the Secretary may allow for the assistance
13 of health professionals, State or local officials,
14 or other individuals designated by the Sec-
15 retary.

16 “(f) EMERGENCY RECALL ORDER.—

17 “(1) IN GENERAL.—If the Secretary has cred-
18 ible evidence or information that a drug subject to
19 an order under subsection (c) presents an imminent
20 threat of serious adverse health consequences or
21 death to humans or animals, the Secretary may
22 issue an order requiring any person who distributes
23 such drug—

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

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

4 “(2) ACTION FOLLOWING ORDER.—Any person
5 who is subject to an emergency recall order under
6 this subsection shall immediately recall such drug
7 and provide notification as required by such order,
8 and may appeal within 24 hours after issuance such
9 order to the Secretary. The person subject to an
10 emergency recall order shall conduct the recall not-
11 withstanding the pendency of any such appeal. An
12 informal hearing shall be held as soon as practicable
13 but not later than 5 calendar days, or less as deter-
14 mined by the Secretary, after such an appeal is filed,
15 unless the parties jointly agree to an extension.
16 After affording an opportunity for an informal hear-
17 ing, the Secretary shall determine whether the order
18 should be amended pursuant to subsection (e)(1). If,
19 after providing an opportunity for such a hearing,
20 the Secretary determines that inadequate grounds
21 exist to support the actions required by the order,
22 the Secretary shall vacate the order.

23 “(g) NOTICE TO CONSUMERS AND HEALTH OFFI-
24 CIALS.—The Secretary shall, as the Secretary determines
25 to be necessary, provide notice of a recall order under this

1 section to consumers to whom the drug was, or may have
2 been, distributed and to appropriate State and local health
3 officials.

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

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

10 “(2) the ability of the Secretary to request any
11 person to perform a voluntary activity related to any
12 drug subject to this Act or the Public Health Service
13 Act.”.

14 (c) ARTICLES SUBJECT TO REFUSAL.—The third
15 sentence of subsection (a) of section 801 of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amend-
17 ed by inserting “or (4) in the case of a drug, such article
18 is subject to an order under section 568 to cease distribu-
19 tion of or recall the article,” before “then such article shall
20 be refused admission”.

21 (d) APPLICATION.—Sections 301(uu) and 568 of the
22 Federal Food, Drug, and Cosmetic Act, as added by sub-
23 sections (a) and (b), shall apply with respect to a drug
24 as of such date, not later than 1 year after the date of

1 the enactment of this Act, as the Secretary of Health and
2 Human Services shall specify.

3 **SEC. 107. NOTIFICATION.**

4 (a) IN GENERAL.—

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

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

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

15 **“SEC. 569. NOTIFICATION.**

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

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

21 “(2) a significant loss or known theft of such
22 drug;

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

1 “(4) repeated failures by a manufacturer of a
2 component or other material used in the manufac-
3 ture of such drug to ensure compliance with applica-
4 ble quality systems requirements under section
5 501(a)(2)(B) or 503C of this Act or section 351 or
6 361 of the Public Health Service Act;

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

9 “(6) any contamination or any significant
10 chemical, physical, or other change or deterioration
11 in such drug after distribution, or any failure of a
12 distributed lot or batch of such drug to meet an es-
13 tablished specification; and

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

17 “(b) MANNER OF NOTIFICATION.—Notification
18 under this section shall be made in such manner and by
19 such means as the Secretary may require by regulation
20 or guidance.

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

1 (b) EXCHANGE OF INFORMATION.—

2 (1) PROHIBITED ACTS.—

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

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

8 (ii) by inserting “, or as specified in
9 section 708,” before “any information ac-
10 quired”.

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

14 (i) by striking “573.” and inserting
15 “573”; and

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

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

21 (A) by striking “The Secretary” and in-
22 serting “(a) The Secretary”; and

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

24 “(b)(1)(A) The Secretary may provide to any Federal
25 agency acting within the scope of its jurisdiction any infor-

1 mation respecting a drug that is exempt from disclosure
2 pursuant to subsection (a) of section 552 of title 5, United
3 States Code, by reason of subsection (b)(4) of such sec-
4 tion.

5 “(B) Any such information provided to another Fed-
6 eral agency shall not be disclosed by such agency except
7 in any investigation within the receiving agency’s jurisdic-
8 tion or in an action or proceeding under the laws of the
9 United States in which the receiving agency or the United
10 States is a party.

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

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

19 “(3) Except as provided by section 301(j), in carrying
20 out this Act, the Secretary may provide to any person any
21 information respecting a drug that is exempt from dislo-
22 sure pursuant to section 552(a) of title 5, United States
23 Code, by reason of subsection (b)(4) of such section, if
24 the Secretary determines that providing the information
25 to the person is appropriate under the circumstances and

1 the recipient provides adequate assurances to the Sec-
2 retary that the recipient will preserve the confidentiality
3 of the information.

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

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

10 “(B) any international organization established
11 by law, treaty, or other governmental action and
12 having responsibility—

13 “(i) to facilitate global or regional harmo-
14 nization of standards and requirements in an
15 area of responsibility of the Food and Drug Ad-
16 ministration; or

17 “(ii) to promote and coordinate public
18 health efforts, if the agency or organization pro-
19 vides adequate assurances to the Secretary that
20 the agency or organization will preserve the
21 confidentiality of the information.

22 “(c) Except as provided by section 301(j), the Sec-
23 retary may disclose to the public any information respect-
24 ing a drug that is exempt from disclosure pursuant to sec-
25 tion 552(a) of title 5, United States Code, by reason of

1 subsection (b)(4) of such section, if the Secretary deter-
2 mines that such disclosure is necessary to protect the pub-
3 lic health.

4 “(d) Except as provided in subsection (e), the Sec-
5 retary shall not be required to disclose under section 552
6 of title 5, United States Code, or any other provision of
7 law any information respecting a drug obtained from a
8 Federal, State, or local government agency, or from a for-
9 eign government agency, or from an international organi-
10 zation described in subsection (b)(4), if the agency or or-
11 ganization has requested that the information be kept con-
12 fidential, or has precluded such disclosure under other use
13 limitations, as a condition of providing the information.

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

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

21 **TITLE II—RESPONSE**

22 **SEC. 201. ADMINISTRATIVE DETENTION.**

23 (a) ADMINISTRATIVE DETENTION OF DRUGS.—Sec-
24 tion 304 of the Federal Food, Drug, and Cosmetic Act

1 (21 U.S.C. 334) is amended by adding at the end the fol-
2 lowing:

3 “(i) ADMINISTRATIVE DETENTION OF DRUGS.—

4 “(1) DETENTION AUTHORITY.—

5 “(A) IN GENERAL.—If during any lawful
6 activity conducted by an officer or employee, a
7 drug which such officer or employee has reason
8 to believe is in violation of any provision of this
9 Act is found, such officer or employee may
10 order the drug detained (in accordance with
11 regulations prescribed by the Secretary) for a
12 reasonable period which may not exceed 20
13 days unless the Secretary determines that a pe-
14 riod of detention greater than 20 days is re-
15 quired to institute an action under subsection
16 (a) or section 302, in which case the Secretary
17 may authorize a detention period of not to ex-
18 ceed 60days.

19 “(B) SECRETARY’S APPROVAL.—Regula-
20 tions of the Secretary prescribed under this
21 paragraph shall require that, before a drug may
22 be ordered detained under this paragraph, the
23 Secretary or an officer or employee designated
24 by the Secretary approve such order.

1 “(C) SECURITY OF DETAINED DRUG.—A
2 detention order under this paragraph may re-
3 quire—

4 “(i) the labeling or marking of a drug
5 during the period of its detention for the
6 purpose of identifying the drug as de-
7 tained; and

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

10 “(D) APPEAL OF DETENTION ORDER.—

11 “(i) RIGHT TO APPEAL.—Any person
12 who would be entitled to claim a drug if it
13 were seized under subsection (a) may ap-
14 peal to the Secretary a detention of such
15 drug under this paragraph.

16 “(ii) HEARING AND RESPONSE.—
17 Within fifteen days of the date an appeal
18 of a detention is filed with the Secretary,
19 the Secretary shall after affording oppor-
20 tunity for an informal hearing by order
21 confirm the detention or revoke it.

22 “(2) LIMITATION ON MOVEMENT OF DETAINED
23 DRUGS.—

24 “(A) IN GENERAL.—Except as authorized
25 by subparagraph (B), a drug subject to a deten-

1 tion order issued under paragraph (1) shall not
2 be moved by any person from the place at
3 which it is ordered detained until—

4 “(i) released by the Secretary; or

5 “(ii) the expiration of the detention
6 period applicable to such order,

7 whichever occurs first.

8 “(B) EXCEPTION.—A drug subject to a de-
9 tention order under paragraph (1) may be
10 moved—

11 “(i) in accordance with regulations
12 prescribed by the Secretary; and

13 “(ii) if not in final form for shipment,
14 at the discretion of the manufacturer of
15 the device for the purpose of completing
16 the work required to put it in such form.”.

17 (b) REGULATIONS.—The Secretary shall issue regula-
18 tions or guidance to implement the amendments made by
19 this section.

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

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

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

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

6 **SEC. 202. DESTRUCTION OF ADULTERATED, MISBRANDED,**
7 **OR COUNTERFEIT DRUGS OFFERED FOR IM-**
8 **PORT.**

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

12 “(q)(1) Subject to paragraph (2), the Secretary of the
13 Treasury shall cause the destruction, upon referral from
14 the Secretary of Health and Human Services, of any drug
15 that—

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

19 “(B) is valued at an amount that is \$2,000 or
20 less (or such higher amount as the Secretary of the
21 Treasury may set by regulation pursuant to section
22 498 of the Tariff Act of 1930).

23 “(2) The Secretary of Health and Human Services
24 shall issue regulations providing for notice and an oppor-
25 tunity for an informal hearing for destruction of drugs

1 under paragraph (1). The regulations under this para-
2 graph shall allow the Secretary of Health and Human
3 Services to provide the notice and opportunity for an infor-
4 mal hearing to the owner or consignee after the destruc-
5 tion has occurred.

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

11 (b) CONFORMING AMENDMENT.—The fifth sentence
12 of subsection (a) of section 801 of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 381) is amended by
14 striking “The Secretary of the Treasury shall” and insert-
15 ing “Except as provided in subsection (q), the Secretary
16 of the Treasury shall”.

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

20 **SEC. 203. CRIMINAL PENALTIES.**

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

23 (1) in subsection (a)—

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

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

5 “(3) Notwithstanding paragraph (1), any person who,
6 with respect to a drug, knowingly violates paragraph (a),
7 (b), (c), (d), (f), (g), (i), (k), or (jj)(3) of section 301 shall
8 be imprisoned for not more than 10 years or fined in ac-
9 cordance with title 18, United States Code, or both.”; and
10 (2) in subsection (b)(1), by striking “fined not
11 more than \$250,000” and inserting “fined in ac-
12 cordance with title 18, United States Code”.

13 **SEC. 204. CIVIL PENALTIES.**

14 (a) IN GENERAL.—Section 303(f) of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 331(f)) is
16 amended by striking paragraph (4) and inserting the fol-
17 lowing:

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

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

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

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

4 (b) CONFORMING AMENDMENTS.—

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

8 (A) in subparagraph (A), by striking “Any
9 person who” and inserting “Notwithstanding
10 paragraph (4), any person who”; and

11 (B) in subparagraph (B), by striking “If a
12 violation of” and inserting “Notwithstanding
13 paragraph (4), if a violation of”.

14 (2) Section 303(g)(1) of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 331(g)(1)) is
16 amended by striking “With respect to a person who”
17 and inserting “Notwithstanding subsection (f)(4),
18 with respect to a person who”.

19 **SEC. 205. SEIZURE.**

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

22 (1) by striking “(b)” and inserting “(b)(1)”;
23 and

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

1 “(2) PROCEDURE WITH RESPECT TO DRUGS; MUL-
2 TIPLICITY OF PENDING PROCEEDINGS.—In the case of a
3 violation relating to a drug, the article, equipment, or
4 other thing proceeded against shall be liable to seizure by
5 process pursuant to the libel, and the procedure in cases
6 under this section shall conform, as nearly as may be, to
7 the procedure in admiralty rather than the procedure used
8 for civil asset forfeiture proceedings set forth in section
9 983 of title 18, United States Code. On demand of either
10 party any issue of fact joined in any such case brought
11 under this section shall be tried by jury. Any such seizure
12 brought under this section is not governed by Rule G of
13 the Supplemental Rules of Admiralty or Maritime Claims
14 and Asset Forfeiture Actions. In addition, exigent cir-
15 cumstances shall be deemed to exist for all such seizures
16 brought under this section, and in such cases, the sum-
17 mons and arrest warrant shall be issued by the clerk of
18 the court without court review. When libel for condemna-
19 tion proceedings relating to a drug under this section, in-
20 volving the same claimant and the same issues of adultera-
21 tion or misbranding, are pending in two or more jurisdic-
22 tions, such pending proceedings, upon application of the
23 claimant seasonably made to the court of one such juris-
24 diction, shall be consolidated for trial by order of such
25 court, and tried in (1) any district selected by the claimant

1 where one of such proceedings is pending; or (2) a district
2 agreed upon by stipulation between the parties. If no order
3 for consolidation is so made within a reasonable time, the
4 claimant may apply to the court of one such jurisdiction,
5 and such court (after giving the United States attorney
6 for such district reasonable notice and opportunity to be
7 heard) shall by order, unless good cause to the contrary
8 is shown, specify a district of reasonable proximity to the
9 claimant's principal place of business, in which all such
10 pending proceedings shall be consolidated for trial and
11 tried. Such order of consolidation shall not apply so as
12 to require the removal of any case the date for trial of
13 which has been fixed. The court granting such order shall
14 give prompt notification thereof to the other courts having
15 jurisdiction of the cases covered thereby.”.

16 **SEC. 206. ASSET FORFEITURE.**

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

20 “(h) FORFEITURE RELATED TO VIOLATIONS WITH
21 RESPECT TO DRUGS.—

22 “(1) CRIMINAL FORFEITURE.—Any person con-
23 victed of a violation of section 301 with respect to
24 drugs, or a conspiracy to commit such violation,
25 shall forfeit to the United States any property, real

1 or personal, constituting or traceable to the gross
2 proceeds obtained, directly or indirectly, as a result
3 of such violation. Pursuant to section 2461(c) of
4 title 28, United States Code, the provisions of sec-
5 tion 413 of the Controlled Substances Act, except
6 subsections (a), (d), and (q) of such section 413,
7 shall apply to criminal forfeitures under this para-
8 graph.

9 “(2) CIVIL FORFEITURE.—Any property, real
10 or personal, constituting or traceable to the gross
11 proceeds obtained, directly or indirectly, as a result
12 of a violation of section 301 with respect to drugs,
13 or a conspiracy to commit such violation, is subject
14 to forfeiture to the United States in accordance with
15 the provisions of chapter 46 of title 18, United
16 States Code, except that such duties as are imposed
17 upon the customs officer or any other person with
18 respect to the seizure and forfeiture of property
19 under the customs laws as described in section
20 981(d) of title 18, United States Code, shall be per-
21 formed with respect to seizures and forfeitures of
22 property under this section by such officers, agents,
23 or other persons as may be authorized or designated
24 for that purpose by the Secretary.”.

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

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

6 **TITLE III—IMPORTATION AND**
7 **EXPORTATION**

8 **SEC. 301. DOCUMENTATION FOR ADMISSIBILITY OF IM-**
9 **PORTS.**

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

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

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

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

23 “(r) DOCUMENTATION.—

24 “(1) SUBMISSION.—The Secretary may require
25 by regulation the submission of documentation or

1 other information for a drug that is imported or of-
2 fered for import into the United States. When devel-
3 oping any regulation in accordance with this para-
4 graph, to the extent that the collection of docu-
5 mentation or other information involves Customs
6 and Border Protection efforts or resources, the Sec-
7 retary shall consult with Customs and Border Pro-
8 tection.

9 “(2) **FORMAT.**—A regulation under paragraph
10 (1) may specify the format for submission of the
11 documentation or other information.

12 “(3) **REFUSAL OF ADMISSION.**—A drug im-
13 ported or offered for import into the United States
14 shall be refused admission unless all documentation
15 and information the Secretary requires under this
16 Act or the Public Health Service Act for such article
17 is submitted.”.

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

19 **FEE.**

20 (a) **REGISTRATION.**—

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

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

3 (2) MISBRANDING.—Section 502(o) of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C.
5 352(o)), as amended, is further amended by insert-
6 ing “if it is imported or offered for import by an im-
7 porter not duly registered under section 801(s),” be-
8 fore “or if it does not bear”.

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

12 “(s) REGISTRATION OF IMPORTERS.—

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

15 “(A) to be registered with the Secretary in
16 a form and manner specified by the Secretary;
17 and

18 “(B) consistent with section 1012, to sub-
19 mit appropriate unique identifiers as a condi-
20 tion of registration.

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

1 “(A) The Secretary, in consultation with
2 Customs and Border Protection, shall promul-
3 gate regulations to establish good importer
4 practices that specify the measures an importer
5 shall take to ensure imported drugs are in com-
6 pliance with the requirements of this Act and
7 the Public Health Service Act.

8 “(B) The measures under subparagraph
9 (A) shall ensure that the importer—

10 “(i) has adequate information about
11 the article, its hazards, and the require-
12 ments of this Act and the Public Health
13 Service Act applicable to such article;

14 “(ii) has adequate information or pro-
15 cedures in place to verify that both the ar-
16 ticle and each person that produced, manu-
17 factured, processed, packed, transported,
18 or held the article, including components of
19 the article, are in compliance with the re-
20 quirements of this Act and the Public
21 Health Service Act; and

22 “(iii) has adequate procedures in
23 place to take corrective action, such as the
24 ability to appropriately trace, withhold,
25 and recall articles, if an article imported by

1 the importer is not in compliance with the
2 requirements of this Act or the Public
3 Health Service Act.

4 “(C) In promulgating good importer prac-
5 tice regulations under this subsection, the Sec-
6 retary may, as appropriate, take into account
7 differences among importers and the types of
8 imports, including based on the level of risk
9 posed by the imported drug.

10 “(3) SUSPENSION OF REGISTRATION.—

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

15 “(i) a violation of this Act; or

16 “(ii) the knowing or repeated making
17 of an inaccurate or incomplete statement
18 or submission of information relating to
19 the importation of a drug.

20 “(B) REQUEST.—The importer whose reg-
21 istration is suspended may request that the
22 Secretary vacate the suspension of registration
23 when such importer has corrected the violation
24 that is the basis for such suspension.

1 “(C) VACATING OF SUSPENSION.—If the
2 Secretary determines that adequate reasons do
3 not exist to continue the suspension of a reg-
4 istration, the Secretary shall vacate such sus-
5 pension.

6 “(4) CANCELLATION OF REGISTRATION.—

7 “(A) IN GENERAL.—Not earlier than 10
8 days after providing the notice under subpara-
9 graph (B), the Secretary may cancel a registra-
10 tion that the Secretary determines was not—

11 “(i) updated in accordance with this
12 section or otherwise contains false, incom-
13 plete, or inaccurate information; or

14 “(ii) for which the registration fee re-
15 quired under section 743 has not been paid
16 within 30 days after the date due.

17 “(B) NOTICE OF CANCELLATION.—Can-
18 cellation shall be preceded by notice to the im-
19 porter of the intent to cancel the registration
20 and the basis for such cancellation.

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

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

3 “(A) shall establish an exemption from the
4 requirements of this subsection for importations
5 for personal use; and

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

8 (4) REGULATIONS.—Not later than 36 months
9 after the date of the enactment of this Act, the Sec-
10 retary of Health and Human Services in consulta-
11 tion with the Commissioner responsible for Customs
12 and Border Protection shall promulgate the regula-
13 tions required to carry out section 801(r) of the
14 Federal Food, Drug, and Cosmetic Act, as added by
15 paragraph (3). In establishing the effective date of
16 a regulation promulgated under section 801(s), the
17 Secretary shall, in consultation with the Commis-
18 sioner responsible for Customs and Border Protec-
19 tion, as appropriate, provide a reasonable period of
20 time for an importer of a drug to comply with good
21 importer practices, taking into account differences
22 among importers and the types of imports, including
23 based on the level of risk posed by the imported
24 product.

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

7 **“PART 6—IMPORTERS OF DRUGS**

8 **“SEC. 743. IMPORTERS OF DRUGS.**

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

12 “(b) AMOUNT OF FEE.—

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

15 “(A) for fiscal year 2011, \$500; and

16 “(B) for fiscal year 2012 and each subse-
17 quent fiscal year, the fee for fiscal year 2011 as
18 adjusted under paragraph (2).

19 “(2) ADJUSTMENT.—For fiscal year 2012 and
20 subsequent fiscal years, the fees established pursu-
21 ant to paragraph (1) shall be adjusted by the Sec-
22 retary by notice, published in the Federal Register,
23 for a fiscal year to reflect the greater of—

24 “(A) the total percentage change that oc-
25 curred in the Consumer Price Index for all

1 urban consumers (all items; United States city
2 average), for the 12-month period ending June
3 30 preceding the fiscal year for which fees are
4 being established;

5 “(B) the total percentage change for the
6 previous fiscal year in basic pay under the Gen-
7 eral Schedule in accordance with section 5332
8 of title 5, United States Code, as adjusted by
9 any locality-based comparability payment pur-
10 suant to section 5304 of such title for Federal
11 employees stationed in the District of Columbia;
12 or

13 “(C) the average annual change in the
14 cost, per full-time equivalent position of the
15 Food and Drug Administration, of all personnel
16 compensation and benefits paid with respect to
17 such positions for the first 5 years of the pre-
18 ceding 6 fiscal years.

19 “(3) COMPOUNDED BASIS.—The adjustment
20 made each fiscal year pursuant this subsection shall
21 be added on a compounded basis to the sum of all
22 adjustments made each fiscal year after fiscal year
23 2011 under this subsection.

24 “(4) WAIVER FOR IMPORTERS REQUIRED TO
25 PAY REGISTRATION FEE.—The Secretary shall waive

1 the fee applicable to a person under this section if
2 such person is required to pay both—

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

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

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

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

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

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

1 “(B) shall only be collected and available
2 to cover the costs associated with registering
3 importers under sections 801(s) and with en-
4 suring compliance with good importer practices.

5 “(3) AUTHORIZATION OF APPROPRIATIONS.—
6 For each of fiscal years 2011 through 2015, there
7 are authorized to be appropriated for fees under this
8 section such sums as may be necessary.”.

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

12 “(h) IMPORTERS.—Every person engaged in the im-
13 porting of any drug shall, upon request of an officer or
14 employee designated by the Secretary, permit such officer
15 or employee at all reasonable times to inspect the facilities
16 of such person and have access to, and to copy and verify,
17 any related records.”.

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

19 (a) REGISTRATION.—

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

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

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

6 (B) by inserting “or 801(t)” after
7 “801(s)”.

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

12 “(t) REGISTRATION OF CUSTOMS BROKER.—

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

16 “(A) to be registered with the Secretary in
17 a form and manner specified by the Secretary;
18 and

19 “(B) consistent with section 1012, to sub-
20 mit appropriate unique identifiers as a condi-
21 tion of registration.

22 “(2) CANCELLATION OF REGISTRATION.—

23 “(A) IN GENERAL.—Not earlier than 10
24 days after providing the notice under subpara-
25 graph (B), the Secretary may cancel a registra-

1 tion that the Secretary determines was not up-
2 dated in accordance with this section or other
3 wise contains false, incomplete, or inaccurate
4 information.

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

9 “(C) TIMELY UPDATE OR CORRECTION.—
10 If the registration for the customs broker is up-
11 dated or corrected no later than 7 days after
12 notice is provided under subparagraph (B), the
13 Secretary shall not cancel such registration.

14 “(3) NOTIFICATION.—The Secretary shall no-
15 tify the Commissioner responsible for Customs and
16 Border Protection whenever the Secretary cancels a
17 registration under this subsection.

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

22 “(A) shall establish an exemption from the
23 requirements of this subsection for importations
24 for personal use; and

1 “(B) may establish other exemptions from
2 the requirements of this subsection.

3 “(5) CIVIL PENALTIES.—Notwithstanding any
4 other provision in this Act, a customs broker who
5 violates section 301 because of a violation of sub-
6 section (ww), (xx), or (yy) of such section shall not
7 be subject to a civil penalty under section
8 303(f)(1)(C) of this Act .”.

9 (4) REGULATIONS.—Not later than 24 months
10 after the date of the enactment of this Act, the Sec-
11 retary of Health and Human Services, in consulta-
12 tion with the Commissioner responsible for Customs
13 and Border Protection, shall promulgate the regula-
14 tions required to carry out section 801(t) of the
15 Federal Food, Drug, and Cosmetic Act, as added by
16 paragraph (3).

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

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

23 “(i) BROKERS.—Every customs broker required to be
24 registered with the Secretary shall, upon request of an of-
25 ficer or employee designated by the Secretary, permit such

1 officer or employee at all reasonable times to inspect the
2 facilities of such person and have access to, and to copy
3 and verify, any related records.”.

4 **SEC. 304. EXPORTATION CERTIFICATE PROGRAM.**

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

7 (1) in subparagraph (B), by striking “If the
8 Secretary” and inserting “With respect to a device,
9 if the Secretary”; and

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

11 “(C) With respect to a drug:

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

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

16 “(iii) Any person who exports from a coun-
17 try other than the United States a drug ap-
18 proved in the United States may request that
19 the Secretary certify that the exported drug
20 meets the applicable requirements of this Act.
21 The Secretary shall issue such a certification
22 within 20 days of the receipt of a request for
23 such certification if the request demonstrates
24 that the drug meets the applicable requirements
25 of this Act.

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

6 “(v) If the Secretary, with respect to a
7 drug, issues an export certification within the
8 20 days prescribed by subparagraph (A) or
9 clause (iii) of this subparagraph, a fee for such
10 certification may be charged but such fee shall
11 not exceed such amount as the Secretary deter-
12 mines is reasonably related to the cost of
13 issuing such certificates. The Secretary may ad-
14 just this fee annually to account for inflation
15 and other cost adjustments. Fees collected for
16 a fiscal year pursuant to this subparagraph
17 shall be credited to the appropriation account
18 for salaries and expenses of the Food and Drug
19 Administration and shall be available in accord-
20 ance with appropriations Acts until expended,
21 without fiscal year limitation. Such fees shall be
22 collected in each fiscal year in an amount equal
23 to the amount specified in appropriations Acts
24 for such fiscal year and shall only be collected
25 and available for the costs of the Food and

1 Drug Administration to cover the cost of
2 issuing such certifications. Such sums as nec-
3 essary may be transferred from such appropria-
4 tion account for salaries and expenses of the
5 Food and Drug Administration without fiscal
6 year limitation to such appropriation account
7 for salaries and expenses with fiscal year limita-
8 tion.”.

9 **SEC. 305. EXTRATERRITORIAL JURISDICTION.**

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

13 **“SEC. 311. EXTRATERRITORIAL JURISDICTION.**

14 “There is extraterritorial jurisdiction over any viola-
15 tion of this Act relating to any drug if such drug was in-
16 tended for import into the United States or if any act in
17 furtherance of the violation was committed in the United
18 States.”.

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

22 “(zz) The production, manufacture, processing, prep-
23 aration, packing, holding, or distribution of an adulterated
24 or misbranded drug with the knowledge or intent that
25 such drug will be imported into the United States, or the

1 production, manufacture, processing, preparation, pack-
2 ing, holding, or distribution of a drug with the knowledge
3 or intent that the drug will be imported into the United
4 States in violation of section 505.”.

5 **SEC. 306. DEDICATED FOREIGN INSPECTORATE.**

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

9 “(j) The Secretary shall establish and maintain a
10 corps of inspectors dedicated to inspections of foreign drug
11 facilities and establishments. This corps shall be staffed
12 and funded by the Secretary at a level sufficient to allow
13 it to conduct inspections of foreign drug facilities and es-
14 tablishments at a frequency at least equivalent to the in-
15 spection rate of domestic drug facilities and establish-
16 ments.”.

17 **TITLE IV—MISCELLANEOUS**

18 **SEC. 401. UNIQUE IDENTIFICATION NUMBER FOR ESTAB-**
19 **LISHMENTS, IMPORTERS, AND CUSTOM BRO-**
20 **KERS.**

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

1 **“SEC. 1012. UNIQUE IDENTIFIER.**

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

6 “(b) REGISTRATION OF IMPORTERS AND CUSTOM
7 BROKERS.—A person required to register pursuant to sec-
8 tion 801(s) or 801(t) shall submit, at the time of registra-
9 tion, a unique identifier for the principal place of business
10 for which such person is required to register under section
11 801(s) or 801(t).

12 “(c) GUIDANCE.—The Secretary may, by guidance,
13 and, with respect to importers and customs brokers, in
14 consultation with the Commissioner responsible for Cus-
15 toms and Border Protection, specify the unique numerical
16 identifier system to be used to meet the requirements of
17 subsections (a) and (b) and the form, manner, and timing
18 of a submission under such subsections. Development of
19 such guidance shall take into account the utilization of ex-
20 isting unique identification schemes and compatibility with
21 customs automated systems.

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

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

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

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

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

9 “(2) the place of manufacture of the finished
10 dosage form of such drug.”.

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

16 (c) EFFECTIVE DATE.—The requirement of section
17 502(aa) of the Federal Food, Drug, and Cosmetic Act,
18 as added by subsection (a), takes effect 4 years after the
19 date of the enactment of this Act.

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

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

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

1 **SEC. 404. SUBPOENA AUTHORITY.**

2 (a) PROHIBITED ACT.—Section 301(f) of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 331(f)) is
4 amended by inserting before the period “or the failure or
5 refusal to obey a subpoena issued pursuant to section
6 312”.

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

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

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

13 “(1) any hearing, investigation, or other pro-
14 ceeding respecting a violation of a provision of this
15 Act, the Public Health Service Act, or the Federal
16 Anti-Tampering Act, relating to a drug; or

17 “(2) any hearing, investigation, or other pro-
18 ceeding to determine if a person is in violation of a
19 specific provision of this Act, the Public Health
20 Service Act, or the Federal Anti-Tampering Act, re-
21 lating to a drug,

22 the Commissioner may issue subpoenas requiring the at-
23 tendance and testimony of witnesses and the production
24 of records and other things.

25 “(b) TIMING OF COMPLIANCE.—When the Commis-
26 sioner deems that immediate compliance with a subpoena

1 issued under this section is necessary to address a threat
2 of serious adverse health consequences or death, the sub-
3 poena may require immediate production.

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

5 “(1) IN GENERAL.—Subpoenas of the Commis-
6 sioner shall be served by a person authorized by the
7 Commissioner by delivering a copy thereof to the
8 person named therein or by certified mail addressed
9 to such person at such person’s last known dwelling
10 place or principal place of business.

11 “(2) CORPORATIONS AND OTHER ENTITIES.—
12 Service on a domestic or foreign corporation, part-
13 nership, unincorporated association, or other entity
14 that is subject to suit under a common name may
15 be made by delivering the subpoena to an officer, a
16 managing or general agent, or any other agent au-
17 thorized by appointment or by law to receive service
18 of process.

19 “(3) PERSON OUTSIDE U.S. JURISDICTION.—
20 Service on any person not found within the terri-
21 torial jurisdiction of any court of the United States
22 may be made in any manner as the Federal Rules
23 of Civil Procedure prescribe for service in a foreign
24 nation.

1 “(4) PROOF OF SERVICE.—A verified return by
2 the person so serving the subpoena setting forth the
3 manner of service, or, in the case of service by cer-
4 tified mail, the return post office receipt therefore
5 signed by the person so served, shall be proof of
6 service.

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

11 “(e) ENFORCEMENT.—In the case of a refusal to
12 obey a subpoena duly served upon any person under sub-
13 section (a), any district court of the United States for the
14 judicial district in which such person charged with refusal
15 to obey is found, resides, or transacts business, upon ap-
16 plication by the Commissioner, shall have jurisdiction to
17 issue an order compelling compliance with the subpoena
18 and requiring such person to appear and give testimony
19 or to appear and produce records and other things, or
20 both. The failure to obey such order of the court may be
21 punished by the court as contempt thereof. If the person
22 charged with failure or refusal to obey is not found within
23 the territorial jurisdiction of the United States, the United
24 States District Court for the District of Columbia shall
25 have the same jurisdiction, consistent with due process,

1 to take any action respecting compliance with the sub-
2 poena by such person that such district court would have
3 if such person were personally within the jurisdiction of
4 such district court.

5 “(f) NONDISCLOSURE.—A United States district
6 court for the district in which the subpoena is or will be
7 served, upon application of the Commissioner, may issue
8 an ex parte order that no person or entity disclose to any
9 other person or entity (other than to an attorney to obtain
10 legal advice) the existence of such subpoena for a period
11 of up to 90 days. Such order may be issued on a showing
12 that the records or things being sought may be relevant
13 to the hearing, investigation, proceeding, or other matter
14 and that there is reason to believe that such disclosure
15 may result in—

16 “(1) furtherance of a potential violation under
17 investigation;

18 “(2) endangerment to the life or physical safety
19 of any person;

20 “(3) flight or other action to avoid prosecution
21 or other enforcement remedies;

22 “(4) destruction of or tampering with evidence;
23 or

24 “(5) intimidation of potential witnesses.

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

5 “(g) RELATION TO OTHER PROVISIONS.—The sub-
6 poena authority vested in the Commissioner and the dis-
7 trict courts of the United States by this section is in addi-
8 tion to any such authority vested in the Commissioner or
9 such courts by other provisions of law, or as is otherwise
10 authorized by law.

11 “(h) NONDELEGATION.—The authority to issue a
12 subpoena under this section is limited to the Commis-
13 sioner or an official designated by the Commissioner. An
14 official may not be so designated unless the official is the
15 director of the district under this Act in which the drug
16 is located, or is an official senior to such director.”.

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

21 “(u)(1) A drug shall be refused admission if any per-
22 son who manufactures, processes, packs, holds, or ships
23 such drug before it is imported or offered for import into
24 the United States fails or refuses to obey a subpoena
25 issued pursuant to section 312 and such subpoena was

1 issued, in whole or in part, for the purpose of determining
2 whether such drug is adulterated, misbranded, or an unap-
3 proved new drug.

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

8 **SEC. 405. WHISTLEBLOWER PROTECTIONS.**

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

12 **“SEC. 1013. PROTECTIONS FOR EMPLOYEES WHO REFUSE**
13 **TO VIOLATE, OR WHO DISCLOSE VIOLATIONS**
14 **OF, THIS ACT.**

15 “(a) IN GENERAL.—No person who submits or is re-
16 quired under this Act or the Public Health Service Act
17 to submit any information related to a drug, or any offi-
18 cer, employee, contractor, subcontractor, or agent of such
19 person, may discharge, demote, suspend, threaten, harass,
20 or in any other manner discriminate against an employee
21 in the terms and conditions of employment because of any
22 lawful act done by the employee (including any lawful act
23 that is within the ordinary course of the job duties of such
24 employee) —

1 “(1) to provide information, cause information
2 to be provided, or otherwise assist in any investiga-
3 tion regarding any conduct which the employee rea-
4 sonably believes constitutes a violation of this Act
5 that is related to a drug, or any other provision of
6 Federal law relating to the safety of a drug, if the
7 information or assistance is provided to, or an inves-
8 tigation stemming from the provided information is
9 conducted by—

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

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

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

19 “(2) to file, cause to be filed, testify, participate
20 in, or otherwise assist in a proceeding filed, or about
21 to be filed (with any knowledge of the employer), in
22 any court or administrative forum relating to any
23 such alleged violation; or

24 “(3) to refuse to commit or assist in any such
25 violation.

1 “(b) ENFORCEMENT ACTION.—

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

6 “(A) filing a complaint with the Secretary
7 of Labor; or

8 “(B) if the Secretary of Labor has not
9 issued a final decision within 210 days of the
10 filing of the complaint and there is no showing
11 that such delay is due to the bad faith of the
12 claimant, or within 90 days after receiving a
13 final decision or order from the Secretary,
14 bringing an action at law or equity for de novo
15 review in the appropriate district court of the
16 United States, which court shall have jurisdic-
17 tion over such action without regard to the
18 amount in controversy, and which action shall,
19 at the request of either party to such action, be
20 tried by the court with a jury.

21 “(2) PROCEDURE.—

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

1 “(B) EXCEPTION.—Notification in an ac-
2 tion under paragraph (1) shall be made in ac-
3 cordance with section 42121(b)(1) of title 49,
4 United States Code, except that such notifica-
5 tion shall be made to the person named in the
6 complaint, the employer, and the Commissioner
7 of Food and Drugs.

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

13 “(D) STATUTE OF LIMITATIONS.—An ac-
14 tion under paragraph (1)(A) shall be com-
15 menced not later than 180 days after the date
16 on which the violation occurs.

17 “(c) REMEDIES.—

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

21 “(2) ISSUANCE OF ORDER.—If, in response to
22 a complaint filed under subsection (b)(1), the Sec-
23 retary of Labor or the district court, as applicable,
24 determines that a violation of subsection (a) has oc-

1 curred, the Secretary or the court shall order the
2 person who committed such violation—

3 “(A) to take affirmative action to abate
4 the violation;

5 “(B) to—

6 “(i) reinstate the complainant to his
7 or her former position together with com-
8 pensation (including back pay); and

9 “(ii) restore the terms, conditions,
10 and privileges associated with his or her
11 employment; and

12 “(C) to provide compensatory damages to
13 the complainant.

14 If such an order is issued under this paragraph, the
15 Secretary or the court, at the request of the com-
16 plainant, shall assess against the person against
17 whom the order is issued a sum equal to the aggre-
18 gate amount of all costs and expenses (including at-
19 torney and expert witness fees) reasonably incurred,
20 as determined by the Secretary, by the complainant
21 for, or in connection with, the bringing of the com-
22 plaint upon which the order was issued.

23 “(d) RIGHTS RETAINED BY EMPLOYEE.—Nothing in
24 this section shall be deemed to diminish the rights, privi-
25 leges, or remedies of any employee under any Federal or

1 State law or under any collective bargaining agreement.
2 The rights and remedies in this section may not be waived
3 by any agreement, policy, form, or condition of employ-
4 ment.”.

5 **SEC. 406. RULE OF CONSTRUCTION.**

6 Nothing in this Act or any amendment made by this
7 Act shall be construed as affecting any authority or re-
8 quirement relating to devices (as defined in section 201
9 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 321)).