

109TH CONGRESS  
1ST SESSION

# S. 334

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 SENATE OF THE UNITED STATES

FEBRUARY 9, 2005

Mr. DORGAN (for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. KENNEDY, Mr. MCCAIN, Ms. STABENOW, Mr. CHAFEE, Mr. JEFFORDS, Mr. LOTT, Mr. DAYTON, Mrs. CLINTON, Mr. BINGAMAN, Mrs. BOXER, Mr. CONRAD, Mr. DURBIN, Mr. FEINGOLD, Mrs. FEINSTEIN, Mr. INOUE, Mr. JOHNSON, Mr. KOHL, Mr. LEAHY, Mr. LEVIN, Mr. NELSON of Florida, Mr. OBAMA, Mr. PRYOR, Mr. SALAZAR, Mr. SARBANES, Mr. SCHUMER, and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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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 2005”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

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

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

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

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

15          (5) American seniors alone will spend  
16 \$1,800,000,000,000 on pharmaceuticals over the  
17 next 10 years; and

18          (6) allowing open pharmaceutical markets could  
19 save American consumers at least \$38,000,000,000  
20 each year.

21 **SEC. 3. REPEAL OF CERTAIN SECTION REGARDING IMPOR-**  
22 **TATION OF PRESCRIPTION DRUGS.**

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

1 **SEC. 4. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER**  
2 **OF CERTAIN IMPORT RESTRICTIONS.**

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

7 **“SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF**  
8 **PRESCRIPTION DRUGS.**

9 “(a) IMPORTATION OF PRESCRIPTION DRUGS.—

10 “(1) IN GENERAL.—In the case of qualifying  
11 drugs imported or offered for import into the United  
12 States from registered exporters or by registered im-  
13 porters—

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

16 “(B) the standards referred to in section  
17 801(a) regarding admission of the drugs are  
18 subject to subsection (g) of this section (includ-  
19 ing with respect to qualifying drugs to which  
20 section 801(d)(1) does not apply).

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

23 “(A) the drug is imported by a pharmacy,  
24 group of pharmacies, or a wholesaler that is a  
25 registered importer; or

1           “(B) the drug is imported by an individual  
2           for personal use or for the use of a family mem-  
3           ber of the individual (not for resale) from a reg-  
4           istered exporter.

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

9           “(A) by a registered importer; or

10           “(B) from a registered exporter to an indi-  
11           vidual.

12           “(4) DEFINITIONS.—

13           “(A) REGISTERED EXPORTER; REG-  
14           ISTERED IMPORTER.—For purposes of this sec-  
15           tion:

16           “(i) The term ‘registered exporter’  
17           means an exporter for which a registration  
18           under subsection (b) has been approved  
19           and is in effect.

20           “(ii) The term ‘registered importer’  
21           means a pharmacy, group of pharmacies,  
22           or a wholesaler for which a registration  
23           under subsection (b) has been approved  
24           and is in effect.

1           “(iii) The term ‘registration condition’  
2           means a condition that must exist for a  
3           registration under subsection (b) to be ap-  
4           proved.

5           “(B) QUALIFYING DRUG.—For purposes of  
6           this section, the term ‘qualifying drug’ means a  
7           drug for which there is a corresponding U.S.  
8           label drug.

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

12                 “(i) with respect to a qualifying drug,  
13                 has the same active ingredient or ingredi-  
14                 ents, route of administration, dosage form,  
15                 and strength as the qualifying drug;

16                 “(ii) with respect to the qualifying  
17                 drug, is manufactured by or for the person  
18                 that manufactures the qualifying drug;

19                 “(iii) is approved under section  
20                 505(e); and

21                 “(iv) is not—

22                         “(I) a controlled substance, as  
23                         defined in section 102 of the Con-  
24                         trolled Substances Act (21 U.S.C.  
25                         802);

1           “(II) a biological product, as de-  
2 fined in section 351 of the Public  
3 Health Service Act (42 U.S.C. 262),  
4 including—

5           “(aa) a therapeutic DNA  
6 plasmid product;

7           “(bb) a therapeutic synthetic  
8 peptide product;

9           “(cc) a monoclonal antibody  
10 product for in vivo use; and

11           “(dd) a therapeutic recom-  
12 binant DNA-derived product;

13           “(III) an infused drug, including  
14 a peritoneal dialysis solution;

15           “(IV) an injected drug;

16           “(V) a drug that is inhaled dur-  
17 ing surgery; or

18           “(VI) a drug that is the listed  
19 drug referred to in 2 or more abbrevi-  
20 ated new drug applications under  
21 which the drug is commercially mar-  
22 keted.

23           “(D) OTHER DEFINITIONS.—For purposes  
24 of this section:

1           “(i)(I) The term ‘exporter’ means a  
2 person that is in the business of exporting  
3 a drug to individuals in the United States  
4 from Canada or from a permitted country  
5 designated by the Secretary under sub-  
6 clause (II), or that, pursuant to submitting  
7 a registration under subsection (b), seeks  
8 to be in such business.

9           “(II) The Secretary shall designate a  
10 permitted country under subparagraph (E)  
11 (other than Canada) as a country from  
12 which an exporter may export a drug to in-  
13 dividuals in the United States if the Sec-  
14 retary determines that—

15                   (aa) the country has statutory or  
16 regulatory standards that are equiva-  
17 lent to the standards in the United  
18 States and Canada with respect to—

19                           “(AA) the training of phar-  
20 macists;

21                           “(BB) the practice of phar-  
22 macy; and

23                           “(CC) the protection of the  
24 privacy of personal medical infor-  
25 mation; and

1                   “(bb) the importation of drugs to  
2                   individuals in the United States from  
3                   the country will not adversely affect  
4                   public health.

5                   “(ii) The term ‘importer’ means a  
6                   pharmacy, a group of pharmacies, or a  
7                   wholesaler that is in the business of im-  
8                   porting a drug into the United States or  
9                   that, pursuant to submitting a registration  
10                  under subsection (b), seeks to be in such  
11                  business.

12                  “(iii) The term ‘pharmacist’ means a  
13                  person licensed by a State to practice  
14                  pharmacy, including the dispensing and  
15                  selling of prescription drugs.

16                  “(iv) The term ‘pharmacy’ means a  
17                  person that—

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

21                         “(II) employs 1 or more phar-  
22                         macists.

23                  “(v) The term ‘prescription drug’  
24                  means a drug that is described in section  
25                  503(b)(1).



1 “(vi) The term ‘wholesaler’—

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

6 “(II) does not include a person  
7 authorized to import drugs under sec-  
8 tion 801(d)(1).

9 “(E) PERMITTED COUNTRY.—The term  
10 ‘permitted country’ means—

11 “(i) Australia;

12 “(ii) Canada;

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

16 “(I) the country’s Annex to the  
17 Treaty of Accession to the European  
18 Union 2003 includes a transitional  
19 measure for the regulation of human  
20 pharmaceutial products that has not  
21 expired; or

22 “(II) the Secretary determines  
23 that the requirements described in  
24 subclauses (I) and (II) of clause (vii)  
25 will not be met by the date on which

1 such transitional measure for the reg-  
2 ulation of human pharmaceutical prod-  
3 ucts expires;

4 “(iv) Japan;

5 “(v) New Zealand;

6 “(vi) Switzerland; and

7 “(vii) a country in which the Sec-  
8 retary determines the following require-  
9 ments are met:

10 “(I) The country has statutory or  
11 regulatory requirements—

12 “(aa) that require the review  
13 of drugs for safety and effective-  
14 ness by an entity of the govern-  
15 ment of the country;

16 “(bb) that authorize the ap-  
17 proval of only those drugs that  
18 have been determined to be safe  
19 and effective by experts employed  
20 by or acting on behalf of such en-  
21 tity and qualified by scientific  
22 training and experience to evalu-  
23 ate the safety and effectiveness of  
24 drugs on the basis of adequate  
25 and well-controlled investigations,

1 including clinical investigations,  
2 conducted by experts qualified by  
3 scientific training and experience  
4 to evaluate the safety and effec-  
5 tiveness of drugs;

6 “(cc) that require the meth-  
7 ods used in, and the facilities and  
8 controls used for the manufac-  
9 ture, processing, and packing of  
10 drugs in the country to be ade-  
11 quate to preserve their identity,  
12 quality, purity, and strength;

13 “(dd) for the reporting of  
14 adverse reactions to drugs and  
15 procedures to withdraw approval  
16 and remove drugs found not to  
17 be safe or effective; and

18 “(ee) that require the label-  
19 ing and promotion of drugs to be  
20 in accordance with the approval  
21 of the drug.

22 “(II) The valid marketing au-  
23 thorization system in the country is  
24 equivalent to the systems in the coun-

1                   tries described in clauses (i) through  
2                   (vi).

3                   “(III) The importation of drugs  
4                   to the United States from the country  
5                   will not adversely affect public health.

6           “(b) REGISTRATION OF IMPORTERS AND EXPORT-  
7   ERS.—

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

13                   “(A)(i) In the case of an exporter, the  
14                   name of the exporter and an identification of all  
15                   places of business of the exporter that relate to  
16                   qualifying drugs, including each warehouse or  
17                   other facility owned or controlled by, or oper-  
18                   ated for, the exporter.

19                   “(ii) In the case of an importer, the name  
20                   of the importer and an identification of the  
21                   places of business of the importer at which the  
22                   importer initially receives a qualifying drug  
23                   after importation (which shall not exceed 3  
24                   places of business except by permission of the  
25                   Secretary).

1           “(B) Such information as the Secretary  
2 determines to be necessary to demonstrate that  
3 the registrant is in compliance with registration  
4 conditions under—

5                   “(i) in the case of an importer, sub-  
6 sections (c), (d), (e), (g), and (j) (relating  
7 to the sources of imported qualifying  
8 drugs; the inspection of facilities of the im-  
9 porter; the payment of fees; compliance  
10 with the standards referred to in section  
11 801(a); and maintenance of records and  
12 samples); or

13                   “(ii) in the case of an exporter, sub-  
14 sections (c), (d), (f), (g), (h), (i), and (j)  
15 (relating to the sources of exported quali-  
16 fying drugs; the inspection of facilities of  
17 the exporter and the marking of compliant  
18 shipments; the payment of fees; and com-  
19 pliance with the standards referred to in  
20 section 801(a); being licensed as a phar-  
21 macist; conditions for individual importa-  
22 tion; and maintenance of records and sam-  
23 ples).

24           “(C) An agreement by the registrant that  
25 the registrant will not under subsection (a) im-

1 port or export any drug that is not a qualifying  
2 drug.

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

4 “(i) notify the Secretary of a recall or  
5 withdrawal of a qualifying drug distributed  
6 in a permitted country that the registrant  
7 has exported or imported, or intends to ex-  
8 port or import, to the United States under  
9 subsection (a);

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

12 “(iii) cease, or not begin, the expor-  
13 tation or importation of such drug unless  
14 the Secretary has notified the registrant  
15 that exportation or importation of such  
16 drug may proceed.

17 “(E) An agreement by the registrant to  
18 ensure and monitor compliance with each reg-  
19 istration condition, to promptly correct any  
20 noncompliance with such a condition, and to  
21 promptly report to the Secretary any such non-  
22 compliance.

23 “(F) A plan describing the manner in  
24 which the registrant will comply with the agree-  
25 ment under subparagraph (E).

1           “(G) An agreement by the registrant to  
2 enforce a contract under subsection (c)(3)(B)  
3 against a party in the chain of custody of a  
4 qualifying drug with respect to the authority of  
5 the Secretary under clauses (ii) and (iii) of that  
6 subsection.

7           “(H) An agreement by the registrant to  
8 notify the Secretary not more than 30 days be-  
9 fore the registrant intends to make the change,  
10 of—

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

14           “(ii) any change that the registrant  
15 intends to make in the compliance plan  
16 under subparagraph (F).

17           “(I) In the case of an exporter—

18           “(i) An agreement by the exporter  
19 that a qualifying drug will not under sub-  
20 section (a) be exported to any individual  
21 not authorized pursuant to subsection  
22 (a)(2)(B) to be an importer of such drug.

23           “(ii) An agreement to post a bond,  
24 payable to the Treasury of the United

1 States that is equal in value to the lesser  
2 of—

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

7 “(II) \$1,000,000;

8 “(iii) An agreement by the exporter to  
9 comply with applicable provisions of Cana-  
10 dian law, or the law of the permitted coun-  
11 try designated under subsection  
12 (a)(4)(D)(i)(II) in which the exporter is lo-  
13 cated, that protect the privacy of personal  
14 information with respect to each individual  
15 importing a prescription drug from the ex-  
16 porter under subsection (a)(2)(B).

17 “(iv) An agreement by the exporter to  
18 report to the Secretary—

19 “(I) not later than August 1 of  
20 each fiscal year, the total price and  
21 the total volume of drugs exported to  
22 the United States by the exporter dur-  
23 ing the 6-month period from January  
24 1 through June 30 of that year; and



1                   “(II) not later than January 1 of  
2                   each fiscal year, the total price and  
3                   the total volume of drugs exported to  
4                   the United States by the exporter dur-  
5                   ing the previous fiscal year.

6                   “(J) In the case of an importer, an agree-  
7                   ment by the importer to report to the Sec-  
8                   retary—

9                   “(i) not later than August 1 of each  
10                  fiscal year, the total price and the total  
11                  volume of drugs imported to the United  
12                  States by the importer during the 6-month  
13                  period from January 1 through June 30 of  
14                  that fiscal year; and

15                  “(ii) not later than January 1 of each  
16                  fiscal year, the total price and the total  
17                  volume of drugs imported to the United  
18                  States by the importer during the previous  
19                  fiscal year.

20                  “(K) Such other provisions as the Sec-  
21                  retary may require by regulation to protect the  
22                  public health while permitting—

23                  “(i) the importation by pharmacies,  
24                  groups of pharmacies, and wholesalers as

1 registered importers of qualifying drugs  
2 under subsection (a); and

3 “(ii) importation by individuals of  
4 qualifying drugs under subsection (a).

5 “(2) APPROVAL OR DISAPPROVAL OF REGISTRA-  
6 TION.—

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

22 “(B) CHANGES IN REGISTRATION INFOR-  
23 MATION.—Not later than 30 days after receiv-  
24 ing a notice under paragraph (1)(H) from a  
25 registrant, the Secretary shall determine wheth-

1           er the change involved affects the approval of  
2           the registration of the registrant under para-  
3           graph (1), and shall inform the registrant of  
4           the determination.

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

16          “(4) SUSPENSION AND TERMINATION.—

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

20                         “(i) Subject to clause (ii), the Sec-  
21                         retary may suspend the registration if the  
22                         Secretary determines, after notice and op-  
23                         portunity for a hearing, that the registrant  
24                         has failed to maintain substantial compli-  
25                         ance with a registration condition.

1           “(ii) If the Secretary determines that,  
2           under color of the registration, the ex-  
3           porter has exported a drug or the importer  
4           has imported a drug that is not a quali-  
5           fying drug, or a drug that does not comply  
6           with subsection (g)(2)(A) or (g)(4), or has  
7           exported a qualifying drug to an individual  
8           in violation of subsection (i)(2)(F), the  
9           Secretary shall immediately suspend the  
10          registration. A suspension under the pre-  
11          ceding sentence is not subject to the provi-  
12          sion by the Secretary of prior notice, and  
13          the Secretary shall provide to the reg-  
14          istrant an opportunity for a hearing not  
15          later than 10 days after the date on which  
16          the registration is suspended.

17          “(iii) The Secretary may reinstate the  
18          registration, whether suspended under  
19          clause (i) or (ii), if the Secretary deter-  
20          mines that the registrant has demonstrated  
21          that further violations of registration con-  
22          ditions will not occur.

23          “(B) TERMINATION.—The Secretary, after  
24          notice and opportunity for a hearing, may ter-  
25          minate the registration under paragraph (1) of

1 a registrant if the Secretary determines that  
2 the registrant has engaged in a pattern or prac-  
3 tice of violating 1 or more registration condi-  
4 tions, or if on 1 or more occasions the Secretary  
5 has under subparagraph (A)(ii) suspended the  
6 registration of the registrant. The Secretary  
7 may make the termination permanent, or for a  
8 fixed period of not less than 1 year. During the  
9 period in which the registration is terminated,  
10 any registration submitted under paragraph (1)  
11 by the registrant, or a person that is a partner  
12 in the export or import enterprise, or a prin-  
13 cipal officer in such enterprise, and any reg-  
14 istration prepared with the assistance of the  
15 registrant or such a person, has no legal effect  
16 under this section.

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

23 “(A) exported a drug to the United States  
24 that is not a qualifying drug or that is not in

1 compliance with subsection (g)(2)(A), (g)(4), or  
2 (i); or

3 “(B) failed to permit the Secretary to con-  
4 duct an inspection described under subsection  
5 (d).

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

11 “(1) The drug was manufactured in an estab-  
12 lishment—

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

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

16 “(ii) for which the Secretary has elected to  
17 rely on a satisfactory report of a good manufac-  
18 turing practice inspection of the establishment  
19 from a permitted country whose regulatory sys-  
20 tem the Secretary recognizes as equivalent  
21 under a mutual recognition agreement, as pro-  
22 vided for under section 510(i)(3), section 803,  
23 or part 26 of title 21, Code of Federal Regula-  
24 tions (or any corresponding successor rule or  
25 regulation).

1           “(2) The establishment is located in any coun-  
2           try, and the establishment manufactured the drug  
3           for distribution in the United States or for distribu-  
4           tion in 1 or more of the permitted countries (without  
5           regard to whether in addition the drug is manufac-  
6           tured for distribution in a foreign country that is  
7           not a permitted country).

8           “(3) The exporter or importer obtained the  
9           drug—

10                   “(A) directly from the establishment; or

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

13                           “(i) provides to the exporter or im-  
14                           porter a statement (in such form and con-  
15                           taining such information as the Secretary  
16                           may require) that, for the chain of custody  
17                           from the establishment, identifies each  
18                           prior sale, purchase, or trade of the drug  
19                           (including the date of the transaction and  
20                           the names and addresses of all parties to  
21                           the transaction);

22                           “(ii) agrees to permit the Secretary to  
23                           inspect such statements and related  
24                           records to determine their accuracy;

1           “(iii) agrees, with respect to the quali-  
2           fying drugs involved, to permit the Sec-  
3           retary to inspect warehouses and other fa-  
4           cilities, including records, of the entity for  
5           purposes of determining whether the facili-  
6           ties are in compliance with any standards  
7           under this Act that are applicable to facili-  
8           ties of that type in the United States; and

9           “(iv) has ensured, through such con-  
10          tractual relationships as may be necessary,  
11          that the Secretary has the same authority  
12          regarding other parties in the chain of cus-  
13          tody from the establishment that the Sec-  
14          retary has under clauses (ii) and (iii) re-  
15          garding such entity.

16          “(4)(A) The foreign country from which the im-  
17          porter will import the drug is a permitted country;  
18          or

19          “(B) The foreign country from which the ex-  
20          porter will export the drug is the permitted country  
21          in which the exporter is located.

22          “(5) During any period in which the drug was  
23          not in the control of the manufacturer of the drug,  
24          the drug did not enter any country that is not a per-  
25          mitted country.



1           “(6) The exporter or importer retains a sample  
2 of each lot of the drug sufficient for testing by the  
3 Secretary.

4           “(d) INSPECTION OF FACILITIES; MARKING OF SHIP-  
5 MENTS.—

6           “(1) INSPECTION OF FACILITIES.—A registra-  
7 tion condition is that, for the purpose of assisting  
8 the Secretary in determining whether the exporter  
9 involved is in compliance with all other registration  
10 conditions—

11                   “(A) the exporter agrees to permit the Sec-  
12 retary—

13                           “(i) to conduct onsite inspections, in-  
14 cluding monitoring on a day-to-day basis,  
15 of places of business of the exporter that  
16 relate to qualifying drugs, including each  
17 warehouse or other facility owned or con-  
18 trolled by, or operated for, the exporter;

19                           “(ii) to have access, including on a  
20 day-to-day basis, to—

21                                   “(I) records of the exporter that  
22 relate to the export of such drugs, in-  
23 cluding financial records; and

24   “(II) samples of such drugs;

1                   “(iii) to carry out the duties described  
2                   in paragraph (3); and

3                   “(iv) to carry out any other functions  
4                   determined by the Secretary to be nec-  
5                   essary regarding the compliance of the ex-  
6                   porter; and

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

15                  “(2) MARKING OF COMPLIANT SHIPMENTS.—A  
16                  registration condition is that the exporter involved  
17                  agrees to affix to each shipping container of quali-  
18                  fying drugs exported under subsection (a) such  
19                  markings as the Secretary determines to be nec-  
20                  essary to identify the shipment as being in compli-  
21                  ance with all registration conditions. Markings under  
22                  the preceding sentence shall—

23                         “(A) be designed to prevent affixation of  
24                         the markings to any shipping container that is  
25                         not authorized to bear the markings; and

1           “(B) include anticounterfeiting or track-  
2           and-trace technologies, taking into account the  
3           economic and technical feasibility of those tech-  
4           nologies.

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

8           “(A) Inspecting, randomly, but not less  
9           than 12 times annually, the places of business  
10          of the exporter at which qualifying drugs are  
11          stored and from which qualifying drugs are  
12          shipped.

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

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

9           “(D) Monitoring the affixing of markings  
10          under paragraph (2).

11          “(E) Inspecting as the Secretary deter-  
12          mines is necessary the warehouses and other fa-  
13          cilities, including records, of other parties in the  
14          chain of custody of qualifying drugs.

15          “(F) Determining whether the exporter is  
16          in compliance with all other registration condi-  
17          tions.

18          “(4) PRIOR NOTICE OF SHIPMENTS.—A reg-  
19          istration condition is that, not less than 8 hours and  
20          not more than 5 days in advance of the time of the  
21          importation of a shipment of qualifying drugs, the  
22          importer involved agrees to submit to the Secretary  
23          a notice with respect to the shipment of drugs to be  
24          imported or offered for import into the United

1 States under subsection (a). A notice under the pre-  
2 ceding sentence shall include—

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

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

7 “(C) the identity of the drug, including the  
8 established name of the drug, the quantity of  
9 the drug, and the lot number assigned by the  
10 manufacturer;

11 “(D) the identity of the manufacturer of  
12 the drug, including the identity of the establish-  
13 ment at which the drug was manufactured;

14 “(E) the country from which the drug is  
15 shipped;

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

18 “(G) anticipated arrival information, in-  
19 cluding the port of arrival and crossing location  
20 within that port, and the date and time;

21 “(H) a summary of the chain of custody of  
22 the drug from the establishment in which the  
23 drug was manufactured to the importer;

24 “(I) a declaration as to whether the Sec-  
25 retary has ordered that importation of the drug

1 from the permitted country cease under sub-  
2 section (g)(2)(C) or (D); and

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

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

19 “(A) be designed to prevent affixation of  
20 the markings or other technology to any con-  
21 tainer that is not authorized to bear the mark-  
22 ings; and

23 “(B) shall include anticounterfeiting or  
24 track-and-trace technologies, taking into ac-

1 count the economic and technical feasibility of  
2 such technologies.

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

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

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

23 “(C) Reviewing notices under paragraph  
24 (4).

1           “(D) Inspecting as the Secretary deter-  
2 mines is necessary the warehouses and other fa-  
3 cilities, including records of other parties in the  
4 chain of custody of qualifying drugs.

5           “(E) Determining whether the importer is  
6 in compliance with all other registration condi-  
7 tions.

8           “(e) IMPORTER FEES.—

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

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

20           “(3) AMOUNT OF INSPECTION FEE.—

21           “(A) AGGREGATE TOTAL OF FEES.—Not  
22 later than 30 days before the start of each fis-  
23 cal year, the Secretary, in consultation with the  
24 Secretary of Homeland Security and the Sec-  
25 retary of the Treasury, shall establish an aggre-



1           gate total of fees to be collected under para-  
2           graph (2) for importers for that fiscal year that  
3           is sufficient, and not more than necessary, to  
4           pay the costs for that fiscal year of admin-  
5           istering this section with respect to registered  
6           importers, including the costs associated with—

7                   “(i) inspecting the facilities of reg-  
8                   istered importers, and of other entities in  
9                   the chain of custody of a qualifying drug  
10                  as necessary, under subsection (d)(6);

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

20                  “(iii) inspecting such shipments as  
21                  necessary, when offered for import into the  
22                  United States to determine if such a ship-  
23                  ment should be refused admission under  
24                  subsection (g)(5).

1           “(B) LIMITATION.—Subject to subpara-  
2 graph (C), the aggregate total of fees collected  
3 under paragraph (2) for a fiscal year shall not  
4 exceed 1 percent of the total price of qualifying  
5 drugs imported during that fiscal year into the  
6 United States by registered importers under  
7 subsection (a).

8           “(C) TOTAL PRICE OF DRUGS.—

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

24           “(ii) CALCULATION.—Not later than  
25 March 1 of the fiscal year that follows the

1 fiscal year for which the estimate under  
2 clause (i) is made, the Secretary shall cal-  
3 culate the total price of qualifying drugs  
4 imported into the United States by reg-  
5 istered importers during that fiscal year by  
6 adding the total price of qualifying drugs  
7 imported by each registered importer dur-  
8 ing that fiscal year, as reported to the Sec-  
9 retary by each registered importer under  
10 subsection (b)(1)(J).

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

22 “(D) INDIVIDUAL IMPORTER FEE.—Sub-  
23 ject to the limitation described in subparagraph  
24 (B), the fee under paragraph (2) to be paid on  
25 October 1 and April 1 by an importer shall be

1 an amount that is proportional to a reasonable  
2 estimate by the Secretary of the semiannual  
3 share of the importer of the volume of quali-  
4 fying drugs imported by importers under sub-  
5 section (a).

6 “(4) USE OF FEES.—

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

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

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

8           “(f) EXPORTER FEES.—

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

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

20           “(3) AMOUNT OF INSPECTION FEE.—

21           “(A) AGGREGATE TOTAL OF FEES.—Not  
22 later than 30 days before the start of each fis-  
23 cal year, the Secretary, in consultation with the  
24 Secretary of Homeland Security and the Sec-  
25 retary of the Treasury, shall establish an aggre-

1           gate total of fees to be collected under para-  
2           graph (2) for exporters for that fiscal year that  
3           is sufficient, and not more than necessary, to  
4           pay the costs for that fiscal year of admin-  
5           istering this section with respect to registered  
6           exporters, including the costs associated with—

7                   “(i) inspecting the facilities of reg-  
8                   istered exporters, and of other entities in  
9                   the chain of custody of a qualifying drug  
10                  as necessary, under subsection (d)(3);

11                  “(ii) developing, implementing, and  
12                  operating under such subsection a system  
13                  to screen marks on shipments of qualifying  
14                  drugs under subsection (a) that indicate  
15                  compliance with all registration conditions,  
16                  when such shipments are offered for im-  
17                  port into the United States; and

18                  “(iii) screening such markings, and  
19                  inspecting such shipments as necessary,  
20                  when offered for import into the United  
21                  States to determine if such a shipment  
22                  should be refused admission under sub-  
23                  section (g)(5).

24                  “(B) LIMITATION.—Subject to subpara-  
25                  graph (C), the aggregate total of fees collected

1 under paragraph (2) for a fiscal year shall not  
2 exceed 1 percent of the total price of qualifying  
3 drugs imported during that fiscal year into the  
4 United States by registered exporters under  
5 subsection (a).

6 “(C) TOTAL PRICE OF DRUGS.—

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

22 “(ii) CALCULATION.—Not later than  
23 March 1 of the fiscal year that follows the  
24 fiscal year for which the estimate under  
25 clause (i) is made, the Secretary shall cal-

1            calculate the total price of qualifying drugs  
2            imported into the United States by reg-  
3            istered exporters during that fiscal year by  
4            adding the total price of qualifying drugs  
5            exported by each registered exporter dur-  
6            ing that fiscal year, as reported to the Sec-  
7            retary by each registered exporter under  
8            subsection (b)(1)(I)(iv).

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

20           “(D) INDIVIDUAL EXPORTER FEE.—Sub-  
21           ject to the limitation described in subparagraph  
22           (B), the fee under paragraph (2) to be paid on  
23           October 1 and April 1 by an exporter shall be  
24           an amount that is proportional to a reasonable  
25           estimate by the Secretary of the semiannual



1 share of the exporter of the volume of quali-  
2 fying drugs exported by exporters under sub-  
3 section (a).

4 “(4) USE OF FEES.—

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

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

24 “(5) COLLECTION OF FEES.—In any case where  
25 the Secretary does not receive payment of a fee as-

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

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

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

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

16               “(A) IN GENERAL.—A qualifying drug that  
17      is imported or offered for import under sub-  
18      section (a) shall comply with the conditions es-  
19      tablished in the approved application under sec-  
20      tion 505(b) for the U.S. label drug as described  
21      under this subsection.

22               “(B) NOTICE BY MANUFACTURER; GEN-  
23      ERAL PROVISIONS.—

24               “(i) IN GENERAL.—The person that  
25      manufactures a qualifying drug that is, or

1 will be, introduced for commercial distribu-  
2 tion in a permitted country shall in accord-  
3 ance with this paragraph submit to the  
4 Secretary a notice that—

5 “(I) includes each difference in  
6 the qualifying drug from a condition  
7 established in the approved applica-  
8 tion for the U.S. label drug beyond—

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

11 “(bb) any difference in label-  
12 ing (except ingredient labeling);  
13 or

14 “(II) states that there is no dif-  
15 ference in the qualifying drug from a  
16 condition established in the approved  
17 application for the U.S. label drug be-  
18 yond—

19 “(aa) the variations provided  
20 for in the application; and

21 “(bb) any difference in label-  
22 ing (except ingredient labeling).

23 “(ii) INFORMATION IN NOTICE.—A  
24 notice under clause (i)(I) shall include the  
25 information that the Secretary may require

1 under section 506A, any additional infor-  
2 mation the Secretary may require (which  
3 may include data on bioequivalence if such  
4 data are not required under section 506A),  
5 and, with respect to the permitted country  
6 that approved the qualifying drug for com-  
7 mercial distribution, or with respect to  
8 which such approval is sought, include the  
9 following:

10 “(I) The date on which the quali-  
11 fying drug with such difference was,  
12 or will be, introduced for commercial  
13 distribution in the permitted country.

14 “(II) Information demonstrating  
15 that the person submitting the notice  
16 has also notified the government of  
17 the permitted country in writing that  
18 the person is submitting to the Sec-  
19 retary a notice under clause (i)(I),  
20 which notice describes the difference  
21 in the qualifying drug from a condi-  
22 tion established in the approved appli-  
23 cation for the U.S. label drug.

24 “(III) The information that the  
25 person submitted or will submit to the

1 government of the permitted country  
2 for purposes of obtaining approval for  
3 commercial distribution of the drug in  
4 the country which, if in a language  
5 other than English, shall be accom-  
6 panied by an English translation  
7 verified to be complete and accurate,  
8 with the name, address, and a brief  
9 statement of the qualifications of the  
10 person that made the translation.

11 “(iii) CERTIFICATIONS.—The chief ex-  
12 ecutive officer and the chief medical officer  
13 of the manufacturer involved shall each  
14 certify in the notice under clause (i) that—

15 “(I) the information provided in  
16 the notice is complete and true; and

17 “(II) a copy of the notice has  
18 been provided to the Federal Trade  
19 Commission and to the State attor-  
20 neys general.

21 “(iv) FEE.—If a notice submitted  
22 under clause (i) includes a difference that  
23 would, under section 506A, require the  
24 submission of a supplemental application if  
25 made as a change to the U.S. label drug,

1 the person that submits the notice shall  
2 pay to the Secretary a fee in the same  
3 amount as would apply if the person were  
4 paying a fee pursuant to section  
5 736(a)(1)(A)(ii). Subject to appropriations  
6 Acts, fees collected by the Secretary under  
7 the preceding sentence are available only to  
8 the Secretary and are for the sole purpose  
9 of paying the costs of reviewing notices  
10 submitted under clause (i).

11 “(v) TIMING OF SUBMISSION OF NO-  
12 TICES.—

13 “(I) PRIOR APPROVAL NO-  
14 TICES.—A notice under clause (i) to  
15 which subparagraph (C) applies shall  
16 be submitted to the Secretary not  
17 later than 120 days before the quali-  
18 fying drug with the difference is intro-  
19 duced for commercial distribution in a  
20 permitted country, unless the country  
21 requires that distribution of the quali-  
22 fying drug with the difference begin  
23 less than 120 days after the country  
24 requires the difference.

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

9           “(III) OTHER NOTICES.—A no-  
10          tice under clause (i) to which subpara-  
11          graph (E) applies shall be submitted  
12          to the Secretary on the date that the  
13          qualifying drug is first introduced for  
14          commercial distribution in a permitted  
15          country and annually thereafter.

16          “(vi) REVIEW BY SECRETARY.—

17          “(I) IN GENERAL.—In this para-  
18          graph, the difference in a qualifying  
19          drug that is submitted in a notice  
20          under clause (i) from the U.S. label  
21          drug shall be treated by the Secretary  
22          as if it were a manufacturing change  
23          to the U.S. label drug under section  
24          506A.

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

10                   “(III) BIOEQUIVALENCE.—If the  
11                   Secretary would approve the dif-  
12                   ference in a notice submitted under  
13                   clause (i) using the safe and effective  
14                   standard under section 506A and if  
15                   the Secretary determines that the  
16                   qualifying drug is not bioequivalent to  
17                   the U.S. label drug, the Secretary  
18                   may—

19                   “(aa) include in the labeling  
20                   provided under paragraph (3) a  
21                   prominent advisory that the  
22                   qualifying drug is safe and effec-  
23                   tive but is not bioequivalent to  
24                   the U.S. label drug if the Sec-  
25                   retary determines that such an



1 advisory is necessary for health  
2 care practitioners and patients to  
3 use the qualifying drug safely  
4 and effectively; or

5 “(bb) decline to approve the  
6 difference if the Secretary deter-  
7 mines that the availability of  
8 both the qualifying drug and the  
9 U.S. label drug would pose a  
10 threat to the public health.

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

19 “(V) ESTABLISHMENT INSPEC-  
20 TION.—If review of such difference  
21 would require an inspection of the es-  
22 tablishment in which the qualifying  
23 drug is manufactured—

1                   “(aa) such inspection by the  
2                   Secretary shall be authorized;  
3                   and

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

17                  “(vii) PUBLICATION OF INFORMATION  
18                  ON NOTICES.—

19                  “(I) IN GENERAL.—Through the  
20                  Internet website of the Food and  
21                  Drug Administration and a toll-free  
22                  telephone number, the Secretary shall  
23                  readily make available to the public a  
24                  list of notices submitted under clause  
25                  (i).

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

5                   “(aa) a notice is under re-  
6                   view;

7                   “(bb) the Secretary has or-  
8                   dered that importation of the  
9                   qualifying drug from a permitted  
10                  country cease; or

11                  “(cc) the importation of the  
12                  drug is permitted under sub-  
13                  section (a).

14                  “(III) UPDATE.—The Secretary  
15                  shall promptly update the Internet  
16                  website with any changes to the list.

17                  “(C) NOTICE; DRUG DIFFERENCE REQUIR-  
18                  ING PRIOR APPROVAL.—In the case of a notice  
19                  under subparagraph (B)(i) that includes a dif-  
20                  ference that would, under section 506A(c) or  
21                  (d)(3)(B)(i), require the approval of a supple-  
22                  mental application before the difference could  
23                  be made to the U.S. label drug the following  
24                  shall occur:

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

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

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

21               “(II) promptly notify registered  
22               exporters, registered importers, the  
23               Federal Trade Commission, and the  
24               State attorneys general of the order.

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

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

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

23                   “(I) vacate the order under  
24                   clause (ii), if any;

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

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

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

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

21                 “(i) During the period in which the  
22                 notice is being reviewed by the Secretary,  
23                 the authority under this subsection to im-  
24                 port the qualifying drug involved continues  
25                 in effect.

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

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

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

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

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

23           “(E) NOTICE; DRUG DIFFERENCE NOT RE-  
24           QUIRING APPROVAL; NO DIFFERENCE.—In the  
25           case of a notice under subparagraph (B)(i) that

1 includes a difference for which, under section  
2 506A(d)(1)(A), a supplemental application  
3 would not be required for the difference to be  
4 made to the U.S. label drug, or that states that  
5 there is no difference, the Secretary—

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

9 “(ii) may not order that the importa-  
10 tion of the qualifying drug involved cease;  
11 and

12 “(iii) shall promptly notify registered  
13 exporters and registered importers.

14 “(F) DIFFERENCES IN ACTIVE INGRE-  
15 DIENT, ROUTE OF ADMINISTRATION, DOSAGE  
16 FORM, OR STRENGTH.—

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



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

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

16          “(ii) APPLICATION UNDER SECTION  
17          505(b).—The application under section  
18          505(b) required under clause (i) shall—

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

23           “(II) include the information that  
24           the person submitted to the govern-  
25           ment of the permitted country for

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

10 “(III) include a right of reference  
11 to the application for the drug ap-  
12 proved under section 505(b); and

13 “(IV) include such additional in-  
14 formation as the Secretary may re-  
15 quire.

16 “(iii) TIMING OF SUBMISSION OF AP-  
17 PPLICATION.—An application under section  
18 505(b) required under clause (i) shall be  
19 submitted to the Secretary not later than  
20 the day on which the information referred  
21 to in clause (ii)(II) is submitted to the gov-  
22 ernment of the permitted country.

23 “(iv) NOTICE OF DECISION ON APPLI-  
24 CATION.—The Secretary shall promptly no-  
25 tify registered exporters, registered import-

1           ers, the Federal Trade Commission, and  
2           the State attorneys general of a determina-  
3           tion to approve or to disapprove an appli-  
4           cation under section 505(b) required under  
5           clause (i).

6           “(v) RELATED ACTIVE INGREDI-  
7           ENTS.—For purposes of clause (i)(II),  
8           active ingredients are related if they are—

9                   “(I) the same; or

10                   “(II) different salts, esters, or  
11                   complexes of the same moiety.

12           “(3) SECTION 502; LABELING.—

13                   “(A) IMPORTATION BY REGISTERED IM-  
14                   PORTER.—

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

23                           “(I) a copy of the labeling ap-  
24                           proved for the U.S. label drug under  
25                           section 505, without regard to wheth-

1 er the copy bears any trademark in-  
2 volved;

3 “(II) the name of the manufac-  
4 turer and location of the manufac-  
5 turer;

6 “(III) the lot number assigned by  
7 the manufacturer;

8 “(IV) the name, location, and  
9 registration number of the importer;  
10 and

11 “(V) the National Drug Code  
12 number assigned to the qualifying  
13 drug by the Secretary.

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

18 “(iii) REQUESTED LABELING.—The  
19 labeling provided by the Secretary under  
20 clause (ii) shall—

21 “(I) include the established  
22 name, as defined in section 502(e)(3),  
23 for each active ingredient in the quali-  
24 fying drug;

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

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

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

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

22 “(bb) a list of the ingredi-  
23 ents of the qualifying drug as  
24 would be required under section  
25 502(e).

1 “(B) IMPORTATION BY INDIVIDUAL.—

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

15 “(I) directions for use by the  
16 consumer;

17 “(II) the lot number assigned by  
18 the manufacturer;

19 “(III) the name and registration  
20 number of the exporter;

21 “(IV) if required under para-  
22 graph (2)(B)(vi)(III), a prominent ad-  
23 visory that the drug is safe and effec-  
24 tive but not bioequivalent to the U.S.  
25 label drug;

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

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

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

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

22                  “(ii) REQUEST FOR COPY OF SPECIAL  
23                  LABELING AND INGREDIENT LIST.—The  
24                  Secretary shall provide to the registered  
25                  exporter involved a copy of the special la-

1                   belong, the advisory, and the ingredient list  
2                   of the drug, upon request of the exporter.

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

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

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

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

19                  “(5) STANDARDS FOR REFUSING ADMISSION.—  
20                  A drug exported under subsection (a) from a reg-  
21                  istered exporter or imported by a registered importer  
22                  may be refused admission into the United States if  
23                  1 or more of the following applies:

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



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

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

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

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

12           “(F) The Secretary becomes aware that—

13               “(i) the drug may be counterfeit;

14               “(ii) the drug may have been pre-  
15 pared, packed, or held under insanitary  
16 conditions; or

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

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

1           “(H) The Secretary has under section  
2           505(e) withdrawn approval of the drug.

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

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

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

12                  “(i) The shipping container for such  
13                  drug does not bear the markings required  
14                  under subsection (d)(2).

15                  “(ii) The markings on the shipping  
16                  container appear to be counterfeit.

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

19          “(h) LICENSING AS PHARMACIST.—A registration  
20          condition is that the exporter involved agrees that a quali-  
21          fying drug will be exported to an individual only if the  
22          Secretary has verified that—

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

1           “(2) the exporter employs persons that are li-  
2           censed under the law of the permitted country in  
3           which the exporter is located to dispense prescription  
4           drugs in sufficient number to dispense safely the  
5           drugs exported by the exporter to individuals, and  
6           the exporter assigns to those persons responsibility  
7           for dispensing such drugs to individuals.

8           “(i) INDIVIDUALS; CONDITIONS FOR IMPORTA-  
9           TION.—

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

14                   “(A) The drug is accompanied by a copy of  
15                   a prescription for the drug, which prescrip-  
16                   tion—

17                           “(i) is valid under applicable Federal  
18                           and State laws; and

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

1           “(B) The drug is accompanied by a copy  
2 of the documentation that was required under  
3 the law or regulations of the permitted country  
4 in which the exporter is located, as a condition  
5 of dispensing the drug to the individual.

6           “(C) The copies referred to in subpara-  
7 graphs (A)(i) and (B) are marked in a manner  
8 sufficient—

9                   “(i) to indicate that the prescription,  
10 and the equivalent document in the per-  
11 mitted country in which the exporter is lo-  
12 cated, have been filled; and

13                   “(ii) to prevent a duplicative filling by  
14 another pharmacist.

15           “(D) The individual has provided to the  
16 registered exporter a complete list of all drugs  
17 used by the individual for review by the individ-  
18 uals who dispense the drug.

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

21           “(F) The drug is not an ineligible subpart  
22 H drug. For purposes of this section, a pre-  
23 scription drug is an ‘ineligible subpart H drug’  
24 if the drug was approved by the Secretary  
25 under subpart H of part 314 of title 21, Code

1 of Federal Regulations (relating to accelerated  
2 approval), with restrictions under section 520 of  
3 such part to assure safe use, and the Secretary  
4 has published in the Federal Register a notice  
5 that the Secretary has determined that good  
6 cause exists to prohibit the drug from being im-  
7 ported pursuant to this subsection.

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

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

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

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

21 “(B) maintain samples of each lot of a  
22 qualifying drug required under this section for  
23 not less than 2 years.

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

4           “(A) in the case of an importer, at the  
5 place of business of the importer at which the  
6 importer initially receives the qualifying drug  
7 after importation; or

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

11       “(k) DRUG RECALLS.—

12           “(1) MANUFACTURERS.—A person that manu-  
13 factures a qualifying drug imported from a per-  
14 mitted country under this section shall promptly in-  
15 form the Secretary—

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

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

20           “(C) the reason for the recall or with-  
21 drawal.

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

24           “(A) enter into an agreement with the gov-  
25 ernment of the country to receive information

1           about recalls and withdrawals of qualifying  
2           drugs in the country; or

3           “(B) monitor recalls and withdrawals of  
4           qualifying drugs in the country using any infor-  
5           mation that is available to the public in any  
6           media.

7           “(3) NOTICE.—The Secretary may notify, as  
8           appropriate, registered exporters, registered import-  
9           ers, wholesalers, pharmacies, or the public of a recall  
10          or withdrawal of a qualifying drug in a permitted  
11          country.

12          “(1) DRUG LABELING.—When a qualifying drug that  
13          is imported into the United States by an importer under  
14          subsection (a) is dispensed by a pharmacist to an indi-  
15          vidual, the pharmacist shall provide that the packaging  
16          and labeling of the drug complies with all applicable regu-  
17          lations promulgated under sections 3 and 4 of the Poison  
18          Prevention Packaging Act of 1970 (15 U.S.C. 1471 et  
19          seq.) and include with any other labeling provided to the  
20          individual the following:

21                  “(1) The lot number assigned by the manufac-  
22          turer.

23                  “(2) The name and registration number of the  
24          importer.

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

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

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

11           “(4) If required under paragraph  
12           (2)(B)(vi)(III) of subsection (g), a prominent advi-  
13           sory that the drug is safe and effective but not bio-  
14           equivalent to the U.S. label drug.

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

23           “(n) UNFAIR AND DISCRIMINATORY ACTS AND PRAC-  
24           TICES.—



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

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

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

24                   “(C) discriminate by denying, restricting,  
25          or delaying supplies of a prescription drug to a

1 registered exporter or other person in a per-  
2 mitted country that exports a qualifying drug to  
3 the United States under this section or to a  
4 registered importer or other person that distrib-  
5 utes, sells, or uses a qualifying drug imported  
6 into the United States under this section;

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

15 “(E) knowingly fail to submit a notice  
16 under subsection (g)(2)(B)(i), knowingly fail to  
17 submit such a notice on or before the date spec-  
18 ified in subsection (g)(2)(B)(v) or as otherwise  
19 required under subsection (e) (3), (4), and (5)  
20 of section 4 of the Pharmaceutical Market Ac-  
21 cess and Drug Safety Act of 2005, knowingly  
22 submit such a notice that makes a materially  
23 false, fictitious, or fraudulent statement, or  
24 knowingly fail to provide promptly any informa-

1           tion requested by the Secretary to review such  
2           a notice;

3           “(F) knowingly fail to submit an applica-  
4           tion required under subsection (g)(2)(F), know-  
5           ingly fail to submit such an application on or  
6           before the date specified in subsection  
7           (g)(2)(F)(ii), knowingly submit such an applica-  
8           tion that makes a materially false, fictitious, or  
9           fraudulent statement, or knowingly fail to pro-  
10          vide promptly any information requested by the  
11          Secretary to review such an application;

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

20          “(H) refuse to allow an inspection author-  
21          ized under this section of an establishment that  
22          manufactures a qualifying drug that is, or will  
23          be, introduced for commercial distribution in a  
24          permitted country;

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

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

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

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

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

23           “(2) AFFIRMATIVE DEFENSE.—

24           “(A) DISCRIMINATION.—It shall be an af-  
25 firmative defense to a charge that a manufac-

1 turer has discriminated under subparagraph  
2 (A), (B), (C), (D), or (M) of paragraph (1) that  
3 the higher price charged for a prescription drug  
4 sold to a person, the denial, restriction, or delay  
5 of supplies of a prescription drug to a person,  
6 the refusal to do business with a person, or  
7 other discriminatory activity against a person,  
8 is not based, in whole or in part, on—

9 “(i) the person exporting or importing  
10 a qualifying drug into the United States  
11 under this section; or

12 “(ii) the person distributing, selling,  
13 or using a qualifying drug imported into  
14 the United States under this section.

15 “(B) DRUG DIFFERENCES.—It shall be an  
16 affirmative defense to a charge that a manufac-  
17 turer has caused there to be a difference de-  
18 scribed in subparagraph (G) of paragraph (1)  
19 that—

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

22 “(ii) the Secretary has determined  
23 that the difference was necessary to im-  
24 prove the safety or effectiveness of the  
25 drug;

1           “(iii) the person manufacturing the  
2           drug for distribution in the United States  
3           has given notice to the Secretary under  
4           subsection (g)(2)(B)(i) that the drug for  
5           distribution in the United States is not dif-  
6           ferent from a drug for distribution in per-  
7           mitted countries whose combined popu-  
8           lation represents at least 50 percent of the  
9           total population of all permitted countries;  
10          or

11          “(iv) the difference was not caused, in  
12          whole or in part, for the purpose of re-  
13          stricting importation of the drug into the  
14          United States under this section.

15          “(3) EFFECT OF SUBSECTION.—

16          “(A) SALES IN OTHER COUNTRIES.—This  
17          subsection applies only to the sale or distribu-  
18          tion of a prescription drug in a country if the  
19          manufacturer of the drug chooses to sell or dis-  
20          tribute the drug in the country. Nothing in this  
21          subsection shall be construed to compel the  
22          manufacturer of a drug to distribute or sell the  
23          drug in a country.

24          “(B) DISCOUNTS TO INSURERS, HEALTH  
25          PLANS, PHARMACY BENEFIT MANAGERS, AND

1 COVERED ENTITIES.—Nothing in this sub-  
2 section shall be construed to—

3 “(i) prevent or restrict a manufac-  
4 turer of a prescription drug from providing  
5 discounts to an insurer, health plan, phar-  
6 macy benefit manager in the United  
7 States, or covered entity in the drug dis-  
8 count program under section 340B of the  
9 Public Health Service Act (42 U.S.C.  
10 256b) in return for inclusion of the drug  
11 on a formulary;

12 “(ii) require that such discounts be  
13 made available to other purchasers of the  
14 prescription drug; or

15 “(iii) prevent or restrict any other  
16 measures taken by an insurer, health plan,  
17 or pharmacy benefit manager to encourage  
18 consumption of such prescription drug.

19 “(C) CHARITABLE CONTRIBUTIONS.—  
20 Nothing in this subsection shall be construed  
21 to—

22 “(i) prevent a manufacturer from do-  
23 nating a prescription drug, or supplying a  
24 prescription drug at nominal cost, to a  
25 charitable or humanitarian organization,

1 including the United Nations and affili-  
2 ates, or to a government of a foreign coun-  
3 try; or

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

6 “(4) ENFORCEMENT.—

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

13 “(B) ACTIONS BY THE COMMISSION.—The  
14 Federal Trade Commission—

15 “(i) shall enforce this subsection in  
16 the same manner, by the same means, and  
17 with the same jurisdiction, powers, and du-  
18 ties as though all applicable terms and pro-  
19 visions of the Federal Trade Commission  
20 Act (15 U.S.C. 41 et seq.) were incor-  
21 porated into and made a part of this sec-  
22 tion; and

23 “(ii) may seek monetary relief three-  
24 fold the damages sustained, in addition to  
25 any other remedy available to the Federal



1 Trade Commission under the Federal  
2 Trade Commission Act (15 U.S.C. 41 et  
3 seq.).

4 “(5) ACTIONS BY STATES.—

5 “(A) IN GENERAL.—

6 “(i) CIVIL ACTIONS.—In any case in  
7 which the attorney general of a State has  
8 reason to believe that an interest of the  
9 residents of that State have been adversely  
10 affected by any manufacturer that violates  
11 paragraph (1), the attorney general of a  
12 State may bring a civil action on behalf of  
13 the residents of the State, and persons  
14 doing business in the State, in a district  
15 court of the United States of appropriate  
16 jurisdiction to—

17 “(I) enjoin that practice;

18 “(II) enforce compliance with  
19 this subsection;

20 “(III) obtain damages, restitu-  
21 tion, or other compensation on behalf  
22 of residents of the State and persons  
23 doing business in the State, including  
24 threefold the damages; or

1           “(IV) obtain such other relief as  
2           the court may consider to be appro-  
3           priate.

4           “(ii) NOTICE.—

5           “(I) IN GENERAL.—Before filing  
6           an action under clause (i), the attor-  
7           ney general of the State involved shall  
8           provide to the Federal Trade Commis-  
9           sion—

10                   “(aa) written notice of that  
11                   action; and

12                   “(bb) a copy of the com-  
13                   plaint for that action.

14           “(II) EXEMPTION.—Subclause  
15           (I) shall not apply with respect to the  
16           filing of an action by an attorney gen-  
17           eral of a State under this paragraph,  
18           if the attorney general determines  
19           that it is not feasible to provide the  
20           notice described in that subclause be-  
21           fore filing of the action. In such case,  
22           the attorney general of a State shall  
23           provide notice and a copy of the com-  
24           plaint to the Federal Trade Commis-

1                   sion at the same time as the attorney  
2                   general files the action.

3                   “(B) INTERVENTION.—

4                   “(i) IN GENERAL.—On receiving no-  
5                   tice under subparagraph (A)(ii), the Fed-  
6                   eral Trade Commission shall have the right  
7                   to intervene in the action that is the sub-  
8                   ject of the notice.

9                   “(ii) EFFECT OF INTERVENTION.—If  
10                  the Federal Trade Commission intervenes  
11                  in an action under subparagraph (A), it  
12                  shall have the right—

13                         “(I) to be heard with respect to  
14                         any matter that arises in that action;  
15                         and

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

17                  “(C) CONSTRUCTION.—For purposes of  
18                  bringing any civil action under subparagraph  
19                  (A), nothing in this subsection shall be con-  
20                  strued to prevent an attorney general of a State  
21                  from exercising the powers conferred on the at-  
22                  torney general by the laws of that State to—

23                         “(i) conduct investigations;

24                         “(ii) administer oaths or affirmations;

25                         or

1           “(iii) compel the attendance of wit-  
2           nesses or the production of documentary  
3           and other evidence.

4           “(D) ACTIONS BY THE COMMISSION.—In  
5           any case in which an action is instituted by or  
6           on behalf of the Federal Trade Commission for  
7           a violation of paragraph (1), a State may not,  
8           during the pendency of that action, institute an  
9           action under subparagraph (A) for the same  
10          violation against any defendant named in the  
11          complaint in that action.

12          “(E) VENUE.—Any action brought under  
13          subparagraph (A) may be brought in the dis-  
14          trict court of the United States that meets ap-  
15          plicable requirements relating to venue under  
16          section 1391 of title 28, United States Code.

17          “(F) SERVICE OF PROCESS.—In an action  
18          brought under subparagraph (A), process may  
19          be served in any district in which the defend-  
20          ant—

21                  “(i) is an inhabitant; or

22                  “(ii) may be found.

23          “(G) MEASUREMENT OF DAMAGES.—In  
24          any action under this paragraph to enforce a  
25          cause of action under this subsection in which

1           there has been a determination that a defend-  
2           ant has violated a provision of this subsection,  
3           damages may be proved and assessed in the ag-  
4           gregate by statistical or sampling methods, by  
5           the computation of illegal overcharges or by  
6           such other reasonable system of estimating ag-  
7           gregate damages as the court in its discretion  
8           may permit without the necessity of separately  
9           proving the individual claim of, or amount of  
10          damage to, persons on whose behalf the suit  
11          was brought.

12                 “(H) EXCLUSION ON DUPLICATIVE RE-  
13           LIEF.—The district court shall exclude from the  
14           amount of monetary relief awarded in an action  
15           under this paragraph brought by the attorney  
16           general of a State any amount of monetary re-  
17           lief which duplicates amounts which have been  
18           awarded for the same injury.

19                 “(6) EFFECT ON ANTITRUST LAWS.—Nothing  
20           in this subsection shall be construed to modify, im-  
21           pair, or supersede the operation of the antitrust  
22           laws. For the purpose of this subsection, the term  
23           ‘antitrust laws’ has the meaning given it in the first  
24           section of the Clayton Act, except that it includes  
25           section 5 of the Federal Trade Commission Act to

1 the extent that such section 5 applies to unfair  
2 methods of competition.

3 “(7) MANUFACTURER.—In this subsection, the  
4 term ‘manufacturer’ means any entity, including any  
5 affiliate or licensee of that entity, that is engaged  
6 in—

7 “(A) the production, preparation, propaga-  
8 tion, compounding, conversion, or processing of  
9 a prescription drug, either directly or indirectly  
10 by extraction from substances of natural origin,  
11 or independently by means of chemical syn-  
12 thesis, or by a combination of extraction and  
13 chemical synthesis; or

14 “(B) the packaging, repackaging, labeling,  
15 relabeling, or distribution of a prescription  
16 drug.”.

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

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

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

1           “(A) a sale at retail made pursuant to dis-  
2           pensing the drug to a customer of the pharmacist or  
3           organization; or

4           “(B) a sale or trade of the drug to a pharmacy  
5           or a wholesaler registered to import drugs under sec-  
6           tion 804.

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

10          “(3) The making of a materially false, fictitious, or  
11          fraudulent statement or representation, or a material  
12          omission, in a notice under clause (i) of section  
13          804(g)(2)(B) or in an application required under section  
14          804(g)(2)(F), or the failure to submit such a notice or  
15          application.

16          “(4) The importation of a drug in violation of a reg-  
17          istration condition or other requirement under section  
18          804, the falsification of any record required to be main-  
19          tained, or provided to the Secretary, under such section,  
20          or the violation of any registration condition or other re-  
21          quirement under such section.”; and

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

24                 “(6) Notwithstanding subsection (a), any person that  
25                 knowingly violates section 301(i) (2) or (3) or section

1 301(aa)(4) shall be imprisoned not more than 10 years,  
2 or fined in accordance with title 18, United States Code,  
3 or both.”.

4 (c) AMENDMENT OF CERTAIN PROVISIONS.—

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

9 “(g) With respect to a prescription drug that is im-  
10 ported or offered for import into the United States by an  
11 individual who is not in the business of such importation,  
12 that is not shipped by a registered exporter under section  
13 804, and that is refused admission under subsection (a),  
14 the Secretary shall notify the individual that—

15 “(1) the drug has been refused admission be-  
16 cause the drug was not a lawful import under sec-  
17 tion 804;

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

20 “(3) the individual may under section 804 law-  
21 fully import certain prescription drugs from export-  
22 ers registered with the Secretary under section 804;  
23 and

24 “(4) the individual can find information about  
25 such importation, including a list of registered ex-



1 porters, on the Internet website of the Food and  
2 Drug Administration or through a toll-free telephone  
3 number required under section 804.”.

4 (2) ESTABLISHMENT REGISTRATION.—Section  
5 510(i) of the Federal Food, Drug, and Cosmetic Act  
6 (21 U.S.C. 360(i)) is amended in paragraph (1) by  
7 inserting after “import into the United States” the  
8 following: “, including a drug that is, or may be, im-  
9 ported or offered for import into the United States  
10 under section 804,”.

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

14 (d) EXHAUSTION.—

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

17 (A) by redesignating subsections (h) and

18 (i) as (i) and (j), respectively; and

19 (B) by inserting after subsection (g) the

20 following:

21 “(h) It shall not be an act of infringement to use,  
22 offer to sell, or sell within the United States or to import  
23 into the United States any patented invention under sec-  
24 tion 804 of the Federal Food, Drug, and Cosmetic Act

1 that was first sold abroad by or under authority of the  
2 owner or licensee of such patent.”.

3 (2) RULE OF CONSTRUCTION.—Nothing in the  
4 amendment made by paragraph (1) shall be con-  
5 strued to affect the ability of a patent owner or li-  
6 censee to enforce their patent, subject to such  
7 amendment.

8 (e) EFFECT OF SECTION 804.—

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

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

18 (B) from permitted countries, as defined in  
19 such section 804, by importers registered under  
20 such section 804 on the date that is 1 year  
21 after the date of enactment of this Act.

22 (2) REVIEW OF REGISTRATION BY CERTAIN EX-  
23 PORTERS.—

24 (A) REVIEW PRIORITY.—In the review of  
25 registrations submitted under subsection (b) of

1 such section 804, registrations submitted by en-  
2 tities in Canada that are significant exporters  
3 of prescription drugs to individuals in the  
4 United States as of the date of enactment of  
5 this Act will have priority during the 90 day pe-  
6 riod that begins on such date of enactment.

7 (B) PERIOD FOR REVIEW.—During such  
8 90-day period, the reference in subsection  
9 (b)(2)(A) of such section 804 to 90 days (relat-  
10 ing to approval or disapproval of registrations)  
11 is, as applied to such entities, deemed to be 30  
12 days.

13 (C) LIMITATION.—That an exporter in  
14 Canada exports, or has exported, prescription  
15 drugs to individuals in the United States on or  
16 before the date that is 90 days after the date  
17 of enactment of this Act shall not serve as a  
18 basis, in whole or in part, for disapproving a  
19 registration under such section 804 from the  
20 exporter.

21 (D) FIRST YEAR LIMIT ON NUMBER OF  
22 EXPORTERS.—During the 1-year period begin-  
23 ning on the date of enactment of this Act, the  
24 Secretary of Health and Human Services (re-  
25 ferred to in this section as the “Secretary”)

1           may limit the number of registered exporters  
2           under such section 804 to not less than 50, so  
3           long as the Secretary gives priority to those ex-  
4           porters with demonstrated ability to process a  
5           high volume of shipments of drugs to individ-  
6           uals in the United States.

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

17          (F) FURTHER LIMIT ON NUMBER OF EX-  
18          PORTERS.—The Secretary shall report to Con-  
19          gress to request the authority to impose a limi-  
20          tation on the number of registered exporters  
21          under such section 804 during any period be-  
22          ginning on a date that is not less than 2 years  
23          after the date of enactment of this Act if the  
24          Secretary determines that—

1 (i) a limitation on the number of reg-  
2 istered exporters is necessary for the effec-  
3 tive and efficient enforcement of the re-  
4 quirements of such section 804 with re-  
5 spect to such exporters; and

6 (ii) such limitation will not restrict  
7 the ability of individuals to import pre-  
8 scription drugs for personal use from reg-  
9 istered exporters under such section 804.

10 (3) LIMITS ON NUMBER OF IMPORTERS.—

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

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

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

12           (C) FURTHER LIMIT ON NUMBER OF IM-  
13          PORTERS.—The Secretary shall report to Con-  
14          gress to request the authority to impose a limi-  
15          tation on the number of registered importers  
16          under such section 804 during any period be-  
17          ginning on a date that is not less than 3 years  
18          after the date of enactment of this Act if the  
19          Secretary determines that—

20                   (i) a limitation on the number of reg-  
21                   istered importers is necessary for the effec-  
22                   tive and efficient enforcement of the re-  
23                   quirements of such section 804 with re-  
24                   spect to such importers; and

1                   (ii) such limitation will not restrict  
2                   the ability of individuals to purchase quali-  
3                   fying drugs imported under such section  
4                   804 or savings available to individuals by  
5                   purchasing such qualifying drugs.

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

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

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

23                   (5) NOTICE FOR DRUGS FOR IMPORT FROM  
24                   OTHER COUNTRIES.—The notice with respect to a  
25                   qualifying drug introduced for commercial distribu-

1       tion in a permitted country other than Canada as of  
2       the date of enactment of this Act that is required  
3       under subsection (g)(2)(B)(i) of such section 804  
4       shall be submitted to the Secretary not later than  
5       180 days after the date of enactment of this Act  
6       if—

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

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

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

16              (A) GUIDANCE ON SUBMISSION DATES.—

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

24              (B) CONSISTENT AND EFFICIENT USE OF  
25              RESOURCES.—The Secretary shall establish the



1 dates described under subparagraph (A) so that  
2 such notices described under subparagraph (A)  
3 are submitted and reviewed at a rate that al-  
4 lows consistent and efficient use of the re-  
5 sources and staff available to the Secretary for  
6 such reviews. Review of all such notices shall be  
7 completed not later than 5 years after the date  
8 of enactment of this Act.

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

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

1       tion 804, without regard to paragraph (4), (5), or  
2       (6).

3           (8) REPORT.—Beginning with fiscal year 2006,  
4       not later than 90 days after the end of each fiscal  
5       year during which the Secretary reviews a notice re-  
6       ferred to in paragraph (4), (5), or (6), the Secretary  
7       shall submit a report to Congress concerning the  
8       progress of the Food and Drug Administration in re-  
9       viewing the notices referred to in paragraphs (4),  
10      (5), and (6).

11          (9) USER FEES.—

12           (A) EXPORTERS.—When establishing an  
13      aggregate total of fees to be collected from ex-  
14      porters under subsection (f)(2) of such section  
15      804, the Secretary shall, under subsection  
16      (f)(3)(C)(i) of such section 804, estimate the  
17      total price of drugs imported under subsection  
18      (a) of such section 804 into the United States  
19      by registered exporters during fiscal year 2006  
20      to be \$1,000,000,000.

21           (B) IMPORTERS.—When establishing an  
22      aggregate total of fees to be collected from im-  
23      porters under subsection (e)(2) of such section  
24      804, the Secretary shall, under subsection  
25      (e)(3)(C)(i) of such section 804, estimate the

1 total price of drugs imported under subsection  
2 (a) of such section 804 into the United States  
3 by registered importers during—

4 (i) fiscal year 2006 to be  
5 \$1,000,000,000; and

6 (ii) fiscal year 2007 to be  
7 \$10,000,000,000.

8 (C) FISCAL YEAR 2007 ADJUSTMENT.—

9 (i) REPORTS.—Not later than Feb-  
10 ruary 20, 2007, registered importers shall  
11 report to the Secretary the total price and  
12 the total volume of drugs imported to the  
13 United States by the importer during the  
14 4-month period from October 1, 2006,  
15 through January 31, 2007.

16 (ii) REESTIMATE.—Notwithstanding  
17 subsection (e)(3)(C)(ii) of such section 804  
18 or subparagraph (B), the Secretary shall  
19 reestimate the total price of qualifying  
20 drugs imported under subsection (a) of  
21 such section 804 into the United States by  
22 registered importers during fiscal year  
23 2007. Such reestimate shall be equal to—

24 (I) the total price of qualifying  
25 drugs imported by each importer as

1 reported under clause (i); multiplied  
2 by

3 (II) 3.

4 (iii) ADJUSTMENT.—The Secretary  
5 shall adjust the fee due on April 1, 2007,  
6 from each importer so that the aggregate  
7 total of fees collected under subsection  
8 (e)(2) for fiscal year 2007 does not exceed  
9 the total price of qualifying drugs imported  
10 under subsection (a) of such section 804  
11 into the United States by registered im-  
12 porters during fiscal year 2007 as reesti-  
13 mated under clause (ii).

14 (D) ANNUAL REPORT.—

15 (i) FOOD AND DRUG ADMINISTRA-  
16 TION.—Beginning with fiscal year 2006,  
17 not later than 180 days after the end of  
18 each fiscal year during which fees are col-  
19 lected under subsection (e), (f), or  
20 (g)(2)(B)(iv) of such section 804, the Sec-  
21 retary shall prepare and submit to the  
22 House of Representatives and the Senate a  
23 report on the implementation of the au-  
24 thority for such fees during such fiscal  
25 year and the use, by the Food and Drug

1 Administration, of the fees collected for the  
2 fiscal year for which the report is made  
3 and credited to the Food and Drug Admin-  
4 istration.

5 (ii) CUSTOMS AND BORDER CON-  
6 TROL.—Beginning with fiscal year 2006,  
7 not later than 180 days after the end of  
8 each fiscal year during which fees are col-  
9 lected under subsection (e) or (f) of such  
10 section 804, the Secretary of Homeland  
11 Security, in consultation with the Sec-  
12 retary of the Treasury, shall prepare and  
13 submit to the House of Representatives  
14 and the Senate a report on the use, by the  
15 Bureau of Customs and Border Protection,  
16 of the fees, if any, transferred by the Sec-  
17 retary to the Bureau of Customs and Bor-  
18 der Protection for the fiscal year for which  
19 the report is made.

20 (f) IMPLEMENTATION OF SECTION 804.—

21 (1) INTERIM RULE.—The Secretary may pro-  
22 mulgate an interim rule for implementing section  
23 804 of the Federal Food, Drug, and Cosmetic Act,  
24 as added by subsection (a) of this section.

1           (2) NO NOTICE OF PROPOSED RULEMAKING.—

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

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

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

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

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

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

12          (h) EFFECT ON ADMINISTRATION PRACTICES.—Not-  
13          withstanding any provision of this Act (and the amend-  
14          ments made by this Act), nothing in this Act (or the  
15          amendments made by this Act) shall be construed to  
16          change, limit, or restrict the practices of the Food and  
17          Drug Administration or the Bureau of Customs and Bor-  
18          der Protection in effect on January 1, 2004, with respect  
19          to the importation of prescription drugs into the United  
20          States by an individual, on the person of such individual,  
21          for personal use.

22          **SEC. 5. DISPOSITION OF CERTAIN DRUGS DENIED ADMIS-**  
23          **SION INTO UNITED STATES.**

24          (a) IN GENERAL.—Chapter VIII of the Federal  
25          Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.),

1 as amended by section 3, is further amended by adding  
2 at the end the following section:

3 **“SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED AD-**  
4 **MISSION.**

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

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

11 “(2)(A) the shipping container for such drugs  
12 does not bear the markings required under section  
13 804(d)(2); or

14 “(B) the Secretary has requested delivery of  
15 such shipment of drugs.

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

21 “(c) DESTRUCTION OF VIOLATIVE SHIPMENT.—The  
22 Secretary shall destroy a shipment of drugs delivered by  
23 the Secretary of Homeland Security to the Secretary  
24 under subsection (a) if—



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

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

9           “(d) CERTAIN PROCEDURES.—

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

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

24           “(e) EVIDENCE EXCEPTION.—Drugs may not be de-  
25 stroyed under subsection (c) to the extent that the Attor-

1 ney General of the United States determines that the  
2 drugs should be preserved as evidence or potential evi-  
3 dence with respect to an offense against the United States.

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

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

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

16 **SEC. 6. CIVIL ACTIONS REGARDING PROPERTY.**

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

20 “(g)(1) If a person is alienating or disposing of prop-  
21 erty, or intends to alienate or dispose of property, that  
22 is obtained as a result of or is traceable to a drug imported  
23 in violation of section 801(a) or 801(d), the Attorney Gen-  
24 eral may commence a civil action in any Federal court—

1           “(A) to enjoin such alienation or disposition of  
2 property; or

3           “(B) for a restraining order to—

4                 “(i) prohibit any person from withdrawing,  
5 transferring, removing, dissipating, or disposing  
6 of any such property or property of equivalent  
7 value; and

8                 “(ii) appoint a temporary receiver to ad-  
9 minister such restraining order.

10           “(2) Proceedings under paragraph (1) shall be car-  
11 ried out in the same manner as applies under section 1345  
12 of title 18, United States Code.”.

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

16 **SEC. 7. WHOLESALE DISTRIBUTION OF DRUGS; STATE-**  
17 **MENTS REGARDING PRIOR SALE, PURCHASE,**  
18 **OR TRADE.**

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

23                 (1) in paragraph (1)—

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

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

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

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

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

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

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

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

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

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

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

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

8       (c) EFFECTIVE DATE.—

9           (1) IN GENERAL.—The amendments made by  
10 paragraphs (1) and (3) of subsection (a) and by sub-  
11 section (b) shall take effect on January 1, 2010.

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

21           (3) HIGH-RISK DRUGS.—

22           (A) IN GENERAL.—Notwithstanding para-  
23 graph (1), the Secretary of Health and Human  
24 Services (referred to in this section as the “Sec-  
25 retary”) may apply the amendments made by

1 paragraphs (1) and (3) of subsection (a) and by  
2 subsection (b) before January 1, 2010, with re-  
3 spect to a prescription drug if the Secretary—

4 (i) determines that the drug is at high  
5 risk for being counterfeited; and

6 (ii) publishes the determination and  
7 the basis for the determination in the Fed-  
8 eral Register.

9 (B) PEDIGREE NOT REQUIRED.—Notwith-  
10 standing a determination under subparagraph  
11 (A) with respect to a prescription drug, the  
12 amendments described in such subparagraph  
13 shall not apply with respect to a wholesale dis-  
14 tribution of such drug if the drug is distributed  
15 by the manufacturer of the drug to a person  
16 that distributes the drug to a retail pharmacy  
17 for distribution to the consumer or patient, with  
18 no other intervening transactions.

19 (C) LIMITATION.—The Secretary may  
20 make the determination under subparagraph  
21 (A) with respect to not more than 50 drugs be-  
22 fore January 1, 2010.

23 (4) EFFECT WITH RESPECT TO REGISTERED  
24 EXPORTERS.—The amendment made by subsection

1 (a)(2) shall take effect on the date that is 90 days  
2 after the date of enactment of this Act.

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

8 (A) January 1, 2008, with respect to a  
9 prescription drug determined under paragraph  
10 (3)(A) to be at high risk for being counter-  
11 feited; and

12 (B) January 1, 2010, with respect to all  
13 other prescription drugs.

14 (6) INTERMEDIATE REQUIREMENTS.—With re-  
15 spect to the prescription drugs described under para-  
16 graph (5)(B), the Secretary shall by regulation re-  
17 quire the use of standardized anti-counterfeiting or  
18 track-and-trace technologies on such prescription  
19 drugs at the case and pallet level effective not later  
20 than January 1, 2008.

21 **SEC. 8. INTERNET SALES OF PRESCRIPTION DRUGS.**

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



1 **“SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.**

2 “(a) REQUIREMENTS REGARDING INFORMATION ON  
3 INTERNET SITE.—

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

7 “(A) the purchaser of the drug submitted  
8 the purchase order for the drug, or conducted  
9 any other part of the sales transaction for the  
10 drug, through an Internet site;

11 “(B) the person dispenses the drug to the  
12 purchaser by mailing or shipping the drug to  
13 the purchaser; and

14 “(C) such site, or any other Internet site  
15 used by such person for purposes of sales of a  
16 prescription drug, fails to meet each of the re-  
17 quirements specified in paragraph (2), other  
18 than a site or pages on a site that—

19 “(i) are not intended to be accessed  
20 by purchasers or prospective purchasers; or

21 “(ii) provide an Internet information  
22 location tool within the meaning of section  
23 231(e)(5) of the Communications Act of  
24 1934 (47 U.S.C. 231(e)(5)).

25 “(2) REQUIREMENTS.—With respect to an  
26 Internet site, the requirements referred to in sub-

1 paragraph (C) of paragraph (1) for a person to  
2 whom such paragraph applies are as follows:

3 “(A) Each page of the site shall include ei-  
4 ther the following information or a link to a  
5 page that provides the following information:

6 “(i) The name of such person.

7 “(ii) Each State in which the person  
8 is authorized by law to dispense prescrip-  
9 tion drugs.

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

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

22 “(v) If the person provides for medical  
23 consultations through the site for purposes  
24 of providing prescriptions, the name of  
25 each individual who provides such con-

1           sultations; each State in which the indi-  
2           vidual is licensed or otherwise authorized  
3           by law to provide such consultations or  
4           practice medicine; and the type or types of  
5           health professions for which the individual  
6           holds such licenses or other authorizations.

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

12          “(b) INTERNET SALES WITHOUT APPROPRIATE  
13          MEDICAL RELATIONSHIPS.—

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

17                         “(A) for purposes of such dispensing or  
18                         sale, the purchaser communicated with the per-  
19                         son through the Internet;

20                         “(B) the patient for whom the drug was  
21                         dispensed or purchased did not, when such  
22                         communications began, have a prescription for  
23                         the drug that is valid in the United States;

24                         “(C) pursuant to such communications, the  
25                         person provided for the involvement of a practi-

1           tioner, or an individual represented by the per-  
2           son as a practitioner, and the practitioner or  
3           such individual issued a prescription for the  
4           drug that was purchased;

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

10           “(E) the person received payment for the  
11           dispensing or sale of the drug.

12           For purposes of subparagraph (E), payment is re-  
13           ceived if money or other other valuable consideration  
14           is received.

15           “(2) EXCEPTIONS.—Paragraph (1) does not  
16           apply to—

17           “(A) the dispensing or selling of a pre-  
18           scription drug pursuant to telemedicine prac-  
19           tices sponsored by—

20           “(i) a hospital that has in effect a  
21           provider agreement under title XVIII of  
22           the Social Security Act (relating to the  
23           Medicare program); or

24           “(ii) a group practice that has not  
25           fewer than 100 physicians who have in ef-

1           fect provider agreements under such title;  
2           or

3           “(B) the dispensing or selling of a pre-  
4           scription drug pursuant to practices that pro-  
5           mote the public health, as determined by the  
6           Secretary by regulation.

7           “(3) QUALIFYING MEDICAL RELATIONSHIP.—

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

13                 “(i) at least one in-person medical  
14                 evaluation of the patient has been con-  
15                 ducted by the practitioner; or

16                 “(ii) the practitioner conducts a med-  
17                 ical evaluation of the patient as a covering  
18                 practitioner.

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

20          A medical evaluation by a practitioner is an in-  
21          person medical evaluation for purposes of this  
22          section if the practitioner is in the physical  
23          presence of the patient as part of conducting  
24          the evaluation, without regard to whether por-

1 tions of the evaluation are conducted by other  
2 health professionals.

3 “(C) COVERING PRACTITIONER.—With re-  
4 spect to a patient, a practitioner is a covering  
5 practitioner for purposes of this section if the  
6 practitioner conducts a medical evaluation of  
7 the patient at the request of a practitioner who  
8 has conducted at least one in-person medical  
9 evaluation of the patient and is temporarily un-  
10 available to conduct the evaluation of the pa-  
11 tient. A practitioner is a covering practitioner  
12 without regard to whether the practitioner has  
13 conducted any in-person medical evaluation of  
14 the patient involved.

15 “(4) RULES OF CONSTRUCTION.—

16 “(A) INDIVIDUALS REPRESENTED AS  
17 PRACTITIONERS.—A person who is not a practi-  
18 tioner (as defined in subsection (e)(1)) lacks  
19 legal capacity under this section to have a  
20 qualifying medical relationship with any patient.

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

1           “(C) APPLICABILITY OF REQUIRE-  
2           MENTS.—Paragraph (3) may not be construed  
3           as having any applicability beyond this section,  
4           and does not affect any State law, or interpre-  
5           tation of State law, concerning the practice of  
6           medicine.

7           “(c) ACTIONS BY STATES.—

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

23          “(2) NOTICE.—The State shall serve prior writ-  
24          ten notice of any civil action under paragraph (1) or  
25          (5)(B) upon the Secretary and provide the Secretary

1 with a copy of its complaint, except that if it is not  
2 feasible for the State to provide such prior notice,  
3 the State shall serve such notice immediately upon  
4 instituting such action. Upon receiving a notice re-  
5 specting a civil action, the Secretary shall have the  
6 right—

7 “(A) to intervene in such action;

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

10 “(C) to file petitions for appeal.

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

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



1 any district in which the defendant is an inhabitant  
2 or in which the defendant may be found.

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

4 “(A) Nothing contained in this section  
5 shall prohibit an authorized State official from  
6 proceeding in State court on the basis of an al-  
7 leged violation of any civil or criminal statute of  
8 such State.

9 “(B) In addition to actions brought by an  
10 attorney general of a State under paragraph  
11 (1), such an action may be brought by officers  
12 of such State who are authorized by the State  
13 to bring actions in such State on behalf of its  
14 residents.

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

18 “(e) GENERAL DEFINITIONS.—For purposes of this  
19 section:

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

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

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

4           “(f) INTERNET-RELATED DEFINITIONS.—

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

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

16                  “(B) The term ‘link’, with respect to the  
17                  Internet, means one or more letters, words,  
18                  numbers, symbols, or graphic items that appear  
19                  on a page of an Internet site for the purpose  
20                  of serving, when activated, as a method for exe-  
21                  cuting an electronic command—

22                          “(i) to move from viewing one portion  
23                          of a page on such site to another portion  
24                          of the page;

1                   “(ii) to move from viewing one page  
2                   on such site to another page on such site;  
3                   or

4                   “(iii) to move from viewing a page on  
5                   one Internet site to a page on another  
6                   Internet site.

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

10                  “(D)(i) The terms ‘site’ and ‘address’, with  
11                  respect to the Internet, mean a specific location  
12                  on the Internet that is determined by Internet  
13                  Protocol numbers. Such term includes the do-  
14                  main name, if any.

15                  “(ii) The term ‘domain name’ means a  
16                  method of representing an Internet address  
17                  without direct reference to the Internet Protocol  
18                  numbers for the address, including methods  
19                  that use designations such as ‘.com’, ‘.edu’,  
20                  ‘.gov’, ‘.net’, or ‘.org’.

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

24                  “(2) AUTHORITY OF SECRETARY.—The Sec-  
25                  retary may by regulation modify any definition

1 under paragraph (1) to take into account changes in  
2 technology.

3 “(g) INTERACTIVE COMPUTER SERVICE; ADVER-  
4 TISING.—No provider of an interactive computer service,  
5 as defined in section 230(f)(2) of the Communications Act  
6 of 1934 (47 U.S.C. 230(f)(2)), or of advertising services  
7 shall be liable under this section for dispensing or selling  
8 prescription drugs in violation of this section on account  
9 of another person’s selling or dispensing such drugs, pro-  
10 vided that the provider of the interactive computer service  
11 or of advertising services does not own or exercise cor-  
12 porate control over such person.”.

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

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

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

1 procedures of public or private entities that certify that  
2 businesses selling prescription drugs through Internet  
3 sites are legitimate businesses, including practices and  
4 procedures regarding disclosure formats and verification  
5 programs.

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

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

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

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

24 (C) submitting, for each fiscal year for  
25 which the award under this subsection is made,

1 a report to the Secretary describing investiga-  
2 tions undertaken with respect to violations de-  
3 scribed in subparagraph (A).

4 (2) AUTHORIZATION OF APPROPRIATIONS.—For  
5 the purpose of carrying out paragraph (1), there is  
6 authorized to be appropriated \$100,000 for each of  
7 the fiscal years 2005 through 2007.

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

17 **SEC. 9. IMPORTATION EXEMPTION UNDER CONTROLLED**  
18 **SUBSTANCES IMPORT AND EXPORT ACT.**

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

1 the United States not more than 10 dosage units com-  
2 bined of all such controlled substances.”.

○