

111TH CONGRESS  
1ST SESSION

# H. R. 1298

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

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 4, 2009

Mr. BERRY (for himself and Mrs. EMERSON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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 2009”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

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

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

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

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

12          (5)     Americans     spend     more     than  
13          \$200,000,000,000 on prescription drugs every year;

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

18          (7) promoting competitive market pricing would  
19          both contribute to health care savings and allow  
20          greater access to therapy, improving health and sav-  
21          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 abbrevi-  
25 ated 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)(2)(F), the  
18 Secretary shall immediately suspend the  
19 registration. A suspension under the pre-  
20 ceding sentence is not subject to the provi-  
21 sion by the Secretary of prior notice, and  
22 the Secretary shall provide to the reg-  
23 istrant an opportunity for a hearing not  
24 later than 10 days after the date on which  
25 the registration is 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.—Subject to appropria-  
14                 tions Acts, fees collected by the Secretary under  
15                 paragraphs (1) and (2) shall be credited to the  
16                 appropriation account for salaries and expenses  
17                 of the Food and Drug Administration until ex-  
18                 pended (without fiscal year limitation), and the  
19                 Secretary may, in consultation with the Sec-  
20                 retary of Homeland Security and the Secretary  
21                 of the Treasury, transfer some proportion of  
22                 such fees to the appropriation account for sala-  
23                 ries and expenses of the Bureau of Customs  
24                 and Border Protection until expended (without  
25                 fiscal year limitation).

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

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

14          “(f) EXPORTER FEES.—

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

20                 “(2) INSPECTION FEE.—A registration condi-  
21                 tion is that the exporter involved pays a fee to the  
22                 Secretary in accordance with this subsection. Such  
23                 fee shall be paid not later than October 1 and April  
24                 1 of each fiscal year in the amount provided for  
25                 under paragraph (3).

1           “(3) AMOUNT OF INSPECTION FEE.—

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

13                           “(i) inspecting the facilities of reg-  
14 istered exporters, and of other entities in  
15 the chain of custody of a qualifying drug  
16 as necessary, under subsection (d)(3);

17                           “(ii) developing, implementing, and  
18 operating under such subsection a system  
19 to screen marks on shipments of qualifying  
20 drugs under subsection (a) that indicate  
21 compliance with all registration conditions,  
22 when such shipments are offered for im-  
23 port into the United States; and

24                           “(iii) screening such markings, and  
25 inspecting such shipments as necessary,

1           when offered for import into the United  
2           States to determine if such a shipment  
3           should be refused admission under sub-  
4           section (g)(5).

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

12          “(C) TOTAL PRICE OF DRUGS.—

13                 “(i) ESTIMATE.—For the purposes of  
14                 complying with the limitation described in  
15                 subparagraph (B) when establishing under  
16                 subparagraph (A) the aggregate total of  
17                 fees to be collected under paragraph (2)  
18                 for a fiscal year, the Secretary shall esti-  
19                 mate the total price of qualifying drugs im-  
20                 ported into the United States by registered  
21                 exporters during that fiscal year by adding  
22                 the total price of qualifying drugs exported  
23                 by each registered exporter during the 6-  
24                 month period from January 1 through  
25                 June 30 of the previous fiscal year, as re-

1           ported to the Secretary by each registered  
2           exporter under subsection (b)(1)(I)(iv).

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

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

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

10          “(4) USE OF FEES.—

11                 “(A) IN GENERAL.—Subject to appropria-  
12                 tions Acts, fees collected by the Secretary under  
13                 paragraphs (1) and (2) shall be credited to the  
14                 appropriation account for salaries and expenses  
15                 of the Food and Drug Administration until ex-  
16                 pended (without fiscal year limitation), and the  
17                 Secretary may, in consultation with the Sec-  
18                 retary of Homeland Security and the Secretary  
19                 of the Treasury, transfer some proportion of  
20                 such fees to the appropriation account for sala-  
21                 ries and expenses of the Bureau of Customs  
22                 and Border Protection until expended (without  
23                 fiscal year limitation).

24                 “(B) SOLE PURPOSE.—Fees collected by  
25                 the Secretary under paragraphs (1) and (2) are

1           only available to the Secretary and, if trans-  
2           ferred, to the Secretary of Homeland Security,  
3           and are for the sole purpose of paying the costs  
4           referred to in paragraph (3)(A).

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

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

13                 “(1) IN GENERAL.—A registration condition is  
14                 that each qualifying drug exported under subsection  
15                 (a) by the registered exporter involved or imported  
16                 under subsection (a) by the registered importer in-  
17                 volved is in compliance with the standards referred  
18                 to in section 801(a) regarding admission of the drug  
19                 into the United States, subject to paragraphs (2),  
20                 (3), and (4).

21          “(2) SECTION 505; APPROVAL STATUS.—

22                 “(A) IN GENERAL.—A qualifying drug that  
23                 is imported or offered for import under sub-  
24                 section (a) shall comply with the conditions es-  
25                 tablished in the approved application under sec-

1           tion 505(b) for the U.S. label drug as described  
2           under this subsection.

3                   “(B) NOTICE BY MANUFACTURER; GEN-  
4           ERAL PROVISIONS.—

5                           “(i) IN GENERAL.—The person that  
6                           manufactures a qualifying drug that is, or  
7                           will be, introduced for commercial distribu-  
8                           tion in a permitted country shall in accord-  
9                           ance with this paragraph submit to the  
10                          Secretary a notice that—

11                                   “(I) includes each difference in  
12                                   the qualifying drug from a condition  
13                                   established in the approved applica-  
14                                   tion for the U.S. label drug beyond—

15   “(aa) the variations provided  
16   for in the application; and

17   “(bb) any difference in label-  
18   ing (except ingredient labeling);  
19   or

20   “(II) states that there is no dif-  
21   ference in the qualifying drug from a  
22   condition established in the approved  
23   application for the U.S. label drug be-  
24   yond—

1                   “(aa) the variations provided  
2                   for in the application; and

3                   “(bb) any difference in label-  
4                   ing (except ingredient labeling).

5                   “(ii) INFORMATION IN NOTICE.—A  
6                   notice under clause (i)(I) shall include the  
7                   information that the Secretary may require  
8                   under section 506A, any additional infor-  
9                   mation the Secretary may require (which  
10                  may include data on bioequivalence if such  
11                  data are not required under section 506A),  
12                  and, with respect to the permitted country  
13                  that approved the qualifying drug for com-  
14                  mercial distribution, or with respect to  
15                  which such approval is sought, include the  
16                  following:

17                   “(I) The date on which the quali-  
18                   fying drug with such difference was,  
19                   or will be, introduced for commercial  
20                   distribution in the permitted country.

21                   “(II) Information demonstrating  
22                   that the person submitting the notice  
23                   has also notified the government of  
24                   the permitted country in writing that  
25                   the person is submitting to the Sec-

1           retary a notice under clause (i)(I),  
2           which notice describes the difference  
3           in the qualifying drug from a condi-  
4           tion established in the approved appli-  
5           cation for the U.S. label drug.

6                   “(III) The information that the  
7           person submitted or will submit to the  
8           government of the permitted country  
9           for purposes of obtaining approval for  
10          commercial distribution of the drug in  
11          the country which, if in a language  
12          other than English, shall be accom-  
13          panied by an English translation  
14          verified to be complete and accurate,  
15          with the name, address, and a brief  
16          statement of the qualifications of the  
17          person that made the translation.

18                   “(iii) CERTIFICATIONS.—The chief ex-  
19          ecutive officer and the chief medical officer  
20          of the manufacturer involved shall each  
21          certify in the notice under clause (i) that—

22                           “(I) the information provided in  
23                           the notice is complete and true; and

24                           “(II) a copy of the notice has  
25                           been provided to the Federal Trade

1 Commission and to the State attor-  
2 neys general.

3 “(iv) FEE.—If a notice submitted  
4 under clause (i) includes a difference that  
5 would, under section 506A, require the  
6 submission of a supplemental application if  
7 made as a change to the U.S. label drug,  
8 the person that submits the notice shall  
9 pay to the Secretary a fee in the same  
10 amount as would apply if the person were  
11 paying a fee pursuant to section  
12 736(a)(1)(A)(ii). Subject to appropriations  
13 Acts, fees collected by the Secretary under  
14 the preceding sentence are available only to  
15 the Secretary and are for the sole purpose  
16 of paying the costs of reviewing notices  
17 submitted under clause (i).

18 “(v) TIMING OF SUBMISSION OF NO-  
19 TICES.—

20 “(I) PRIOR APPROVAL NO-  
21 TICES.—A notice under clause (i) to  
22 which subparagraph (C) applies shall  
23 be submitted to the Secretary not  
24 later than 120 days before the quali-  
25 fying drug with the difference is intro-

1           duced for commercial distribution in a  
2           permitted country, unless the country  
3           requires that distribution of the quali-  
4           fying drug with the difference begin  
5           less than 120 days after the country  
6           requires the difference.

7           “(II) OTHER APPROVAL NO-  
8           TICES.—A notice under clause (i) to  
9           which subparagraph (D) applies shall  
10          be submitted to the Secretary not  
11          later than the day on which the quali-  
12          fying drug with the difference is intro-  
13          duced for commercial distribution in a  
14          permitted country.

15          “(III) OTHER NOTICES.—A no-  
16          tice under clause (i) to which subpara-  
17          graph (E) applies shall be submitted  
18          to the Secretary on the date that the  
19          qualifying drug is first introduced for  
20          commercial distribution in a permitted  
21          country and annually thereafter.

22          “(vi) REVIEW BY SECRETARY.—

23          “(I) IN GENERAL.—In this para-  
24          graph, the difference in a qualifying  
25          drug that is submitted in a notice

1 under clause (i) from the U.S. label  
2 drug shall be treated by the Secretary  
3 as if it were a manufacturing change  
4 to the U.S. label drug under section  
5 506A.

6 “(II) STANDARD OF REVIEW.—  
7 Except as provided in subclause (III),  
8 the Secretary shall review and approve  
9 or disapprove the difference in a no-  
10 tice submitted under clause (i), if re-  
11 quired under section 506A, using the  
12 safe and effective standard for ap-  
13 proving or disapproving a manufac-  
14 turing change under section 506A.

15 “(III) BIOEQUIVALENCE.—If the  
16 Secretary would approve the dif-  
17 ference in a notice submitted under  
18 clause (i) using the safe and effective  
19 standard under section 506A and if  
20 the Secretary determines that the  
21 qualifying drug is not bioequivalent to  
22 the U.S. label drug, the Secretary  
23 shall—

24 “(aa) include in the labeling  
25 provided under paragraph (3) a

1 prominent advisory that the  
2 qualifying drug is safe and effec-  
3 tive but is not bioequivalent to  
4 the U.S. label drug if the Sec-  
5 retary determines that such an  
6 advisory is necessary for health  
7 care practitioners and patients to  
8 use the qualifying drug safely  
9 and effectively; or

10 “(bb) decline to approve the  
11 difference if the Secretary deter-  
12 mines that the availability of  
13 both the qualifying drug and the  
14 U.S. label drug would pose a  
15 threat to the public health.

16 “(IV) REVIEW BY THE SEC-  
17 RETARY.—The Secretary shall review  
18 and approve or disapprove the dif-  
19 ference in a notice submitted under  
20 clause (i), if required under section  
21 506A, not later than 120 days after  
22 the date on which the notice is sub-  
23 mitted.

24 “(V) ESTABLISHMENT INSPEC-  
25 TION.—If review of such difference

1 would require an inspection of the es-  
2 tablishment in which the qualifying  
3 drug is manufactured—

4 “(aa) such inspection by the  
5 Secretary shall be authorized;  
6 and

7 “(bb) the Secretary may rely  
8 on a satisfactory report of a good  
9 manufacturing practice inspec-  
10 tion of the establishment from a  
11 permitted country whose regu-  
12 latory system the Secretary re-  
13 cognizes as equivalent under a  
14 mutual recognition agreement, as  
15 provided under section 510(i)(3),  
16 section 803, or part 26 of title  
17 21, Code of Federal Regulations  
18 (or any corresponding successor  
19 rule or regulation).

20 “(vii) PUBLICATION OF INFORMATION  
21 ON NOTICES.—

22 “(I) IN GENERAL.—Through the  
23 Internet website of the Food and  
24 Drug Administration and a toll-free  
25 telephone number, the Secretary shall

1 readily make available to the public a  
2 list of notices submitted under clause  
3 (i).

4 “(II) CONTENTS.—The list under  
5 subclause (I) shall include the date on  
6 which a notice is submitted and  
7 whether—

8 “(aa) a notice is under re-  
9 view;

10 “(bb) the Secretary has or-  
11 dered that importation of the  
12 qualifying drug from a permitted  
13 country cease; or

14 “(cc) the importation of the  
15 drug is permitted under sub-  
16 section (a).

17 “(III) UPDATE.—The Secretary  
18 shall promptly update the Internet  
19 website with any changes to the list.

20 “(C) NOTICE; DRUG DIFFERENCE REQUIR-  
21 ING PRIOR APPROVAL.—In the case of a notice  
22 under subparagraph (B)(i) that includes a dif-  
23 ference that would, under section 506A(c) or  
24 (d)(3)(B)(i), require the approval of a supple-  
25 mental application before the difference could

1           be made to the U.S. label drug the following  
2           shall occur:

3                   “(i) Promptly after the notice is sub-  
4                   mitted, the Secretary shall notify reg-  
5                   istered exporters, registered importers, the  
6                   Federal Trade Commission, and the State  
7                   attorneys general that the notice has been  
8                   submitted with respect to the qualifying  
9                   drug involved.

10                   “(ii) If the Secretary has not made a  
11                   determination whether such a supple-  
12                   mental application regarding the U.S. label  
13                   drug would be approved or disapproved by  
14                   the date on which the qualifying drug in-  
15                   volved is to be introduced for commercial  
16                   distribution in a permitted country, the  
17                   Secretary shall—

18                           “(I) order that the importation of  
19                           the qualifying drug involved from the  
20                           permitted country not begin until the  
21                           Secretary completes review of the no-  
22                           tice; and

23                           “(II) promptly notify registered  
24                           exporters, registered importers, the

1 Federal Trade Commission, and the  
2 State attorneys general of the order.

3 “(iii) If the Secretary determines that  
4 such a supplemental application regarding  
5 the U.S. label drug would not be approved,  
6 the Secretary shall—

7 “(I) order that the importation of  
8 the qualifying drug involved from the  
9 permitted country cease, or provide  
10 that an order under clause (ii), if any,  
11 remains in effect;

12 “(II) notify the permitted coun-  
13 try that approved the qualifying drug  
14 for commercial distribution of the de-  
15 termination; and

16 “(III) promptly notify registered  
17 exporters, registered importers, the  
18 Federal Trade Commission, and the  
19 State attorneys general of the deter-  
20 mination.

21 “(iv) If the Secretary determines that  
22 such a supplemental application regarding  
23 the U.S. label drug would be approved, the  
24 Secretary shall—

1                   “(I) vacate the order under  
2                   clause (ii), if any;

3                   “(II) consider the difference to  
4                   be a variation provided for in the ap-  
5                   proved application for the U.S. label  
6                   drug;

7                   “(III) permit importation of the  
8                   qualifying drug under subsection (a);  
9                   and

10                  “(IV) promptly notify registered  
11                  exporters, registered importers, the  
12                  Federal Trade Commission, and the  
13                  State attorneys general of the deter-  
14                  mination.

15                  “(D) NOTICE; DRUG DIFFERENCE NOT RE-  
16                  QUIRING PRIOR APPROVAL.—In the case of a  
17                  notice under subparagraph (B)(i) that includes  
18                  a difference that would, under section  
19                  506A(d)(3)(B)(ii), not require the approval of a  
20                  supplemental application before the difference  
21                  could be made to the U.S. label drug the fol-  
22                  lowing shall occur:

23                  “(i) During the period in which the  
24                  notice is being reviewed by the Secretary,  
25                  the authority under this subsection to im-

1 port the qualifying drug involved continues  
2 in effect.

3 “(ii) If the Secretary determines that  
4 such a supplemental application regarding  
5 the U.S. label drug would not be approved,  
6 the Secretary shall—

7 “(I) order that the importation of  
8 the qualifying drug involved from the  
9 permitted country cease;

10 “(II) notify the permitted coun-  
11 try that approved the qualifying drug  
12 for commercial distribution of the de-  
13 termination; and

14 “(III) promptly notify registered  
15 exporters, registered importers, the  
16 Federal Trade Commission, and the  
17 State attorneys general of the deter-  
18 mination.

19 “(iii) If the Secretary determines that  
20 such a supplemental application regarding  
21 the U.S. label drug would be approved, the  
22 difference shall be considered to be a vari-  
23 ation provided for in the approved applica-  
24 tion for the U.S. label drug.

1           “(E) NOTICE; DRUG DIFFERENCE NOT RE-  
2           QUIRING APPROVAL; NO DIFFERENCE.—In the  
3           case of a notice under subparagraph (B)(i) that  
4           includes a difference for which, under section  
5           506A(d)(1)(A), a supplemental application  
6           would not be required for the difference to be  
7           made to the U.S. label drug, or that states that  
8           there is no difference, the Secretary—

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

12                   “(ii) may not order that the importa-  
13                   tion of the qualifying drug involved cease;  
14                   and

15                   “(iii) shall promptly notify registered  
16                   exporters and registered importers.

17           “(F) DIFFERENCES IN ACTIVE INGRE-  
18           DIENT, ROUTE OF ADMINISTRATION, DOSAGE  
19           FORM, OR STRENGTH.—

20                   “(i) IN GENERAL.—A person who  
21                   manufactures a drug approved under sec-  
22                   tion 505(b) shall submit an application  
23                   under section 505(b) for approval of an-  
24                   other drug that is manufactured for dis-  
25                   tribution in a permitted country by or for

1 the person that manufactures the drug ap-  
2 proved under section 505(b) if—

3 “(I) there is no qualifying drug  
4 in commercial distribution in per-  
5 mitted countries whose combined pop-  
6 ulation represents at least 50 percent  
7 of the total population of all permitted  
8 countries with the same active ingre-  
9 dient or ingredients, route of adminis-  
10 tration, dosage form, and strength as  
11 the drug approved under section  
12 505(b); and

13 “(II) each active ingredient of  
14 the other drug is related to an active  
15 ingredient of the drug approved under  
16 section 505(b), as defined in clause  
17 (v).

18 “(ii) APPLICATION UNDER SECTION  
19 505(b).—The application under section  
20 505(b) required under clause (i) shall—

21 “(I) request approval of the other  
22 drug for the indication or indications  
23 for which the drug approved under  
24 section 505(b) is labeled;

1                   “(II) include the information that  
2                   the person submitted to the govern-  
3                   ment of the permitted country for  
4                   purposes of obtaining approval for  
5                   commercial distribution of the other  
6                   drug in that country, which if in a  
7                   language other than English, shall be  
8                   accompanied by an English trans-  
9                   lation verified to be complete and ac-  
10                  curate, with the name, address, and a  
11                  brief statement of the qualifications of  
12                  the person that made the translation;

13                   “(III) include a right of reference  
14                   to the application for the drug ap-  
15                   proved under section 505(b); and

16                   “(IV) include such additional in-  
17                   formation as the Secretary may re-  
18                   quire.

19                   “(iii) TIMING OF SUBMISSION OF AP-  
20                   PLICATION.—An application under section  
21                   505(b) required under clause (i) shall be  
22                   submitted to the Secretary not later than  
23                   the day on which the information referred  
24                   to in clause (ii)(II) is submitted to the gov-  
25                   ernment of the permitted country.

1           “(iv) NOTICE OF DECISION ON APPLI-  
2           CATION.—The Secretary shall promptly no-  
3           tify registered exporters, registered import-  
4           ers, the Federal Trade Commission, and  
5           the State attorneys general of a determina-  
6           tion to approve or to disapprove an appli-  
7           cation under section 505(b) required under  
8           clause (i).

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

12                   “(I) the same; or

13                   “(II) different salts, esters, or  
14                   complexes of the same moiety.

15          “(3) SECTION 502; LABELING.—

16           “(A) IMPORTATION BY REGISTERED IM-  
17          PORTER.—

18           “(i) IN GENERAL.—In the case of a  
19           qualifying drug that is imported or offered  
20           for import by a registered importer, such  
21           drug shall be considered to be in compli-  
22           ance with section 502 and the labeling re-  
23           quirements under the approved application  
24           for the U.S. label drug if the qualifying  
25           drug bears—

1           “(I) a copy of the labeling ap-  
2           proved for the U.S. label drug under  
3           section 505, without regard to wheth-  
4           er the copy bears any trademark in-  
5           volved;

6           “(II) the name of the manufac-  
7           turer and location of the manufac-  
8           turer;

9           “(III) the lot number assigned by  
10          the manufacturer;

11          “(IV) the name, location, and  
12          registration number of the importer;  
13          and

14          “(V) the National Drug Code  
15          number assigned to the qualifying  
16          drug by the Secretary.

17          “(ii) REQUEST FOR COPY OF THE LA-  
18          BELING.—The Secretary shall provide such  
19          copy to the registered importer involved,  
20          upon request of the importer.

21          “(iii) REQUESTED LABELING.—The  
22          labeling provided by the Secretary under  
23          clause (ii) shall—

24                 “(I) include the established  
25                 name, as defined in section 502(e)(3),

1 for each active ingredient in the quali-  
2 fying drug;

3 “(II) not include the proprietary  
4 name of the U.S. label drug or any  
5 active ingredient thereof;

6 “(III) if required under para-  
7 graph (2)(B)(vi)(III), a prominent ad-  
8 visory that the qualifying drug is safe  
9 and effective but not bioequivalent to  
10 the U.S. label drug; and

11 “(IV) if the inactive ingredients  
12 of the qualifying drug are different  
13 from the inactive ingredients for the  
14 U.S. label drug, include—

15 “(aa) a prominent notice  
16 that the ingredients of the quali-  
17 fying drug differ from the ingre-  
18 dients of the U.S. label drug and  
19 that the qualifying drug must be  
20 dispensed with an advisory to  
21 people with allergies about this  
22 difference and a list of ingredi-  
23 ents; and

24 “(bb) a list of the ingredi-  
25 ents of the qualifying drug as

1 would be required under section  
2 502(e).

3 “(B) IMPORTATION BY INDIVIDUAL.—

4 “(i) IN GENERAL.—In the case of a  
5 qualifying drug that is imported or offered  
6 for import by a registered exporter to an  
7 individual, such drug shall be considered to  
8 be in compliance with section 502 and the  
9 labeling requirements under the approved  
10 application for the U.S. label drug if the  
11 packaging and labeling of the qualifying  
12 drug complies with all applicable regula-  
13 tions promulgated under sections 3 and 4  
14 of the Poison Prevention Packaging Act of  
15 1970 (15 U.S.C. 1471 et seq.) and the la-  
16 beling of the qualifying drug includes—

17 “(I) directions for use by the  
18 consumer;

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

21 “(III) the name and registration  
22 number of the exporter;

23 “(IV) if required under para-  
24 graph (2)(B)(vi)(III), a prominent ad-  
25 visory that the drug is safe and effec-

1           tive but not bioequivalent to the U.S.  
2           label drug;

3           “(V) if the inactive ingredients of  
4           the drug are different from the inac-  
5           tive ingredients for the U.S. label  
6           drug—

7                   “(aa) a prominent advisory  
8                   that persons with an allergy  
9                   should check the ingredient list  
10                  of the drug because the ingredi-  
11                  ents of the drug differ from the  
12                  ingredients of the U.S. label  
13                  drug; and

14                  “(bb) a list of the ingredi-  
15                  ents of the drug as would be re-  
16                  quired under section 502(e); and

17           “(VI) a copy of any special label-  
18           ing that would be required by the Sec-  
19           retary had the U.S. label drug been  
20           dispensed by a pharmacist in the  
21           United States, without regard to  
22           whether the special labeling bears any  
23           trademark involved.

24           “(ii) PACKAGING.—A qualifying drug  
25           offered for import to an individual by an

1 exporter under this section that is pack-  
2 aged in a unit-of-use container (as those  
3 items are defined in the United States  
4 Pharmacopeia and National Formulary)  
5 shall not be repackaged, provided that—

6 “(I) the packaging complies with  
7 all applicable regulations under sec-  
8 tions 3 and 4 of the Poison Preven-  
9 tion Packaging Act of 1970 (15  
10 U.S.C. 1471 et seq.); or

11 “(II) the consumer consents to  
12 waive the requirements of such Act,  
13 after being informed that the pack-  
14 aging does not comply with such Act  
15 and that the exporter will provide the  
16 drug in packaging that is compliant at  
17 no additional cost.

18 “(iii) REQUEST FOR COPY OF SPECIAL  
19 LABELING AND INGREDIENT LIST.—The  
20 Secretary shall provide to the registered  
21 exporter involved a copy of the special la-  
22 beling, the advisory, and the ingredient list  
23 described under clause (i), upon request of  
24 the exporter.

1                   “(iv) REQUESTED LABELING AND IN-  
2                   GREDIENT LIST.—The labeling and ingre-  
3                   dient list provided by the Secretary under  
4                   clause (iii) shall—

5                   “(I) include the established  
6                   name, as defined in section 502(e)(3),  
7                   for each active ingredient in the drug;  
8                   and

9                   “(II) not include the proprietary  
10                  name of the U.S. label drug or any  
11                  active ingredient thereof.

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

17                 “(5) STANDARDS FOR REFUSING ADMISSION.—  
18                 A drug exported under subsection (a) from a reg-  
19                 istered exporter or imported by a registered importer  
20                 may be refused admission into the United States if  
21                 1 or more of the following applies:

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

23                   “(B) A notice for the drug required under  
24                   paragraph (2)(B) has not been submitted to the  
25                   Secretary.

1           “(C) The Secretary has ordered that im-  
2           portation of the drug from the permitted coun-  
3           try cease under paragraph (2) (C) or (D).

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

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

9           “(F) The Secretary becomes aware that—

10                   “(i) the drug may be counterfeit;

11                   “(ii) the drug may have been pre-  
12                   pared, packed, or held under insanitary  
13                   conditions; or

14                   “(iii) the methods used in, or the fa-  
15                   cilities or controls used for, the manufac-  
16                   turing, processing, packing, or holding of  
17                   the drug do not conform to good manufac-  
18                   turing practice.

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

22           “(H) The Secretary has under section  
23           505(e) withdrawn approval of the drug.

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

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

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

8                   “(i) The shipping container for such  
9 drug does not bear the markings required  
10 under subsection (d)(2).

11                   “(ii) The markings on the shipping  
12 container appear to be counterfeit.

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

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

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

22                   “(2) the exporter employs persons that are li-  
23 censed under the law of the permitted country in  
24 which the exporter is located to dispense prescription  
25 drugs in sufficient number to dispense safely the

1 drugs exported by the exporter to individuals, and  
2 the exporter assigns to those persons responsibility  
3 for dispensing such drugs to individuals.

4 “(i) INDIVIDUALS; CONDITIONS FOR IMPORTA-  
5 TION.—

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

10 “(A) The drug is accompanied by a copy of  
11 a prescription for the drug, which prescrip-  
12 tion—

13 “(i) is valid under applicable Federal  
14 and State laws; and

15 “(ii) was issued by a practitioner who,  
16 under the law of a State of which the indi-  
17 vidual is a resident, or in which the indi-  
18 vidual receives care from the practitioner  
19 who issues the prescription, is authorized  
20 to administer prescription drugs.

21 “(B) The drug is accompanied by a copy  
22 of the documentation that was required under  
23 the law or regulations of the permitted country  
24 in which the exporter is located, as a condition  
25 of dispensing the drug to the individual.

1           “(C) The copies referred to in subpara-  
2 graphs (A)(i) and (B) are marked in a manner  
3 sufficient—

4                   “(i) to indicate that the prescription,  
5 and the equivalent document in the per-  
6 mitted country in which the exporter is lo-  
7 cated, have been filled; and

8                   “(ii) to prevent a duplicative filling by  
9 another pharmacist.

10           “(D) The individual has provided to the  
11 registered exporter a complete list of all drugs  
12 used by the individual for review by the individ-  
13 uals who dispense the drug.

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

16           “(F) The drug is not an ineligible subpart  
17 H drug. For purposes of this section, a pre-  
18 scription drug is an ‘ineligible subpart H drug’  
19 if the drug was approved by the Secretary  
20 under subpart H of part 314 of title 21, Code  
21 of Federal Regulations (relating to accelerated  
22 approval), with restrictions under section 520 of  
23 such part to assure safe use, and the Secretary  
24 has published in the Federal Register a notice  
25 that the Secretary has determined that good

1           cause exists to prohibit the drug from being im-  
2           ported pursuant to this subsection.

3           “(2) NOTICE REGARDING DRUG REFUSED AD-  
4           MISSION.—If a registered exporter ships a drug to  
5           an individual pursuant to subsection (a)(2)(B) and  
6           the drug is refused admission to the United States,  
7           a written notice shall be sent to the individual and  
8           to the exporter that informs the individual and the  
9           exporter of such refusal and the reason for the re-  
10          fusal.

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

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

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

16           “(B) maintain samples of each lot of a  
17          qualifying drug required under this section for  
18          not more than 2 years.

19          “(2) PLACE OF RECORD MAINTENANCE.—The  
20          records described under paragraph (1) shall be  
21          maintained—

22           “(A) in the case of an importer, at the  
23          place of business of the importer at which the  
24          importer initially receives the qualifying drug  
25          after importation; or

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

4           “(k) DRUG RECALLS.—

5           “(1) MANUFACTURERS.—A person that manu-  
6           factures a qualifying drug imported from a per-  
7           mitted country under this section shall promptly in-  
8           form the Secretary—

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

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

13          “(C) the reason for the recall or with-  
14          drawal.

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

17          “(A) enter into an agreement with the gov-  
18          ernment of the country to receive information  
19          about recalls and withdrawals of qualifying  
20          drugs in the country; or

21          “(B) monitor recalls and withdrawals of  
22          qualifying drugs in the country using any infor-  
23          mation that is available to the public in any  
24          media.

1           “(3) NOTICE.—The Secretary may notify, as  
2 appropriate, registered exporters, registered import-  
3 ers, wholesalers, pharmacies, or the public of a recall  
4 or withdrawal of a qualifying drug in a permitted  
5 country.

6           “(1) DRUG LABELING AND PACKAGING.—

7           “(1) IN GENERAL.—When a qualifying drug  
8 that is imported into the United States by an im-  
9 porter under subsection (a) is dispensed by a phar-  
10 macist to an individual, the pharmacist shall provide  
11 that the packaging and labeling of the drug complies  
12 with all applicable regulations promulgated under  
13 sections 3 and 4 of the Poison Prevention Packaging  
14 Act of 1970 (15 U.S.C. 1471 et seq.) and shall in-  
15 clude with any other labeling provided to the indi-  
16 vidual the following:

17                   “(A) The lot number assigned by the man-  
18 ufacturer.

19                   “(B) The name and registration number of  
20 the importer.

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

1           “(D) If the inactive ingredients of the drug  
2           are different from the inactive ingredients for  
3           the U.S. label drug—

4                   “(i) a prominent advisory that persons  
5                   with allergies should check the ingredient  
6                   list of the drug because the ingredients of  
7                   the drug differ from the ingredients of the  
8                   U.S. label drug; and

9                   “(ii) a list of the ingredients of the  
10                  drug as would be required under section  
11                  502(e).

12           “(2) PACKAGING.—A qualifying drug that is  
13           packaged in a unit-of-use container (as those terms  
14           are defined in the United States Pharmacopeia and  
15           National Formulary) shall not be repackaged, pro-  
16           vided that—

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

21                   “(B) the consumer consents to waive the  
22                   requirements of such Act, after being informed  
23                   that the packaging does not comply with such  
24                   Act and that the pharmacist will provide the

1 drug in packaging that is compliant at no addi-  
2 tional cost.

3 “(m) CHARITABLE CONTRIBUTIONS.—Notwith-  
4 standing any other provision of this section, this section  
5 does not authorize the importation into the United States  
6 of a qualifying drug donated or otherwise supplied for free  
7 or at nominal cost by the manufacturer of the drug to  
8 a charitable or humanitarian organization, including the  
9 United Nations and affiliates, or to a government of a for-  
10 eign country.

11 “(n) UNFAIR AND DISCRIMINATORY ACTS AND PRAC-  
12 TICES.—

13 “(1) IN GENERAL.—It is unlawful for a manu-  
14 facturer, directly or indirectly (including by being a  
15 party to a licensing agreement or other agreement),  
16 to—

17 “(A) discriminate by charging a higher  
18 price for a prescription drug sold to a registered  
19 exporter or other person in a permitted country  
20 that exports a qualifying drug to the United  
21 States under this section than the price that is  
22 charged, inclusive of rebates or other incentives  
23 to the permitted country or other person, to an-  
24 other person that is in the same country and

1 that does not export a qualifying drug into the  
2 United States under this section;

3 “(B) discriminate by charging a higher  
4 price for a prescription drug sold to a registered  
5 importer or other person that distributes, sells,  
6 or uses a qualifying drug imported into the  
7 United States under this section than the price  
8 that is charged to another person in the United  
9 States that does not import a qualifying drug  
10 under this section, or that does not distribute,  
11 sell, or use such a drug;

12 “(C) discriminate by denying, restricting,  
13 or delaying supplies of a prescription drug to a  
14 registered exporter or other person in a per-  
15 mitted country that exports a qualifying drug to  
16 the United States under this section or to a  
17 registered importer or other person that distrib-  
18 utes, sells, or uses a qualifying drug imported  
19 into the United States under this section;

20 “(D) discriminate by publicly, privately, or  
21 otherwise refusing to do business with a reg-  
22 istered exporter or other person in a permitted  
23 country that exports a qualifying drug to the  
24 United States under this section or with a reg-  
25 istered importer or other person that distrib-

1           utes, sells, or uses a qualifying drug imported  
2           into the United States under this section;

3           “(E) knowingly fail to submit a notice  
4           under subsection (g)(2)(B)(i), knowingly fail to  
5           submit such a notice on or before the date spec-  
6           ified in subsection (g)(2)(B)(v) or as otherwise  
7           required under subsection (e) (3), (4), and (5)  
8           of section 4 of the Pharmaceutical Market Ac-  
9           cess and Drug Safety Act of 2009, knowingly  
10          submit such a notice that makes a materially  
11          false, fictitious, or fraudulent statement, or  
12          knowingly fail to provide promptly any informa-  
13          tion requested by the Secretary to review such  
14          a notice;

15          “(F) knowingly fail to submit an applica-  
16          tion required under subsection (g)(2)(F), know-  
17          ingly fail to submit such an application on or  
18          before the date specified in subsection  
19          (g)(2)(F)(ii), knowingly submit such an applica-  
20          tion that makes a materially false, fictitious, or  
21          fraudulent statement, or knowingly fail to pro-  
22          vide promptly any information requested by the  
23          Secretary to review such an application;

24          “(G) cause there to be a difference (includ-  
25          ing a difference in active ingredient, route of

1 administration, dosage form, strength, formula-  
2 tion, manufacturing establishment, manufac-  
3 turing process, or person that manufactures the  
4 drug) between a prescription drug for distribu-  
5 tion in the United States and the drug for dis-  
6 tribution in a permitted country;

7 “(H) refuse to allow an inspection author-  
8 ized under this section of an establishment that  
9 manufactures a qualifying drug that is, or will  
10 be, introduced for commercial distribution in a  
11 permitted country;

12 “(I) fail to conform to the methods used  
13 in, or the facilities used for, the manufacturing,  
14 processing, packing, or holding of a qualifying  
15 drug that is, or will be, introduced for commer-  
16 cial distribution in a permitted country to good  
17 manufacturing practice under this Act;

18 “(J) become a party to a licensing agree-  
19 ment or other agreement related to a qualifying  
20 drug that fails to provide for compliance with  
21 all requirements of this section with respect to  
22 such drug;

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

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

4           “(M) engage in any other action that the  
5           Federal Trade Commission determines to dis-  
6           criminate against a person that engages or at-  
7           tempts to engage in the importation of a quali-  
8           fying drug under this section.

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

14          “(3) AFFIRMATIVE DEFENSE.—

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

1           “(i) the person exporting or importing  
2           a qualifying drug into the United States  
3           under this section; or

4           “(ii) the person distributing, selling,  
5           or using a qualifying drug imported into  
6           the United States under this section.

7           “(B) DRUG DIFFERENCES.—It shall be an  
8           affirmative defense to a charge that a manufac-  
9           turer has caused there to be a difference de-  
10          scribed in subparagraph (G) of paragraph (1)  
11          that—

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

14           “(ii) the Secretary has determined  
15           that the difference was necessary to im-  
16           prove the safety or effectiveness of the  
17           drug;

18           “(iii) the person manufacturing the  
19           drug for distribution in the United States  
20           has given notice to the Secretary under  
21           subsection (g)(2)(B)(i) that the drug for  
22           distribution in the United States is not dif-  
23           ferent from a drug for distribution in per-  
24           mitted countries whose combined popu-  
25           lation represents at least 50 percent of the

1 total population of all permitted countries;  
2 or

3 “(iv) the difference was not caused, in  
4 whole or in part, for the purpose of re-  
5 stricting importation of the drug into the  
6 United States under this section.

7 “(4) EFFECT OF SUBSECTION.—

8 “(A) SALES IN OTHER COUNTRIES.—This  
9 subsection applies only to the sale or distribu-  
10 tion of a prescription drug in a country if the  
11 manufacturer of the drug chooses to sell or dis-  
12 tribute the drug in the country. Nothing in this  
13 subsection shall be construed to compel the  
14 manufacturer of a drug to distribute or sell the  
15 drug in a country.

16 “(B) DISCOUNTS TO INSURERS, HEALTH  
17 PLANS, PHARMACY BENEFIT MANAGERS, AND  
18 COVERED ENTITIES.—Nothing in this sub-  
19 section shall be construed to—

20 “(i) prevent or restrict a manufac-  
21 turer of a prescription drug from providing  
22 discounts to an insurer, health plan, phar-  
23 macy benefit manager in the United  
24 States, or covered entity in the drug dis-  
25 count program under section 340B of the

1 Public Health Service Act (42 U.S.C.  
2 256b) in return for inclusion of the drug  
3 on a formulary;

4 “(ii) require that such discounts be  
5 made available to other purchasers of the  
6 prescription drug; or

7 “(iii) prevent or restrict any other  
8 measures taken by an insurer, health plan,  
9 or pharmacy benefit manager to encourage  
10 consumption of such prescription drug.

11 “(C) CHARITABLE CONTRIBUTIONS.—  
12 Nothing in this subsection shall be construed  
13 to—

14 “(i) prevent a manufacturer from do-  
15 nating a prescription drug, or supplying a  
16 prescription drug at nominal cost, to a  
17 charitable or humanitarian organization,  
18 including the United Nations and affili-  
19 ates, or to a government of a foreign coun-  
20 try; or

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

23 “(5) ENFORCEMENT.—

24 “(A) UNFAIR OR DECEPTIVE ACT OR PRAC-  
25 TICE.—A violation of this subsection shall be

1 treated as a violation of a rule defining an un-  
2 fair or deceptive act or practice prescribed  
3 under section 18(a)(1)(B) of the Federal Trade  
4 Commission Act (15 U.S.C. 57a(a)(1)(B)).

5 “(B) ACTIONS BY THE COMMISSION.—The  
6 Federal Trade Commission—

7 “(i) shall enforce this subsection in  
8 the same manner, by the same means, and  
9 with the same jurisdiction, powers, and du-  
10 ties as though all applicable terms and pro-  
11 visions of the Federal Trade Commission  
12 Act (15 U.S.C. 41 et seq.) were incor-  
13 porated into and made a part of this sec-  
14 tion; and

15 “(ii) may seek monetary relief three-  
16 fold the damages sustained, in addition to  
17 any other remedy available to the Federal  
18 Trade Commission under the Federal  
19 Trade Commission Act (15 U.S.C. 41 et  
20 seq.).

21 “(6) ACTIONS BY STATES.—

22 “(A) IN GENERAL.—

23 “(i) CIVIL ACTIONS.—In any case in  
24 which the attorney general of a State has  
25 reason to believe that an interest of the

1 residents of that State have been adversely  
2 affected by any manufacturer that violates  
3 paragraph (1), the attorney general of a  
4 State may bring a civil action on behalf of  
5 the residents of the State, and persons  
6 doing business in the State, in a district  
7 court of the United States of appropriate  
8 jurisdiction to—

9 “(I) enjoin that practice;

10 “(II) enforce compliance with  
11 this subsection;

12 “(III) obtain damages, restitu-  
13 tion, or other compensation on behalf  
14 of residents of the State and persons  
15 doing business in the State, including  
16 threefold the damages; or

17 “(IV) obtain such other relief as  
18 the court may consider to be appro-  
19 priate.

20 “(ii) NOTICE.—

21 “(I) IN GENERAL.—Before filing  
22 an action under clause (i), the attor-  
23 ney general of the State involved shall  
24 provide to the Federal Trade Commis-  
25 sion—

1                   “(aa) written notice of that  
2                   action; and

3                   “(bb) a copy of the com-  
4                   plaint for that action.

5                   “(II)     EXEMPTION.—Subclause  
6                   (I) shall not apply with respect to the  
7                   filing of an action by an attorney gen-  
8                   eral of a State under this paragraph,  
9                   if the attorney general determines  
10                  that it is not feasible to provide the  
11                  notice described in that subclause be-  
12                  fore filing of the action. In such case,  
13                  the attorney general of a State shall  
14                  provide notice and a copy of the com-  
15                  plaint to the Federal Trade Commis-  
16                  sion at the same time as the attorney  
17                  general files the action.

18                  “(B) INTERVENTION.—

19                         “(i) IN GENERAL.—On receiving no-  
20                         tice under subparagraph (A)(ii), the Fed-  
21                         eral Trade Commission shall have the right  
22                         to intervene in the action that is the sub-  
23                         ject of the notice.

24                         “(ii) EFFECT OF INTERVENTION.—If  
25                         the Federal Trade Commission intervenes

1 in an action under subparagraph (A), it  
2 shall have the right—

3 “(I) to be heard with respect to  
4 any matter that arises in that action;  
5 and

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

7 “(C) CONSTRUCTION.—For purposes of  
8 bringing any civil action under subparagraph  
9 (A), nothing in this subsection shall be con-  
10 strued to prevent an attorney general of a State  
11 from exercising the powers conferred on the at-  
12 torney general by the laws of that State to—

13 “(i) conduct investigations;

14 “(ii) administer oaths or affirmations;

15 or

16 “(iii) compel the attendance of wit-  
17 nesses or the production of documentary  
18 and other evidence.

19 “(D) ACTIONS BY THE COMMISSION.—In  
20 any case in which an action is instituted by or  
21 on behalf of the Federal Trade Commission for  
22 a violation of paragraph (1), a State may not,  
23 during the pendency of that action, institute an  
24 action under subparagraph (A) for the same

1 violation against any defendant named in the  
2 complaint in that action.

3 “(E) VENUE.—Any action brought under  
4 subparagraph (A) may be brought in the dis-  
5 trict court of the United States that meets ap-  
6 plicable requirements relating to venue under  
7 section 1391 of title 28, United States Code.

8 “(F) SERVICE OF PROCESS.—In an action  
9 brought under subparagraph (A), process may  
10 be served in any district in which the defend-  
11 ant—

12 “(i) is an inhabitant; or

13 “(ii) may be found.

14 “(G) MEASUREMENT OF DAMAGES.—In  
15 any action under this paragraph to enforce a  
16 cause of action under this subsection in which  
17 there has been a determination that a defend-  
18 ant has violated a provision of this subsection,  
19 damages may be proved and assessed in the ag-  
20 gregate by statistical or sampling methods, by  
21 the computation of illegal overcharges or by  
22 such other reasonable system of estimating ag-  
23 gregate damages as the court in its discretion  
24 may permit without the necessity of separately  
25 proving the individual claim of, or amount of

1 damage to, persons on whose behalf the suit  
2 was brought.

3 “(H) EXCLUSION ON DUPLICATIVE RE-  
4 LIEF.—The district court shall exclude from the  
5 amount of monetary relief awarded in an action  
6 under this paragraph brought by the attorney  
7 general of a State any amount of monetary re-  
8 lief which duplicates amounts which have been  
9 awarded for the same injury.

10 “(7) EFFECT ON ANTITRUST LAWS.—Nothing  
11 in this subsection shall be construed to modify, im-  
12 pair, or supersede the operation of the antitrust  
13 laws. For the purpose of this subsection, the term  
14 ‘antitrust laws’ has the meaning given it in the first  
15 section of the Clayton Act, except that it includes  
16 section 5 of the Federal Trade Commission Act to  
17 the extent that such section 5 applies to unfair  
18 methods of competition.

19 “(8) MANUFACTURER.—In this subsection, the  
20 term ‘manufacturer’ means any entity, including any  
21 affiliate or licensee of that entity, that is engaged  
22 in—

23 “(A) the production, preparation, propaga-  
24 tion, compounding, conversion, or processing of  
25 a prescription drug, either directly or indirectly

1 by extraction from substances of natural origin,  
2 or independently by means of chemical syn-  
3 thesis, or by a combination of extraction and  
4 chemical synthesis; or

5 “(B) the packaging, repackaging, labeling,  
6 relabeling, or distribution of a prescription  
7 drug.”.

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

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

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

16 “(A) a sale at retail made pursuant to dis-  
17 pensing the drug to a customer of the pharmacist or  
18 organization; or

19 “(B) a sale or trade of the drug to a pharmacy  
20 or a wholesaler registered to import drugs under sec-  
21 tion 804.

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

1       “(3) The making of a materially false, fictitious, or  
2 fraudulent statement or representation, or a material  
3 omission, in a notice under clause (i) of section  
4 804(g)(2)(B) or in an application required under section  
5 804(g)(2)(F), or the failure to submit such a notice or  
6 application.

7       “(4) The importation of a drug in violation of a reg-  
8 istration condition or other requirement under section  
9 804, the falsification of any record required to be main-  
10 tained, or provided to the Secretary, under such section,  
11 or the violation of any registration condition or other re-  
12 quirement under such section.”; and

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

15       “(6) Notwithstanding subsection (a), any person that  
16 knowingly violates section 301(i) (2) or (3) or section  
17 301(aa)(4) shall be imprisoned not more than 10 years,  
18 or fined in accordance with title 18, United States Code,  
19 or both.”.

20       (c) AMENDMENT OF CERTAIN PROVISIONS.—

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

1       “(g) With respect to a prescription drug that is im-  
2 ported or offered for import into the United States by an  
3 individual who is not in the business of such importation,  
4 that is not shipped by a registered exporter under section  
5 804, and that is refused admission under subsection (a),  
6 the Secretary shall notify the individual that—

7               “(1) the drug has been refused admission be-  
8 cause the drug was not a lawful import under sec-  
9 tion 804;

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

12              “(3) the individual may under section 804 law-  
13 fully import certain prescription drugs from export-  
14 ers registered with the Secretary under section 804;  
15 and

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

21              (2) ESTABLISHMENT REGISTRATION.—Section  
22 510(i) of the Federal Food, Drug, and Cosmetic Act  
23 (21 U.S.C. 360(i)) is amended in paragraph (1) by  
24 inserting after “import into the United States” the  
25 following: “, including a drug that is, or may be, im-

1 ported or offered for import into the United States  
2 under section 804,”.

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

6 (d) EXHAUSTION.—

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

9 (A) by redesignating subsections (h) and  
10 (i) as (i) and (j), respectively; and

11 (B) by inserting after subsection (g) the  
12 following:

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

19 (2) RULE OF CONSTRUCTION.—Nothing in the  
20 amendment made by paragraph (1) shall be con-  
21 strued to affect the ability of a patent owner or li-  
22 censee to enforce their patent, subject to such  
23 amendment.

24 (e) EFFECT OF SECTION 804.—

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

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

10          (B) from permitted countries, as defined in  
11 such section 804, by importers registered under  
12 such section 804 on the date that is 1 year  
13 after the date of enactment of this Act.

14          (2) REVIEW OF REGISTRATION BY CERTAIN EX-  
15 PORTERS.—

16          (A) REVIEW PRIORITY.—In the review of  
17 registrations submitted under subsection (b) of  
18 such section 804, registrations submitted by en-  
19 tities in Canada that are significant exporters  
20 of prescription drugs to individuals in the  
21 United States as of the date of enactment of  
22 this Act will have priority during the 90-day pe-  
23 riod that begins on such date of enactment.

24          (B) PERIOD FOR REVIEW.—During such  
25 90-day period, the reference in subsection

1 (b)(2)(A) of such section 804 to 90 days (relat-  
2 ing to approval or disapproval of registrations)  
3 is, as applied to such entities, deemed to be 30  
4 days.

5 (C) LIMITATION.—That an exporter in  
6 Canada exports, or has exported, prescription  
7 drugs to individuals in the United States on or  
8 before the date that is 90 days after the date  
9 of enactment of this Act shall not serve as a  
10 basis, in whole or in part, for disapproving a  
11 registration under such section 804 from the  
12 exporter.

13 (D) FIRST YEAR LIMIT ON NUMBER OF  
14 EXPORTERS.—During the 1-year period begin-  
15 ning on the date of enactment of this Act, the  
16 Secretary of Health and Human Services (re-  
17 ferred to in this section as the “Secretary”)  
18 may limit the number of registered exporters  
19 under such section 804 to not less than 50, so  
20 long as the Secretary gives priority to those ex-  
21 porters with demonstrated ability to process a  
22 high volume of shipments of drugs to individ-  
23 uals in the United States.

24 (E) SECOND YEAR LIMIT ON NUMBER OF  
25 EXPORTERS.—During the 1-year period begin-

1           ning on the date that is 1 year 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 100, so long  
5           as the Secretary gives priority to those export-  
6           ers with demonstrated ability to process a high  
7           volume of shipments of drugs to individuals in  
8           the United States.

9           (F) FURTHER LIMIT ON NUMBER OF EX-  
10          PORTERS.—During any 1-year period beginning  
11          on a date that is 2 or more years after the date  
12          of enactment of this Act, the Secretary may  
13          limit the number of registered exporters under  
14          such section 804 to not less than 25 more than  
15          the number of such exporters during the pre-  
16          vious 1-year period, so long as the Secretary  
17          gives priority to those exporters with dem-  
18          onstrated ability to process a high volume of  
19          shipments of drugs to individuals in the United  
20          States.

21          (3) LIMITS ON NUMBER OF IMPORTERS.—

22          (A) FIRST YEAR LIMIT ON NUMBER OF IM-  
23          PORTERS.—During the 1-year period beginning  
24          on the date that is 1 year after the date of en-  
25          actment of this Act, the Secretary may limit the

1 number of registered importers under such sec-  
2 tion 804 to not less than 100 (of which at least  
3 a significant number shall be groups of phar-  
4 macies, to the extent feasible given the applica-  
5 tions submitted by such groups), so long as the  
6 Secretary gives priority to those importers with  
7 demonstrated ability to process a high volume  
8 of shipments of drugs imported into the United  
9 States.

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

23 (C) FURTHER LIMIT ON NUMBER OF IM-  
24 PORTERS.—During any 1-year period beginning  
25 on a date that is 3 or more years after the date

1 of enactment of this Act, the Secretary may  
2 limit the number of registered importers under  
3 such section 804 to not less than 50 more (of  
4 which at least a significant number shall be  
5 groups of pharmacies, to the extent feasible  
6 given the applications submitted by such  
7 groups) than the number of such importers  
8 during the previous 1-year period, so long as  
9 the Secretary gives priority to those importers  
10 with demonstrated ability to process a high vol-  
11 ume of shipments of drugs to the United  
12 States.

13 (4) NOTICES FOR DRUGS FOR IMPORT FROM  
14 CANADA.—The notice with respect to a qualifying  
15 drug introduced for commercial distribution in Can-  
16 ada as of the date of enactment of this Act that is  
17 required under subsection (g)(2)(B)(i) of such sec-  
18 tion 804 shall be submitted to the Secretary not  
19 later than 30 days after the date of enactment of  
20 this Act if—

21 (A) the U.S. label drug (as defined in such  
22 section 804) for the qualifying drug is 1 of the  
23 100 prescription drugs with the highest dollar  
24 volume of sales in the United States based on  
25 the 12-calendar-month period most recently

1 completed before the date of enactment of this  
2 Act; or

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

5 (5) NOTICE FOR DRUGS FOR IMPORT FROM  
6 OTHER COUNTRIES.—The notice with respect to a  
7 qualifying drug introduced for commercial distribu-  
8 tion in a permitted country other than Canada as of  
9 the date of enactment of this Act that is required  
10 under subsection (g)(2)(B)(i) of such section 804  
11 shall be submitted to the Secretary not later than  
12 180 days after the date of enactment of this Act  
13 if—

14 (A) the U.S. label drug for the qualifying  
15 drug is 1 of the 100 prescription drugs with the  
16 highest dollar volume of sales in the United  
17 States based on the 12-calendar-month period  
18 that is first completed on the date that is 120  
19 days after the date of enactment of this Act; or

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

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

23 (A) GUIDANCE ON SUBMISSION DATES.—  
24 The Secretary shall by guidance establish a se-  
25 ries of submission dates for the notices under

1 subsection (g)(2)(B)(i) of such section 804 with  
2 respect to qualifying drugs introduced for com-  
3 mercial distribution as of the date of enactment  
4 of this Act and that are not required to be sub-  
5 mitted under paragraph (4) or (5).

6 (B) CONSISTENT AND EFFICIENT USE OF  
7 RESOURCES.—The Secretary shall establish the  
8 dates described under subparagraph (A) so that  
9 such notices described under subparagraph (A)  
10 are submitted and reviewed at a rate that al-  
11 lows consistent and efficient use of the re-  
12 sources and staff available to the Secretary for  
13 such reviews. The Secretary may condition the  
14 requirement to submit such a notice, and the  
15 review of such a notice, on the submission by a  
16 registered exporter or a registered importer to  
17 the Secretary of a notice that such exporter or  
18 importer intends to import such qualifying drug  
19 to the United States under such section 804.

20 (C) PRIORITY FOR DRUGS WITH HIGHER  
21 SALES.—The Secretary shall establish the dates  
22 described under subparagraph (A) so that the  
23 Secretary reviews the notices described under  
24 such subparagraph with respect to qualifying  
25 drugs with higher dollar volume of sales in the

1 United States before the notices with respect to  
2 drugs with lower sales in the United States.

3 (7) NOTICES FOR DRUGS APPROVED AFTER EF-  
4 FECTIVE DATE.—The notice required under sub-  
5 section (g)(2)(B)(i) of such section 804 for a quali-  
6 fying drug first introduced for commercial distribu-  
7 tion in a permitted country (as defined in such sec-  
8 tion 804) after the date of enactment of this Act  
9 shall be submitted to and reviewed by the Secretary  
10 as provided under subsection (g)(2)(B) of such sec-  
11 tion 804, without regard to paragraph (4), (5), or  
12 (6).

13 (8) REPORT.—Beginning with the first full fis-  
14 cal year after the date of enactment of this Act, not  
15 later than 90 days after the end of each fiscal year  
16 during which the Secretary reviews a notice referred  
17 to in paragraph (4), (5), or (6), the Secretary shall  
18 submit a report to Congress concerning the progress  
19 of the Food and Drug Administration in reviewing  
20 the notices referred to in paragraphs (4), (5), and  
21 (6).

22 (9) USER FEES.—

23 (A) EXPORTERS.—When establishing an  
24 aggregate total of fees to be collected from ex-  
25 porters under subsection (f)(2) of such section

1           804, the Secretary shall, under subsection  
2           (f)(3)(C)(i) of such section 804, estimate the  
3           total price of drugs imported under subsection  
4           (a) of such section 804 into the United States  
5           by registered exporters during the first fiscal  
6           year in which this Act takes effect to be an  
7           amount equal to the amount which bears the  
8           same ratio to \$1,000,000,000 as the number of  
9           days in such fiscal year during which this Act  
10          is effective bears to 365.

11           (B) IMPORTERS.—When establishing an  
12          aggregate total of fees to be collected from im-  
13          porters under subsection (e)(2) of such section  
14          804, the Secretary shall, under subsection  
15          (e)(3)(C)(i) of such section 804, estimate the  
16          total price of drugs imported under subsection  
17          (a) of such section 804 into the United States  
18          by registered importers during—

19                   (i) the first fiscal year in which this  
20                   Act takes effect to be an amount equal to  
21                   the amount which bears the same ratio to  
22                   \$1,000,000,000 as the number of days in  
23                   such fiscal year during which this Act is  
24                   effective bears to 365; and

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

3 (C) SECOND YEAR ADJUSTMENT.—

4 (i) REPORTS.—Not later than Feb-  
5 ruary 20 of the second fiscal year in which  
6 this Act is in effect, registered importers  
7 shall report to the Secretary the total price  
8 and the total volume of drugs imported to  
9 the United States by the importer during  
10 the 4-month period from October 1  
11 through January 31 of such fiscal year.

12 (ii) REESTIMATE.—Notwithstanding  
13 subsection (e)(3)(C)(ii) of such section 804  
14 or subparagraph (B), the Secretary shall  
15 reestimate the total price of qualifying  
16 drugs imported under subsection (a) of  
17 such section 804 into the United States by  
18 registered importers during the second fis-  
19 cal year in which this Act is in effect. Such  
20 reestimate shall be equal to—

21 (I) the total price of qualifying  
22 drugs imported by each importer as  
23 reported under clause (i); multiplied  
24 by

25 (II) 3.

1           (iii) ADJUSTMENT.—The Secretary  
2           shall adjust the fee due on April 1 of the  
3           second fiscal year in which this Act is in  
4           effect, from each importer so that the ag-  
5           gregate total of fees collected under sub-  
6           section (e)(2) for such fiscal year does not  
7           exceed the total price of qualifying drugs  
8           imported under subsection (a) of such sec-  
9           tion 804 into the United States by reg-  
10          istered importers during such fiscal year as  
11          reestimated under clause (ii).

12          (D) FAILURE TO PAY FEES.—Notwith-  
13          standing any other provision of this section, the  
14          Secretary may prohibit a registered importer or  
15          exporter that is required to pay user fees under  
16          subsection (e) or (f) of such section 804 and  
17          that fails to pay such fees within 30 days after  
18          the date on which it is due, from importing or  
19          offering for importation a qualifying drug under  
20          such section 804 until such fee is paid.

21          (E) ANNUAL REPORT.—

22                 (i) FOOD AND DRUG ADMINISTRA-  
23                 TION.—Not later than 180 days after the  
24                 end of each fiscal year during which fees  
25                 are collected under subsection (e), (f), or

1 (g)(2)(B)(iv) of such section 804, the Sec-  
2 retary shall prepare and submit to the  
3 House of Representatives and the Senate a  
4 report on the implementation of the au-  
5 thority for such fees during such fiscal  
6 year and the use, by the Food and Drug  
7 Administration, of the fees collected for the  
8 fiscal year for which the report is made  
9 and credited to the Food and Drug Admin-  
10 istration.

11 (ii) CUSTOMS AND BORDER CON-  
12 TROL.—Not later than 180 days after the  
13 end of each fiscal year during which fees  
14 are collected under subsection (e) or (f) of  
15 such section 804, the Secretary of Home-  
16 land Security, in consultation with the Sec-  
17 retary of the Treasury, shall prepare and  
18 submit to the House of Representatives  
19 and the Senate a report on the use, by the  
20 Bureau of Customs and Border Protection,  
21 of the fees, if any, transferred by the Sec-  
22 retary to the Bureau of Customs and Bor-  
23 der Protection for the fiscal year for which  
24 the report is made.

1           (10) SPECIAL RULE REGARDING IMPORTATION  
2 BY INDIVIDUALS.—

3           (A) IN GENERAL.—Notwithstanding any  
4 provision of this Act (or an amendment made  
5 by this Act), the Secretary shall expedite the  
6 designation of any additional countries from  
7 which an individual may import a qualifying  
8 drug into the United States under such section  
9 804 if any action implemented by the Govern-  
10 ment of Canada has the effect of limiting or  
11 prohibiting the importation of qualifying drugs  
12 into the United States from Canada.

13           (B) TIMING AND CRITERIA.—The Sec-  
14 retary shall designate such additional countries  
15 under subparagraph (A)—

16           (i) not later than 6 months after the  
17 date of the action by the Government of  
18 Canada described under such subpara-  
19 graph; and

20           (ii) using the criteria described under  
21 subsection (a)(4)(D)(i)(II) of such section  
22 804.

23 (f) IMPLEMENTATION OF SECTION 804.—

24           (1) INTERIM RULE.—The Secretary may pro-  
25 mulgate an interim rule for implementing section

1 804 of the Federal Food, Drug, and Cosmetic Act,  
2 as added by subsection (a) of this section.

3 (2) NO NOTICE OF PROPOSED RULEMAKING.—

4 The interim rule described under paragraph (1) may  
5 be developed and promulgated by the Secretary with-  
6 out providing general notice of proposed rulemaking.

7 (3) FINAL RULE.—Not later than 1 year after  
8 the date on which the Secretary promulgates an in-  
9 terim rule under paragraph (1), the Secretary shall,  
10 in accordance with procedures under section 553 of  
11 title 5, United States Code, promulgate a final rule  
12 for implementing such section 804, which may incor-  
13 porate by reference provisions of the interim rule  
14 provided for under paragraph (1), to the extent that  
15 such provisions are not modified.

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

18 (1) with regard to the availability of qualifying  
19 drugs for import for personal use from an exporter  
20 registered with and approved by the Food and Drug  
21 Administration under section 804 of the Federal  
22 Food, Drug, and Cosmetic Act, as added by this sec-  
23 tion, including information on how to verify whether  
24 an exporter is registered and approved by use of the  
25 Internet website of the Food and Drug Administra-

1       tion and the toll-free telephone number required by  
2       this Act;

3           (2) that drugs that consumers attempt to im-  
4       port from an exporter that is not registered with and  
5       approved by the Food and Drug Administration can  
6       be seized by the United States Customs Service and  
7       destroyed, and that such drugs may be counterfeit,  
8       unapproved, unsafe, or ineffective;

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

12          (4) with regard to the availability at domestic  
13      retail pharmacies of qualifying drugs imported under  
14      such section 804 by domestic wholesalers and phar-  
15      macies registered with and approved by the Food  
16      and Drug Administration.

17      (h) EFFECT ON ADMINISTRATION PRACTICES.—Not-  
18      withstanding any provision of this Act (and the amend-  
19      ments made by this Act), the practices and policies of the  
20      Food and Drug Administration and Bureau of Customs  
21      and Border Protection, in effect on January 1, 2004, with  
22      respect to the importation of prescription drugs into the  
23      United States by an individual, on the person of such indi-  
24      vidual, for personal use, shall remain in effect.

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

8 **SEC. 5. DISPOSITION OF CERTAIN DRUGS DENIED ADMIS-**  
9 **SION INTO UNITED STATES.**

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

14 **“SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED AD-**  
15 **MISSION.**

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

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

22 “(2)(A) the shipping container for such drugs  
23 does not bear the markings required under section  
24 804(d)(2); or

1           “(B) the Secretary has requested delivery of  
2           such shipment of drugs.

3           “(b) NO BOND OR EXPORT.—Section 801(b) does  
4           not authorize the delivery to the owner or consignee of  
5           drugs delivered to the Secretary under subsection (a) pur-  
6           suant to the execution of a bond, and such drugs may not  
7           be exported.

8           “(c) DESTRUCTION OF VIOLATIVE SHIPMENT.—The  
9           Secretary shall destroy a shipment of drugs delivered by  
10          the Secretary of Homeland Security to the Secretary  
11          under subsection (a) if—

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

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

20          “(d) CERTAIN PROCEDURES.—

21                 “(1) IN GENERAL.—The delivery and destruc-  
22                 tion of drugs under this section may be carried out  
23                 without notice to the importer, owner, or consignee  
24                 of the drugs except as required by section 801(g) or  
25                 section 804(i)(2). The issuance of receipts for the

1 drugs, and recordkeeping activities regarding the  
2 drugs, may be carried out on a summary basis.

3 “(2) OBJECTIVE OF PROCEDURES.—Procedures  
4 promulgated under paragraph (1) shall be designed  
5 toward the objective of ensuring that, with respect to  
6 efficiently utilizing Federal resources available for  
7 carrying out this section, a substantial majority of  
8 shipments of drugs subject to described in sub-  
9 section (c) are identified and destroyed.

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

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

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

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

4 **SEC. 6. WHOLESALE DISTRIBUTION OF DRUGS; STATE-**  
5 **MENTS REGARDING PRIOR SALE, PURCHASE,**  
6 **OR TRADE.**

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

11 (1) in paragraph (1)—

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

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

17 (C) by striking subparagraph (B) and in-  
18 serting the following:

19 “(B) The fact that a drug subject to subsection (b)  
20 is exported from the United States does not with respect  
21 to such drug exempt any person that is engaged in the  
22 business of the wholesale distribution of the drug from  
23 providing the statement described in subparagraph (A) to  
24 the person that receives the drug pursuant to the export  
25 of the drug.

1           “(C)(i) The Secretary shall by regulation establish re-  
2     quirements that supersede subparagraph (A) (referred to  
3     in this subparagraph as ‘alternative requirements’) to  
4     identify the chain of custody of a drug subject to sub-  
5     section (b) from the manufacturer of the drug throughout  
6     the wholesale distribution of the drug to a pharmacist who  
7     intends to sell the drug at retail if the Secretary deter-  
8     mines that the alternative requirements, which may in-  
9     clude standardized anti-counterfeiting or track-and-trace  
10    technologies, will identify such chain of custody or the  
11    identity of the discrete package of the drug from which  
12    the drug is dispensed with equal or greater certainty to  
13    the requirements of subparagraph (A), and that the alter-  
14    native requirements are economically and technically fea-  
15    sible.

16           “(ii) When the Secretary promulgates a final rule to  
17    establish such alternative requirements, the final rule in  
18    addition shall, with respect to the registration condition  
19    established in clause (i) of section 804(c)(3)(B), establish  
20    a condition equivalent to the alternative requirements, and  
21    such equivalent condition may be met in lieu of the reg-  
22    istration condition established in such clause (i).”;

23           (2) in paragraph (2)(A), by adding at the end  
24    the following: “The preceding sentence may not be

1 construed as having any applicability with respect to  
2 a registered exporter under section 804.”; and

3 (3) in paragraph (3), by striking “and sub-  
4 section (d)—” in the matter preceding subparagraph  
5 (A) and all that follows through “the term ‘whole-  
6 sale distribution’ means” in subparagraph (B) and  
7 inserting the following: “and subsection (d), the  
8 term ‘wholesale distribution’ means”.

9 (b) CONFORMING AMENDMENT.—Section 503(d) of  
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
11 353(d)) is amended by adding at the end the following:

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

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

19 (c) EFFECTIVE DATE.—

20 (1) IN GENERAL.—The amendments made by  
21 paragraphs (1) and (3) of subsection (a) and by sub-  
22 section (b) shall take effect on January 1, 2012.

23 (2) DRUGS IMPORTED BY REGISTERED IMPORT-  
24 ERS UNDER SECTION 804.—Notwithstanding para-  
25 graph (1), the amendments made by paragraphs (1)

1 and (3) of subsection (a) and by subsection (b) shall  
2 take effect on the date that is 90 days after the date  
3 of enactment of this Act with respect to qualifying  
4 drugs imported under section 804 of the Federal  
5 Food, Drug, and Cosmetic Act, as added by section  
6 4.

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

11 (4) ALTERNATIVE REQUIREMENTS.—The Sec-  
12 retary shall issue regulations to establish the alter-  
13 native requirements, referred to in the amendment  
14 made by subsection (a)(1), that take effect not later  
15 than January 1, 2012.

16 (5) INTERMEDIATE REQUIREMENTS.—The Sec-  
17 retary shall by regulation require the use of stand-  
18 ardized anti-counterfeiting or track-and-trace tech-  
19 nologies on prescription drugs at the case and pallet  
20 level effective not later than 1 year after the date of  
21 enactment of this Act.

22 (6) ADDITIONAL REQUIREMENTS.—

23 (A) IN GENERAL.—Notwithstanding any  
24 other provision of this section, the Secretary  
25 shall, not later than 18 months after the date

1 of enactment of this Act, require that the pack-  
2 aging of any prescription drug incorporates—

3 (i) a standardized numerical identifier  
4 unique to each package of such drug, ap-  
5 plied at the point of manufacturing and re-  
6 packaging (in which case the numerical  
7 identifier shall be linked to the numerical  
8 identifier applied at the point of manufac-  
9 turing); and

10 (ii)(I) overt optically variable counter-  
11 feit-resistant technologies that—

12 (aa) are visible to the naked eye,  
13 providing for visual identification of  
14 product authenticity without the need  
15 for readers, microscopes, lighting de-  
16 vices, or scanners;

17 (bb) are similar to that used by  
18 the Bureau of Engraving and Printing  
19 to secure United States currency;

20 (cc) are manufactured and dis-  
21 tributed in a highly secure, tightly  
22 controlled environment; and

23 (dd) incorporate additional layers  
24 of nonvisible covert security features  
25 up to and including forensic capa-

1 bility, as described in subparagraph  
2 (B); or

3 (II) technologies that have a function  
4 of security comparable to that described in  
5 subclause (I), as determined by the Sec-  
6 retary.

7 (B) STANDARDS FOR PACKAGING.—For  
8 the purpose of making it more difficult to coun-  
9 terfeit the packaging of drugs subject to this  
10 paragraph, the manufacturers of such drugs  
11 shall incorporate the technologies described in  
12 subparagraph (A) into at least 1 additional ele-  
13 ment of the physical packaging of the drugs, in-  
14 cluding blister packs, shrink wrap, package la-  
15 bels, package seals, bottles, and boxes.

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

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

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

21 **“(a) REQUIREMENTS REGARDING INFORMATION ON**  
22 **INTERNET SITE.—**

23 **“(1) IN GENERAL.—**A person may not dispense  
24 a prescription drug pursuant to a sale of the drug  
25 by such person if—

1           “(A) the purchaser of the drug submitted  
2           the purchase order for the drug, or conducted  
3           any other part of the sales transaction for the  
4           drug, through an Internet site;

5           “(B) the person dispenses the drug to the  
6           purchaser by mailing or shipping the drug to  
7           the purchaser; and

8           “(C) such site, or any other Internet site  
9           used by such person for purposes of sales of a  
10          prescription drug, fails to meet each of the re-  
11          quirements specified in paragraph (2), other  
12          than a site or pages on a site that—

13                  “(i) are not intended to be accessed  
14                  by purchasers or prospective purchasers; or

15                  “(ii) provide an Internet information  
16                  location tool within the meaning of section  
17                  231(e)(5) of the Communications Act of  
18                  1934 (47 U.S.C. 231(e)(5)).

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

23                  “(A) Each page of the site shall include ei-  
24                  ther the following information or a link to a  
25                  page that provides the following information:

1           “(i) The name of such person.

2           “(ii) Each State in which the person  
3 is authorized by law to dispense prescrip-  
4 tion drugs.

5           “(iii) The address and telephone num-  
6 ber of each place of business of the person  
7 with respect to sales of prescription drugs  
8 through the Internet, other than a place of  
9 business that does not mail or ship pre-  
10 scription drugs to purchasers.

11           “(iv) The name of each individual who  
12 serves as a pharmacist for prescription  
13 drugs that are mailed or shipped pursuant  
14 to the site, and each State in which the in-  
15 dividual is authorized by law to dispense  
16 prescription drugs.

17           “(v) If the person provides for medical  
18 consultations through the site for purposes  
19 of providing prescriptions, the name of  
20 each individual who provides such con-  
21 sultations; each State in which the indi-  
22 vidual is licensed or otherwise authorized  
23 by law to provide such consultations or  
24 practice medicine; and the type or types of

1 health professions for which the individual  
2 holds such licenses or other authorizations.

3 “(B) A link to which paragraph (1) applies  
4 shall be displayed in a clear and prominent  
5 place and manner, and shall include in the cap-  
6 tion for the link the words ‘licensing and con-  
7 tact information’.

8 “(b) INTERNET SALES WITHOUT APPROPRIATE  
9 MEDICAL RELATIONSHIPS.—

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

13 “(A) for purposes of such dispensing or  
14 sale, the purchaser communicated with the per-  
15 son through the Internet;

16 “(B) the patient for whom the drug was  
17 dispensed or purchased did not, when such  
18 communications began, have a prescription for  
19 the drug that is valid in the United States;

20 “(C) pursuant to such communications, the  
21 person provided for the involvement of a practi-  
22 tioner, or an individual represented by the per-  
23 son as a practitioner, and the practitioner or  
24 such individual issued a prescription for the  
25 drug that was purchased;

1           “(D) the person knew, or had reason to  
2 know, that the practitioner or the individual re-  
3 ferred to in subparagraph (C) did not, when  
4 issuing the prescription, have a qualifying med-  
5 ical relationship with the patient; and

6           “(E) the person received payment for the  
7 dispensing or sale of the drug.

8 For purposes of subparagraph (E), payment is re-  
9 ceived if money or other valuable consideration is re-  
10 ceived.

11           “(2) EXCEPTIONS.—Paragraph (1) does not  
12 apply to—

13           “(A) the dispensing or selling of a pre-  
14 scription drug pursuant to telemedicine prac-  
15 tices sponsored by—

16           “(i) a hospital that has in effect a  
17 provider agreement under title XVIII of  
18 the Social Security Act (relating to the  
19 Medicare program); or

20           “(ii) a group practice that has not  
21 fewer than 100 physicians who have in ef-  
22 fect provider agreements under such title;  
23 or

24           “(B) the dispensing or selling of a pre-  
25 scription drug pursuant to practices that pro-

1           mote the public health, as determined by the  
2           Secretary by regulation.

3           “(3) QUALIFYING MEDICAL RELATIONSHIP.—

4                   “(A) IN GENERAL.—With respect to  
5           issuing a prescription for a drug for a patient,  
6           a practitioner has a qualifying medical relation-  
7           ship with the patient for purposes of this sec-  
8           tion if—

9                           “(i) at least one in-person medical  
10                          evaluation of the patient has been con-  
11                          ducted by the practitioner; or

12                           “(ii) the practitioner conducts a med-  
13                          ical evaluation of the patient as a covering  
14                          practitioner.

15                   “(B) IN-PERSON MEDICAL EVALUATION.—

16           A medical evaluation by a practitioner is an in-  
17           person medical evaluation for purposes of this  
18           section if the practitioner is in the physical  
19           presence of the patient as part of conducting  
20           the evaluation, without regard to whether por-  
21           tions of the evaluation are conducted by other  
22           health professionals.

23                   “(C) COVERING PRACTITIONER.—With re-  
24           spect to a patient, a practitioner is a covering  
25           practitioner for purposes of this section if the

1 practitioner conducts a medical evaluation of  
2 the patient at the request of a practitioner who  
3 has conducted at least one in-person medical  
4 evaluation of the patient and is temporarily un-  
5 available to conduct the evaluation of the pa-  
6 tient. A practitioner is a covering practitioner  
7 without regard to whether the practitioner has  
8 conducted any in-person medical evaluation of  
9 the patient involved.

10 “(4) RULES OF CONSTRUCTION.—

11 “(A) INDIVIDUALS REPRESENTED AS  
12 PRACTITIONERS.—A person who is not a practi-  
13 tioner (as defined in subsection (e)(1)) lacks  
14 legal capacity under this section to have a  
15 qualifying medical relationship with any patient.

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

20 “(C) APPLICABILITY OF REQUIRE-  
21 MENTS.—Paragraph (3) may not be construed  
22 as having any applicability beyond this section,  
23 and does not affect any State law, or interpre-  
24 tation of State law, concerning the practice of  
25 medicine.

1 “(c) ACTIONS BY STATES.—

2 “(1) IN GENERAL.—Whenever an attorney gen-  
3 eral of any State has reason to believe that the in-  
4 terests of the residents of that State have been or  
5 are being threatened or adversely affected because  
6 any person has engaged or is engaging in a pattern  
7 or practice that violates section 301(l), the State  
8 may bring a civil action on behalf of its residents in  
9 an appropriate district court of the United States to  
10 enjoin such practice, to enforce compliance with such  
11 section (including a nationwide injunction), to obtain  
12 damages, restitution, or other compensation on be-  
13 half of residents of such State, to obtain reasonable  
14 attorneys fees and costs if the State prevails in the  
15 civil action, or to obtain such further and other relief  
16 as the court may deem appropriate.

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

1           “(A) to intervene in such action;

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

4           “(C) to file petitions for appeal.

5           “(3) CONSTRUCTION.—For purposes of bring-  
6 ing any civil action under paragraph (1), nothing in  
7 this chapter shall prevent an attorney general of a  
8 State from exercising the powers conferred on the  
9 attorney general by the laws of such State to con-  
10 duct investigations or to administer oaths or affir-  
11 mations or to compel the attendance of witnesses or  
12 the production of documentary and other evidence.

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

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

23           “(A) Nothing contained in this section  
24 shall prohibit an authorized State official from  
25 proceeding in State court on the basis of an al-

1           leged violation of any civil or criminal statute of  
2           such State.

3           “(B) In addition to actions brought by an  
4           attorney general of a State under paragraph  
5           (1), such an action may be brought by officers  
6           of such State who are authorized by the State  
7           to bring actions in such State on behalf of its  
8           residents.

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

12          “(e) GENERAL DEFINITIONS.—For purposes of this  
13          section:

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

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

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

22          “(f) INTERNET-RELATED DEFINITIONS.—

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

1           “(A) The term ‘Internet’ means collectively  
2 the myriad of computer and telecommunications  
3 facilities, including equipment and operating  
4 software, which comprise the interconnected  
5 world-wide network of networks that employ the  
6 transmission control protocol/internet protocol,  
7 or any predecessor or successor protocols to  
8 such protocol, to communicate information of  
9 all kinds by wire or radio.

10           “(B) The term ‘link’, with respect to the  
11 Internet, means one or more letters, words,  
12 numbers, symbols, or graphic items that appear  
13 on a page of an Internet site for the purpose  
14 of serving, when activated, as a method for exe-  
15 cuting an electronic command—

16           “(i) to move from viewing one portion  
17 of a page on such site to another portion  
18 of the page;

19           “(ii) to move from viewing one page  
20 on such site to another page on such site;  
21 or

22           “(iii) to move from viewing a page on  
23 one Internet site to a page on another  
24 Internet site.

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

4           “(D)(i) The terms ‘site’ and ‘address’, with  
5 respect to the Internet, mean a specific location  
6 on the Internet that is determined by Internet  
7 Protocol numbers. Such term includes the do-  
8 main name, if any.

9           “(ii) The term ‘domain name’ means a  
10 method of representing an Internet address  
11 without direct reference to the Internet Protocol  
12 numbers for the address, including methods  
13 that use designations such as ‘.com’, ‘.edu’,  
14 ‘.gov’, ‘.net’, or ‘.org’.

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

18           “(2) AUTHORITY OF SECRETARY.—The Sec-  
19 retary may by regulation modify any definition  
20 under paragraph (1) to take into account changes in  
21 technology.

22           “(g) INTERACTIVE COMPUTER SERVICE; ADVER-  
23 TISING.—No provider of an interactive computer service,  
24 as defined in section 230(f)(2) of the Communications Act  
25 of 1934 (47 U.S.C. 230(f)(2)), or of advertising services

1 shall be liable under this section for dispensing or selling  
2 prescription drugs in violation of this section on account  
3 of another person's selling or dispensing such drugs, pro-  
4 vided that the provider of the interactive computer service  
5 or of advertising services does not own or exercise cor-  
6 porate control over such person.”.

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

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

13 (c) INTERNET SALES OF PRESCRIPTION DRUGS;  
14 CONSIDERATION BY SECRETARY OF PRACTICES AND PRO-  
15 CEDURES FOR CERTIFICATION OF LEGITIMATE BUSI-  
16 NESSES.—In carrying out section 503C of the Federal  
17 Food, Drug, and Cosmetic Act (as added by subsection  
18 (a) of this section), the Secretary of Health and Human  
19 Services shall take into consideration the practices and  
20 procedures of public or private entities that certify that  
21 businesses selling prescription drugs through Internet  
22 sites are legitimate businesses, including practices and  
23 procedures regarding disclosure formats and verification  
24 programs.

1 (d) REPORTS REGARDING INTERNET-RELATED VIO-  
2 LATIONS OF FEDERAL AND STATE LAWS ON DISPENSING  
3 OF DRUGS.—

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

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

15 (B) reporting such sites to State medical  
16 licensing boards and State pharmacy licensing  
17 boards, and to the Attorney General and the  
18 Secretary, for further investigation; and

19 (C) submitting, for each fiscal year for  
20 which the award under this subsection is made,  
21 a report to the Secretary describing investiga-  
22 tions undertaken with respect to violations de-  
23 scribed in subparagraph (A).

24 (2) AUTHORIZATION OF APPROPRIATIONS.—For  
25 the purpose of carrying out paragraph (1), there is

1 authorized to be appropriated \$100,000 for each of  
2 the first 3 fiscal years in which this section is in ef-  
3 fect.

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

13 **SEC. 8. PROHIBITING PAYMENTS TO UNREGISTERED FOR-**  
14 **EIGN PHARMACIES.**

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

18 “(h) RESTRICTED TRANSACTIONS.—

19 “(1) IN GENERAL.—The introduction of re-  
20 stricted transactions into a payment system or the  
21 completion of restricted transactions using a pay-  
22 ment system is prohibited.

23 “(2) PAYMENT SYSTEM.—

24 “(A) IN GENERAL.—The term ‘payment  
25 system’ means a system used by a person de-

1           scribed in subparagraph (B) to effect a credit  
2           transaction, electronic fund transfer, or money  
3           transmitting service that may be used in con-  
4           nection with, or to facilitate, a restricted trans-  
5           action, and includes—

6                   “(i) a credit card system;

7                   “(ii) an international, national, re-  
8                   gional, or local network used to effect a  
9                   credit transaction, an electronic fund  
10                  transfer, or a money transmitting service;  
11                  and

12                  “(iii) any other system that is cen-  
13                  trally managed and is primarily engaged in  
14                  the transmission and settlement of credit  
15                  transactions, electronic fund transfers, or  
16                  money transmitting services.

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

19                   “(i) a creditor;

20                   “(ii) a credit card issuer;

21                   “(iii) a financial institution;

22                   “(iv) an operator of a terminal at  
23                  which an electronic fund transfer may be  
24                  initiated;

1                   “(v) a money transmitting business;

2                   or

3                   “(vi) a participant in an international,  
4                   national, regional, or local network used to  
5                   effect a credit transaction, electronic fund  
6                   transfer, or money transmitting service.

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

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

18                  “(B) an electronic fund transfer or funds  
19                  transmitted by or through a money transmit-  
20                  ting business, or the proceeds of an electronic  
21                  fund transfer or money transmitting service,  
22                  from or on behalf of the individual for the pur-  
23                  pose of the unlawful drug importation request;

24                  “(C) a check, draft, or similar instrument  
25                  which is drawn by or on behalf of the individual

1 for the purpose of the unlawful drug importa-  
2 tion request and is drawn on or payable at or  
3 through any financial institution; or

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

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

19 “(5) UNREGISTERED FOREIGN PHARMACY.—  
20 The term ‘unregistered foreign pharmacy’ means a  
21 person in a country other than the United States  
22 that is not a registered exporter under section 804.

23 “(6) OTHER DEFINITIONS.—

24 “(A) CREDIT; CREDITOR; CREDIT CARD.—  
25 The terms ‘credit’, ‘creditor’, and ‘credit card’

1 have the meanings given the terms in section  
2 103 of the Truth in Lending Act (15 U.S.C.  
3 1602).

4 “(B) ACCESS DEVICE; ELECTRONIC FUND  
5 TRANSFER.—The terms ‘access device’ and  
6 ‘electronic fund transfer’—

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

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

14 “(C) FINANCIAL INSTITUTION.—The term  
15 ‘financial institution’—

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

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

22 “(D) MONEY TRANSMITTING BUSINESS;  
23 MONEY TRANSMITTING SERVICE.—The terms  
24 ‘money transmitting business’ and ‘money  
25 transmitting service’ have the meaning given

1 the terms in section 5330(d) of title 31, United  
2 States Code.

3 “(E) BOARD.—The term ‘Board’ means  
4 the Board of Governors of the Federal Reserve  
5 System.

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

8 “(A) REGULATIONS.—The Board shall  
9 promulgate regulations requiring—

10 “(i) an operator of a credit card sys-  
11 tem;

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

17 “(iii) an operator of any other pay-  
18 ment system that is centrally managed and  
19 is primarily engaged in the transmission  
20 and settlement of credit transactions, elec-  
21 tronic transfers or money transmitting  
22 services where at least one party to the  
23 transaction or transfer is an individual;  
24 and

1           “(iv) any other person described in  
2           paragraph (2)(B) and specified by the  
3           Board in such regulations,  
4           to establish policies and procedures that are  
5           reasonably designed to prevent the introduction  
6           of a restricted transaction into a payment sys-  
7           tem or the completion of a restricted trans-  
8           action using a payment system

9           “(B) REQUIREMENTS FOR POLICIES AND  
10          PROCEDURES.—In promulgating regulations  
11          under subparagraph (A), the Board shall—

12           “(i) identify types of policies and pro-  
13           cedures, including nonexclusive examples,  
14           that shall be considered to be reasonably  
15           designed to prevent the introduction of re-  
16           stricted transactions into a payment sys-  
17           tem or the completion of restricted trans-  
18           actions using a payment system; and

19           “(ii) to the extent practicable, permit  
20           any payment system, or person described  
21           in paragraph (2)(B), as applicable, to  
22           choose among alternative means of pre-  
23           venting the introduction or completion of  
24           restricted transactions.

1           “(C) NO LIABILITY FOR BLOCKING OR RE-  
2 FUSING TO HONOR RESTRICTED TRANS-  
3 ACTION.—

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

15           “(ii) COMPLIANCE.—A person de-  
16 scribed in paragraph (2)(B) meets the re-  
17 quirements of this subsection if the person  
18 relies on and complies with the policies and  
19 procedures of a payment system of which  
20 the person is a member or in which the  
21 person is a participant, and such policies  
22 and procedures of the payment system  
23 comply with the requirements of the regu-  
24 lations promulgated under subparagraph  
25 (A).

1 “(D) ENFORCEMENT.—

2 “(i) IN GENERAL.—This section shall  
3 be enforced by the Federal functional regu-  
4 lators and the Federal Trade Commission  
5 under applicable law in the manner pro-  
6 vided in section 505(a) of the Gramm-  
7 Leach-Bliley Act (15 U.S.C. 6805(a)).

8 “(ii) FACTORS TO BE CONSIDERED.—  
9 In considering any enforcement action  
10 under this subsection against a payment  
11 system or person described in paragraph  
12 (2)(B), the Federal functional regulators  
13 and the Federal Trade Commission shall  
14 consider the following factors:

15 “(I) The extent to which the pay-  
16 ment system or person knowingly per-  
17 mits restricted transactions.

18 “(II) The history of the payment  
19 system or person in connection with  
20 permitting restricted transactions.

21 “(III) The extent to which the  
22 payment system or person has estab-  
23 lished and is maintaining policies and  
24 procedures in compliance with regula-  
25 tions prescribed under this subsection.

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

13           “(9) RELATION TO STATE LAWS.—No require-  
14          ment, prohibition, or liability may be imposed on a  
15          payment system, or a person described in paragraph  
16          (2)(B) that is subject to a regulation issued under  
17          this subsection, under the laws of any State with re-  
18          spect to any payment transaction by an individual  
19          because the payment transaction involves a payment  
20          to a foreign pharmacy.

21           “(10) TIMING OF REQUIREMENTS.—A payment  
22          system, or a person described in paragraph (2)(B)  
23          that is subject to a regulation issued under this sub-  
24          section, must adopt policies and procedures reason-  
25          ably designed to comply with any regulations re-

1       quired under paragraph (7) within 60 days after  
2       such regulations are issued in final form.”.

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

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

12 **SEC. 9. IMPORTATION EXEMPTION UNDER CONTROLLED**  
13 **SUBSTANCES IMPORT AND EXPORT ACT.**

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

21 **SEC. 10. SEVERABILITY.**

22       If any provision of this Act, an amendment by this  
23 Act, or the application of such provision or amendment  
24 to any person or circumstance is held to be unconstitu-  
25 tional, the remainder of this Act, the amendments made

1 by this Act, and the application of the provisions of such  
2 to any person or circumstance shall not affected thereby.

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