

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.

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

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), 2
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 “(l) 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) 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.”.

○