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S. 319

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 10, 2011

Ms. SNOWE (for herself, Ms. STABENOW, Mr. VITTER, Mr. MCCAIN, Ms. KLOBUCHAR, Mr. GRASSLEY, Mr. KOHL, Ms. COLLINS, Mr. BROWN of Ohio, Mr. KERRY, Mr. SANDERS, Mr. LEVIN, Mrs. SHAHEEN, Mr. LEAHY, Mr. JOHNSON of South Dakota, Mr. BINGAMAN, Mrs. MCCASKILL, Mr. BEGICH, and Mr. NELSON of Florida) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription 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 “Pharmaceutical Mar-
5 ket Access and Drug Safety Act of 2011”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

1 (1) Americans unjustly pay up to 5 times more
2 to fill their prescriptions than consumers in other
3 countries;

4 (2) the United States is the largest market for
5 pharmaceuticals in the world, yet American con-
6 sumers pay the highest prices for brand pharma-
7 ceuticals in the world;

8 (3) a prescription drug is neither safe nor effec-
9 tive to an individual who cannot afford it;

10 (4) allowing and structuring the importation of
11 prescription drugs to ensure access to safe and af-
12 fordable drugs approved by the Food and Drug Ad-
13 ministration will provide a level of safety to Amer-
14 ican consumers that they do not currently enjoy;

15 (5) Americans spend more than
16 \$200,000,000,000 on prescription drugs every year;

17 (6) the Congressional Budget Office has found
18 that the cost of prescription drugs are between 35
19 to 55 percent less in other highly-developed coun-
20 tries than in the United States; and

21 (7) promoting competitive market pricing would
22 both contribute to health care savings and allow
23 greater access to therapy, improving health and sav-
24 ing lives.

1 **SEC. 3. REPEAL OF CERTAIN SECTION REGARDING IMPOR-**
2 **TATION OF PRESCRIPTION DRUGS.**

3 Chapter VIII of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 381 et seq.) is amended by striking
5 section 804.

6 **SEC. 4. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER**
7 **OF CERTAIN IMPORT RESTRICTIONS.**

8 (a) IN GENERAL.—Chapter VIII of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.),
10 as amended by section 3, is further amended by inserting
11 after section 803 the following:

12 **“SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF**
13 **PRESCRIPTION DRUGS.**

14 “(a) IMPORTATION OF PRESCRIPTION DRUGS.—

15 “(1) IN GENERAL.—In the case of qualifying
16 drugs imported or offered for import into the United
17 States from registered exporters or by registered im-
18 porters—

19 “(A) the limitation on importation that is
20 established in section 801(d)(1) is waived; and

21 “(B) the standards referred to in section
22 801(a) regarding admission of the drugs are
23 subject to subsection (g) of this section (includ-
24 ing with respect to qualifying drugs to which
25 section 801(d)(1) does not apply).

1 “(2) IMPORTERS.—A qualifying drug may not
2 be imported under paragraph (1) unless—

3 “(A) the drug is imported by a pharmacy,
4 group of pharmacies, or a wholesaler that is a
5 registered importer; or

6 “(B) the drug is imported by an individual
7 for personal use or for the use of a family mem-
8 ber of the individual (not for resale) from a reg-
9 istered exporter.

10 “(3) RULE OF CONSTRUCTION.—This section
11 shall apply only with respect to a drug that is im-
12 ported or offered for import into the United
13 States—

14 “(A) by a registered importer; or

15 “(B) from a registered exporter to an indi-
16 vidual.

17 “(4) DEFINITIONS.—

18 “(A) REGISTERED EXPORTER; REG-
19 ISTERED IMPORTER.—For purposes of this sec-
20 tion:

21 “(i) The term ‘registered exporter’
22 means an exporter for which a registration
23 under subsection (b) has been approved
24 and is in effect.

1 “(ii) The term ‘registered importer’
2 means a pharmacy, group of pharmacies,
3 or a wholesaler for which a registration
4 under subsection (b) has been approved
5 and is in effect.

6 “(iii) The term ‘registration condition’
7 means a condition that must exist for a
8 registration under subsection (b) to be ap-
9 proved.

10 “(B) QUALIFYING DRUG.—For purposes of
11 this section, the term ‘qualifying drug’ means a
12 drug for which there is a corresponding U.S.
13 label drug.

14 “(C) U.S. LABEL DRUG.—For purposes of
15 this section, the term ‘U.S. label drug’ means
16 a prescription drug that—

17 “(i) with respect to a qualifying drug,
18 has the same active ingredient or ingredi-
19 ents, route of administration, dosage form,
20 and strength as the qualifying drug;

21 “(ii) with respect to the qualifying
22 drug, is manufactured by or for the person
23 that manufactures the qualifying drug;

24 “(iii) is approved under section
25 505(c); and

1 “(iv) is not—

2 “(I) a controlled substance, as
3 defined in section 102 of the Con-
4 trolled Substances Act (21 U.S.C.
5 802);

6 “(II) a biological product, as de-
7 fined in section 351 of the Public
8 Health Service Act (42 U.S.C. 262),
9 including—

10 “(aa) a therapeutic DNA
11 plasmid product;

12 “(bb) a therapeutic synthetic
13 peptide product;

14 “(cc) a monoclonal antibody
15 product for in vivo use; and

16 “(dd) a therapeutic recom-
17 binant DNA-derived product;

18 “(III) an infused drug, including
19 a peritoneal dialysis solution;

20 “(IV) an injected drug;

21 “(V) a drug that is inhaled dur-
22 ing surgery;

23 “(VI) a drug that is the listed
24 drug referred to in 2 or more abbrev-
25 viated new drug applications under

1 which the drug is commercially mar-
2 keted; or

3 “(VII) a sterile ophthalmic drug
4 intended for topical use on or in the
5 eye.

6 “(D) OTHER DEFINITIONS.—For purposes
7 of this section:

8 “(i)(I) The term ‘exporter’ means a
9 person that is in the business of exporting
10 a drug to individuals in the United States
11 from Canada or from a permitted country
12 designated by the Secretary under sub-
13 clause (II), or that, pursuant to submitting
14 a registration under subsection (b), seeks
15 to be in such business.

16 “(II) The Secretary shall designate a
17 permitted country under subparagraph (E)
18 (other than Canada) as a country from
19 which an exporter may export a drug to in-
20 dividuals in the United States if the Sec-
21 retary determines that—

22 “(aa) the country has statutory
23 or regulatory standards that are
24 equivalent to the standards in the

1 United States and Canada with re-
2 spect to—

3 “(AA) the training of phar-
4 macists;

5 “(BB) the practice of phar-
6 macy; and

7 “(CC) the protection of the
8 privacy of personal medical infor-
9 mation; and

10 “(bb) the importation of drugs to
11 individuals in the United States from
12 the country will not adversely affect
13 public health.

14 “(ii) The term ‘importer’ means a
15 pharmacy, a group of pharmacies, or a
16 wholesaler that is in the business of im-
17 porting a drug into the United States or
18 that, pursuant to submitting a registration
19 under subsection (b), seeks to be in such
20 business.

21 “(iii) The term ‘pharmacist’ means a
22 person licensed by a State to practice
23 pharmacy, including the dispensing and
24 selling of prescription drugs.

1 “(iv) The term ‘pharmacy’ means a
2 person that—

3 “(I) is licensed by a State to en-
4 gage in the business of selling pre-
5 scription drugs at retail; and

6 “(II) employs 1 or more phar-
7 macists.

8 “(v) The term ‘prescription drug’
9 means a drug that is described in section
10 503(b)(1).

11 “(vi) The term ‘wholesaler’—

12 “(I) means a person licensed as a
13 wholesaler or distributor of prescrip-
14 tion drugs in the United States under
15 section 503(e)(2)(A); and

16 “(II) does not include a person
17 authorized to import drugs under sec-
18 tion 801(d)(1).

19 “(E) PERMITTED COUNTRY.—The term
20 ‘permitted country’ means—

21 “(i) Australia;

22 “(ii) Canada;

23 “(iii) a member country of the Euro-
24 pean Union, but does not include a mem-
25 ber country with respect to which—

1 “(I) the country’s Annex to the
2 Treaty of Accession to the European
3 Union 2003 includes a transitional
4 measure for the regulation of human
5 pharmaceutical products that has not
6 expired; or

7 “(II) the Secretary determines
8 that the requirements described in
9 subclauses (I) and (II) of clause (vii)
10 will not be met by the date on which
11 such transitional measure for the reg-
12 ulation of human pharmaceutical
13 products expires;

14 “(iv) Japan;

15 “(v) New Zealand;

16 “(vi) Switzerland; and

17 “(vii) a country in which the Sec-
18 retary determines the following require-
19 ments are met:

20 “(I) The country has statutory or
21 regulatory requirements—

22 “(aa) that require the review
23 of drugs for safety and effective-
24 ness by an entity of the govern-
25 ment of the country;

1 “(bb) that authorize the ap-
2 proval of only those drugs that
3 have been determined to be safe
4 and effective by experts employed
5 by or acting on behalf of such en-
6 tity and qualified by scientific
7 training and experience to evalu-
8 ate the safety and effectiveness of
9 drugs on the basis of adequate
10 and well-controlled investigations,
11 including clinical investigations,
12 conducted by experts qualified by
13 scientific training and experience
14 to evaluate the safety and effec-
15 tiveness of drugs;

16 “(cc) that require the meth-
17 ods used in, and the facilities and
18 controls used for the manufac-
19 ture, processing, and packing of
20 drugs in the country to be ade-
21 quate to preserve their identity,
22 quality, purity, and strength;

23 “(dd) for the reporting of
24 adverse reactions to drugs and
25 procedures to withdraw approval

1 and remove drugs found not to
2 be safe or effective; and

3 “(ee) that require the label-
4 ing and promotion of drugs to be
5 in accordance with the approval
6 of the drug.

7 “(II) The valid marketing au-
8 thorization system in the country is
9 equivalent to the systems in the coun-
10 tries described in clauses (i) through
11 (vi).

12 “(III) The importation of drugs
13 to the United States from the country
14 will not adversely affect public health.

15 “(b) REGISTRATION OF IMPORTERS AND EXPORT-
16 ERS.—

17 “(1) REGISTRATION OF IMPORTERS AND EX-
18 PORTERS.—A registration condition is that the im-
19 porter or exporter involved (referred to in this sub-
20 section as a ‘registrant’) submits to the Secretary a
21 registration containing the following:

22 “(A)(i) In the case of an exporter, the
23 name of the exporter and an identification of all
24 places of business of the exporter that relate to
25 qualifying drugs, including each warehouse or

1 other facility owned or controlled by, or oper-
2 ated for, the exporter.

3 “(ii) In the case of an importer, the name
4 of the importer and an identification of the
5 places of business of the importer at which the
6 importer initially receives a qualifying drug
7 after importation (which shall not exceed 3
8 places of business except by permission of the
9 Secretary).

10 “(B) Such information as the Secretary
11 determines to be necessary to demonstrate that
12 the registrant is in compliance with registration
13 conditions under—

14 “(i) in the case of an importer, sub-
15 sections (c), (d), (e), (g), and (j) (relating
16 to the sources of imported qualifying
17 drugs; the inspection of facilities of the im-
18 porter; the payment of fees; compliance
19 with the standards referred to in section
20 801(a); and maintenance of records and
21 samples); or

22 “(ii) in the case of an exporter, sub-
23 sections (c), (d), (f), (g), (h), (i), and (j)
24 (relating to the sources of exported quali-
25 fying drugs; the inspection of facilities of

1 the exporter and the marking of compliant
2 shipments; the payment of fees; and com-
3 pliance with the standards referred to in
4 section 801(a); being licensed as a phar-
5 macist; conditions for individual importa-
6 tion; and maintenance of records and sam-
7 ples).

8 “(C) An agreement by the registrant that
9 the registrant will not under subsection (a) im-
10 port or export any drug that is not a qualifying
11 drug.

12 “(D) An agreement by the registrant to—

13 “(i) notify the Secretary of a recall or
14 withdrawal of a qualifying drug distributed
15 in a permitted country that the registrant
16 has exported or imported, or intends to ex-
17 port or import, to the United States under
18 subsection (a);

19 “(ii) provide for the return to the reg-
20 istrant of such drug; and

21 “(iii) cease, or not begin, the expor-
22 tation or importation of such drug unless
23 the Secretary has notified the registrant
24 that exportation or importation of such
25 drug may proceed.

1 “(E) An agreement by the registrant to
2 ensure and monitor compliance with each reg-
3 istration condition, to promptly correct any
4 noncompliance with such a condition, and to
5 promptly report to the Secretary any such non-
6 compliance.

7 “(F) A plan describing the manner in
8 which the registrant will comply with the agree-
9 ment under subparagraph (E).

10 “(G) An agreement by the registrant to
11 enforce a contract under subsection (c)(3)(B)
12 against a party in the chain of custody of a
13 qualifying drug with respect to the authority of
14 the Secretary under clauses (ii) and (iii) of that
15 subsection.

16 “(H) An agreement by the registrant to
17 notify the Secretary not more than 30 days be-
18 fore the registrant intends to make the change,
19 of—

20 “(i) any change that the registrant in-
21 tends to make regarding information pro-
22 vided under subparagraph (A) or (B); and

23 “(ii) any change that the registrant
24 intends to make in the compliance plan
25 under subparagraph (F).

1 “(I) In the case of an exporter:

2 “(i) An agreement by the exporter
3 that a qualifying drug will not under sub-
4 section (a) be exported to any individual
5 not authorized pursuant to subsection
6 (a)(2)(B) to be an importer of such drug.

7 “(ii) An agreement to post a bond,
8 payable to the Treasury of the United
9 States that is equal in value to the lesser
10 of—

11 “(I) the value of drugs exported
12 by the exporter to the United States
13 in a typical 4-week period over the
14 course of a year under this section; or

15 “(II) \$1,000,000.

16 “(iii) An agreement by the exporter to
17 comply with applicable provisions of Cana-
18 dian law, or the law of the permitted coun-
19 try designated under subsection
20 (a)(4)(D)(i)(II) in which the exporter is lo-
21 cated, that protect the privacy of personal
22 information with respect to each individual
23 importing a prescription drug from the ex-
24 porter under subsection (a)(2)(B).

1 “(iv) An agreement by the exporter to
2 report to the Secretary—

3 “(I) not later than August 1 of
4 each fiscal year, the total price and
5 the total volume of drugs exported to
6 the United States by the exporter dur-
7 ing the 6-month period from January
8 1 through June 30 of that year; and

9 “(II) not later than January 1 of
10 each fiscal year, the total price and
11 the total volume of drugs exported to
12 the United States by the exporter dur-
13 ing the previous fiscal year.

14 “(J) In the case of an importer, an agree-
15 ment by the importer to report to the Sec-
16 retary—

17 “(i) not later than August 1 of each
18 fiscal year, the total price and the total
19 volume of drugs imported to the United
20 States by the importer during the 6-month
21 period from January 1 through June 30 of
22 that fiscal year; and

23 “(ii) not later than January 1 of each
24 fiscal year, the total price and the total
25 volume of drugs imported to the United

1 States by the importer during the previous
2 fiscal year.

3 “(K) Such other provisions as the Sec-
4 retary may require by regulation to protect the
5 public health while permitting—

6 “(i) the importation by pharmacies,
7 groups of pharmacies, and wholesalers as
8 registered importers of qualifying drugs
9 under subsection (a); and

10 “(ii) importation by individuals of
11 qualifying drugs under subsection (a).

12 “(2) APPROVAL OR DISAPPROVAL OF REGISTRA-
13 TION.—

14 “(A) IN GENERAL.—Not later than 90
15 days after the date on which a registrant sub-
16 mits to the Secretary a registration under para-
17 graph (1), the Secretary shall notify the reg-
18 istrant whether the registration is approved or
19 is disapproved. The Secretary shall disapprove
20 a registration if there is reason to believe that
21 the registrant is not in compliance with one or
22 more registration conditions, and shall notify
23 the registrant of such reason. In the case of a
24 disapproved registration, the Secretary shall
25 subsequently notify the registrant that the reg-

1 istration is approved if the Secretary deter-
2 mines that the registrant is in compliance with
3 such conditions.

4 “(B) CHANGES IN REGISTRATION INFOR-
5 MATION.—Not later than 30 days after receiv-
6 ing a notice under paragraph (1)(H) from a
7 registrant, the Secretary shall determine wheth-
8 er the change involved affects the approval of
9 the registration of the registrant under para-
10 graph (1), and shall inform the registrant of
11 the determination.

12 “(3) PUBLICATION OF CONTACT INFORMATION
13 FOR REGISTERED EXPORTERS.—Through the Inter-
14 net website of the Food and Drug Administration
15 and a toll-free telephone number, the Secretary shall
16 make readily available to the public a list of reg-
17 istered exporters, including contact information for
18 the exporters. Promptly after the approval of a reg-
19 istration submitted under paragraph (1), the Sec-
20 retary shall update the Internet website and the in-
21 formation provided through the toll-free telephone
22 number accordingly.

23 “(4) SUSPENSION AND TERMINATION.—

1 “(A) SUSPENSION.—With respect to the
2 effectiveness of a registration submitted under
3 paragraph (1):

4 “(i) Subject to clause (ii), the Sec-
5 retary may suspend the registration if the
6 Secretary determines, after notice and op-
7 portunity for a hearing, that the registrant
8 has failed to maintain substantial compli-
9 ance with a registration condition.

10 “(ii) If the Secretary determines that,
11 under color of the registration, the ex-
12 porter has exported a drug or the importer
13 has imported a drug that is not a quali-
14 fying drug, or a drug that does not comply
15 with subsection (g)(2)(A) or (g)(4), or has
16 exported a qualifying drug to an individual
17 in violation of subsection (i), the Secretary
18 shall immediately suspend the registration.
19 A suspension under the preceding sentence
20 is not subject to the provision by the Sec-
21 retary of prior notice, and the Secretary
22 shall provide to the registrant an oppor-
23 tunity for a hearing not later than 10 days
24 after the date on which the registration is
25 suspended.

1 “(iii) The Secretary may reinstate the
2 registration, whether suspended under
3 clause (i) or (ii), if the Secretary deter-
4 mines that the registrant has demonstrated
5 that further violations of registration con-
6 ditions will not occur.

7 “(B) TERMINATION.—The Secretary, after
8 notice and opportunity for a hearing, may ter-
9minate the registration under paragraph (1) of
10 a registrant if the Secretary determines that
11 the registrant has engaged in a pattern or prac-
12 tice of violating 1 or more registration condi-
13 tions, or if on 1 or more occasions the Secretary
14 has under subparagraph (A)(ii) suspended the
15 registration of the registrant. The Secretary
16 may make the termination permanent, or for a
17 fixed period of not less than 1 year. During the
18 period in which the registration is terminated,
19 any registration submitted under paragraph (1)
20 by the registrant, or a person that is a partner
21 in the export or import enterprise, or a prin-
22 cipal officer in such enterprise, and any reg-
23 istration prepared with the assistance of the
24 registrant or such a person, has no legal effect
25 under this section.

1 “(5) DEFAULT OF BOND.—A bond required to
2 be posted by an exporter under paragraph (1)(I)(ii)
3 shall be defaulted and paid to the Treasury of the
4 United States if, after opportunity for an informal
5 hearing, the Secretary determines that the exporter
6 has—

7 “(A) exported a drug to the United States
8 that is not a qualifying drug or that is not in
9 compliance with subsection (g)(2)(A), (g)(4), or
10 (i); or

11 “(B) failed to permit the Secretary to con-
12 duct an inspection described under subsection
13 (d).

14 “(c) SOURCES OF QUALIFYING DRUGS.—A registra-
15 tion condition is that the exporter or importer involved
16 agrees that a qualifying drug will under subsection (a) be
17 exported or imported into the United States only if there
18 is compliance with the following:

19 “(1) The drug was manufactured in an estab-
20 lishment—

21 “(A) required to register under subsection
22 (h) or (i) of section 510; and

23 “(B)(i) inspected by the Secretary; or

24 “(ii) for which the Secretary has elected to
25 rely on a satisfactory report of a good manufac-

1 turing practice inspection of the establishment
2 from a permitted country whose regulatory sys-
3 tem the Secretary recognizes as equivalent
4 under a mutual recognition agreement, as pro-
5 vided for under section 510(i)(3), section 803,
6 or part 26 of title 21, Code of Federal Regula-
7 tions (or any corresponding successor rule or
8 regulation).

9 “(2) The establishment is located in any coun-
10 try, and the establishment manufactured the drug
11 for distribution in the United States or for distribu-
12 tion in 1 or more of the permitted countries (without
13 regard to whether in addition the drug is manufac-
14 tured for distribution in a foreign country that is
15 not a permitted country).

16 “(3) The exporter or importer obtained the
17 drug—

18 “(A) directly from the establishment; or

19 “(B) directly from an entity that, by con-
20 tract with the exporter or importer—

21 “(i) provides to the exporter or im-
22 porter a statement (in such form and con-
23 taining such information as the Secretary
24 may require) that, for the chain of custody
25 from the establishment, identifies each

1 prior sale, purchase, or trade of the drug
2 (including the date of the transaction and
3 the names and addresses of all parties to
4 the transaction);

5 “(ii) agrees to permit the Secretary to
6 inspect such statements and related
7 records to determine their accuracy;

8 “(iii) agrees, with respect to the quali-
9 fying drugs involved, to permit the Sec-
10 retary to inspect warehouses and other fa-
11 cilities, including records, of the entity for
12 purposes of determining whether the facili-
13 ties are in compliance with any standards
14 under this Act that are applicable to facili-
15 ties of that type in the United States; and

16 “(iv) has ensured, through such con-
17 tractual relationships as may be necessary,
18 that the Secretary has the same authority
19 regarding other parties in the chain of cus-
20 tody from the establishment that the Sec-
21 retary has under clauses (ii) and (iii) re-
22 garding such entity.

23 “(4)(A) The foreign country from which the im-
24 porter will import the drug is a permitted country;
25 or

1 “(B) the foreign country from which the ex-
2 porter will export the drug is the permitted country
3 in which the exporter is located.

4 “(5) During any period in which the drug was
5 not in the control of the manufacturer of the drug,
6 the drug did not enter any country that is not a per-
7 mitted country.

8 “(6) The exporter or importer retains a sample
9 of each lot of the drug for testing by the Secretary.

10 “(d) INSPECTION OF FACILITIES; MARKING OF SHIP-
11 MENTS.—

12 “(1) INSPECTION OF FACILITIES.—A registra-
13 tion condition is that, for the purpose of assisting
14 the Secretary in determining whether the exporter
15 involved is in compliance with all other registration
16 conditions—

17 “(A) the exporter agrees to permit the Sec-
18 retary—

19 “(i) to conduct onsite inspections, in-
20 cluding monitoring on a day-to-day basis,
21 of places of business of the exporter that
22 relate to qualifying drugs, including each
23 warehouse or other facility owned or con-
24 trolled by, or operated for, the exporter;

1 “(ii) to have access, including on a
2 day-to-day basis, to—

3 “(I) records of the exporter that
4 relate to the export of such drugs, in-
5 cluding financial records; and

6 “(II) samples of such drugs;

7 “(iii) to carry out the duties described
8 in paragraph (3); and

9 “(iv) to carry out any other functions
10 determined by the Secretary to be nec-
11 essary regarding the compliance of the ex-
12 porter; and

13 “(B) the Secretary has assigned 1 or more
14 employees of the Secretary to carry out the
15 functions described in this subsection for the
16 Secretary randomly, but not less than 12 times
17 annually, on the premises of places of busi-
18 nesses referred to in subparagraph (A)(i), and
19 such an assignment remains in effect on a con-
20 tinuous basis.

21 “(2) MARKING OF COMPLIANT SHIPMENTS.—A
22 registration condition is that the exporter involved
23 agrees to affix to each shipping container of quali-
24 fying drugs exported under subsection (a) such
25 markings as the Secretary determines to be nec-

1 essary to identify the shipment as being in compli-
2 ance with all registration conditions. Markings under
3 the preceding sentence shall—

4 “(A) be designed to prevent affixation of
5 the markings to any shipping container that is
6 not authorized to bear the markings; and

7 “(B) include anticounterfeiting or track-
8 and-trace technologies, taking into account the
9 economic and technical feasibility of those tech-
10 nologies.

11 “(3) CERTAIN DUTIES RELATING TO EXPORT-
12 ERS.—Duties of the Secretary with respect to an ex-
13 porter include the following:

14 “(A) Inspecting, randomly, but not less
15 than 12 times annually, the places of business
16 of the exporter at which qualifying drugs are
17 stored and from which qualifying drugs are
18 shipped.

19 “(B) During the inspections under sub-
20 paragraph (A), verifying the chain of custody of
21 a statistically significant sample of qualifying
22 drugs from the establishment in which the drug
23 was manufactured to the exporter, which shall
24 be accomplished or supplemented by the use of
25 anticounterfeiting or track-and-trace tech-

1 nologies, taking into account the economic and
2 technical feasibility of those technologies, except
3 that a drug that lacks such technologies from
4 the point of manufacture shall not for that rea-
5 son be excluded from importation by an ex-
6 porter.

7 “(C) Randomly reviewing records of ex-
8 ports to individuals for the purpose of deter-
9 mining whether the drugs are being imported
10 by the individuals in accordance with the condi-
11 tions under subsection (i). Such reviews shall be
12 conducted in a manner that will result in a sta-
13 tistically significant determination of compli-
14 ance with all such conditions.

15 “(D) Monitoring the affixing of markings
16 under paragraph (2).

17 “(E) Inspecting as the Secretary deter-
18 mines is necessary the warehouses and other fa-
19 cilities, including records, of other parties in the
20 chain of custody of qualifying drugs.

21 “(F) Determining whether the exporter is
22 in compliance with all other registration condi-
23 tions.

24 “(4) PRIOR NOTICE OF SHIPMENTS.—A reg-
25 istration condition is that, not less than 8 hours and

1 not more than 5 days in advance of the time of the
2 importation of a shipment of qualifying drugs, the
3 importer involved agrees to submit to the Secretary
4 a notice with respect to the shipment of drugs to be
5 imported or offered for import into the United
6 States under subsection (a). A notice under the pre-
7 ceding sentence shall include—

8 “(A) the name and complete contact infor-
9 mation of the person submitting the notice;

10 “(B) the name and complete contact infor-
11 mation of the importer involved;

12 “(C) the identity of the drug, including the
13 established name of the drug, the quantity of
14 the drug, and the lot number assigned by the
15 manufacturer;

16 “(D) the identity of the manufacturer of
17 the drug, including the identity of the establish-
18 ment at which the drug was manufactured;

19 “(E) the country from which the drug is
20 shipped;

21 “(F) the name and complete contact infor-
22 mation for the shipper of the drug;

23 “(G) anticipated arrival information, in-
24 cluding the port of arrival and crossing location
25 within that port, and the date and time;

1 “(H) a summary of the chain of custody of
2 the drug from the establishment in which the
3 drug was manufactured to the importer;

4 “(I) a declaration as to whether the Sec-
5 retary has ordered that importation of the drug
6 from the permitted country cease under sub-
7 section (g)(2)(C) or (D); and

8 “(J) such other information as the Sec-
9 retary may require by regulation.

10 “(5) MARKING OF COMPLIANT SHIPMENTS.—A
11 registration condition is that the importer involved
12 agrees, before wholesale distribution (as defined in
13 section 503(e)) of a qualifying drug that has been
14 imported under subsection (a), to affix to each con-
15 tainer of such drug such markings or other tech-
16 nology as the Secretary determines necessary to
17 identify the shipment as being in compliance with all
18 registration conditions, except that the markings or
19 other technology shall not be required on a drug
20 that bears comparable, compatible markings or tech-
21 nology from the manufacturer of the drug. Markings
22 or other technology under the preceding sentence
23 shall—

24 “(A) be designed to prevent affixation of
25 the markings or other technology to any con-

1 tainer that is not authorized to bear the mark-
2 ings; and

3 “(B) shall include anticounterfeiting or
4 track-and-trace technologies, taking into ac-
5 count the economic and technical feasibility of
6 such technologies.

7 “(6) CERTAIN DUTIES RELATING TO IMPORT-
8 ERS.—Duties of the Secretary with respect to an im-
9 porter include the following:

10 “(A) Inspecting, randomly, but not less
11 than 12 times annually, the places of business
12 of the importer at which a qualifying drug is
13 initially received after importation.

14 “(B) During the inspections under sub-
15 paragraph (A), verifying the chain of custody of
16 a statistically significant sample of qualifying
17 drugs from the establishment in which the drug
18 was manufactured to the importer, which shall
19 be accomplished or supplemented by the use of
20 anticounterfeiting or track-and-trace tech-
21 nologies, taking into account the economic and
22 technical feasibility of those technologies, except
23 that a drug that lacks such technologies from
24 the point of manufacture shall not for that rea-

1 son be excluded from importation by an im-
2 porter.

3 “(C) Reviewing notices under paragraph
4 (4).

5 “(D) Inspecting as the Secretary deter-
6 mines is necessary the warehouses and other fa-
7 cilities, including records of other parties in the
8 chain of custody of qualifying drugs.

9 “(E) Determining whether the importer is
10 in compliance with all other registration condi-
11 tions.

12 “(e) IMPORTER FEES.—

13 “(1) REGISTRATION FEE.—A registration con-
14 dition is that the importer involved pays to the Sec-
15 retary a fee of \$10,000 due on the date on which
16 the importer first submits the registration to the
17 Secretary under subsection (b).

18 “(2) INSPECTION FEE.—A registration condi-
19 tion is that the importer involved pays a fee to the
20 Secretary in accordance with this subsection. Such
21 fee shall be paid not later than October 1 and April
22 1 of each fiscal year in the amount provided for
23 under paragraph (3).

24 “(3) AMOUNT OF INSPECTION FEE.—

1 “(A) AGGREGATE TOTAL OF FEES.—Not
2 later than 30 days before the start of each fis-
3 cal year, the Secretary, in consultation with the
4 Secretary of Homeland Security and the Sec-
5 retary of the Treasury, shall establish an aggre-
6 gate total of fees to be collected under para-
7 graph (2) for importers for that fiscal year that
8 is sufficient, and not more than necessary, to
9 pay the costs for that fiscal year of admin-
10 istering this section with respect to registered
11 importers, including the costs associated with—

12 “(i) inspecting the facilities of reg-
13 istered importers, and of other entities in
14 the chain of custody of a qualifying drug
15 as necessary, under subsection (d)(6);

16 “(ii) developing, implementing, and
17 operating under such subsection an elec-
18 tronic system for submission and review of
19 the notices required under subsection
20 (d)(4) with respect to shipments of quali-
21 fying drugs under subsection (a) to assess
22 compliance with all registration conditions
23 when such shipments are offered for im-
24 port into the United States; and

1 “(iii) inspecting such shipments as
2 necessary, when offered for import into the
3 United States to determine if such a ship-
4 ment should be refused admission under
5 subsection (g)(5).

6 “(B) LIMITATION.—Subject to subpara-
7 graph (C), the aggregate total of fees collected
8 under paragraph (2) for a fiscal year shall not
9 exceed 2.5 percent of the total price of quali-
10 fying drugs imported during that fiscal year
11 into the United States by registered importers
12 under subsection (a).

13 “(C) TOTAL PRICE OF DRUGS.—

14 “(i) ESTIMATE.—For the purposes of
15 complying with the limitation described in
16 subparagraph (B) when establishing under
17 subparagraph (A) the aggregate total of
18 fees to be collected under paragraph (2)
19 for a fiscal year, the Secretary shall esti-
20 mate the total price of qualifying drugs im-
21 ported into the United States by registered
22 importers during that fiscal year by adding
23 the total price of qualifying drugs imported
24 by each registered importer during the 6-
25 month period from January 1 through

1 June 30 of the previous fiscal year, as re-
2 ported to the Secretary by each registered
3 importer under subsection (b)(1)(J).

4 “(ii) CALCULATION.—Not later than
5 March 1 of the fiscal year that follows the
6 fiscal year for which the estimate under
7 clause (i) is made, the Secretary shall cal-
8 culate the total price of qualifying drugs
9 imported into the United States by reg-
10 istered importers during that fiscal year by
11 adding the total price of qualifying drugs
12 imported by each registered importer dur-
13 ing that fiscal year, as reported to the Sec-
14 retary by each registered importer under
15 subsection (b)(1)(J).

16 “(iii) ADJUSTMENT.—If the total
17 price of qualifying drugs imported into the
18 United States by registered importers dur-
19 ing a fiscal year as calculated under clause
20 (ii) is less than the aggregate total of fees
21 collected under paragraph (2) for that fis-
22 cal year, the Secretary shall provide for a
23 pro-rata reduction in the fee due from each
24 registered importer on April 1 of the sub-

1 sequent fiscal year so that the limitation
2 described in subparagraph (B) is observed.

3 “(D) INDIVIDUAL IMPORTER FEE.—Sub-
4 ject to the limitation described in subparagraph
5 (B), the fee under paragraph (2) to be paid on
6 October 1 and April 1 by an importer shall be
7 an amount that is proportional to a reasonable
8 estimate by the Secretary of the semiannual
9 share of the importer of the volume of quali-
10 fying drugs imported by importers under sub-
11 section (a).

12 “(4) USE OF FEES.—

13 “(A) IN GENERAL.—Fees collected by the
14 Secretary under paragraphs (1) and (2) shall be
15 credited to the appropriation account for sala-
16 ries and expenses of the Food and Drug Ad-
17 ministration until expended (without fiscal year
18 limitation), and the Secretary may, in consulta-
19 tion with the Secretary of Homeland Security
20 and the Secretary of the Treasury, transfer
21 some proportion of such fees to the appropria-
22 tion account for salaries and expenses of the
23 Bureau of Customs and Border Protection until
24 expended (without fiscal year limitation).

1 “(B) AVAILABILITY.—Fees collected by the
2 Secretary under paragraphs (1) and (2) shall be
3 made available to the Food and Drug Adminis-
4 tration.

5 “(C) SOLE PURPOSE.—Fees collected by
6 the Secretary under paragraphs (1) and (2) are
7 only available to the Secretary and, if trans-
8 ferred, to the Secretary of Homeland Security,
9 and are for the sole purpose of paying the costs
10 referred to in paragraph (3)(A).

11 “(5) COLLECTION OF FEES.—In any case where
12 the Secretary does not receive payment of a fee as-
13 sessed under paragraph (1) or (2) within 30 days
14 after it is due, such fee shall be treated as a claim
15 of the United States Government subject to sub-
16 chapter II of chapter 37 of title 31, United States
17 Code.

18 “(f) EXPORTER FEES.—

19 “(1) REGISTRATION FEE.—A registration con-
20 dition is that the exporter involved pays to the Sec-
21 retary a fee of \$10,000 due on the date on which
22 the exporter first submits that registration to the
23 Secretary under subsection (b).

24 “(2) INSPECTION FEE.—A registration condi-
25 tion is that the exporter involved pays a fee to the

1 Secretary in accordance with this subsection. Such
2 fee shall be paid not later than October 1 and April
3 1 of each fiscal year in the amount provided for
4 under paragraph (3).

5 “(3) AMOUNT OF INSPECTION FEE.—

6 “(A) AGGREGATE TOTAL OF FEES.—Not
7 later than 30 days before the start of each fis-
8 cal year, the Secretary, in consultation with the
9 Secretary of Homeland Security and the Sec-
10 retary of the Treasury, shall establish an aggre-
11 gate total of fees to be collected under para-
12 graph (2) for exporters for that fiscal year that
13 is sufficient, and not more than necessary, to
14 pay the costs for that fiscal year of admin-
15 istering this section with respect to registered
16 exporters, including the costs associated with—

17 “(i) inspecting the facilities of reg-
18 istered exporters, and of other entities in
19 the chain of custody of a qualifying drug
20 as necessary, under subsection (d)(3);

21 “(ii) developing, implementing, and
22 operating under such subsection a system
23 to screen marks on shipments of qualifying
24 drugs under subsection (a) that indicate
25 compliance with all registration conditions,

1 when such shipments are offered for im-
2 port into the United States; and

3 “(iii) screening such markings, and
4 inspecting such shipments as necessary,
5 when offered for import into the United
6 States to determine if such a shipment
7 should be refused admission under sub-
8 section (g)(5).

9 “(B) LIMITATION.—Subject to subpara-
10 graph (C), the aggregate total of fees collected
11 under paragraph (2) for a fiscal year shall not
12 exceed 2.5 percent of the total price of quali-
13 fying drugs imported during that fiscal year
14 into the United States by registered exporters
15 under subsection (a).

16 “(C) TOTAL PRICE OF DRUGS.—

17 “(i) ESTIMATE.—For the purposes of
18 complying with the limitation described in
19 subparagraph (B) when establishing under
20 subparagraph (A) the aggregate total of
21 fees to be collected under paragraph (2)
22 for a fiscal year, the Secretary shall esti-
23 mate the total price of qualifying drugs im-
24 ported into the United States by registered
25 exporters during that fiscal year by adding

1 the total price of qualifying drugs exported
2 by each registered exporter during the 6-
3 month period from January 1 through
4 June 30 of the previous fiscal year, as re-
5 ported to the Secretary by each registered
6 exporter under subsection (b)(1)(I)(iv).

7 “(ii) CALCULATION.—Not later than
8 March 1 of the fiscal year that follows the
9 fiscal year for which the estimate under
10 clause (i) is made, the Secretary shall cal-
11 culate the total price of qualifying drugs
12 imported into the United States by reg-
13 istered exporters during that fiscal year by
14 adding the total price of qualifying drugs
15 exported by each registered exporter dur-
16 ing that fiscal year, as reported to the Sec-
17 retary by each registered exporter under
18 subsection (b)(1)(I)(iv).

19 “(iii) ADJUSTMENT.—If the total
20 price of qualifying drugs imported into the
21 United States by registered exporters dur-
22 ing a fiscal year as calculated under clause
23 (ii) is less than the aggregate total of fees
24 collected under paragraph (2) for that fis-
25 cal year, the Secretary shall provide for a

1 pro-rata reduction in the fee due from each
2 registered exporter on April 1 of the subse-
3 quent fiscal year so that the limitation de-
4 scribed in subparagraph (B) is observed.

5 “(D) INDIVIDUAL EXPORTER FEE.—Sub-
6 ject to the limitation described in subparagraph
7 (B), the fee under paragraph (2) to be paid on
8 October 1 and April 1 by an exporter shall be
9 an amount that is proportional to a reasonable
10 estimate by the Secretary of the semiannual
11 share of the exporter of the volume of quali-
12 fying drugs exported by exporters under sub-
13 section (a).

14 “(4) USE OF FEES.—

15 “(A) IN GENERAL.—Fees collected by the
16 Secretary under paragraphs (1) and (2) shall be
17 credited to the appropriation account for sala-
18 ries and expenses of the Food and Drug Ad-
19 ministration until expended (without fiscal year
20 limitation), and the Secretary may, in consulta-
21 tion with the Secretary of Homeland Security
22 and the Secretary of the Treasury, transfer
23 some proportion of such fees to the appropria-
24 tion account for salaries and expenses of the

1 Bureau of Customs and Border Protection until
2 expended (without fiscal year limitation).

3 “(B) AVAILABILITY.—Fees collected by the
4 Secretary under paragraphs (1) and (2) shall be
5 made available to the Food and Drug Adminis-
6 tration.

7 “(C) SOLE PURPOSE.—Fees collected by
8 the Secretary under paragraphs (1) and (2) are
9 only available to the Secretary and, if trans-
10 ferred, to the Secretary of Homeland Security,
11 and are for the sole purpose of paying the costs
12 referred to in paragraph (3)(A).

13 “(5) COLLECTION OF FEES.—In any case where
14 the Secretary does not receive payment of a fee as-
15 sessed under paragraph (1) or (2) within 30 days
16 after it is due, such fee shall be treated as a claim
17 of the United States Government subject to sub-
18 chapter II of chapter 37 of title 31, United States
19 Code.

20 “(g) COMPLIANCE WITH SECTION 801(a).—

21 “(1) IN GENERAL.—A registration condition is
22 that each qualifying drug exported under subsection
23 (a) by the registered exporter involved or imported
24 under subsection (a) by the registered importer in-
25 volved is in compliance with the standards referred

1 to in section 801(a) regarding admission of the drug
2 into the United States, subject to paragraphs (2),
3 (3), and (4).

4 “(2) SECTION 505; APPROVAL STATUS.—

5 “(A) IN GENERAL.—A qualifying drug that
6 is imported or offered for import under sub-
7 section (a) shall comply with the conditions es-
8 tablished in the approved application under sec-
9 tion 505(b) for the U.S. label drug as described
10 under this subsection.

11 “(B) NOTICE BY MANUFACTURER; GEN-
12 ERAL PROVISIONS.—

13 “(i) IN GENERAL.—The person that
14 manufactures a qualifying drug that is, or
15 will be, introduced for commercial distribu-
16 tion in a permitted country shall in accord-
17 ance with this paragraph submit to the
18 Secretary a notice that—

19 “(I) includes each difference in
20 the qualifying drug from a condition
21 established in the approved applica-
22 tion for the U.S. label drug beyond—

23 “(aa) the variations provided
24 for in the application; and

1 “(bb) any difference in label-
2 ing (except ingredient labeling);

3 or

4 “(II) states that there is no dif-
5 ference in the qualifying drug from a
6 condition established in the approved
7 application for the U.S. label drug be-
8 yond—

9 “(aa) the variations provided
10 for in the application; and

11 “(bb) any difference in label-
12 ing (except ingredient labeling).

13 “(ii) INFORMATION IN NOTICE.—A
14 notice under clause (i)(I) shall include the
15 information that the Secretary may require
16 under section 506A, any additional infor-
17 mation the Secretary may require (which
18 may include data on bioequivalence if such
19 data are not required under section 506A),
20 and, with respect to the permitted country
21 that approved the qualifying drug for com-
22 mercial distribution, or with respect to
23 which such approval is sought, include the
24 following:

1 “(I) The date on which the quali-
2 fying drug with such difference was,
3 or will be, introduced for commercial
4 distribution in the permitted country.

5 “(II) Information demonstrating
6 that the person submitting the notice
7 has also notified the government of
8 the permitted country in writing that
9 the person is submitting to the Sec-
10 retary a notice under clause (i)(I),
11 which notice describes the difference
12 in the qualifying drug from a condi-
13 tion established in the approved appli-
14 cation for the U.S. label drug.

15 “(III) The information that the
16 person submitted or will submit to the
17 government of the permitted country
18 for purposes of obtaining approval for
19 commercial distribution of the drug in
20 the country which, if in a language
21 other than English, shall be accom-
22 panied by an English translation
23 verified to be complete and accurate,
24 with the name, address, and a brief

1 statement of the qualifications of the
2 person that made the translation.

3 “(iii) CERTIFICATIONS.—The chief ex-
4 ecutive officer and the chief medical officer
5 of the manufacturer involved shall each
6 certify in the notice under clause (i) that—

7 “(I) the information provided in
8 the notice is complete and true; and

9 “(II) a copy of the notice has
10 been provided to the Federal Trade
11 Commission and to the State attor-
12 neys general.

13 “(iv) FEE.—

14 “(I) IN GENERAL.—If a notice
15 submitted under clause (i) includes a
16 difference that would, under section
17 506A, require the submission of a
18 supplemental application if made as a
19 change to the U.S. label drug, the
20 person that submits the notice shall
21 pay to the Secretary a fee in the same
22 amount as would apply if the person
23 were paying a fee pursuant to section
24 736(a)(1)(A)(ii). Fees collected by the
25 Secretary under the preceding sen-

1 tence are available only to the Sec-
2 retary and are for the sole purpose of
3 paying the costs of reviewing notices
4 submitted under clause (i).

5 “(II) FEE AMOUNT FOR CERTAIN
6 YEARS.—If no fee amount is in effect
7 under section 736(a)(1)(A)(ii) for a
8 fiscal year, then the amount paid by a
9 person under subclause (I) shall—

10 “(aa) for the first fiscal year
11 in which no fee amount under
12 such section in effect, be equal to
13 the fee amount under section
14 736(a)(1)(A)(ii) for the most re-
15 cent fiscal year for which such
16 section was in effect, adjusted in
17 accordance with section 736(c);
18 and

19 “(bb) for each subsequent
20 fiscal year in which no fee
21 amount under such section is ef-
22 fect, be equal to the applicable
23 fee amount for the previous fiscal
24 year, adjusted in accordance with
25 section 736(c).

1 “(v) TIMING OF SUBMISSION OF NO-
2 TICES.—

3 “(I) PRIOR APPROVAL NO-
4 TICES.—A notice under clause (i) to
5 which subparagraph (C) applies shall
6 be submitted to the Secretary not
7 later than 120 days before the quali-
8 fying drug with the difference is intro-
9 duced for commercial distribution in a
10 permitted country, unless the country
11 requires that distribution of the quali-
12 fying drug with the difference begin
13 less than 120 days after the country
14 requires the difference.

15 “(II) OTHER APPROVAL NO-
16 TICES.—A notice under clause (i) to
17 which subparagraph (D) applies shall
18 be submitted to the Secretary not
19 later than the day on which the quali-
20 fying drug with the difference is intro-
21 duced for commercial distribution in a
22 permitted country.

23 “(III) OTHER NOTICES.—A no-
24 tice under clause (i) to which subpara-
25 graph (E) applies shall be submitted

1 to the Secretary on the date that the
2 qualifying drug is first introduced for
3 commercial distribution in a permitted
4 country and annually thereafter.

5 “(vi) REVIEW BY SECRETARY.—

6 “(I) IN GENERAL.—In this para-
7 graph, the difference in a qualifying
8 drug that is submitted in a notice
9 under clause (i) from the U.S. label
10 drug shall be treated by the Secretary
11 as if it were a manufacturing change
12 to the U.S. label drug under section
13 506A.

14 “(II) STANDARD OF REVIEW.—
15 Except as provided in subclause (III),
16 the Secretary shall review and approve
17 or disapprove the difference in a no-
18 tice submitted under clause (i), if re-
19 quired under section 506A, using the
20 safe and effective standard for ap-
21 proving or disapproving a manufac-
22 turing change under section 506A.

23 “(III) BIOEQUIVALENCE.—If the
24 Secretary would approve the dif-
25 ference in a notice submitted under

1 clause (i) using the safe and effective
2 standard under section 506A and if
3 the Secretary determines that the
4 qualifying drug is not bioequivalent to
5 the U.S. label drug, the Secretary
6 shall—

7 “(aa) include in the labeling
8 provided under paragraph (3) a
9 prominent advisory that the
10 qualifying drug is safe and effec-
11 tive but is not bioequivalent to
12 the U.S. label drug if the Sec-
13 retary determines that such an
14 advisory is necessary for health
15 care practitioners and patients to
16 use the qualifying drug safely
17 and effectively; or

18 “(bb) decline to approve the
19 difference if the Secretary deter-
20 mines that the availability of
21 both the qualifying drug and the
22 U.S. label drug would pose a
23 threat to the public health.

24 “(IV) REVIEW BY THE SEC-
25 RETARY.—The Secretary shall review

1 and approve or disapprove the dif-
2 ference in a notice submitted under
3 clause (i), if required under section
4 506A, not later than 120 days after
5 the date on which the notice is sub-
6 mitted.

7 “(V) ESTABLISHMENT INSPEC-
8 TION.—If review of such difference
9 would require an inspection of the es-
10 tablishment in which the qualifying
11 drug is manufactured—

12 “(aa) such inspection by the
13 Secretary shall be authorized;
14 and

15 “(bb) the Secretary may rely
16 on a satisfactory report of a good
17 manufacturing practice inspec-
18 tion of the establishment from a
19 permitted country whose regu-
20 latory system the Secretary rec-
21 ognizes as equivalent under a
22 mutual recognition agreement, as
23 provided under section 510(i)(3),
24 section 803, or part 26 of title
25 21, Code of Federal Regulations

1 (or any corresponding successor
2 rule or regulation).

3 “(vii) PUBLICATION OF INFORMATION
4 ON NOTICES.—

5 “(I) IN GENERAL.—Through the
6 Internet website of the Food and
7 Drug Administration and a toll-free
8 telephone number, the Secretary shall
9 readily make available to the public a
10 list of notices submitted under clause
11 (i).

12 “(II) CONTENTS.—The list under
13 subclause (I) shall include the date on
14 which a notice is submitted and
15 whether—

16 “(aa) a notice is under re-
17 view;

18 “(bb) the Secretary has or-
19 dered that importation of the
20 qualifying drug from a permitted
21 country cease; or

22 “(cc) the importation of the
23 drug is permitted under sub-
24 section (a).

1 “(III) UPDATE.—The Secretary
2 shall promptly update the Internet
3 website with any changes to the list.

4 “(C) NOTICE; DRUG DIFFERENCE REQUIR-
5 ING PRIOR APPROVAL.—In the case of a notice
6 under subparagraph (B)(i) that includes a dif-
7 ference that would, under subsection (c) or
8 (d)(3)(B)(i) of section 506A, require the ap-
9 proval of a supplemental application before the
10 difference could be made to the U.S. label drug
11 the following shall occur:

12 “(i) Promptly after the notice is sub-
13 mitted, the Secretary shall notify reg-
14 istered exporters, registered importers, the
15 Federal Trade Commission, and the State
16 attorneys general that the notice has been
17 submitted with respect to the qualifying
18 drug involved.

19 “(ii) If the Secretary has not made a
20 determination whether such a supple-
21 mental application regarding the U.S. label
22 drug would be approved or disapproved by
23 the date on which the qualifying drug in-
24 volved is to be introduced for commercial

1 distribution in a permitted country, the
2 Secretary shall—

3 “(I) order that the importation of
4 the qualifying drug involved from the
5 permitted country not begin until the
6 Secretary completes review of the no-
7 tice; and

8 “(II) promptly notify registered
9 exporters, registered importers, the
10 Federal Trade Commission, and the
11 State attorneys general of the order.

12 “(iii) If the Secretary determines that
13 such a supplemental application regarding
14 the U.S. label drug would not be approved,
15 the Secretary shall—

16 “(I) order that the importation of
17 the qualifying drug involved from the
18 permitted country cease, or provide
19 that an order under clause (ii), if any,
20 remains in effect;

21 “(II) notify the permitted coun-
22 try that approved the qualifying drug
23 for commercial distribution of the de-
24 termination; and

1 “(III) promptly notify registered
2 exporters, registered importers, the
3 Federal Trade Commission, and the
4 State attorneys general of the deter-
5 mination.

6 “(iv) If the Secretary determines that
7 such a supplemental application regarding
8 the U.S. label drug would be approved, the
9 Secretary shall—

10 “(I) vacate the order under
11 clause (ii), if any;

12 “(II) consider the difference to
13 be a variation provided for in the ap-
14 proved application for the U.S. label
15 drug;

16 “(III) permit importation of the
17 qualifying drug under subsection (a);
18 and

19 “(IV) promptly notify registered
20 exporters, registered importers, the
21 Federal Trade Commission, and the
22 State attorneys general of the deter-
23 mination.

24 “(D) NOTICE; DRUG DIFFERENCE NOT RE-
25 QUIRING PRIOR APPROVAL.—In the case of a

1 notice under subparagraph (B)(i) that includes
2 a difference that would, under section
3 506A(d)(3)(B)(ii), not require the approval of a
4 supplemental application before the difference
5 could be made to the U.S. label drug the fol-
6 lowing shall occur:

7 “(i) During the period in which the
8 notice is being reviewed by the Secretary,
9 the authority under this subsection to im-
10 port the qualifying drug involved continues
11 in effect.

12 “(ii) If the Secretary determines that
13 such a supplemental application regarding
14 the U.S. label drug would not be approved,
15 the Secretary shall—

16 “(I) order that the importation of
17 the qualifying drug involved from the
18 permitted country cease;

19 “(II) notify the permitted coun-
20 try that approved the qualifying drug
21 for commercial distribution of the de-
22 termination; and

23 “(III) promptly notify registered
24 exporters, registered importers, the
25 Federal Trade Commission, and the

1 State attorneys general of the deter-
2 mination.

3 “(iii) If the Secretary determines that
4 such a supplemental application regarding
5 the U.S. label drug would be approved, the
6 difference shall be considered to be a vari-
7 ation provided for in the approved applica-
8 tion for the U.S. label drug.

9 “(E) NOTICE; DRUG DIFFERENCE NOT RE-
10 QUIRING APPROVAL; NO DIFFERENCE.—In the
11 case of a notice under subparagraph (B)(i) that
12 includes a difference for which, under section
13 506A(d)(1)(A), a supplemental application
14 would not be required for the difference to be
15 made to the U.S. label drug, or that states that
16 there is no difference, the Secretary—

17 “(i) shall consider such difference to
18 be a variation provided for in the approved
19 application for the U.S. label drug;

20 “(ii) may not order that the importa-
21 tion of the qualifying drug involved cease;
22 and

23 “(iii) shall promptly notify registered
24 exporters and registered importers.

1 “(F) DIFFERENCES IN ACTIVE INGRE-
2 DIENT, ROUTE OF ADMINISTRATION, DOSAGE
3 FORM, OR STRENGTH.—

4 “(i) IN GENERAL.—A person who
5 manufactures a drug approved under sec-
6 tion 505(b) shall submit an application
7 under section 505(b) for approval of an-
8 other drug that is manufactured for dis-
9 tribution in a permitted country by or for
10 the person that manufactures the drug ap-
11 proved under section 505(b) if—

12 “(I) there is no qualifying drug
13 in commercial distribution in per-
14 mitted countries whose combined pop-
15 ulation represents at least 50 percent
16 of the total population of all permitted
17 countries with the same active ingre-
18 dient or ingredients, route of adminis-
19 tration, dosage form, and strength as
20 the drug approved under section
21 505(b); and

22 “(II) each active ingredient of
23 the other drug is related to an active
24 ingredient of the drug approved under

1 section 505(b), as defined in clause
2 (v).

3 “(ii) APPLICATION UNDER SECTION
4 505(b).—The application under section
5 505(b) required under clause (i) shall—

6 “(I) request approval of the other
7 drug for the indication or indications
8 for which the drug approved under
9 section 505(b) is labeled;

10 “(II) include the information that
11 the person submitted to the govern-
12 ment of the permitted country for
13 purposes of obtaining approval for
14 commercial distribution of the other
15 drug in that country, which if in a
16 language other than English, shall be
17 accompanied by an English trans-
18 lation verified to be complete and ac-
19 curate, with the name, address, and a
20 brief statement of the qualifications of
21 the person that made the translation;

22 “(III) include a right of reference
23 to the application for the drug ap-
24 proved under section 505(b); and

1 “(IV) include such additional in-
2 formation as the Secretary may re-
3 quire.

4 “(iii) TIMING OF SUBMISSION OF AP-
5 PLICATION.—An application under section
6 505(b) required under clause (i) shall be
7 submitted to the Secretary not later than
8 the day on which the information referred
9 to in clause (ii)(II) is submitted to the gov-
10 ernment of the permitted country.

11 “(iv) NOTICE OF DECISION ON APPLI-
12 CATION.—The Secretary shall promptly no-
13 tify registered exporters, registered import-
14 ers, the Federal Trade Commission, and
15 the State attorneys general of a determina-
16 tion to approve or to disapprove an appli-
17 cation under section 505(b) required under
18 clause (i).

19 “(v) RELATED ACTIVE INGREDI-
20 ENTS.—For purposes of clause (i)(II), 2
21 active ingredients are related if they are—

22 “(I) the same; or

23 “(II) different salts, esters, or
24 complexes of the same moiety.

25 “(3) SECTION 502; LABELING.—

1 “(A) IMPORTATION BY REGISTERED IM-
2 PORTER.—

3 “(i) IN GENERAL.—In the case of a
4 qualifying drug that is imported or offered
5 for import by a registered importer, such
6 drug shall be considered to be in compli-
7 ance with section 502 and the labeling re-
8 quirements under the approved application
9 for the U.S. label drug if the qualifying
10 drug bears—

11 “(I) a copy of the labeling ap-
12 proved for the U.S. label drug under
13 section 505, without regard to wheth-
14 er the copy bears any trademark in-
15 volved;

16 “(II) the name of the manufac-
17 turer and location of the manufac-
18 turer;

19 “(III) the lot number assigned by
20 the manufacturer;

21 “(IV) the name, location, and
22 registration number of the importer;
23 and

1 “(V) the National Drug Code
2 number assigned to the qualifying
3 drug by the Secretary.

4 “(ii) REQUEST FOR COPY OF THE LA-
5 BELING.—The Secretary shall provide such
6 copy to the registered importer involved,
7 upon request of the importer.

8 “(iii) REQUESTED LABELING.—The
9 labeling provided by the Secretary under
10 clause (ii) shall—

11 “(I) include the established
12 name, as defined in section 502(e)(3),
13 for each active ingredient in the quali-
14 fying drug;

15 “(II) not include the proprietary
16 name of the U.S. label drug or any
17 active ingredient thereof;

18 “(III) if required under para-
19 graph (2)(B)(vi)(III), a prominent ad-
20 visory that the qualifying drug is safe
21 and effective but not bioequivalent to
22 the U.S. label drug; and

23 “(IV) if the inactive ingredients
24 of the qualifying drug are different

1 from the inactive ingredients for the
2 U.S. label drug, include—

3 “(aa) a prominent notice
4 that the ingredients of the quali-
5 fying drug differ from the ingre-
6 dients of the U.S. label drug and
7 that the qualifying drug must be
8 dispensed with an advisory to
9 people with allergies about this
10 difference and a list of ingredi-
11 ents; and

12 “(bb) a list of the ingredi-
13 ents of the qualifying drug as
14 would be required under section
15 502(e).

16 “(B) IMPORTATION BY INDIVIDUAL.—

17 “(i) IN GENERAL.—In the case of a
18 qualifying drug that is imported or offered
19 for import by a registered exporter to an
20 individual, such drug shall be considered to
21 be in compliance with section 502 and the
22 labeling requirements under the approved
23 application for the U.S. label drug if the
24 packaging and labeling of the qualifying
25 drug complies with all applicable regula-

1 tions promulgated under sections 3 and 4
2 of the Poison Prevention Packaging Act of
3 1970 (15 U.S.C. 1471 et seq.) and the la-
4 beling of the qualifying drug includes—

5 “(I) directions for use by the
6 consumer;

7 “(II) the lot number assigned by
8 the manufacturer;

9 “(III) the name and registration
10 number of the exporter;

11 “(IV) if required under para-
12 graph (2)(B)(vi)(III), a prominent ad-
13 visory that the drug is safe and effec-
14 tive but not bioequivalent to the U.S.
15 label drug;

16 “(V) if the inactive ingredients of
17 the drug are different from the inac-
18 tive ingredients for the U.S. label
19 drug—

20 “(aa) a prominent advisory
21 that persons with an allergy
22 should check the ingredient list
23 of the drug because the ingredi-
24 ents of the drug differ from the

1 ingredients of the U.S. label
2 drug; and

3 “(bb) a list of the ingredi-
4 ents of the drug as would be re-
5 quired under section 502(e); and

6 “(VI) a copy of any special label-
7 ing that would be required by the Sec-
8 retary had the U.S. label drug been
9 dispensed by a pharmacist in the
10 United States, without regard to
11 whether the special labeling bears any
12 trademark involved.

13 “(ii) PACKAGING.—A qualifying drug
14 offered for import to an individual by an
15 exporter under this section that is pack-
16 aged in a unit-of-use container (as those
17 items are defined in the United States
18 Pharmacopeia and National Formulary)
19 shall not be repackaged, provided that—

20 “(I) the packaging complies with
21 all applicable regulations under sec-
22 tions 3 and 4 of the Poison Preven-
23 tion Packaging Act of 1970 (15
24 U.S.C. 1471 et seq.); or

1 “(II) the consumer consents to
2 waive the requirements of such Act,
3 after being informed that the pack-
4 aging does not comply with such Act
5 and that the exporter will provide the
6 drug in packaging that is compliant at
7 no additional cost.

8 “(iii) REQUEST FOR COPY OF SPECIAL
9 LABELING AND INGREDIENT LIST.—The
10 Secretary shall provide to the registered
11 exporter involved a copy of the special la-
12 beling, the advisory, and the ingredient list
13 described under clause (i), upon request of
14 the exporter.

15 “(iv) REQUESTED LABELING AND IN-
16 GREDIENT LIST.—The labeling and ingre-
17 dient list provided by the Secretary under
18 clause (iii) shall—

19 “(I) include the established
20 name, as defined in section 502(e)(3),
21 for each active ingredient in the drug;
22 and

23 “(II) not include the proprietary
24 name of the U.S. label drug or any
25 active ingredient thereof.

1 “(4) SECTION 501; ADULTERATION.—A quali-
2 fying drug that is imported or offered for import
3 under subsection (a) shall be considered to be in
4 compliance with section 501 if the drug is in compli-
5 ance with subsection (c).

6 “(5) STANDARDS FOR REFUSING ADMISSION.—
7 A drug exported under subsection (a) from a reg-
8 istered exporter or imported by a registered importer
9 may be refused admission into the United States if
10 1 or more of the following applies:

11 “(A) The drug is not a qualifying drug.

12 “(B) A notice for the drug required under
13 paragraph (2)(B) has not been submitted to the
14 Secretary.

15 “(C) The Secretary has ordered that im-
16 portation of the drug from the permitted coun-
17 try cease under subparagraph (C) or (D) of
18 paragraph (2).

19 “(D) The drug does not comply with para-
20 graph (3) or (4).

21 “(E) The shipping container appears dam-
22 aged in a way that may affect the strength,
23 quality, or purity of the drug.

24 “(F) The Secretary becomes aware that—

25 “(i) the drug may be counterfeit;

1 “(ii) the drug may have been pre-
2 pared, packed, or held under insanitary
3 conditions; or

4 “(iii) the methods used in, or the fa-
5 cilities or controls used for, the manufac-
6 turing, processing, packing, or holding of
7 the drug do not conform to good manufac-
8 turing practice.

9 “(G) The Secretary has obtained an in-
10 junction under section 302 that prohibits the
11 distribution of the drug in interstate commerce.

12 “(H) The Secretary has under section
13 505(e) withdrawn approval of the drug.

14 “(I) The manufacturer of the drug has in-
15 stituted a recall of the drug.

16 “(J) If the drug is imported or offered for
17 import by a registered importer without submis-
18 sion of a notice in accordance with subsection
19 (d)(4).

20 “(K) If the drug is imported or offered for
21 import from a registered exporter to an indi-
22 vidual and 1 or more of the following applies:

23 “(i) The shipping container for such
24 drug does not bear the markings required
25 under subsection (d)(2).

1 “(ii) The markings on the shipping
2 container appear to be counterfeit.

3 “(iii) The shipping container or mark-
4 ings appear to have been tampered with.

5 “(h) EXPORTER LICENSURE IN PERMITTED COUN-
6 TRY.—A registration condition is that the exporter in-
7 volved agrees that a qualifying drug will be exported to
8 an individual only if the Secretary has verified that—

9 “(1) the exporter is authorized under the law of
10 the permitted country in which the exporter is lo-
11 cated to dispense prescription drugs; and

12 “(2) the exporter employs persons that are li-
13 censed under the law of the permitted country in
14 which the exporter is located to dispense prescription
15 drugs in sufficient number to dispense safely the
16 drugs exported by the exporter to individuals, and
17 the exporter assigns to those persons responsibility
18 for dispensing such drugs to individuals.

19 “(i) INDIVIDUALS; CONDITIONS FOR IMPORTA-
20 TION.—

21 “(1) IN GENERAL.—For purposes of subsection
22 (a)(2)(B), the importation of a qualifying drug by
23 an individual is in accordance with this subsection if
24 the following conditions are met:

1 “(A) The drug is accompanied by a copy of
2 a prescription for the drug, which prescrip-
3 tion—

4 “(i) is valid under applicable Federal
5 and State laws; and

6 “(ii) was issued by a practitioner who,
7 under the law of a State of which the indi-
8 vidual is a resident, or in which the indi-
9 vidual receives care from the practitioner
10 who issues the prescription, is authorized
11 to administer prescription drugs.

12 “(B) The drug is accompanied by a copy
13 of the documentation that was required under
14 the law or regulations of the permitted country
15 in which the exporter is located, as a condition
16 of dispensing the drug to the individual.

17 “(C) The copies referred to in subpara-
18 graphs (A)(i) and (B) are marked in a manner
19 sufficient—

20 “(i) to indicate that the prescription,
21 and the equivalent document in the per-
22 mitted country in which the exporter is lo-
23 cated, have been filled; and

24 “(ii) to prevent a duplicative filling by
25 another pharmacist.

1 “(D) The individual has provided to the
2 registered exporter a complete list of all drugs
3 used by the individual for review by the individ-
4 uals who dispense the drug.

5 “(E) The quantity of the drug does not ex-
6 ceed a 90-day supply.

7 “(F) The drug is not an ineligible subpart
8 H drug. For purposes of this section, a pre-
9 scription drug is an ‘ineligible subpart H drug’
10 if the drug was approved by the Secretary
11 under subpart H of part 314 of title 21, Code
12 of Federal Regulations (relating to accelerated
13 approval), with restrictions under section 520 of
14 such part to assure safe use, and the Secretary
15 has published in the Federal Register a notice
16 that the Secretary has determined that good
17 cause exists to prohibit the drug from being im-
18 ported pursuant to this subsection.

19 “(2) NOTICE REGARDING DRUG REFUSED AD-
20 MISSION.—If a registered exporter ships a drug to
21 an individual pursuant to subsection (a)(2)(B) and
22 the drug is refused admission to the United States,
23 a written notice shall be sent to the individual and
24 to the exporter that informs the individual and the

1 exporter of such refusal and the reason for the re-
2 fusal.

3 “(j) MAINTENANCE OF RECORDS AND SAMPLES.—

4 “(1) IN GENERAL.—A registration condition is
5 that the importer or exporter involved shall—

6 “(A) maintain records required under this
7 section for not less than 2 years; and

8 “(B) maintain samples of each lot of a
9 qualifying drug required under this section for
10 not more than 2 years.

11 “(2) PLACE OF RECORD MAINTENANCE.—The
12 records described under paragraph (1) shall be
13 maintained—

14 “(A) in the case of an importer, at the
15 place of business of the importer at which the
16 importer initially receives the qualifying drug
17 after importation; or

18 “(B) in the case of an exporter, at the fa-
19 cility from which the exporter ships the quali-
20 fying drug to the United States.

21 “(k) DRUG RECALLS.—

22 “(1) MANUFACTURERS.—A person that manu-
23 factures a qualifying drug imported from a per-
24 mitted country under this section shall promptly in-
25 form the Secretary—

1 “(A) if the drug is recalled or withdrawn
2 from the market in a permitted country;

3 “(B) how the drug may be identified, in-
4 cluding lot number; and

5 “(C) the reason for the recall or with-
6 drawal.

7 “(2) SECRETARY.—With respect to each per-
8 mitted country, the Secretary shall—

9 “(A) enter into an agreement with the gov-
10 ernment of the country to receive information
11 about recalls and withdrawals of qualifying
12 drugs in the country; or

13 “(B) monitor recalls and withdrawals of
14 qualifying drugs in the country using any infor-
15 mation that is available to the public in any
16 media.

17 “(3) NOTICE.—The Secretary may notify, as
18 appropriate, registered exporters, registered import-
19 ers, wholesalers, pharmacies, or the public of a recall
20 or withdrawal of a qualifying drug in a permitted
21 country.

22 “(1) DRUG LABELING AND PACKAGING.—

23 “(1) IN GENERAL.—When a qualifying drug
24 that is imported into the United States by an im-
25 porter under subsection (a) is dispensed by a phar-

1 macist to an individual, the pharmacist shall provide
2 that the packaging and labeling of the drug complies
3 with all applicable regulations promulgated under
4 sections 3 and 4 of the Poison Prevention Packaging
5 Act of 1970 (15 U.S.C. 1471 et seq.) and shall in-
6 clude with any other labeling provided to the indi-
7 vidual the following:

8 “(A) The lot number assigned by the man-
9 ufacturer.

10 “(B) The name and registration number of
11 the importer.

12 “(C) If required under paragraph
13 (2)(B)(vi)(III) of subsection (g), a prominent
14 advisory that the drug is safe and effective but
15 not bioequivalent to the U.S. label drug.

16 “(D) If the inactive ingredients of the drug
17 are different from the inactive ingredients for
18 the U.S. label drug—

19 “(i) a prominent advisory that persons
20 with allergies should check the ingredient
21 list of the drug because the ingredients of
22 the drug differ from the ingredients of the
23 U.S. label drug; and

1 “(ii) a list of the ingredients of the
2 drug as would be required under section
3 502(e).

4 “(2) PACKAGING.—A qualifying drug that is
5 packaged in a unit-of-use container (as those terms
6 are defined in the United States Pharmacopeia and
7 National Formulary) shall not be repackaged, pro-
8 vided that—

9 “(A) the packaging complies with all appli-
10 cable regulations under sections 3 and 4 of the
11 Poison Prevention Packaging Act of 1970 (15
12 U.S.C. 1471 et seq.); or

13 “(B) the consumer consents to waive the
14 requirements of such Act, after being informed
15 that the packaging does not comply with such
16 Act and that the pharmacist will provide the
17 drug in packaging that is compliant at no addi-
18 tional cost.

19 “(m) CHARITABLE CONTRIBUTIONS.—Notwith-
20 standing any other provision of this section, this section
21 does not authorize the importation into the United States
22 of a qualifying drug donated or otherwise supplied for free
23 or at nominal cost by the manufacturer of the drug to
24 a charitable or humanitarian organization, including the

1 United Nations and affiliates, or to a government of a for-
2 eign country.

3 “(n) UNFAIR AND DISCRIMINATORY ACTS AND PRAC-
4 TICES.—

5 “(1) IN GENERAL.—It is unlawful for a manu-
6 facturer, directly or indirectly (including by being a
7 party to a licensing agreement or other agreement),
8 to—

9 “(A) discriminate by charging a higher
10 price for a prescription drug sold to a registered
11 exporter or other person in a permitted country
12 that exports a qualifying drug to the United
13 States under this section than the price that is
14 charged, inclusive of rebates or other incentives
15 to the permitted country or other person, to an-
16 other person that is in the same country and
17 that does not export a qualifying drug into the
18 United States under this section;

19 “(B) discriminate by charging a higher
20 price for a prescription drug sold to a registered
21 importer or other person that distributes, sells,
22 or uses a qualifying drug imported into the
23 United States under this section than the price
24 that is charged to another person in the United
25 States that does not import a qualifying drug

1 under this section, or that does not distribute,
2 sell, or use such a drug;

3 “(C) discriminate by denying, restricting,
4 or delaying supplies of a prescription drug to a
5 registered exporter or other person in a per-
6 mitted country that exports a qualifying drug to
7 the United States under this section or to a
8 registered importer or other person that distrib-
9 utes, sells, or uses a qualifying drug imported
10 into the United States under this section;

11 “(D) discriminate by publicly, privately, or
12 otherwise refusing to do business with a reg-
13 istered exporter or other person in a permitted
14 country that exports a qualifying drug to the
15 United States under this section or with a reg-
16 istered importer or other person that distrib-
17 utes, sells, or uses a qualifying drug imported
18 into the United States under this section;

19 “(E) knowingly fail to submit a notice
20 under subsection (g)(2)(B)(i), knowingly fail to
21 submit such a notice on or before the date spec-
22 ified in subsection (g)(2)(B)(v) or as otherwise
23 required under paragraphs (3), (4), and (5) of
24 section 4(e) of the Pharmaceutical Market Ac-
25 cess and Drug Safety Act of 2011, knowingly

1 submit such a notice that makes a materially
2 false, fictitious, or fraudulent statement, or
3 knowingly fail to provide promptly any informa-
4 tion requested by the Secretary to review such
5 a notice;

6 “(F) knowingly fail to submit an applica-
7 tion required under subsection (g)(2)(F), know-
8 ingly fail to submit such an application on or
9 before the date specified in subsection
10 (g)(2)(F)(iii), knowingly submit such an appli-
11 cation that makes a materially false, fictitious,
12 or fraudulent statement, or knowingly fail to
13 provide promptly any information requested by
14 the Secretary to review such an application;

15 “(G) cause there to be a difference (includ-
16 ing a difference in active ingredient, route of
17 administration, dosage form, strength, formula-
18 tion, manufacturing establishment, manufac-
19 turing process, or person that manufactures the
20 drug) between a prescription drug for distribu-
21 tion in the United States and the drug for dis-
22 tribution in a permitted country;

23 “(H) refuse to allow an inspection author-
24 ized under this section of an establishment that
25 manufactures a qualifying drug that is, or will

1 be, introduced for commercial distribution in a
2 permitted country;

3 “(I) fail to conform to the methods used
4 in, or the facilities used for, the manufacturing,
5 processing, packing, or holding of a qualifying
6 drug that is, or will be, introduced for commer-
7 cial distribution in a permitted country to good
8 manufacturing practice under this Act;

9 “(J) become a party to a licensing agree-
10 ment or other agreement related to a qualifying
11 drug that fails to provide for compliance with
12 all requirements of this section with respect to
13 such drug;

14 “(K) enter into a contract that restricts,
15 prohibits, or delays the importation of a quali-
16 fying drug under this section;

17 “(L) engage in any other action to restrict,
18 prohibit, or delay the importation of a quali-
19 fying drug under this section; or

20 “(M) engage in any other action that the
21 Federal Trade Commission determines to dis-
22 criminate against a person that engages or at-
23 tempts to engage in the importation of a quali-
24 fying drug under this section.

1 “(2) REFERRAL OF POTENTIAL VIOLATIONS.—
2 The Secretary shall promptly refer to the Federal
3 Trade Commission each potential violation of sub-
4 paragraph (E), (F), (G), (H), or (I) of paragraph
5 (1) that becomes known to the Secretary.

6 “(3) AFFIRMATIVE DEFENSE.—

7 “(A) DISCRIMINATION.—It shall be an af-
8 firmative defense to a charge that a manufac-
9 turer has discriminated under subparagraph
10 (A), (B), (C), (D), or (M) of paragraph (1) that
11 the higher price charged for a prescription drug
12 sold to a person, the denial, restriction, or delay
13 of supplies of a prescription drug to a person,
14 the refusal to do business with a person, or
15 other discriminatory activity against a person,
16 is not based, in whole or in part, on—

17 “(i) the person exporting or importing
18 a qualifying drug into the United States
19 under this section; or

20 “(ii) the person distributing, selling,
21 or using a qualifying drug imported into
22 the United States under this section.

23 “(B) DRUG DIFFERENCES.—It shall be an
24 affirmative defense to a charge that a manufac-
25 turer has caused there to be a difference de-

1 scribed in subparagraph (G) of paragraph (1)
2 that—

3 “(i) the difference was required by the
4 country in which the drug is distributed;

5 “(ii) the Secretary has determined
6 that the difference was necessary to im-
7 prove the safety or effectiveness of the
8 drug;

9 “(iii) the person manufacturing the
10 drug for distribution in the United States
11 has given notice to the Secretary under
12 subsection (g)(2)(B)(i) that the drug for
13 distribution in the United States is not dif-
14 ferent from a drug for distribution in per-
15 mitted countries whose combined popu-
16 lation represents at least 50 percent of the
17 total population of all permitted countries;
18 or

19 “(iv) the difference was not caused, in
20 whole or in part, for the purpose of re-
21 stricting importation of the drug into the
22 United States under this section.

23 “(4) EFFECT OF SUBSECTION.—

24 “(A) SALES IN OTHER COUNTRIES.—This
25 subsection applies only to the sale or distribu-

1 tion of a prescription drug in a country if the
2 manufacturer of the drug chooses to sell or dis-
3 tribute the drug in the country. Nothing in this
4 subsection shall be construed to compel the
5 manufacturer of a drug to distribute or sell the
6 drug in a country.

7 “(B) DISCOUNTS TO INSURERS, HEALTH
8 PLANS, PHARMACY BENEFIT MANAGERS, AND
9 COVERED ENTITIES.—Nothing in this sub-
10 section shall be construed to—

11 “(i) prevent or restrict a manufac-
12 turer of a prescription drug from providing
13 discounts to an insurer, health plan, phar-
14 macy benefit manager in the United
15 States, or covered entity in the drug dis-
16 count program under section 340B of the
17 Public Health Service Act (42 U.S.C.
18 256b) in return for inclusion of the drug
19 on a formulary;

20 “(ii) require that such discounts be
21 made available to other purchasers of the
22 prescription drug; or

23 “(iii) prevent or restrict any other
24 measures taken by an insurer, health plan,

1 or pharmacy benefit manager to encourage
2 consumption of such prescription drug.

3 “(C) CHARITABLE CONTRIBUTIONS.—

4 Nothing in this subsection shall be construed
5 to—

6 “(i) prevent a manufacturer from do-
7 nating a prescription drug, or supplying a
8 prescription drug at nominal cost, to a
9 charitable or humanitarian organization,
10 including the United Nations and affili-
11 ates, or to a government of a foreign coun-
12 try; or

13 “(ii) apply to such donations or sup-
14 plying of a prescription drug.

15 “(5) ENFORCEMENT.—

16 “(A) UNFAIR OR DECEPTIVE ACT OR PRAC-
17 TICE.—A violation of this subsection shall be
18 treated as a violation of a rule defining an un-
19 fair or deceptive act or practice prescribed
20 under section 18(a)(1)(B) of the Federal Trade
21 Commission Act (15 U.S.C. 57a(a)(1)(B)).

22 “(B) ACTIONS BY THE COMMISSION.—The
23 Federal Trade Commission—

24 “(i) shall enforce this subsection in
25 the same manner, by the same means, and

1 with the same jurisdiction, powers, and du-
2 ties as though all applicable terms and pro-
3 visions of the Federal Trade Commission
4 Act (15 U.S.C. 41 et seq.) were incor-
5 porated into and made a part of this sec-
6 tion; and

7 “(ii) may seek monetary relief three-
8 fold the damages sustained, in addition to
9 any other remedy available to the Federal
10 Trade Commission under the Federal
11 Trade Commission Act (15 U.S.C. 41 et
12 seq.).

13 “(6) ACTIONS BY STATES.—

14 “(A) IN GENERAL.—

15 “(i) CIVIL ACTIONS.—In any case in
16 which the attorney general of a State has
17 reason to believe that an interest of the
18 residents of that State have been adversely
19 affected by any manufacturer that violates
20 paragraph (1), the attorney general of a
21 State may bring a civil action on behalf of
22 the residents of the State, and persons
23 doing business in the State, in a district
24 court of the United States of appropriate
25 jurisdiction to—

1 “(I) enjoin that practice;

2 “(II) enforce compliance with
3 this subsection;

4 “(III) obtain damages, restitu-
5 tion, or other compensation on behalf
6 of residents of the State and persons
7 doing business in the State, including
8 threefold the damages; or

9 “(IV) obtain such other relief as
10 the court may consider to be appro-
11 priate.

12 “(ii) NOTICE.—

13 “(I) IN GENERAL.—Before filing
14 an action under clause (i), the attor-
15 ney general of the State involved shall
16 provide to the Federal Trade Commis-
17 sion—

18 “(aa) written notice of that
19 action; and

20 “(bb) a copy of the com-
21 plaint for that action.

22 “(II) EXEMPTION.—Subclause
23 (I) shall not apply with respect to the
24 filing of an action by an attorney gen-
25 eral of a State under this paragraph,

1 if the attorney general determines
2 that it is not feasible to provide the
3 notice described in that subclause be-
4 fore filing of the action. In such case,
5 the attorney general of a State shall
6 provide notice and a copy of the com-
7 plaint to the Federal Trade Commis-
8 sion at the same time as the attorney
9 general files the action.

10 “(B) INTERVENTION.—

11 “(i) IN GENERAL.—On receiving no-
12 tice under subparagraph (A)(ii), the Fed-
13 eral Trade Commission shall have the right
14 to intervene in the action that is the sub-
15 ject of the notice.

16 “(ii) EFFECT OF INTERVENTION.—If
17 the Federal Trade Commission intervenes
18 in an action under subparagraph (A), it
19 shall have the right—

20 “(I) to be heard with respect to
21 any matter that arises in that action;
22 and

23 “(II) to file a petition for appeal.

24 “(C) CONSTRUCTION.—For purposes of
25 bringing any civil action under subparagraph

1 (A), nothing in this subsection shall be con-
2 strued to prevent an attorney general of a State
3 from exercising the powers conferred on the at-
4 torney general by the laws of that State to—

5 “(i) conduct investigations;

6 “(ii) administer oaths or affirmations;

7 or

8 “(iii) compel the attendance of wit-
9 nesses or the production of documentary
10 and other evidence.

11 “(D) ACTIONS BY THE COMMISSION.—In
12 any case in which an action is instituted by or
13 on behalf of the Federal Trade Commission for
14 a violation of paragraph (1), a State may not,
15 during the pendency of that action, institute an
16 action under subparagraph (A) for the same
17 violation against any defendant named in the
18 complaint in that action.

19 “(E) VENUE.—Any action brought under
20 subparagraph (A) may be brought in the dis-
21 trict court of the United States that meets ap-
22 plicable requirements relating to venue under
23 section 1391 of title 28, United States Code.

24 “(F) SERVICE OF PROCESS.—In an action
25 brought under subparagraph (A), process may

1 be served in any district in which the defend-
2 ant—

3 “(i) is an inhabitant; or

4 “(ii) may be found.

5 “(G) MEASUREMENT OF DAMAGES.—In
6 any action under this paragraph to enforce a
7 cause of action under this subsection in which
8 there has been a determination that a defend-
9 ant has violated a provision of this subsection,
10 damages may be proved and assessed in the ag-
11 gregate by statistical or sampling methods, by
12 the computation of illegal overcharges or by
13 such other reasonable system of estimating ag-
14 gregate damages as the court in its discretion
15 may permit without the necessity of separately
16 proving the individual claim of, or amount of
17 damage to, persons on whose behalf the suit
18 was brought.

19 “(H) EXCLUSION ON DUPLICATIVE RE-
20 LIEF.—The district court shall exclude from the
21 amount of monetary relief awarded in an action
22 under this paragraph brought by the attorney
23 general of a State any amount of monetary re-
24 lief which duplicates amounts which have been
25 awarded for the same injury.

1 “(7) EFFECT ON ANTITRUST LAWS.—Nothing
2 in this subsection shall be construed to modify, im-
3 pair, or supersede the operation of the antitrust
4 laws. For the purpose of this subsection, the term
5 ‘antitrust laws’ has the meaning given it in the first
6 section of the Clayton Act, except that it includes
7 section 5 of the Federal Trade Commission Act to
8 the extent that such section 5 applies to unfair
9 methods of competition.

10 “(8) MANUFACTURER.—In this subsection, the
11 term ‘manufacturer’ means any entity, including any
12 affiliate or licensee of that entity, that is engaged
13 in—

14 “(A) the production, preparation, propaga-
15 tion, compounding, conversion, or processing of
16 a prescription drug, either directly or indirectly
17 by extraction from substances of natural origin,
18 or independently by means of chemical syn-
19 thesis, or by a combination of extraction and
20 chemical synthesis; or

21 “(B) the packaging, repackaging, labeling,
22 relabeling, or distribution of a prescription
23 drug.”.

24 (b) PROHIBITED ACTS.—The Federal Food, Drug,
25 and Cosmetic Act is amended—

1 (1) in section 301 (21 U.S.C. 331), by striking
2 paragraph (aa) and inserting the following:

3 “(aa)(1) The sale or trade by a pharmacist, or by
4 a business organization of which the pharmacist is a part,
5 of a qualifying drug that under section 804(a)(2)(A) was
6 imported by the pharmacist, other than—

7 “(A) a sale at retail made pursuant to dis-
8 pensing the drug to a customer of the pharmacist or
9 organization; or

10 “(B) a sale or trade of the drug to a pharmacy
11 or a wholesaler registered to import drugs under sec-
12 tion 804.

13 “(2) The sale or trade by an individual of a qualifying
14 drug that under section 804(a)(2)(B) was imported by the
15 individual.

16 “(3) The making of a materially false, fictitious, or
17 fraudulent statement or representation, or a material
18 omission, in a notice under clause (i) of section
19 804(g)(2)(B) or in an application required under section
20 804(g)(2)(F), or the failure to submit such a notice or
21 application.

22 “(4) The importation of a drug in violation of a reg-
23 istration condition or other requirement under section
24 804, the falsification of any record required to be main-
25 tained, or provided to the Secretary, under such section,

1 or the violation of any registration condition or other re-
2 quirement under such section.”; and

3 (2) in section 303(a) (21 U.S.C. 333(a)), by
4 striking paragraph (6) and inserting the following:

5 “(6) Notwithstanding subsection (a), any person that
6 knowingly violates section 301(i) (2) or (3) or section
7 301(aa)(4) shall be imprisoned not more than 10 years,
8 or fined in accordance with title 18, United States Code,
9 or both.”.

10 (c) AMENDMENT OF CERTAIN PROVISIONS.—

11 (1) IN GENERAL.—Section 801 of the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C. 381) is
13 amended by striking subsection (g) and inserting the
14 following:

15 “(g) With respect to a prescription drug that is im-
16 ported or offered for import into the United States by an
17 individual who is not in the business of such importation,
18 that is not shipped by a registered exporter under section
19 804, and that is refused admission under subsection (a),
20 the Secretary shall notify the individual that—

21 “(1) the drug has been refused admission be-
22 cause the drug was not a lawful import under sec-
23 tion 804;

24 “(2) the drug is not otherwise subject to a
25 waiver of the requirements of subsection (a);

1 “(3) the individual may under section 804 law-
2 fully import certain prescription drugs from export-
3 ers registered with the Secretary under section 804;
4 and

5 “(4) the individual can find information about
6 such importation, including a list of registered ex-
7 porters, on the Internet website of the Food and
8 Drug Administration or through a toll-free telephone
9 number required under section 804.”.

10 (2) ESTABLISHMENT REGISTRATION.—Section
11 510(i) of the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 360(i)) is amended in paragraph (1) by
13 inserting after “import into the United States” the
14 following: “, including a drug that is, or may be, im-
15 ported or offered for import into the United States
16 under section 804,”.

17 (3) EFFECTIVE DATE.—The amendments made
18 by this subsection shall take effect on the date that
19 is 90 days after the date of enactment of this Act.

20 (d) EXHAUSTION.—

21 (1) IN GENERAL.—Section 271 of title 35,
22 United States Code, is amended—

23 (A) by redesignating subsections (h) and
24 (i) as (i) and (j), respectively; and

1 (B) by inserting after subsection (g) the
2 following:

3 “(h) It shall not be an act of infringement to use,
4 offer to sell, or sell within the United States or to import
5 into the United States any patented invention under sec-
6 tion 804 of the Federal Food, Drug, and Cosmetic Act
7 that was first sold abroad by or under authority of the
8 owner or licensee of such patent.”.

9 (2) RULE OF CONSTRUCTION.—Nothing in the
10 amendment made by paragraph (1) shall be con-
11 strued to affect the ability of a patent owner or li-
12 censee to enforce their patent, subject to such
13 amendment.

14 (e) EFFECT OF SECTION 804.—

15 (1) IN GENERAL.—Section 804 of the Federal
16 Food, Drug, and Cosmetic Act, as added by sub-
17 section (a), shall permit the importation of quali-
18 fying drugs (as defined in such section 804) into the
19 United States without regard to the status of the
20 issuance of implementing regulations—

21 (A) from exporters registered under such
22 section 804 on the date that is 90 days after
23 the date of enactment of this Act; and

24 (B) from permitted countries, as defined in
25 such section 804, by importers registered under

1 such section 804 on the date that is 1 year
2 after the date of enactment of this Act.

3 (2) REVIEW OF REGISTRATION BY CERTAIN EX-
4 PORTERS.—

5 (A) REVIEW PRIORITY.—In the review of
6 registrations submitted under subsection (b) of
7 such section 804, registrations submitted by en-
8 tities in Canada that are significant exporters
9 of prescription drugs to individuals in the
10 United States as of the date of enactment of
11 this Act will have priority during the 90 day pe-
12 riod that begins on such date of enactment.

13 (B) PERIOD FOR REVIEW.—During such
14 90-day period, the reference in subsection
15 (b)(2)(A) of such section 804 to 90 days (relat-
16 ing to approval or disapproval of registrations)
17 is, as applied to such entities, deemed to be 30
18 days.

19 (C) LIMITATION.—That an exporter in
20 Canada exports, or has exported, prescription
21 drugs to individuals in the United States on or
22 before the date that is 90 days after the date
23 of enactment of this Act shall not serve as a
24 basis, in whole or in part, for disapproving a

1 registration under such section 804 from the
2 exporter.

3 (D) FIRST YEAR LIMIT ON NUMBER OF
4 EXPORTERS.—During the 1-year period begin-
5 ning on the date of enactment of this Act, the
6 Secretary of Health and Human Services (re-
7 ferred to in this section as the “Secretary”)
8 may limit the number of registered exporters
9 under such section 804 to not less than 50, so
10 long as the Secretary gives priority to those ex-
11 porters with demonstrated ability to process a
12 high volume of shipments of drugs to individ-
13 uals in the United States.

14 (E) SECOND YEAR LIMIT ON NUMBER OF
15 EXPORTERS.—During the 1-year period begin-
16 ning on the date that is 1 year after the date
17 of enactment of this Act, the Secretary may
18 limit the number of registered exporters under
19 such section 804 to not less than 100, so long
20 as the Secretary gives priority to those export-
21 ers with demonstrated ability to process a high
22 volume of shipments of drugs to individuals in
23 the United States.

24 (F) FURTHER LIMIT ON NUMBER OF EX-
25 PORTERS.—During any 1-year period beginning

1 on a date that is 2 or more years after the date
2 of enactment of this Act, the Secretary may
3 limit the number of registered exporters under
4 such section 804 to not less than 25 more than
5 the number of such exporters during the pre-
6 vious 1-year period, so long as the Secretary
7 gives priority to those exporters with dem-
8 onstrated ability to process a high volume of
9 shipments of drugs to individuals in the United
10 States.

11 (3) LIMITS ON NUMBER OF IMPORTERS.—

12 (A) FIRST YEAR LIMIT ON NUMBER OF IM-
13 PORTERS.—During the 1-year period beginning
14 on the date that is 1 year after the date of en-
15 actment of this Act, the Secretary may limit the
16 number of registered importers under such sec-
17 tion 804 to not less than 100 (of which at least
18 a significant number shall be groups of phar-
19 macies, to the extent feasible given the applica-
20 tions submitted by such groups), so long as the
21 Secretary gives priority to those importers with
22 demonstrated ability to process a high volume
23 of shipments of drugs imported into the United
24 States.

1 (B) SECOND YEAR LIMIT ON NUMBER OF
2 IMPORTERS.—During the 1-year period begin-
3 ning on the date that is 2 years after the date
4 of enactment of this Act, the Secretary may
5 limit the number of registered importers under
6 such section 804 to not less than 200 (of which
7 at least a significant number shall be groups of
8 pharmacies, to the extent feasible given the ap-
9 plications submitted by such groups), so long as
10 the Secretary gives priority to those importers
11 with demonstrated ability to process a high vol-
12 ume of shipments of drugs into the United
13 States.

14 (C) FURTHER LIMIT ON NUMBER OF IM-
15 PORTERS.—During any 1-year period beginning
16 on a date that is 3 or more years after the date
17 of enactment of this Act, the Secretary may
18 limit the number of registered importers under
19 such section 804 to not less than 50 more (of
20 which at least a significant number shall be
21 groups of pharmacies, to the extent feasible
22 given the applications submitted by such
23 groups) than the number of such importers
24 during the previous 1-year period, so long as
25 the Secretary gives priority to those importers

1 with demonstrated ability to process a high vol-
2 ume of shipments of drugs to the United
3 States.

4 (4) NOTICES FOR DRUGS FOR IMPORT FROM
5 CANADA.—The notice with respect to a qualifying
6 drug introduced for commercial distribution in Can-
7 ada as of the date of enactment of this Act that is
8 required under subsection (g)(2)(B)(i) of such sec-
9 tion 804 shall be submitted to the Secretary not
10 later than 30 days after the date of enactment of
11 this Act if—

12 (A) the U.S. label drug (as defined in such
13 section 804) for the qualifying drug is 1 of the
14 100 prescription drugs with the highest dollar
15 volume of sales in the United States based on
16 the 12 calendar month period most recently
17 completed before the date of enactment of this
18 Act; or

19 (B) the notice is a notice under subsection
20 (g)(2)(B)(i)(II) of such section 804.

21 (5) NOTICE FOR DRUGS FOR IMPORT FROM
22 OTHER COUNTRIES.—The notice with respect to a
23 qualifying drug introduced for commercial distribu-
24 tion in a permitted country other than Canada as of
25 the date of enactment of this Act that is required

1 under subsection (g)(2)(B)(i) of such section 804
2 shall be submitted to the Secretary not later than
3 180 days after the date of enactment of this Act
4 if—

5 (A) the U.S. label drug for the qualifying
6 drug is 1 of the 100 prescription drugs with the
7 highest dollar volume of sales in the United
8 States based on the 12 calendar month period
9 that is first completed on the date that is 120
10 days after the date of enactment of this Act; or

11 (B) the notice is a notice under subsection
12 (g)(2)(B)(i)(II) of such section 804.

13 (6) NOTICE FOR OTHER DRUGS FOR IMPORT.—

14 (A) GUIDANCE ON SUBMISSION DATES.—

15 The Secretary shall by guidance establish a se-
16 ries of submission dates for the notices under
17 subsection (g)(2)(B)(i) of such section 804 with
18 respect to qualifying drugs introduced for com-
19 mercial distribution as of the date of enactment
20 of this Act and that are not required to be sub-
21 mitted under paragraph (4) or (5).

22 (B) CONSISTENT AND EFFICIENT USE OF
23 RESOURCES.—The Secretary shall establish the
24 dates described under subparagraph (A) so that
25 such notices described under subparagraph (A)

1 are submitted and reviewed at a rate that al-
2 lows consistent and efficient use of the re-
3 sources and staff available to the Secretary for
4 such reviews. The Secretary may condition the
5 requirement to submit such a notice, and the
6 review of such a notice, on the submission by a
7 registered exporter or a registered importer to
8 the Secretary of a notice that such exporter or
9 importer intends to import such qualifying drug
10 to the United States under such section 804.

11 (C) PRIORITY FOR DRUGS WITH HIGHER
12 SALES.—The Secretary shall establish the dates
13 described under subparagraph (A) so that the
14 Secretary reviews the notices described under
15 such subparagraph with respect to qualifying
16 drugs with higher dollar volume of sales in the
17 United States before the notices with respect to
18 drugs with lower sales in the United States.

19 (7) NOTICES FOR DRUGS APPROVED AFTER EF-
20 FECTIVE DATE.—The notice required under sub-
21 section (g)(2)(B)(i) of such section 804 for a quali-
22 fying drug first introduced for commercial distribu-
23 tion in a permitted country (as defined in such sec-
24 tion 804) after the date of enactment of this Act
25 shall be submitted to and reviewed by the Secretary

1 as provided under subsection (g)(2)(B) of such sec-
2 tion 804, without regard to paragraph (4), (5), or
3 (6).

4 (8) REPORT.—Beginning with the first full fis-
5 cal year after the date of enactment of this Act, not
6 later than 90 days after the end of each fiscal year
7 during which the Secretary reviews a notice referred
8 to in paragraph (4), (5), or (6), the Secretary shall
9 submit a report to Congress concerning the progress
10 of the Food and Drug Administration in reviewing
11 the notices referred to in paragraphs (4), (5), and
12 (6).

13 (9) USER FEES.—

14 (A) EXPORTERS.—When establishing an
15 aggregate total of fees to be collected from ex-
16 porters under subsection (f)(2) of such section
17 804, the Secretary shall, under subsection
18 (f)(3)(C)(i) of such section 804, estimate the
19 total price of drugs imported under subsection
20 (a) of such section 804 into the United States
21 by registered exporters during the first fiscal
22 year in which this Act takes effect to be an
23 amount equal to the amount which bears the
24 same ratio to \$1,000,000,000 as the number of

1 days in such fiscal year during which this Act
2 is effective bears to 365.

3 (B) IMPORTERS.—When establishing an
4 aggregate total of fees to be collected from im-
5 porters under subsection (e)(2) of such section
6 804, the Secretary shall, under subsection
7 (e)(3)(C)(i) of such section 804, estimate the
8 total price of drugs imported under subsection
9 (a) of such section 804 into the United States
10 by registered importers during—

11 (i) the first fiscal year in which this
12 Act takes effect to be an amount equal to
13 the amount which bears the same ratio to
14 \$1,000,000,000 as the number of days in
15 such fiscal year during which this Act is
16 effective bears to 365; and

17 (ii) the second fiscal year in which
18 this Act is in effect to be \$3,000,000,000.

19 (C) SECOND YEAR ADJUSTMENT.—

20 (i) REPORTS.—Not later than Feb-
21 ruary 20 of the second fiscal year in which
22 this Act is in effect, registered importers
23 shall report to the Secretary the total price
24 and the total volume of drugs imported to
25 the United States by the importer during

1 the 4-month period from October 1
2 through January 31 of such fiscal year.

3 (ii) REESTIMATE.—Notwithstanding
4 subsection (e)(3)(C)(ii) of such section 804
5 or subparagraph (B), the Secretary shall
6 reestimate the total price of qualifying
7 drugs imported under subsection (a) of
8 such section 804 into the United States by
9 registered importers during the second fis-
10 cal year in which this Act is in effect. Such
11 reestimate shall be equal to—

12 (I) the total price of qualifying
13 drugs imported by each importer as
14 reported under clause (i); multiplied
15 by

16 (II) 3.

17 (iii) ADJUSTMENT.—The Secretary
18 shall adjust the fee due on April 1 of the
19 second fiscal year in which this Act is in
20 effect, from each importer so that the ag-
21 gregate total of fees collected under sub-
22 section (e)(2) for such fiscal year does not
23 exceed the total price of qualifying drugs
24 imported under subsection (a) of such sec-
25 tion 804 into the United States by reg-

1 istered importers during such fiscal year as
2 reestimated under clause (ii).

3 (D) FAILURE TO PAY FEES.—Notwith-
4 standing any other provision of this section, the
5 Secretary may prohibit a registered importer or
6 exporter that is required to pay user fees under
7 subsection (e) or (f) of such section 804 and
8 that fails to pay such fees within 30 days after
9 the date on which it is due, from importing or
10 offering for importation a qualifying drug under
11 such section 804 until such fee is paid.

12 (E) ANNUAL REPORT.—

13 (i) FOOD AND DRUG ADMINISTRA-
14 TION.—Not later than 180 days after the
15 end of each fiscal year during which fees
16 are collected under subsection (e), (f), or
17 (g)(2)(B)(iv) of such section 804, the Sec-
18 retary shall prepare and submit to the
19 House of Representatives and the Senate a
20 report on the implementation of the au-
21 thority for such fees during such fiscal
22 year and the use, by the Food and Drug
23 Administration, of the fees collected for the
24 fiscal year for which the report is made

1 and credited to the Food and Drug Admin-
2 istration.

3 (ii) CUSTOMS AND BORDER PROTEC-
4 TION.—Not later than 180 days after the
5 end of each fiscal year during which fees
6 are collected under subsection (e) or (f) of
7 such section 804, the Secretary of Home-
8 land Security, in consultation with the Sec-
9 retary of the Treasury, shall prepare and
10 submit to the House of Representatives
11 and the Senate a report on the use, by the
12 Bureau of Customs and Border Protection,
13 of the fees, if any, transferred by the Sec-
14 retary to the Bureau of Customs and Bor-
15 der Protection for the fiscal year for which
16 the report is made.

17 (10) SPECIAL RULE REGARDING IMPORTATION
18 BY INDIVIDUALS.—

19 (A) IN GENERAL.—Notwithstanding any
20 provision of this Act (or an amendment made
21 by this Act), the Secretary shall expedite the
22 designation of any additional permitted coun-
23 tries from which an individual may import a
24 qualifying drug into the United States under
25 such section 804 if any action implemented by

1 the Government of Canada has the effect of
2 limiting or prohibiting the importation of quali-
3 fying drugs into the United States from Can-
4 ada.

5 (B) TIMING AND CRITERIA.—The Sec-
6 retary shall designate such additional permitted
7 countries under subparagraph (A)—

8 (i) not later than 6 months after the
9 date of the action by the Government of
10 Canada described under such subpara-
11 graph; and

12 (ii) using the criteria described under
13 subsection (a)(4)(D)(i)(II) of such section
14 804.

15 (f) IMPLEMENTATION OF SECTION 804.—

16 (1) INTERIM RULE.—The Secretary may pro-
17 mulgate an interim rule for implementing section
18 804 of the Federal Food, Drug, and Cosmetic Act,
19 as added by subsection (a) of this section.

20 (2) NO NOTICE OF PROPOSED RULEMAKING.—
21 The interim rule described under paragraph (1) may
22 be developed and promulgated by the Secretary with-
23 out providing general notice of proposed rulemaking.

24 (3) FINAL RULE.—Not later than 1 year after
25 the date on which the Secretary promulgates an in-

1 terim rule under paragraph (1), the Secretary shall,
2 in accordance with procedures under section 553 of
3 title 5, United States Code, promulgate a final rule
4 for implementing such section 804, which may incor-
5 porate by reference provisions of the interim rule
6 provided for under paragraph (1), to the extent that
7 such provisions are not modified.

8 (g) CONSUMER EDUCATION.—The Secretary shall
9 carry out activities that educate consumers—

10 (1) with regard to the availability of qualifying
11 drugs for import for personal use from an exporter
12 registered with and approved by the Food and Drug
13 Administration under section 804 of the Federal
14 Food, Drug, and Cosmetic Act, as added by this sec-
15 tion, including information on how to verify whether
16 an exporter is registered and approved by use of the
17 Internet website of the Food and Drug Administra-
18 tion and the toll-free telephone number required by
19 this Act;

20 (2) that drugs that consumers attempt to im-
21 port from an exporter that is not registered with and
22 approved by the Food and Drug Administration can
23 be seized by the United States Customs Service and
24 destroyed, and that such drugs may be counterfeit,
25 unapproved, unsafe, or ineffective;

1 (3) with regard to the suspension and termi-
2 nation of any registration of a registered importer or
3 exporter under such section 804; and

4 (4) with regard to the availability at domestic
5 retail pharmacies of qualifying drugs imported under
6 such section 804 by domestic wholesalers and phar-
7 macies registered with and approved by the Food
8 and Drug Administration.

9 (h) EFFECT ON ADMINISTRATION PRACTICES.—Not-
10 withstanding any provision of this Act (and the amend-
11 ments made by this Act), the practices and policies of the
12 Food and Drug Administration and Bureau of Customs
13 and Border Protection, in effect on January 1, 2004, with
14 respect to the importation of prescription drugs into the
15 United States by an individual, on the person of such indi-
16 vidual, for personal use, shall remain in effect.

17 (i) REPORT TO CONGRESS.—The Federal Trade
18 Commission shall, on an annual basis, submit to Congress
19 a report that describes any action taken during the period
20 for which the report is being prepared to enforce the provi-
21 sions of section 804(n) of the Federal Food, Drug, and
22 Cosmetic Act (as added by this Act), including any pend-
23 ing investigations or civil actions under such section.

1 **SEC. 5. DISPOSITION OF CERTAIN DRUGS DENIED ADMIS-**
2 **SION INTO UNITED STATES.**

3 (a) IN GENERAL.—Chapter VIII of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.),
5 as amended by section 4, is further amended by adding
6 at the end the following section:

7 **“SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED AD-**
8 **MISSION.**

9 “(a) IN GENERAL.—The Secretary of Homeland Se-
10 curity shall deliver to the Secretary a shipment of drugs
11 that is imported or offered for import into the United
12 States if—

13 “(1) the shipment has a declared value of less
14 than \$10,000; and

15 “(2)(A) the shipping container for such drugs
16 does not bear the markings required under section
17 804(d)(2); or

18 “(B) the Secretary has requested delivery of
19 such shipment of drugs.

20 “(b) NO BOND OR EXPORT.—Section 801(b) does
21 not authorize the delivery to the owner or consignee of
22 drugs delivered to the Secretary under subsection (a) pur-
23 suant to the execution of a bond, and such drugs may not
24 be exported.

25 “(c) DESTRUCTION OF VIOLATIVE SHIPMENT.—The
26 Secretary shall destroy a shipment of drugs delivered by

1 the Secretary of Homeland Security to the Secretary
2 under subsection (a) if—

3 “(1) in the case of drugs that are imported or
4 offered for import from a registered exporter under
5 section 804, the drugs are in violation of any stand-
6 ard described in section 804(g)(5); or

7 “(2) in the case of drugs that are not imported
8 or offered for import from a registered exporter
9 under section 804, the drugs are in violation of a
10 standard referred to in section 801(a) or 801(d)(1).

11 “(d) CERTAIN PROCEDURES.—

12 “(1) IN GENERAL.—The delivery and destruc-
13 tion of drugs under this section may be carried out
14 without notice to the importer, owner, or consignee
15 of the drugs except as required by section 801(g) or
16 section 804(i)(2). The issuance of receipts for the
17 drugs, and recordkeeping activities regarding the
18 drugs, may be carried out on a summary basis.

19 “(2) OBJECTIVE OF PROCEDURES.—Procedures
20 promulgated under paragraph (1) shall be designed
21 toward the objective of ensuring that, with respect to
22 efficiently utilizing Federal resources available for
23 carrying out this section, a substantial majority of
24 shipments of drugs subject to described in sub-
25 section (c) are identified and destroyed.

1 “(e) EVIDENCE EXCEPTION.—Drugs may not be de-
 2 stroyed under subsection (c) to the extent that the Attor-
 3 ney General of the United States determines that the
 4 drugs should be preserved as evidence or potential evi-
 5 dence with respect to an offense against the United States.

6 “(f) RULE OF CONSTRUCTION.—This section may
 7 not be construed as having any legal effect on applicable
 8 law with respect to a shipment of drugs that is imported
 9 or offered for import into the United States and has a
 10 declared value equal to or greater than \$10,000.”.

11 (b) PROCEDURES.—Procedures for carrying out sec-
 12 tion 805 of the Federal Food, Drug, and Cosmetic Act,
 13 as added by subsection (a), shall be established not later
 14 than 90 days after the date of the enactment of this Act.

15 (c) EFFECTIVE DATE.—The amendments made by
 16 this section shall take effect on the date that is 90 days
 17 after the date of enactment of this Act.

18 **SEC. 6. WHOLESALE DISTRIBUTION OF DRUGS; STATE-**
 19 **MENTS REGARDING PRIOR SALE, PURCHASE,**
 20 **OR TRADE.**

21 (a) STRIKING OF EXEMPTIONS; APPLICABILITY TO
 22 REGISTERED EXPORTERS.—Section 503(e) of the Federal
 23 Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is
 24 amended—

25 (1) in paragraph (1)—

1 (A) by striking “and who is not the manu-
2 facturer or an authorized distributor of record
3 of such drug”;

4 (B) by striking “to an authorized dis-
5 tributor of record or”; and

6 (C) by striking subparagraph (B) and in-
7 serting the following:

8 “(B) The fact that a drug subject to subsection (b)
9 is exported from the United States does not with respect
10 to such drug exempt any person that is engaged in the
11 business of the wholesale distribution of the drug from
12 providing the statement described in subparagraph (A) to
13 the person that receives the drug pursuant to the export
14 of the drug.

15 “(C)(i) The Secretary shall by regulation establish re-
16 quirements that supersede subparagraph (A) (referred to
17 in this subparagraph as ‘alternative requirements’) to
18 identify the chain of custody of a drug subject to sub-
19 section (b) from the manufacturer of the drug throughout
20 the wholesale distribution of the drug to a pharmacist who
21 intends to sell the drug at retail if the Secretary deter-
22 mines that the alternative requirements, which may in-
23 clude standardized anti-counterfeiting or track-and-trace
24 technologies, will identify such chain of custody or the
25 identity of the discrete package of the drug from which

1 the drug is dispensed with equal or greater certainty to
2 the requirements of subparagraph (A), and that the alter-
3 native requirements are economically and technically fea-
4 sible.

5 “(ii) When the Secretary promulgates a final rule to
6 establish such alternative requirements, the final rule in
7 addition shall, with respect to the registration condition
8 established in clause (i) of section 804(c)(3)(B), establish
9 a condition equivalent to the alternative requirements, and
10 such equivalent condition may be met in lieu of the reg-
11 istration condition established in such clause (i).”;

12 (2) in paragraph (2)(A), by adding at the end
13 the following: “The preceding sentence may not be
14 construed as having any applicability with respect to
15 a registered exporter under section 804.”; and

16 (3) in paragraph (3), by striking “and sub-
17 section (d)—” in the matter preceding subparagraph
18 (A) and all that follows through “the term ‘whole-
19 sale distribution’ means” in subparagraph (B) and
20 inserting the following: “and subsection (d), the
21 term ‘wholesale distribution’ means”.

22 (b) CONFORMING AMENDMENT.—Section 503(d) of
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 353(d)) is amended by adding at the end the following:

1 “(4) Each manufacturer of a drug subject to sub-
2 section (b) shall maintain at its corporate offices a current
3 list of the authorized distributors of record of such drug.

4 “(5) For purposes of this subsection, the term ‘au-
5 thorized distributors of record’ means those distributors
6 with whom a manufacturer has established an ongoing re-
7 lationship to distribute such manufacturer’s products.”.

8 (c) EFFECTIVE DATE.—

9 (1) IN GENERAL.—The amendments made by
10 paragraphs (1) and (3) of subsection (a) and by sub-
11 section (b) shall take effect on January 1, 2013.

12 (2) DRUGS IMPORTED BY REGISTERED IMPORT-
13 ERS UNDER SECTION 804.—Notwithstanding para-
14 graph (1), the amendments made by paragraphs (1)
15 and (3) of subsection (a) and by subsection (b) shall
16 take effect on the date that is 90 days after the date
17 of enactment of this Act with respect to qualifying
18 drugs imported under section 804 of the Federal
19 Food, Drug, and Cosmetic Act, as added by section
20 4.

21 (3) EFFECT WITH RESPECT TO REGISTERED
22 EXPORTERS.—The amendment made by subsection
23 (a)(2) shall take effect on the date that is 90 days
24 after the date of enactment of this Act.

1 (4) ALTERNATIVE REQUIREMENTS.—The Sec-
2 retary shall issue regulations to establish the alter-
3 native requirements, referred to in the amendment
4 made by subsection (a)(1), that take effect not later
5 than January 1, 2013.

6 (5) INTERMEDIATE REQUIREMENTS.—The Sec-
7 retary shall by regulation require the use of stand-
8 ardized anti-counterfeiting or track-and-trace tech-
9 nologies on prescription drugs at the case and pallet
10 level effective not later than 1 year after the date of
11 enactment of this Act.

12 (6) ADDITIONAL REQUIREMENTS.—

13 (A) IN GENERAL.—Notwithstanding any
14 other provision of this section, the Secretary
15 shall, not later than 18 months after the date
16 of enactment of this Act, require that the pack-
17 aging of any prescription drug incorporates—

18 (i) a standardized numerical identifier
19 unique to each package of such drug, ap-
20 plied at the point of manufacturing and re-
21 packaging (in which case the numerical
22 identifier shall be linked to the numerical
23 identifier applied at the point of manufac-
24 turing); and

1 (ii)(I) overt optically variable counter-
2 feit-resistant technologies that—

3 (aa) are visible to the naked eye,
4 providing for visual identification of
5 product authenticity without the need
6 for readers, microscopes, lighting de-
7 vices, or scanners;

8 (bb) are similar to that used by
9 the Bureau of Engraving and Printing
10 to secure United States currency;

11 (cc) are manufactured and dis-
12 tributed in a highly secure, tightly
13 controlled environment; and

14 (dd) incorporate additional layers
15 of nonvisible covert security features
16 up to and including forensic capa-
17 bility, as described in subparagraph
18 (B); or

19 (II) technologies that have a function
20 of security comparable to that described in
21 subclause (I), as determined by the Sec-
22 retary.

23 (B) STANDARDS FOR PACKAGING.—For
24 the purpose of making it more difficult to coun-
25 terfeit the packaging of drugs subject to this

1 paragraph, the manufacturers of such drugs
2 shall incorporate the technologies described in
3 subparagraph (A) into at least 1 additional ele-
4 ment of the physical packaging of the drugs, in-
5 cluding blister packs, shrink wrap, package la-
6 bels, package seals, bottles, and boxes.

7 **SEC. 7. INTERNET SALES OF PRESCRIPTION DRUGS.**

8 (a) IN GENERAL.—Chapter V of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
10 ed by inserting after section 503B the following:

11 **“SEC. 503C. INTERNET SALES OF PRESCRIPTION DRUGS.**

12 “(a) REQUIREMENTS REGARDING INFORMATION ON
13 INTERNET SITE.—

14 “(1) IN GENERAL.—A person may not dispense
15 a prescription drug pursuant to a sale of the drug
16 by such person if—

17 “(A) the purchaser of the drug submitted
18 the purchase order for the drug, or conducted
19 any other part of the sales transaction for the
20 drug, through an Internet site;

21 “(B) the person dispenses the drug to the
22 purchaser by mailing or shipping the drug to
23 the purchaser; and

24 “(C) such site, or any other Internet site
25 used by such person for purposes of sales of a

1 prescription drug, fails to meet each of the re-
2 quirements specified in paragraph (2), other
3 than a site or pages on a site that—

4 “(i) are not intended to be accessed
5 by purchasers or prospective purchasers; or

6 “(ii) provide an Internet information
7 location tool within the meaning of section
8 231(e)(5) of the Communications Act of
9 1934 (47 U.S.C. 231(e)(5)).

10 “(2) REQUIREMENTS.—With respect to an
11 Internet site, the requirements referred to in sub-
12 paragraph (C) of paragraph (1) for a person to
13 whom such paragraph applies are as follows:

14 “(A) Each page of the site shall include ei-
15 ther the following information or a link to a
16 page that provides the following information:

17 “(i) The name of such person.

18 “(ii) Each State in which the person
19 is authorized by law to dispense prescrip-
20 tion drugs.

21 “(iii) The address and telephone num-
22 ber of each place of business of the person
23 with respect to sales of prescription drugs
24 through the Internet, other than a place of

1 business that does not mail or ship pre-
2 scription drugs to purchasers.

3 “(iv) The name of each individual who
4 serves as a pharmacist for prescription
5 drugs that are mailed or shipped pursuant
6 to the site, and each State in which the in-
7 dividual is authorized by law to dispense
8 prescription drugs.

9 “(v) If the person provides for medical
10 consultations through the site for purposes
11 of providing prescriptions, the name of
12 each individual who provides such con-
13 sultations; each State in which the indi-
14 vidual is licensed or otherwise authorized
15 by law to provide such consultations or
16 practice medicine; and the type or types of
17 health professions for which the individual
18 holds such licenses or other authorizations.

19 “(B) A link to which paragraph (1) applies
20 shall be displayed in a clear and prominent
21 place and manner, and shall include in the cap-
22 tion for the link the words ‘licensing and con-
23 tact information’.

24 “(b) INTERNET SALES WITHOUT APPROPRIATE
25 MEDICAL RELATIONSHIPS.—

1 “(1) IN GENERAL.—Except as provided in para-
2 graph (2), a person may not dispense a prescription
3 drug, or sell such a drug, if—

4 “(A) for purposes of such dispensing or
5 sale, the purchaser communicated with the per-
6 son through the Internet;

7 “(B) the patient for whom the drug was
8 dispensed or purchased did not, when such
9 communications began, have a prescription for
10 the drug that is valid in the United States;

11 “(C) pursuant to such communications, the
12 person provided for the involvement of a practi-
13 tioner, or an individual represented by the per-
14 son as a practitioner, and the practitioner or
15 such individual issued a prescription for the
16 drug that was purchased;

17 “(D) the person knew, or had reason to
18 know, that the practitioner or the individual re-
19 ferred to in subparagraph (C) did not, when
20 issuing the prescription, have a qualifying med-
21 ical relationship with the patient; and

22 “(E) the person received payment for the
23 dispensing or sale of the drug.

1 For purposes of subparagraph (E), payment is re-
2 ceived if money or other valuable consideration is re-
3 ceived.

4 “(2) EXCEPTIONS.—Paragraph (1) does not
5 apply to—

6 “(A) the dispensing or selling of a pre-
7 scription drug pursuant to telemedicine prac-
8 tices sponsored by—

9 “(i) a hospital that has in effect a
10 provider agreement under title XVIII of
11 the Social Security Act (relating to the
12 Medicare program); or

13 “(ii) a group practice that has not
14 fewer than 100 physicians who have in ef-
15 fect provider agreements under such title;
16 or

17 “(B) the dispensing or selling of a pre-
18 scription drug pursuant to practices that pro-
19 mote the public health, as determined by the
20 Secretary by regulation.

21 “(3) QUALIFYING MEDICAL RELATIONSHIP.—

22 “(A) IN GENERAL.—With respect to
23 issuing a prescription for a drug for a patient,
24 a practitioner has a qualifying medical relation-

1 ship with the patient for purposes of this sec-
2 tion if—

3 “(i) at least one in-person medical
4 evaluation of the patient has been con-
5 ducted by the practitioner; or

6 “(ii) the practitioner conducts a med-
7 ical evaluation of the patient as a covering
8 practitioner.

9 “(B) IN-PERSON MEDICAL EVALUATION.—

10 A medical evaluation by a practitioner is an in-
11 person medical evaluation for purposes of this
12 section if the practitioner is in the physical
13 presence of the patient as part of conducting
14 the evaluation, without regard to whether por-
15 tions of the evaluation are conducted by other
16 health professionals.

17 “(C) COVERING PRACTITIONER.—With re-
18 spect to a patient, a practitioner is a covering
19 practitioner for purposes of this section if the
20 practitioner conducts a medical evaluation of
21 the patient at the request of a practitioner who
22 has conducted at least one in-person medical
23 evaluation of the patient and is temporarily un-
24 available to conduct the evaluation of the pa-
25 tient. A practitioner is a covering practitioner

1 without regard to whether the practitioner has
2 conducted any in-person medical evaluation of
3 the patient involved.

4 “(4) RULES OF CONSTRUCTION.—

5 “(A) INDIVIDUALS REPRESENTED AS
6 PRACTITIONERS.—A person who is not a practi-
7 tioner (as defined in subsection (e)(1)) lacks
8 legal capacity under this section to have a
9 qualifying medical relationship with any patient.

10 “(B) STANDARD PRACTICE OF PHAR-
11 MACY.—Paragraph (1) may not be construed as
12 prohibiting any conduct that is a standard prac-
13 tice in the practice of pharmacy.

14 “(C) APPLICABILITY OF REQUIRE-
15 MENTS.—Paragraph (3) may not be construed
16 as having any applicability beyond this section,
17 and does not affect any State law, or interpre-
18 tation of State law, concerning the practice of
19 medicine.

20 “(c) ACTIONS BY STATES.—

21 “(1) IN GENERAL.—Whenever an attorney gen-
22 eral of any State has reason to believe that the in-
23 terests of the residents of that State have been or
24 are being threatened or adversely affected because
25 any person has engaged or is engaging in a pattern

1 or practice that violates section 301(l), the State
2 may bring a civil action on behalf of its residents in
3 an appropriate district court of the United States to
4 enjoin such practice, to enforce compliance with such
5 section (including a nationwide injunction), to obtain
6 damages, restitution, or other compensation on be-
7 half of residents of such State, to obtain reasonable
8 attorneys fees and costs if the State prevails in the
9 civil action, or to obtain such further and other relief
10 as the court may deem appropriate.

11 “(2) NOTICE.—The State shall serve prior writ-
12 ten notice of any civil action under paragraph (1) or
13 (5)(B) upon the Secretary and provide the Secretary
14 with a copy of its complaint, except that if it is not
15 feasible for the State to provide such prior notice,
16 the State shall serve such notice immediately upon
17 instituting such action. Upon receiving a notice re-
18 specting a civil action, the Secretary shall have the
19 right—

20 “(A) to intervene in such action;

21 “(B) upon so intervening, to be heard on
22 all matters arising therein; and

23 “(C) to file petitions for appeal.

24 “(3) CONSTRUCTION.—For purposes of bring-
25 ing any civil action under paragraph (1), nothing in

1 this chapter shall prevent an attorney general of a
2 State from exercising the powers conferred on the
3 attorney general by the laws of such State to con-
4 duct investigations or to administer oaths or affir-
5 mations or to compel the attendance of witnesses or
6 the production of documentary and other evidence.

7 “(4) VENUE; SERVICE OF PROCESS.—Any civil
8 action brought under paragraph (1) in a district
9 court of the United States may be brought in the
10 district in which the defendant is found, is an inhab-
11 itant, or transacts business or wherever venue is
12 proper under section 1391 of title 28, United States
13 Code. Process in such an action may be served in
14 any district in which the defendant is an inhabitant
15 or in which the defendant may be found.

16 “(5) ACTIONS BY OTHER STATE OFFICIALS.—

17 “(A) Nothing contained in this section
18 shall prohibit an authorized State official from
19 proceeding in State court on the basis of an al-
20 leged violation of any civil or criminal statute of
21 such State.

22 “(B) In addition to actions brought by an
23 attorney general of a State under paragraph
24 (1), such an action may be brought by officers
25 of such State who are authorized by the State

1 to bring actions in such State on behalf of its
2 residents.

3 “(d) EFFECT OF SECTION.—This section shall not
4 apply to a person that is a registered exporter under sec-
5 tion 804.

6 “(e) GENERAL DEFINITIONS.—For purposes of this
7 section:

8 “(1) The term ‘practitioner’ means a practi-
9 tioner referred to in section 503(b)(1) with respect
10 to issuing a written or oral prescription.

11 “(2) The term ‘prescription drug’ means a drug
12 that is described in section 503(b)(1).

13 “(3) The term ‘qualifying medical relationship’,
14 with respect to a practitioner and a patient, has the
15 meaning indicated for such term in subsection (b).

16 “(f) INTERNET-RELATED DEFINITIONS.—

17 “(1) IN GENERAL.—For purposes of this sec-
18 tion:

19 “(A) The term ‘Internet’ means collectively
20 the myriad of computer and telecommunications
21 facilities, including equipment and operating
22 software, which comprise the interconnected
23 world-wide network of networks that employ the
24 transmission control protocol/internet protocol,
25 or any predecessor or successor protocols to

1 such protocol, to communicate information of
2 all kinds by wire or radio.

3 “(B) The term ‘link’, with respect to the
4 Internet, means one or more letters, words,
5 numbers, symbols, or graphic items that appear
6 on a page of an Internet site for the purpose
7 of serving, when activated, as a method for exe-
8 cuting an electronic command—

9 “(i) to move from viewing one portion
10 of a page on such site to another portion
11 of the page;

12 “(ii) to move from viewing one page
13 on such site to another page on such site;
14 or

15 “(iii) to move from viewing a page on
16 one Internet site to a page on another
17 Internet site.

18 “(C) The term ‘page’, with respect to the
19 Internet, means a document or other file
20 accessed at an Internet site.

21 “(D)(i) The terms ‘site’ and ‘address’, with
22 respect to the Internet, mean a specific location
23 on the Internet that is determined by Internet
24 Protocol numbers. Such term includes the do-
25 main name, if any.

1 “(ii) The term ‘domain name’ means a
2 method of representing an Internet address
3 without direct reference to the Internet Protocol
4 numbers for the address, including methods
5 that use designations such as ‘.com’, ‘.edu’,
6 ‘.gov’, ‘.net’, or ‘.org’.

7 “(iii) The term ‘Internet Protocol num-
8 bers’ includes any successor protocol for deter-
9 mining a specific location on the Internet.

10 “(2) AUTHORITY OF SECRETARY.—The Sec-
11 retary may by regulation modify any definition
12 under paragraph (1) to take into account changes in
13 technology.

14 “(g) INTERACTIVE COMPUTER SERVICE; ADVER-
15 TISING.—No provider of an interactive computer service,
16 as defined in section 230(f)(2) of the Communications Act
17 of 1934 (47 U.S.C. 230(f)(2)), or of advertising services
18 shall be liable under this section for dispensing or selling
19 prescription drugs in violation of this section on account
20 of another person’s selling or dispensing such drugs, pro-
21 vided that the provider of the interactive computer service
22 or of advertising services does not own or exercise cor-
23 porate control over such person.

24 “(h) NO EFFECT ON OTHER REQUIREMENTS; CO-
25 ORDINATION.—The requirements of this section are in ad-

1 dition to, and do not supersede, any requirements under
2 the Controlled Substances Act or the Controlled Sub-
3 stances Import and Export Act (or any regulation promul-
4 gated under either such Act) regarding Internet phar-
5 macies and controlled substances. In promulgating regula-
6 tions to carry out this section, the Secretary shall coordi-
7 nate with the Attorney General to ensure that such regula-
8 tions do not duplicate or conflict with the requirements
9 described in the previous sentence, and that such regula-
10 tions and requirements coordinate to the extent prac-
11 ticable.”.

12 (b) INCLUSION AS PROHIBITED ACT.—Section 301 of
13 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 331) is amended by inserting after paragraph (k) the fol-
15 lowing:

16 “(l) The dispensing or selling of a prescription drug
17 in violation of section 503C.”.

18 (c) INTERNET SALES OF PRESCRIPTION DRUGS;
19 CONSIDERATION BY SECRETARY OF PRACTICES AND PRO-
20 CEDURES FOR CERTIFICATION OF LEGITIMATE BUSI-
21 NESSES.—In carrying out section 503C of the Federal
22 Food, Drug, and Cosmetic Act (as added by subsection
23 (a) of this section), the Secretary of Health and Human
24 Services shall take into consideration the practices and
25 procedures of public or private entities that certify that

1 businesses selling prescription drugs through Internet
2 sites are legitimate businesses, including practices and
3 procedures regarding disclosure formats and verification
4 programs.

5 (d) REPORTS REGARDING INTERNET-RELATED VIO-
6 LATIONS OF FEDERAL AND STATE LAWS ON DISPENSING
7 OF DRUGS.—

8 (1) IN GENERAL.—The Secretary of Health and
9 Human Services (referred to in this subsection as
10 the “Secretary”) shall, pursuant to the submission
11 of an application meeting the criteria of the Sec-
12 retary, make an award of a grant or contract to the
13 National Clearinghouse on Internet Prescribing (op-
14 erated by the Federation of State Medical Boards)
15 for the purpose of—

16 (A) identifying Internet sites that appear
17 to be in violation of Federal or State laws con-
18 cerning the dispensing of drugs;

19 (B) reporting such sites to State medical
20 licensing boards and State pharmacy licensing
21 boards, and to the Attorney General and the
22 Secretary, for further investigation; and

23 (C) submitting, for each fiscal year for
24 which the award under this subsection is made,
25 a report to the Secretary describing investiga-

1 tions undertaken with respect to violations de-
2 scribed in subparagraph (A).

3 (2) AUTHORIZATION OF APPROPRIATIONS.—For
4 the purpose of carrying out paragraph (1), there is
5 authorized to be appropriated \$100,000 for each of
6 the first 3 fiscal years in which this section is in ef-
7 fect.

8 (e) EFFECTIVE DATE.—The amendments made by
9 subsections (a) and (b) take effect 90 days after the date
10 of enactment of this Act, without regard to whether a final
11 rule to implement such amendments has been promulgated
12 by the Secretary of Health and Human Services under
13 section 701(a) of the Federal Food, Drug, and Cosmetic
14 Act. The preceding sentence may not be construed as af-
15 fecting the authority of such Secretary to promulgate such
16 a final rule.

17 **SEC. 8. PROHIBITING PAYMENTS TO UNREGISTERED FOR-**
18 **EIGN PHARMACIES.**

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

22 “(h) RESTRICTED TRANSACTIONS.—

23 “(1) IN GENERAL.—The introduction of re-
24 stricted transactions into a payment system or the

1 completion of restricted transactions using a pay-
2 ment system is prohibited.

3 “(2) PAYMENT SYSTEM.—

4 “(A) IN GENERAL.—The term ‘payment
5 system’ means a system used by a person de-
6 scribed in subparagraph (B) to effect a credit
7 transaction, electronic fund transfer, or money
8 transmitting service that may be used in con-
9 nection with, or to facilitate, a restricted trans-
10 action, and includes—

11 “(i) a credit card system;

12 “(ii) an international, national, re-
13 gional, or local network used to effect a
14 credit transaction, an electronic fund
15 transfer, or a money transmitting service;
16 and

17 “(iii) any other system that is cen-
18 trally managed and is primarily engaged in
19 the transmission and settlement of credit
20 transactions, electronic fund transfers, or
21 money transmitting services.

22 “(B) PERSONS DESCRIBED.—A person re-
23 ferred to in subparagraph (A) is—

24 “(i) a creditor;

25 “(ii) a credit card issuer;

1 “(iii) a financial institution;

2 “(iv) an operator of a terminal at
3 which an electronic fund transfer may be
4 initiated;

5 “(v) a money transmitting business;
6 or

7 “(vi) a participant in an international,
8 national, regional, or local network used to
9 effect a credit transaction, electronic fund
10 transfer, or money transmitting service.

11 “(3) RESTRICTED TRANSACTION.—The term
12 ‘restricted transaction’ means a transaction or trans-
13 mittal, on behalf of an individual who places an un-
14 lawful drug importation request to any person en-
15 gaged in the operation of an unregistered foreign
16 pharmacy, of—

17 “(A) credit, or the proceeds of credit, ex-
18 tended to or on behalf of the individual for the
19 purpose of the unlawful drug importation re-
20 quest (including credit extended through the
21 use of a credit card);

22 “(B) an electronic fund transfer or funds
23 transmitted by or through a money transmit-
24 ting business, or the proceeds of an electronic
25 fund transfer or money transmitting service,

1 from or on behalf of the individual for the pur-
2 pose of the unlawful drug importation request;

3 “(C) a check, draft, or similar instrument
4 which is drawn by or on behalf of the individual
5 for the purpose of the unlawful drug importa-
6 tion request and is drawn on or payable at or
7 through any financial institution; or

8 “(D) the proceeds of any other form of fi-
9 nancial transaction (identified by the Board by
10 regulation) that involves a financial institution
11 as a payor or financial intermediary on behalf
12 of or for the benefit of the individual for the
13 purpose of the unlawful drug importation re-
14 quest.

15 “(4) UNLAWFUL DRUG IMPORTATION RE-
16 QUEST.—The term ‘unlawful drug importation re-
17 quest’ means the request, or transmittal of a re-
18 quest, made to an unregistered foreign pharmacy for
19 a prescription drug by mail (including a private car-
20 rier), facsimile, phone, or electronic mail, or by a
21 means that involves the use, in whole or in part, of
22 the Internet.

23 “(5) UNREGISTERED FOREIGN PHARMACY.—
24 The term ‘unregistered foreign pharmacy’ means a

1 person in a country other than the United States
2 that is not a registered exporter under section 804.

3 “(6) OTHER DEFINITIONS.—

4 “(A) CREDIT; CREDITOR; CREDIT CARD.—

5 The terms ‘credit’, ‘creditor’, and ‘credit card’
6 have the meanings given the terms in section
7 103 of the Truth in Lending Act (15 U.S.C.
8 1602).

9 “(B) ACCESS DEVICE; ELECTRONIC FUND

10 TRANSFER.—The terms ‘access device’ and
11 ‘electronic fund transfer’—

12 “(i) have the meaning given the term
13 in section 903 of the Electronic Fund
14 Transfer Act (15 U.S.C. 1693a); and

15 “(ii) the term ‘electronic fund trans-
16 fer’ also includes any fund transfer covered
17 under Article 4A of the Uniform Commer-
18 cial Code, as in effect in any State.

19 “(C) FINANCIAL INSTITUTION.—The term

20 ‘financial institution’—

21 “(i) has the meaning given the term
22 in section 903 of the Electronic Transfer
23 Fund Act (15 U.S.C. 1693a); and

1 “(ii) includes a financial institution
2 (as defined in section 509 of the Gramm-
3 Leach-Bliley Act (15 U.S.C. 6809)).

4 “(D) MONEY TRANSMITTING BUSINESS;
5 MONEY TRANSMITTING SERVICE.—The terms
6 ‘money transmitting business’ and ‘money
7 transmitting service’ have the meaning given
8 the terms in section 5330(d) of title 31, United
9 States Code.

10 “(E) BOARD.—The term ‘Board’ means
11 the Board of Governors of the Federal Reserve
12 System.

13 “(7) POLICIES AND PROCEDURES REQUIRED TO
14 PREVENT RESTRICTED TRANSACTIONS.—

15 “(A) REGULATIONS.—The Board shall
16 promulgate regulations requiring—

17 “(i) an operator of a credit card sys-
18 tem;

19 “(ii) an operator of an international,
20 national, regional, or local network used to
21 effect a credit transaction, an electronic
22 fund transfer, or a money transmitting
23 service;

24 “(iii) an operator of any other pay-
25 ment system that is centrally managed and

1 is primarily engaged in the transmission
2 and settlement of credit transactions, elec-
3 tronic transfers or money transmitting
4 services where at least one party to the
5 transaction or transfer is an individual;
6 and

7 “(iv) any other person described in
8 paragraph (2)(B) and specified by the
9 Board in such regulations,

10 to establish policies and procedures that are
11 reasonably designed to prevent the introduction
12 of a restricted transaction into a payment sys-
13 tem or the completion of a restricted trans-
14 action using a payment system.

15 “(B) REQUIREMENTS FOR POLICIES AND
16 PROCEDURES.—In promulgating regulations
17 under subparagraph (A), the Board shall—

18 “(i) identify types of policies and pro-
19 cedures, including nonexclusive examples,
20 that shall be considered to be reasonably
21 designed to prevent the introduction of re-
22 stricted transactions into a payment sys-
23 tem or the completion of restricted trans-
24 actions using a payment system; and

1 “(ii) to the extent practicable, permit
2 any payment system, or person described
3 in paragraph (2)(B), as applicable, to
4 choose among alternative means of pre-
5 venting the introduction or completion of
6 restricted transactions.

7 “(C) NO LIABILITY FOR BLOCKING OR RE-
8 FUSING TO HONOR RESTRICTED TRANS-
9 ACTION.—

10 “(i) IN GENERAL.—A payment sys-
11 tem, or a person described in paragraph
12 (2)(B) that is subject to a regulation
13 issued under this subsection, and any par-
14 ticipant in such payment system that pre-
15 vents or otherwise refuses to honor trans-
16 actions in an effort to implement the poli-
17 cies and procedures required under this
18 subsection or to otherwise comply with this
19 subsection shall not be liable to any party
20 for such action.

21 “(ii) COMPLIANCE.—A person de-
22 scribed in paragraph (2)(B) meets the re-
23 quirements of this subsection if the person
24 relies on and complies with the policies and
25 procedures of a payment system of which

1 the person is a member or in which the
2 person is a participant, and such policies
3 and procedures of the payment system
4 comply with the requirements of the regu-
5 lations promulgated under subparagraph
6 (A).

7 “(D) ENFORCEMENT.—

8 “(i) IN GENERAL.—This subsection,
9 and the regulations promulgated under
10 this subsection, shall be enforced exclu-
11 sively by the Federal functional regulators
12 and the Federal Trade Commission under
13 applicable law in the manner provided in
14 section 505(a) of the Gramm-Leach-Bliley
15 Act (15 U.S.C. 6805(a)).

16 “(ii) FACTORS TO BE CONSIDERED.—

17 In considering any enforcement action
18 under this subsection against a payment
19 system or person described in paragraph
20 (2)(B), the Federal functional regulators
21 and the Federal Trade Commission shall
22 consider the following factors:

23 “(I) The extent to which the pay-
24 ment system or person knowingly per-
25 mits restricted transactions.

1 “(II) The history of the payment
2 system or person in connection with
3 permitting restricted transactions.

4 “(III) The extent to which the
5 payment system or person has estab-
6 lished and is maintaining policies and
7 procedures in compliance with regula-
8 tions prescribed under this subsection.

9 “(8) TRANSACTIONS PERMITTED.—A payment
10 system, or a person described in paragraph (2)(B)
11 that is subject to a regulation issued under this sub-
12 section, is authorized to engage in transactions with
13 foreign pharmacies in connection with investigating
14 violations or potential violations of any rule or re-
15 quirement adopted by the payment system or person
16 in connection with complying with paragraph (7). A
17 payment system, or such a person, and its agents
18 and employees shall not be found to be in violation
19 of, or liable under, any Federal, State or other law
20 by virtue of engaging in any such transaction.

21 “(9) RELATION TO STATE LAWS.—No require-
22 ment, prohibition, or liability may be imposed on a
23 payment system, or a person described in paragraph
24 (2)(B) that is subject to a regulation issued under
25 this subsection, under the laws of any state with re-

1 spect to any payment transaction by an individual
2 because the payment transaction involves a payment
3 to a foreign pharmacy.

4 “(10) TIMING OF REQUIREMENTS.—A payment
5 system, or a person described in paragraph (2)(B)
6 that is subject to a regulation issued under this sub-
7 section, must adopt policies and procedures reason-
8 ably designed to comply with any regulations re-
9 quired under paragraph (7) within 60 days after
10 such regulations are issued in final form.

11 “(11) COMPLIANCE.—A payment system, and
12 any person described in paragraph (2)(B), shall not
13 be deemed to be in violation of paragraph (1)—

14 “(A)(i) if an alleged violation of paragraph
15 (1) occurs prior to the mandatory compliance
16 date of the regulations issued under paragraph
17 (7); and

18 “(ii) such entity has adopted or relied on
19 policies and procedures that are reasonably de-
20 signed to prevent the introduction of restricted
21 transactions into a payment system or the com-
22 pletion of restricted transactions using a pay-
23 ment system; or

1 “(B)(i) if an alleged violation of paragraph
2 (1) occurs after the mandatory compliance date
3 of such regulations; and

4 “(ii) such entity is in compliance with such
5 regulations.”.

6 (b) **EFFECTIVE DATE.**—The amendment made by
7 this section shall take effect on the day that is 90 days
8 after the date of enactment of this Act.

9 (c) **IMPLEMENTATION.**—The Board of Governors of
10 the Federal Reserve System shall promulgate regulations
11 as required by subsection (h)(7) of section 303 of the Fed-
12 eral Food, Drug, and Cosmetic Act (21 U.S.C. 333), as
13 added by subsection (a), not later than 90 days after the
14 date of enactment of this Act.

15 **SEC. 9. IMPORTATION EXEMPTION UNDER CONTROLLED**
16 **SUBSTANCES IMPORT AND EXPORT ACT.**

17 Section 1006(a)(2) of the Controlled Substances Im-
18 port and Export Act (21 U.S.C. 956(a)(2)) is amended
19 by striking “not import the controlled substance into the
20 United States in an amount that exceeds 50 dosage units
21 of the controlled substance.” and inserting “import into
22 the United States not more than 10 dosage units com-
23 bined of all such controlled substances.”.

1 SEC. 10. SEVERABILITY.

2 If any provision of this Act, an amendment by this
3 Act, or the application of such provision or amendment
4 to any person or circumstance is held to be unconstitu-
5 tional, the remainder of this Act, the amendments made
6 by this Act, and the application of the provisions of such
7 to any person or circumstance shall not affected thereby.

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