

108TH CONGRESS  
2D SESSION

# S. 2328

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

APRIL 21, 2004

Mr. DORGAN (for himself, Ms. SNOWE, Mr. KENNEDY, Mr. MCCAIN, Mr. DASCHLE, Mr. LOTT, Ms. STABENOW, Mr. CHAFEE, Mr. JOHNSON, Mr. PRYOR, and Mr. FEINGOLD) 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 2004”.

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 of this Act, is further amended  
6 by inserting 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.—The Secretary shall in ac-  
11 cordance with this section provide by regulation  
12 that, in the case of qualifying drugs imported or of-  
13 fered for import into the United States from reg-  
14 istered exporters or by registered importers—

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

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

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

24 “(A) the drug is imported by a pharmacy  
25 or a wholesaler that is a 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           prescription drug, other than any of the fol-  
8           lowing:

9                   “(i) A controlled substance, as defined  
10                  in section 102 of the Controlled Sub-  
11                  stances Act (21 U.S.C. 802).

12                  “(ii) A biological product, as defined  
13                  in section 351 of the Public Health Service  
14                  Act (42 U.S.C. 262).

15                  “(iii) An infused drug, including a  
16                  peritoneal dialysis solution.

17                  “(iv) An intravenously injected drug.

18                  “(v) A drug that is inhaled during  
19                  surgery.

20           “(C) OTHER DEFINITIONS.—For purposes  
21           of this section:

22                   “(i) The term ‘exporter’ means a per-  
23                  son that is in the business of exporting a  
24                  drug from Canada to individuals in the  
25                  United States or that, pursuant to submit-

1           ting a registration under subsection (b),  
2           seeks to be in such business.

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

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

14           “(iv) The term ‘pharmacy’ means a  
15           person that—

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

19                   “(II) employs 1 or more phar-  
20                   macists.

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

24           “(vi) The term ‘wholesaler’—

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

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

8                   “(D) PERMITTED COUNTRY.—The term  
9                   ‘permitted country’ means—

10                   “(i) Australia;

11                   “(ii) Canada;

12                   “(iii) a member country of the Euro-  
13                   pean Union as of January 1, 2003;

14                   “(iv) Japan;

15                   “(v) New Zealand; and

16                   “(vi) Switzerland.

17                   “(b) REGISTRATION OF IMPORTERS AND EXPORT-  
18                   ERS.—

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

24                   “(A) The name of the registrant and an  
25                   identification of all places of business of the

1           registrant that relate to qualifying drugs, in-  
2           cluding each warehouse or other facility owned  
3           or controlled by, or operated for, the registrant.

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

8                   “(i) in the case of an importer, sub-  
9                   sections (c), (d), (e), (g), and (j) (relating  
10                  to the sources of exported drugs; the in-  
11                  spection of facilities of the importer; the  
12                  payment of fees; compliance with the  
13                  standards referred to in section 801(a);  
14                  and maintenance of records and samples);  
15                  or

16                  “(ii) in the case of an exporter, sub-  
17                  sections (c), (d), (f), (g), (h), (i), and (j)  
18                  (relating to the sources of exported drugs;  
19                  the inspection of facilities of the exporter  
20                  and the marking of compliant shipments;  
21                  the payment of fees; and compliance with  
22                  the standards referred to in section 801(a);  
23                  being licensed as a pharmacist; conditions  
24                  for individual importation from Canada;  
25                  and maintenance of records and samples).

1           “(C) An agreement by the registrant that  
2 the registrant will not under subsection (a) im-  
3 port or export any drug that is not a qualifying  
4 drug.

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

6           “(i) notify the Secretary of a recall or  
7 withdrawal of a drug distributed in a per-  
8 mitted country that the registrant has ex-  
9 ported or imported, or intends to export or  
10 import, to the United States under sub-  
11 section (a);

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

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

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

1           “(F) A plan describing the manner in  
2 which the registrant will comply with the agree-  
3 ment under subparagraph (E).

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

10           “(H) An agreement by the registrant to  
11 notify the Secretary of—

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

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

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

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

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

1 States if, after opportunity for an informal  
2 hearing, the Secretary determines that the  
3 exporter has exported a drug to the United  
4 States that is not a qualifying drug or that  
5 is not in compliance with subsections (g)  
6 or (i), that is equal in value to the lesser  
7 of—

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

12 “(II) \$1,000,000.

13 “(J) Such other provisions as the Sec-  
14 retary may require to protect the public health  
15 while permitting—

16 “(i) the importation by pharmacies,  
17 groups of pharmacies, wholesalers as reg-  
18 istered importers of qualifying drugs under  
19 subsection (a); and

20 “(ii) importation by individuals of  
21 qualifying drugs under subsection (a).

22 “(2) APPROVAL OR DISAPPROVAL OF REGISTRA-  
23 TION.—

24 “(A) IN GENERAL.—Not later than 90  
25 days after the date on which a registrant sub-

1 mits to the Secretary a registration under para-  
2 graph (1), the Secretary shall notify the reg-  
3 istrant whether the registration is approved or  
4 is disapproved. The Secretary shall disapprove  
5 a registration if there is reason to believe that  
6 the registrant is not in compliance with one or  
7 more registration conditions, and shall notify  
8 the registrant of such reason. In the case of a  
9 disapproved registration, the Secretary shall  
10 subsequently notify the registrant that the reg-  
11 istration is approved if the Secretary deter-  
12 mines that the registrant is in compliance with  
13 such conditions.

14 “(B) CHANGES IN REGISTRATION INFOR-  
15 MATION.—Not later than 30 days after receiv-  
16 ing a notice under paragraph (1)(G) from a  
17 registrant, the Secretary shall determine wheth-  
18 er the change involved affects the approval of  
19 the registration of the registrant under para-  
20 graph (1), and shall inform the registrant of  
21 the determination.

22 “(3) PUBLICATION OF CONTACT INFORMATION  
23 FOR REGISTERED EXPORTERS.—Through the Inter-  
24 net website of the Food and Drug Administration,  
25 the Secretary shall make readily available to the

1 public a list of registered exporters, including con-  
2 tact information for the exporters. Promptly after  
3 the approval of a registration submitted under para-  
4 graph (1), the Secretary shall update the Internet  
5 website accordingly.

6 “(4) SUSPENSION AND TERMINATION.—

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

10 “(i) Subject to clause (ii), if the Sec-  
11 retary determines, after notice and oppor-  
12 tunity for a hearing, that the registrant  
13 has failed to maintain substantial compli-  
14 ance with all registration conditions, the  
15 Secretary may suspend the registration.

16 “(ii) If the Secretary determines that,  
17 under color of the registration, the ex-  
18 porter has exported a drug or the importer  
19 has imported a drug that is not a quali-  
20 fying drug, or a drug that does not meet  
21 the criteria under subsection (g)(2)(A), or  
22 has exported a qualifying drug to an indi-  
23 vidual in violation of subsection (i)(1)(F),  
24 the Secretary shall immediately suspend  
25 the registration. A suspension under the

1 preceding sentence is not subject to the  
2 provision by the Secretary of prior notice,  
3 and the Secretary shall provide to the reg-  
4 istrant an opportunity for a hearing not  
5 later than 10 days after the date on which  
6 the registration is suspended.

7 “(iii) The Secretary may reinstate the  
8 registration, whether suspended under  
9 clause (i) or (ii), if the Secretary deter-  
10 mines that the registrant has demonstrated  
11 that further violations of registration con-  
12 ditions will not occur.

13 “(B) TERMINATION.—The Secretary, after  
14 notice and opportunity for a hearing, may ter-  
15 minate the registration under paragraph (1) of  
16 a registrant if the Secretary determines that  
17 the registrant has engaged in a pattern or prac-  
18 tice of violating 1 or more registration condi-  
19 tions, or if on 1 or more occasions the Secretary  
20 has under subparagraph (A)(ii) suspended the  
21 registration of the registrant. The Secretary  
22 may make the termination permanent, or for a  
23 fixed period of not less than 1 year. During the  
24 period in which the registration is terminated,  
25 any registration submitted under paragraph (1)

1 by the registrant, or a person that is a partner  
2 in the export or import enterprise, or a principal  
3 officer in such enterprise, and any registration  
4 prepared with the assistance of the registrant or  
5 such a person, has no legal effect under this sec-  
6 tion.

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

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

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

16 “(B) inspected by the Secretary as pro-  
17 vided by this section.

18 “(2) The establishment is located in the United  
19 States or in any foreign country, and the establish-  
20 ment manufactured the drug for distribution in the  
21 United States or for distribution in 1 or more of the  
22 permitted countries (without regard to whether in  
23 addition the drug was manufactured for distribution  
24 in a foreign country that is not a permitted coun-  
25 try).

1           “(3) The exporter or importer obtained the  
2 drug—

3           “(A) directly from the establishment; or

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

6           “(i) provides to the exporter or im-  
7 porter a statement (in such form and con-  
8 taining such information as the Secretary  
9 may require) that, for the chain of custody  
10 from the establishment, identifies each  
11 prior sale, purchase, or trade of the drug  
12 (including the date of the transaction and  
13 the names and addresses of all parties to  
14 the transaction);

15           “(ii) agrees to permit the Secretary to  
16 inspect such statements and related  
17 records to determine their accuracy;

18           “(iii) agrees, with respect to the quali-  
19 fying drugs involved, to permit the Sec-  
20 retary to inspect warehouses and other fa-  
21 cilities of the entity for purposes of deter-  
22 mining whether the facilities are in compli-  
23 ance with any standards under this Act  
24 that are applicable to facilities of that type  
25 in the United States; and

1                   “(iv) has ensured, through such con-  
2                   tractual relationships as may be necessary,  
3                   that the Secretary has the same authority  
4                   regarding other parties in the chain of cus-  
5                   tody from the establishment that the Sec-  
6                   retary has under clauses (ii) and (iii) re-  
7                   garding such entity.

8                   “(4) The foreign country from which the im-  
9                   porter will import the drug is a permitted country.

10                  “(5) The foreign country from which the ex-  
11                  porter will export the drug is Canada.

12                  “(6) During any period in which the drug was  
13                  not in the control of the manufacturer of the drug,  
14                  the drug did not enter any country that is not a per-  
15                  mitted country.

16                  “(7) The exporter or importer retains a sample  
17                  of each lot of the drug sufficient for testing by the  
18                  Secretary.

19                  “(d) INSPECTION OF FACILITIES; MARKING OF SHIP-  
20                  MENTS.—

21                  “(1) INSPECTION OF FACILITIES.—A registra-  
22                  tion condition is that, for the purpose of assisting  
23                  the Secretary in determining whether the exporter  
24                  involved is in compliance with all other registration  
25                  conditions—

1           “(A) the exporter agrees to permit the Sec-  
2           retary—

3                   “(i) to conduct onsite inspections, in-  
4                   cluding monitoring on a day-to-day basis,  
5                   of places of business of the exporter that  
6                   relate to qualifying drugs, including each  
7                   warehouse or other facility owned or con-  
8                   trolled by, or operated for, the exporter;

9                   “(ii) to have access, including on a  
10                  day-to-day basis, to—

11                           “(I) records of the exporter that  
12                           relate to the export of such drugs, in-  
13                           cluding financial records; and

14                           “(II) samples of such drugs;

15                           “(iii) to carry out the duties described  
16                           in paragraph (3); and

17                           “(iv) to carry out any other functions  
18                           determined by the Secretary to be nec-  
19                           essary regarding the compliance of the ex-  
20                           porter; and

21           “(B) the Secretary has assigned 1 or more  
22           employees of the Secretary to carry out the  
23           functions described in this subsection for the  
24           Secretary not less than every 3 weeks on the  
25           premises of places of businesses referred to in

1           subparagraph (A)(i), and such an assignment  
2           remains in effect on a continuous basis.

3           “(2) MARKING OF COMPLIANT SHIPMENTS.—A  
4           registration condition is that the exporter involved  
5           agrees to affix to each shipping container of quali-  
6           fying drugs exported under subsection (a) such  
7           markings as the Secretary determines to be nec-  
8           essary to identify the shipment as being in compli-  
9           ance with all registration conditions. Markings under  
10          the preceding sentence—

11                   “(A) shall be designed to prevent affixation  
12                   of the markings to any shipping container that  
13                   is not authorized to bear the markings; and

14                   “(B) may include anti-counterfeiting or  
15                   track-and-trace technologies.

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

19                   “(A) Verifying the chain of custody of a  
20                   statistically significant sample of qualifying  
21                   drugs from the establishment in which the drug  
22                   was manufactured to the exporter, which may  
23                   be accomplished by the use of anticounterfeiting  
24                   or track-and-trace technologies, if available.

1           “(B) 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           “(C) Monitoring the affixing of markings  
10 under paragraph (2).

11           “(D) Inspect as the Secretary determines  
12 is necessary the warehouses and other facilities  
13 of other parties in the chain of custody of quali-  
14 fying drugs.

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

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

21           “(A) As authorized under section 704, in-  
22 spect not less than every 3 weeks, the places of  
23 business of the importer that relate to the re-  
24 ceipt and distribution of a qualifying drug, in-  
25 cluding each warehouse or other facility owned

1 or controlled by, or operated for, the importer  
2 at which qualifying drugs are received or from  
3 which they are distributed to pharmacies.

4 “(B) During the inspections under sub-  
5 paragraph (A), verify the chain of custody of a  
6 statistically significant sample of qualifying  
7 drugs from the establishment in which the drug  
8 was manufactured to the importer, which may  
9 be accomplished by the use of anticounterfeiting  
10 or track-and-trace technologies, if available.

11 “(C) Inspect as the Secretary determines  
12 is necessary the warehouses and other facilities  
13 of other parties in the chain of custody of quali-  
14 fying drugs.

15 “(D) Determine whether the importer is in  
16 compliance with all other registration condi-  
17 tions.

18 “(e) IMPORTER FEES.—

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

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

1       retary in accordance with this subsection a fee on a  
2       semiannual basis, with the first fee due on the date  
3       that is 6 months after the date on which the reg-  
4       istration of the importer under subsection (b) is first  
5       approved by the Secretary.

6               “(3) AMOUNT OF INSPECTION FEE.—

7               “(A) AGGREGATE TOTAL OF FEES.—The  
8       Secretary shall ensure that the aggregate total  
9       of fees collected under paragraph (2) for a fis-  
10      cal year from all importers is sufficient, and no  
11      more than necessary, to pay the costs of admin-  
12      istering this section with respect to registered  
13      importers for a fiscal year, including—

14              “(i) inspection of the facilities of im-  
15              porters under subsection (d)(4);

16              “(ii) reviewing qualifying drugs of-  
17              fered for import to importers; and

18              “(iii) determining the compliance of  
19              importers with registration conditions.

20              “(B) LIMITATION.—The aggregate total of  
21      fees collected under paragraph (2) shall not ex-  
22      ceed 1 percent of the total price of drugs im-  
23      ported annually to the United States by reg-  
24      istered importers under this section.

1           “(C) INDIVIDUAL IMPORTER FEE.—Sub-  
2           ject to the limitation described in subparagraph  
3           (B), a fee under paragraph (2) for an importer  
4           shall be an amount that is a reasonable esti-  
5           mate by the Secretary of the semiannual share  
6           of the importer of the volume of drugs imported  
7           by importers under this section.

8           “(D) ADJUSTMENT OF FEE.—The Sec-  
9           retary shall annually adjust the fees under  
10          paragraph (2) to ensure that the fees accurately  
11          reflect the actual costs referred to in subpara-  
12          graph (A) and do not exceed, in the aggregate,  
13          1 percent of the total price of drugs imported  
14          annually to the United States under this sec-  
15          tion.

16          “(4) USE OF FEES.—Subject to appropriations  
17          Acts, fees collected by the Secretary under para-  
18          graphs (1) and (2) are available only to the Sec-  
19          retary and are for the sole purpose of paying the  
20          costs referred to in paragraph (3)(A).

21          “(f) EXPORTER FEES.—

22                 “(1) REGISTRATION FEE.—A registration con-  
23                 dition is that the exporter involved pays to the Sec-  
24                 retary a fee of \$10,000 due on the date on which

1 the exporter first submits that registration to the  
2 Secretary under subsection (b).

3 “(2) INSPECTION FEE.—A registration condi-  
4 tion is that the exporter involved pays to the Sec-  
5 retary in accordance with this subsection a fee on a  
6 semiannual basis, with the first fee due on the date  
7 that is 6 months after the date on which the reg-  
8 istration of the exporter under subsection (b) is first  
9 approved by the Secretary.

10 “(3) AMOUNT OF INSPECTION FEE.—

11 “(A) AGGREGATE TOTAL OF FEES.—The  
12 Secretary shall ensure that the aggregate total  
13 of fees collected under paragraph (2) for a fis-  
14 cal year from all exporters is sufficient, and not  
15 more than necessary, to pay the costs of admin-  
16 istering this section with respect to registered  
17 exporters for a fiscal year, including—

18 “(i) monitoring foreign facilities under  
19 subsection (d);

20 “(ii) developing, implementing, and  
21 maintaining under such subsection a sys-  
22 tem to mark shipments to indicate compli-  
23 ance with all registration conditions; and

24 “(iii) conducting under such sub-  
25 section inspections within the United

1 States to determine compliance with condi-  
2 tions under subsections (h) and (i).

3 “(B) LIMITATION.—The aggregate total of  
4 fees collected under paragraph (2) shall not ex-  
5 ceed 1 percent of the total price of drugs im-  
6 ported annually to the United States by reg-  
7 istered exporters under this section.

8 “(C) INDIVIDUAL EXPORTER FEE.—Sub-  
9 ject to the limitation described in subparagraph  
10 (B), a fee under paragraph (2) for an exporter  
11 shall be an amount that is a reasonable esti-  
12 mate by the Secretary of the semiannual share  
13 of the exporter of the volume of drugs exported  
14 by exporters under this section.

15 “(D) ADJUSTMENT OF FEE.—The Sec-  
16 retary shall annually adjust the fees under  
17 paragraph (2) to ensure that the fees accurately  
18 reflect the actual costs referred to in subpara-  
19 graph (A) and do not exceed, in the aggregate,  
20 1 percent of the total price of drugs imported  
21 annually to the United States under this sec-  
22 tion.

23 “(4) USE OF FEES.—Subject to appropriations  
24 Acts, fees collected by the Secretary under para-  
25 graphs (1) and (2) are only available to the Sec-

1       retary and are for the sole purpose of paying the  
2       costs referred to in paragraph (3)(A).

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

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

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

13             “(A) IN GENERAL.—For purposes of ad-  
14      ministrative and judicial procedure, there is a  
15      presumption that a drug proposed for export or  
16      import under subsection (a) is an approved  
17      drug under section 505(b) if the following cri-  
18      teria are met:

19                 “(i) The drug proposed for export or  
20                 import is in compliance with subsection  
21                 (c).

22                 “(ii) The drug proposed for export or  
23                 import has the same active ingredient or  
24                 ingredients, route of administration, dos-  
25                 age form, and strength, according to infor-

1           mation provided by the labeling of the drug  
2           proposed for export or import, as a drug  
3           (referred to in this subsection as a ‘U.S.  
4           label drug’) that—

5                   “(I) is manufactured by or for  
6                   the person that manufactures the  
7                   drug proposed for export or import;  
8                   and

9                   “(II) is approved under section  
10                  505(b).

11           “(B) IMPORTATION.—Subject to subpara-  
12           graphs (D) and (E), a drug meeting the criteria  
13           described in subparagraph (A) may, in accord-  
14           ance with the other subsections of this section,  
15           be imported into the United States.

16           “(C) NOTICE BY MANUFACTURER; GEN-  
17           ERAL PROVISIONS.—

18                   “(i) IN GENERAL.—The person that  
19                   manufactures a drug that may be imported  
20                   under subsection (a) shall in accordance  
21                   with this paragraph submit to the Sec-  
22                   retary a notice that—

23                   “(I) includes each difference in  
24                   the drug from a condition established  
25                   in the approved application for the

1 U.S. label drug beyond the variations  
2 provided for in the application, any  
3 difference in labeling, the date on  
4 which the drug with such difference  
5 was, or will be, introduced for com-  
6 mercial distribution in a permitted  
7 country, and such additional informa-  
8 tion as the Secretary may require; or

9 “(II) states that there is no dif-  
10 ference in the drug from a condition  
11 established in the approved applica-  
12 tion for the U.S. label drug beyond  
13 the variations provided for in the ap-  
14 plication and differences in labeling.

15 “(ii) INFORMATION REGARDING FOR-  
16 EIGN GOVERNMENT.—A notice under  
17 clause (i)(I) shall with respect to the per-  
18 mitted country that approved the drug for  
19 commercial distribution, or with respect to  
20 which such approval is sought, include the  
21 following:

22 “(I) Information demonstrating  
23 that the person submitting the notice  
24 has also notified the government of  
25 the permitted country in writing that

1 the person is submitting to the Sec-  
2 retary a notice under clause (i)(I),  
3 which notice describes the difference  
4 in the drug from a condition estab-  
5 lished in the approved application for  
6 the U.S. label drug.

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

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

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

1                   “(II) a copy of the notice has  
2                   been provided to the Federal Trade  
3                   Commission and to the Assistant At-  
4                   torney General in charge of the Anti-  
5                   trust Division of the Department of  
6                   Justice (referred to in this subsection  
7                   as the ‘Assistant Attorney General’).

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

23                  “(v) TIMING OF SUBMISSION OF NO-  
24                  TICES.—

1                   “(I) PRIOR 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 120 days before the drug  
6                   with the difference is introduced for  
7                   commercial distribution in a permitted  
8                   country, unless the country requires  
9                   that distribution of the drug with the  
10                  difference begin less than 120 days  
11                  after the country requires the dif-  
12                  ference.

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

21                  “(III) OTHER NOTICES.—A no-  
22                  tice under clause (i) to which subpara-  
23                  graph (F) applies shall be submitted  
24                  to the Secretary on the date that the  
25                  drug is first introduced for commer-

1           cial distribution in a permitted coun-  
2           try and annually thereafter.

3           “(vi) REVIEW BY SECRETARY.—

4                   “(I) IN GENERAL.—In this para-  
5           graph, the difference in a drug that  
6           may be imported under subsection (a)  
7           from the U.S. label drug shall be  
8           treated by the Secretary as if it was  
9           a manufacturing change to the U.S.  
10          label drug under section 506A.

11                   “(II) 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                   “(III) ESTABLISHMENT INSPEC-  
20          TION.—If review of such difference  
21          would require an inspection by the  
22          Secretary of the establishment in  
23          which the drug is manufactured, such  
24          inspection shall be authorized by sec-  
25          tion 704.

1                   “(vii) PUBLICATION OF INFORMATION  
2                   ON NOTICES.—

3                   “(I) IN GENERAL.—Through the  
4                   Internet website of the Food and  
5                   Drug Administration, the Secretary  
6                   shall readily make available to the  
7                   public a list of notices submitted  
8                   under clause (i).

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

13                  “(aa) a notice is under re-  
14                  view;

15                  “(bb) the Secretary has or-  
16                  dered that importation of the  
17                  drug from a permitted country  
18                  cease; or

19                  “(cc) the importation of the  
20                  drug is permitted under sub-  
21                  section (a).

22                  “(III) UPDATE.—The Secretary  
23                  shall promptly update the Internet  
24                  website with any changes to the list.

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

9                   “(i) Promptly after the notice is sub-  
10                  mitted, the Secretary shall notify reg-  
11                  istered exporters, registered importers, the  
12                  Federal Trade Commission, and the As-  
13                  sistant Attorney General that the notice  
14                  has been submitted with respect to the  
15                  drug involved.

16                  “(ii) If the Secretary has not made a  
17                  determination whether a supplemental ap-  
18                  plication regarding the U.S. label drug  
19                  would be approved or disapproved by the  
20                  date on which the drug involved is to be in-  
21                  troduced for commercial distribution in a  
22                  permitted country, the Secretary shall—

23                           “(I) order that the importation of  
24                           the drug involved from the permitted  
25                           country cease for the period in which

1 the Secretary completes review of the  
2 notice; and

3 “(II) promptly notify registered  
4 exporters, registered importers, the  
5 Federal Trade Commission, and the  
6 Attorney General of the order.

7 “(iii) If the Secretary determines that  
8 such a supplemental application regarding  
9 the U.S. label drug would not be approved,  
10 the Secretary shall—

11 “(I) order that the importation of  
12 the drug involved from the permitted  
13 country cease, or provide that an  
14 order under clause (ii), if any, re-  
15 mains in effect;

16 “(II) notify the permitted coun-  
17 try that approved the drug for com-  
18 mercial distribution of the determina-  
19 tion; and

20 “(III) promptly notify registered  
21 exporters, registered importers, the  
22 Federal Trade Commission, and the  
23 Assistant Attorney General of the de-  
24 termination.

1           “(iv) If the Secretary determines that  
2           such a supplemental application regarding  
3           the U.S. label drug would be approved, the  
4           Secretary shall vacate the order under  
5           clause (ii), if any, permit importation of  
6           the drug under subsection (a), and  
7           promptly notify registered exporters, reg-  
8           istered importers, the Federal Trade Com-  
9           mission, and the Assistant Attorney Gen-  
10          eral of the determination.

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

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

23               “(ii) If the Secretary determines that  
24               such a supplemental application regarding  
25               the U.S. label drug would not be approved,

1 the Secretary shall order that the importa-  
2 tion of the drug involved from the per-  
3 mitted country cease, shall notify the per-  
4 mitted country that approved the drug for  
5 commercial distribution of the determina-  
6 tion, and shall promptly notify registered  
7 exporters, registered importers, the Fed-  
8 eral Trade Commission, and the Assistant  
9 Attorney General of the determination.

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

18 “(i) may not order that the importa-  
19 tion of the drug involved cease; and

20 “(ii) shall promptly notify registered  
21 exporters and registered importers.

22 “(G) DIFFERENCES IN ACTIVE INGRE-  
23 DIENT, ROUTE OF ADMINISTRATION, DOSAGE  
24 FORM, OR STRENGTH.—

1           “(i) IN GENERAL.—A person who  
2 manufactures a U.S. label drug shall sub-  
3 mit an application under section 505(b) for  
4 a drug that is manufactured for distribu-  
5 tion in a permitted country by or for the  
6 person that manufactures the U.S. label  
7 drug if—

8                   “(I) there is no drug for export  
9 from at least half of the permitted  
10 countries with the same active ingre-  
11 dient or ingredients, route of adminis-  
12 tration, dosage form, and strength as  
13 the U.S. label drug; and

14                   “(II) each active ingredient of  
15 the drug is related to an active ingre-  
16 dient of the U.S. label drug, as de-  
17 fined in clause (v).

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

21                   “(I) request approval of the drug  
22 for the indication or indications for  
23 which the U.S. label drug is approved  
24 under section 505;

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

13           “(III) include a right of reference  
14          to the application under section  
15          505(b) for the U.S. label drug; and

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

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

1           “(iv) NOTICE OF DECISION ON APPLI-  
2           CATION.—The Secretary shall promptly no-  
3           tify registered exporters, registered import-  
4           ers, the Federal Trade Commission, and  
5           the Assistant Attorney General of a deter-  
6           mination to approve or to disapprove an  
7           application under section 505(b) required  
8           under clause (i).

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

12                   “(I) the same; or

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

15          “(3) SECTION 502; LABELING.—

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

18                   “(i) IN GENERAL.—In the case of a  
19                   qualifying drug that is imported or offered  
20                   for import by a registered importer, such  
21                   drug shall be considered to be in compli-  
22                   ance with section 502 if the drug bears—

23                           “(I) a copy of the labeling ap-  
24                           proved for the drug under section

1                   505, without regard to whether the  
2                   copy bears the trademark involved;

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; and

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

10                  “(ii) REQUEST FOR COPY OF THE LA-  
11                  BELING.—The Secretary shall provide such  
12                  copy to the registered importer involved,  
13                  upon request of the importer.

14                  “(B) IMPORTATION BY INDIVIDUAL.—In  
15                  the case of a qualifying drug that is imported  
16                  or offered for import by a registered exporter to  
17                  an individual, such drug shall be considered to  
18                  be in compliance with section 502 if the drug  
19                  bears a label providing the directions for use by  
20                  the consumer, and bears a copy of any special  
21                  labeling that would be required by the Secretary  
22                  had the drug been dispensed by a pharmacist in  
23                  the United States, without regard to whether  
24                  the special labeling bears the trademark in-  
25                  volved. The Secretary shall provide to the reg-

1           istered exporter involved a copy of the special  
2           labeling, upon request of the exporter.

3           “(4) SECTION 501; STANDARDS FOR REFUSING  
4           ADMISSION.—

5                   “(A) IN GENERAL.—For purposes of ad-  
6           ministrative and judicial procedure, there is a  
7           presumption that a drug proposed for export or  
8           import under subsection (a) is in compliance  
9           with section 501 if the drug is in compliance  
10          with subsection (c).

11                   “(B) STANDARDS FOR REFUSING ADMIS-  
12          SION.—A qualifying drug exported under sub-  
13          section (a) from a registered exporter or im-  
14          ported by a registered importer may be refused  
15          admission into the United States if 1 or more  
16          of the following applies:

17                           “(i) The shipping container appears  
18                           damaged in a way that may affect the  
19                           strength, quality, or purity of the drug.

20                           “(ii) The Secretary becomes aware  
21                           that—

22                                   “(I) the drug may be counterfeit;

23                                   “(II) the drug may have been  
24                           prepared, packed, or held under in-  
25                           sanitary conditions; or

1                   “(III) the methods used in, or  
2                   the facilities or controls used for, the  
3                   manufacturing, processing, packing,  
4                   or holding of the drug do not conform  
5                   to good manufacturing practice.

6                   “(iii) The Secretary has obtained an  
7                   injunction under section 302 that prohibits  
8                   the distribution of the drug in interstate  
9                   commerce.

10                  “(iv) The Secretary has under section  
11                  505(e) withdrawn approval of the drug.

12                  “(v) The manufacturer of the drug  
13                  has instituted a recall of the drug.

14                  “(vi) If the qualifying drug is ex-  
15                  ported from a registered exporter to an in-  
16                  dividual and 1 or more of the following ap-  
17                  plies:

18                         “(I) The shipping container for  
19                         such drug does not bear the markings  
20                         required under subsection (d)(2).

21                         “(II) The markings on the ship-  
22                         ping container appear to be counter-  
23                         feit.

1                   “(III) The shipping container or  
2                   markings appear to have been tam-  
3                   pered with.

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

8                   “(1) the exporter is authorized under Canadian  
9                   law to dispense prescription drugs; and

10                   “(2) the exporter employs persons that are li-  
11                   censed under Canadian law to dispense prescription  
12                   drugs in sufficient number to dispense safely the  
13                   qualifying drugs exported by the exporter to individ-  
14                   uals, and the exporter assigns to those persons re-  
15                   sponsibility for dispensing such qualifying drugs to  
16                   individuals.

17           “(i) INDIVIDUALS; CONDITIONS FOR IMPORTATION  
18           FROM CANADA.—

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

23                           “(A) The drug is accompanied by a copy of  
24                           a prescription for the drug, which prescrip-  
25                           tion—

1           “(i) is valid under applicable Federal  
2           and State laws; and

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

9           “(B) The drug is accompanied by a copy  
10          of the documentation that was required under  
11          the law or regulations of Canada as a condition  
12          of dispensing the drug to the individual.

13          “(C) The copies referred to in subpara-  
14          graphs (A)(i) and (B) are marked in a manner  
15          sufficient—

16               “(i) to indicate that the prescription,  
17               and the equivalent document in Canada,  
18               have been filled; and

19               “(ii) to prevent a duplicative filling by  
20               another pharmacist.

21          “(D) The individual has provided to the  
22          registered exporter a complete list of all drugs  
23          used by the individual for review by the individ-  
24          uals who dispense the drug.

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

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

15          “(2) NOTICE REGARDING DRUG REFUSED AD-  
16          MISSION.—If a registered exporter ships a drug to  
17          an individual pursuant to subsection (a)(2)(B) and  
18          the drug is refused admission to the United States,  
19          a written notice shall be sent to the individual and  
20          to the exporter that informs the individual and the  
21          exporter of such refusal and the reason for the re-  
22          fusal.

23          “(j) MAINTENANCE OF RECORDS AND SAMPLES.—A  
24          registration condition is that the importer or exporter in-  
25          volved shall—

1           “(1) maintain records required under this sec-  
2           tion for not less than 2 years; and

3           “(2) maintain samples of each lot of a drug re-  
4           quired under this section for not less than 2 years.

5           “(k) DRUG RECALLS.—

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

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

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

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

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

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

22           “(B) monitor recalls and withdrawals of  
23           prescription drugs in the country using any in-  
24           formation that is available to the public in any  
25           media.

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

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

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

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

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

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

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

23          “(3) The making of a materially false, fictitious, or  
24          fraudulent statement or representation, or a material  
25          omission, in a notice under clause (i) of section

1 804(g)(2)(C) or in an application required under section  
2 804(g)(2)(G), or the failure to submit such a notice or  
3 application.

4 “(4) The importation of a drug in violation of a re-  
5 quirement under section 804.”; and

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

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

12 (c) IMPLEMENTATION.—

13 (1) RULEMAKING.—

14 (A) IN GENERAL.—

15 (i) PROMULGATION BY SECRETARY.—

16 Not later than 90 days after the date of  
17 the enactment of this Act, the Secretary of  
18 Health and Human Services shall promul-  
19 gate an interim rule for implementing sec-  
20 tion 804 of the Federal Food, Drug, and  
21 Cosmetic Act, as added by subsection (a)  
22 of this section. Such rule shall be devel-  
23 oped and promulgated by the Secretary  
24 without providing general notice of pro-  
25 posed rulemaking. Not later than 1 year

1 after the date on which the interim rule is  
2 promulgated, the Secretary shall, in accord-  
3 ance with procedures under section 553 of  
4 title 5, United States Code, promulgate a  
5 final rule for implementing such section  
6 804, which may incorporate by reference  
7 provisions of the interim rule, to the extent  
8 that such provisions are not modified.

9 (ii) EFFECT OF RULES.—The rules  
10 promulgated under clause (i) shall permit  
11 the importation of prescription drugs—

12 (I) from registered exporters by  
13 individuals effective on the date of the  
14 promulgation of the interim rule;

15 (II) from Canada by registered  
16 importers effective on the date of the  
17 promulgation of the interim rule; and

18 (III) from Australia, a member  
19 country of the European Union as of  
20 January 1, 2003, Japan, New Zea-  
21 land, or Switzerland by registered im-  
22 porters on the date that is 1 year  
23 after the date of the enactment of this  
24 Act.

1           (B) CERTAIN EXPORTERS.—The interim  
2 rule under subparagraph (A) shall provide that,  
3 in the review of registrations submitted under  
4 subsection (b) of the section 804 referred to in  
5 such subparagraph, registrations submitted by  
6 entities in Canada that are significant exporters  
7 of prescription drugs to individuals in the  
8 United States as of the date of the enactment  
9 of this Act will have priority during the period  
10 in which the interim rule under subparagraph  
11 (A) is in effect. During such period, the ref-  
12 erence in subsection (b)(2)(A) of such section  
13 804 to 90 days (relating to approval or dis-  
14 approval of registrations) is, as applied to such  
15 entities, deemed to be 30 days.

16           (C) DRUGS FOR IMPORT FROM CANADA.—  
17 The notices with respect to drugs to be im-  
18 ported from Canada that are required under  
19 subsection (g)(2)(C)(i)(I) of such section 804  
20 and that require approval under subsection  
21 (g)(2)(D) or (E) of such section 804 shall be  
22 submitted to the Secretary not later than 30  
23 days after the date of enactment of this Act.  
24 The notices with respect to drugs to be im-  
25 ported from Canada that are required under

1 subsection (g)(2)(C)(i) of such section 804 and  
2 that do not require approval under subsection  
3 (g)(2)(D) or (E) of such section 804 shall be  
4 submitted to the Secretary not later than 90  
5 days after the date of enactment of this Act.

6 (D) DRUGS FOR IMPORT FROM OTHER  
7 COUNTRIES.—The notices with respect to drugs  
8 to be imported from Australia, a member coun-  
9 try of the European Union as of January 1,  
10 2003, Japan, New Zealand, or Switzerland that  
11 are required under subsection (g)(2)(C)(i)(I) of  
12 such section 804 and that require approval  
13 under subsection (g)(2)(D) or (E) of such sec-  
14 tion 804 shall be submitted to the Secretary not  
15 later than 180 days after the date of enactment  
16 of this Act. The notices with respect to drugs  
17 to be imported from such countries that are re-  
18 quired under subsection (g)(2)(C)(i)(II) of such  
19 section 804 and that do not require approval  
20 under subsection (g)(2)(D) or (E) of such sec-  
21 tion 804 shall be submitted to the Secretary not  
22 later than 270 days after the date of enactment  
23 of this Act.

24 (2) PERSONAL IMPORTATION FROM CANADA.—

25 Until the expiration of the 60-day period beginning

1 on the date on which the interim rule under para-  
2 graph (1)(A) is promulgated, an individual may im-  
3 port a prescription drug from Canada for personal  
4 use or for the use of a family member of the indi-  
5 vidual (rather than for resale), subject to compliance  
6 with the following conditions:

7 (A) The drug is not—

8 (i) a controlled substance, as defined  
9 in section 102 of the Controlled Sub-  
10 stances Act (21 U.S.C. 802);

11 (ii) a biological product, as defined in  
12 section 351 of the Public Health Service  
13 Act (42 U.S.C. 262);

14 (iii) an infused drug, including a peri-  
15 toneal dialysis solution;

16 (iv) an intravenously injected drug;

17 (v) a drug that is inhaled during sur-  
18 gery; or

19 (vi) a drug approved by the Secretary  
20 under subpart H of part 314 of title 21,  
21 Code of Federal Regulations (relating to  
22 accelerated approval) with restrictions  
23 under section 520 of such part to assure  
24 safe use.

1           (B) The drug is dispensed by a person li-  
2 censed in Canada to dispense such drugs.

3           (C) The drug is accompanied by a copy of  
4 the prescription for the drug, which prescrip-  
5 tion—

6                 (i) is valid under applicable Federal  
7 and State laws; and

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

14           (D) The drug is accompanied by a copy of  
15 the document that was required in Canada as  
16 a condition of dispensing the drug to the indi-  
17 vidual.

18           (E) The copies referred to in subpara-  
19 graphs (C) and (D) are marked in a manner  
20 sufficient—

21                 (i) to indicate that the prescription,  
22 and the equivalent document in Canada,  
23 have been filled; and

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

1           (F) The quantity of the drug does not ex-  
2           ceed a 90-day supply.

3           (3) FACILITATION OF CANADIAN IMPORTS.—

4           Not less than 15 days after the enactment of this  
5           Act and until the expiration of the 60-day period  
6           that begins on the date on which the interim rule  
7           under paragraph (1)(A) is promulgated, the Sec-  
8           retary shall, through the Internet website of the  
9           Food and Drug Administration, make readily avail-  
10          able to the public a list of persons licensed in Can-  
11          ada to dispense prescription drugs who are willing to  
12          export drugs under paragraph (2) to individuals in  
13          the United States.

14          (4) EFFECT OF PROVISIONS.—The amendments  
15          made in subsection (d), section 6, and section 7 of  
16          this Act shall have no effect with respect to imports  
17          made under paragraph (2).

18          (d) AMENDMENT OF CERTAIN PROVISION.—Section  
19          801 of the Federal Food, Drug, and Cosmetic Act (21  
20          U.S.C. 381) is amended by striking subsection (g) and in-  
21          serting the following:

22          “(g) With respect to a prescription drug that is im-  
23          ported or offered for import into the United States by an  
24          individual who is not in the business of such importation,  
25          that is not shipped by a registered exporter under section

1 804, and that is refused admission under subsection (a),  
 2 the Secretary shall notify the individual that—

3 “(1) the drug has been refused admission be-  
 4 cause the drug was not a lawful import under sec-  
 5 tion 804;

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

8 “(3) the individual may under section 804 law-  
 9 fully import certain prescription drugs from Cana-  
 10 dian exporters registered with the Secretary; and

11 “(4) the individual can find information about  
 12 such importation, including a list of registered ex-  
 13 porters, on the Internet website of the Food and  
 14 Drug Administration.”.

15 (e) ANTICOMPETITIVE PRACTICES RELATING TO IM-  
 16 PORTING AND EXPORTING DRUGS TO THE UNITED  
 17 STATES.—

18 (1) IN GENERAL.—The Clayton Act (15 U.S.C.  
 19 12 et seq.) is amended by adding at the end the fol-  
 20 lowing:

21 **“SEC. 27. RESTRAINT OF TRADE REGARDING PRESCRIP-**  
 22 **TION DRUGS.**

23 “(a) IN GENERAL.—It shall be unlawful for any per-  
 24 son engaged in commerce, directly or indirectly to—

1           “(1) charge a higher price for prescription  
2 drugs sold to a registered exporter or other person  
3 that exports prescription drugs to the United States  
4 under section 804 of the Federal Food, Drug, and  
5 Cosmetic Act than the price that is charged to an-  
6 other person that is in the same country and that  
7 does not export prescription drugs into the United  
8 States under section 804 of such Act;

9           “(2) charge a higher price for prescription  
10 drugs sold to a registered importer or other person  
11 that distributes, sells, or uses prescription drugs im-  
12 ported to the United States under section 804 of  
13 such Act than the price that is charged to another  
14 person in the United States that does not import  
15 prescription drugs under section 804 of such Act, or  
16 that does not distribute, sell, or use such drugs;

17           “(3) deny supplies of prescription drugs to a  
18 registered exporter or other person that exports pre-  
19 scription drugs to the United States under section  
20 804 of such Act or to a registered importer or other  
21 person that distributes, sells, or uses prescription  
22 drugs imported to the United States under section  
23 804 of such Act;

24           “(4) publicly, privately, or otherwise refuse to  
25 do business with a registered exporter or other per-

1 son that exports prescription drugs to the United  
2 States under section 804 of such Act or with a reg-  
3 istered importer or other person that distributes,  
4 sells, or uses prescription drugs imported to the  
5 United States under section 804 of such Act;

6 “(5) specifically restrict supplies of prescription  
7 drugs to a registered exporter or other person that  
8 exports prescription drugs to the United States  
9 under section 804 of such Act or to a registered im-  
10 porter or other person that distributes, sells, or uses  
11 prescription drugs imported to the United States  
12 under section 804 of such Act;

13 “(6) fail to submit a notice under subsection  
14 (g)(2)(C)(i) of section 804 of such Act, fail to sub-  
15 mit such a notice on or before the date specified in  
16 subsection (g)(2)(C)(v) of section 804 of such Act,  
17 submit such a notice that makes a materially false,  
18 fictitious, or fraudulent statement, or fail to provide  
19 promptly any information requested by the Secretary  
20 of Health and Human Services to review such a no-  
21 tice;

22 “(7) fail to submit an application required  
23 under subsection (g)(2)(G) of section 804 of such  
24 Act, fail to submit such an application on or before  
25 the date specified in subsection (g)(2)(G)(ii) of sec-

1       tion 804 of such Act, submit such an application  
2       that makes a materially false, fictitious, or fraudu-  
3       lent statement, or fail to provide promptly any infor-  
4       mation requested by the Secretary of Health and  
5       Human Services to review such an application;

6               “(8) cause there to be a difference (including a  
7       difference in active ingredient, route of administra-  
8       tion, dosage form, strength, formulation, manufac-  
9       turing establishment, manufacturing process, or per-  
10      son that manufactures the drug) between a prescrip-  
11      tion drug for distribution in the United States and  
12      a prescription drug for distribution in Australia,  
13      Canada, a member country of the European Union  
14      as of January 1, 2003, Japan, New Zealand, or  
15      Switzerland for the purpose of restricting importa-  
16      tion of the drug to the United States under section  
17      804 of such Act;

18              “(9) refuse to allow an inspection authorized  
19      under section 804 of such Act of an establishment  
20      that manufactures a prescription drug that is of-  
21      fered for import under such section;

22              “(10) fail to conform to the methods used in,  
23      or the facilities used for, the manufacturing, proc-  
24      essing, packing, or holding of a prescription drug of-

1       ferred for import under section 804 to good manufac-  
2       turing practice under such Act; or

3               “(11) engage in any other action that the Fed-  
4       eral Trade Commission determines to unfairly re-  
5       strict competition under section 804 of such Act.

6       “(b) PRESUMPTION.—A difference (including a dif-  
7       ference in active ingredient, route of administration, dos-  
8       age form, strength, formulation, manufacturing establish-  
9       ment, manufacturing process, or person that manufac-  
10      tures the drug) between a prescription drug for distribu-  
11      tion in the United States and a prescription drug for dis-  
12      tribution in Australia, Canada, a member country of the  
13      European Union as of January 1, 2003, Japan, New Zea-  
14      land, or Switzerland made after January 1, 2004, shall  
15      be presumed to be for the purpose of restricting importa-  
16      tion of the drug to the United States under section 804  
17      of the Federal Food, Drug, and Cosmetic Act unless—

18               “(1) the person manufacturing the drug for dis-  
19      tribution in the United States proves that the dif-  
20      ference was required by the country in which the  
21      drug is distributed;

22               “(2) the Secretary of Health and Human Serv-  
23      ices, acting through the Commissioner of Food and  
24      Drug, determines that the difference was necessary  
25      to improve the safety or efficacy of the drug; or

1           “(3) the person manufacturing the drug for dis-  
2           tribution in the United States has given notice to  
3           the Secretary of Health and Human Services under  
4           subsection (g)(2)(C)(i) of section 804 of such Act  
5           that the drug for distribution in the United States  
6           is not different from a drug for distribution in not  
7           fewer than half of those countries.

8           “(c) AFFIRMATIVE DEFENSE.—It shall be an affirm-  
9           ative defense to a charge that a person has violated para-  
10          graph (1), (2), (3), (4), or (5) of subsection (a) that the  
11          higher prices charged for prescription drugs sold to a per-  
12          son, the denial of supplies of prescription drugs to a per-  
13          son, the refusal to do business with a person, or the spe-  
14          cific restriction or delay of supplies to a person is not  
15          based, in whole or in part, on—

16                 “(1) the person exporting or importing pre-  
17                 scription drugs to the United States under section  
18                 804 of the Federal Food, Drug, and Cosmetic Act;  
19                 or

20                 “(2) the person distributing, selling, or using  
21                 prescription drugs imported to the United States  
22                 under section 804 of such Act.

23          “(d) DEFINITIONS.—In this section:

24                 “(1) PRESCRIPTION DRUG.—The term ‘pre-  
25                 scription drug’ means a drug that is described in

1 section 503(b)(1) of the Federal Food, Drug, and  
2 Cosmetic Act (21 U.S.C. 353(b)(1)).

3 “(2) REGISTERED IMPORTER.—The term ‘reg-  
4 istered importer’ has the meaning given such term  
5 in section 804 of the Federal Food, Drug, and Cos-  
6 metic Act.

7 “(3) REGISTERED EXPORTER.—The term ‘reg-  
8 istered exporter’ has the same meaning as in section  
9 804 of the Federal Food, Drug, and Cosmetic Act.”.

10 (2) APPLICABILITY OF AMENDMENTS TO IM-  
11 PORTATION UNDER THE PHARMACEUTICAL MARKET  
12 ACCESS AND FAIR TRADE ACT OF 2004.—

13 (A) PERSONAL IMPORTATION FROM CAN-  
14 ADA.—Paragraphs (1) through (5) and (11) of  
15 subsection (a) of section 27 of the Clayton Act  
16 (15 U.S.C. et seq.) (as amended by paragraph  
17 (1)) shall apply with respect to the importation  
18 of drugs from Canada under subsection (c)(2).

19 (B) NOTICES RESPECTING DRUG FOR IM-  
20 PORT.—Paragraph (6) of subsection (a) of sec-  
21 tion 27 of the Clayton Act (15 U.S.C. et seq.)  
22 (as amended by paragraph (1)) shall apply with  
23 respect to notices required under section  
24 804(g)(2)(C)(i) of the Federal Food Drug and  
25 Cosmetic Act (21 U.S.C. 384(g)(2)(C)(i)) that

1           are not submitted by the dates required under  
2           subsections (c)(1)(C) and (D).

3       (f) EXHAUSTION.—

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

6           (A) by redesignating subsections (h) and  
7           (i) as (i) and (j), respectively; and

8           (B) by inserting after subsection (g) the  
9       following:

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

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

1 **SEC. 5. ADDITIONAL WAIVERS REGARDING PERSONAL IM-**  
2 **PORTATION; ENFORCEMENT POLICIES OF**  
3 **SECRETARY.**

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

7 “(p)(1) Waivers under this subsection are in addition  
8 to, and independent of, the waiver pursuant to section  
9 804(a)(2)(B).

10 “(2) With respect to the standards referred to in sub-  
11 section (d)(1), the Secretary shall establish by regulation  
12 a waiver of such standards in the case of the importation  
13 by an individual of a drug into the United States in the  
14 following circumstances:

15 “(A) The drug was dispensed to the individual  
16 while the individual was in the United States, the  
17 drug was dispensed by a pharmacist or by a practi-  
18 tioner licensed by law to administer the drug, and  
19 the individual traveled from the United States with  
20 the drug.

21 “(B) The individual is entering the United  
22 States and the drug accompanies the individual at  
23 the time of entry.

24 “(C) The drug does not appear to the Secretary  
25 to be adulterated.

1           “(D) The quantity of the drug does not exceed  
2 a 90-day supply.

3           “(E) The drug is accompanied by a statement  
4 that the individual seeks to import the drug into the  
5 United States under a personal importation waiver.

6           “(F) Such additional standards as the Sec-  
7 retary determines to be appropriate to protect the  
8 public health.

9           “(3) With respect to the standards referred to in sub-  
10 sections (a) and (d)(1), the Secretary shall establish by  
11 regulation a waiver of such standards in the case of the  
12 importation by an individual of a drug into the United  
13 States in the following circumstances:

14           “(A) The drug was dispensed to the individual  
15 while the individual was in a foreign country, and  
16 the drug was dispensed in accordance with the laws  
17 and regulations of such country.

18           “(B) The individual is entering the United  
19 States and the drug accompanies the individual at  
20 the time of entry.

21           “(C) The drug is approved for commercial dis-  
22 tribution in the foreign country in which the drug  
23 was obtained.

24           “(D) The drug does not appear to the Secretary  
25 to be adulterated.

1           “(E) The quantity of the drug does not ex-  
2       ceed—

3                   “(i) a 90-day supply if the drug is dis-  
4                   pensed in Australia, Canada, a member country  
5                   of the European Union as of January 1, 2003,  
6                   Japan, New Zealand, or Switzerland; or

7                   “(ii) a 14-day supply otherwise.

8           “(F) The drug is accompanied by a statement  
9       that the individual seeks to import the drug into the  
10      United States under a personal importation waiver.

11           “(G) Such additional standards as the Sec-  
12      retary determines to be appropriate to protect the  
13      public health.

14           “(q) The Secretary may not administer any enforce-  
15      ment policy that has the effect of permitting the importa-  
16      tion of a prescription drug into the United States in viola-  
17      tion of this Act or section 351 of the Public Health Service  
18      Act.”.

19           (b) ADDITIONAL WAIVER.—This Act and the amend-  
20      ments made by this Act shall not be construed as limiting  
21      the authority of the Secretary of Health and Human Serv-  
22      ices to establish a waiver of the standards referred to in  
23      section 801(a) of the Federal Food, Drug, and Cosmetic  
24      Act (21 U.S.C. 381(a)) with respect to the importation  
25      by an individual of a drug into the United States that does

1 not meet such standards, provided that such waiver is no  
2 more permissive than the guidance, as in effect on Janu-  
3 ary 1, 2004, that is provided in the item numbered 2 (re-  
4 lating to a specific situation, consisting of conditions (a)  
5 through (d)) under the heading “Drugs, Biologics, and  
6 Devices” in chapter 9 of the FDA/ORA Regulatory Proce-  
7 dures Manual (relating to import operations/actions), in  
8 the subchapter relating to coverage of personal importa-  
9 tions.

10 **SEC. 6. DISPOSITION OF CERTAIN DRUGS DENIED ADMIS-**  
11 **SION INTO UNITED STATES.**

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

16 **“SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED AD-**  
17 **MISSION.**

18 “(a) IN GENERAL.—The Secretary of Homeland Se-  
19 curity shall refuse admission to a shipment of drugs that  
20 is imported or offered for import into the United States  
21 if the shipment has a declared value of less than \$10,000  
22 and the drugs are in violation of any standard referred  
23 to in section 801(a) or 801(d)(1), including any drugs im-  
24 ported or offered for import under enforcement policies  
25 prohibited under section 801(q).

1       “(b) IMPORTATION UNDER SECTION 804.—In the  
2 case of a drug that under section 804 is imported or of-  
3 fered for import from a registered exporter, the reference  
4 in subsection (a) to standards referred to in section 801(a)  
5 or 801(d)(1) shall be considered a reference to standards  
6 referred to in section 804(g)(4)(B).

7       “(c) DESTRUCTION OF VIOLATIVE SHIPMENTS.—  
8 Drugs refused admission under subsection (a) or (b) shall  
9 be destroyed, subject to subsection (e). Section 801(b)  
10 does not authorize the delivery of the drugs pursuant to  
11 the execution of a bond, and the drugs may not be ex-  
12 ported.

13       “(d) CERTAIN PROCEDURES.—

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

21               “(2) OBJECTIVE OF PROCEDURES.—Procedures  
22 promulgated under paragraph (1) shall be designed  
23 toward the objective of ensuring that, with respect to  
24 efficiently utilizing Federal resources available for  
25 carrying out this section, a substantial majority of

1 shipments of drugs subject to subsection (a) or (b)  
2 are identified and refused admission and destroyed.

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

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

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

17 **SEC. 7. CIVIL ACTIONS REGARDING PROPERTY.**

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

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

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

3           “(B) for a restraining order to—

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

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

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

13       **SEC. 8. WHOLESALE DISTRIBUTION OF DRUGS; STATE-**  
14                   **MENTS REGARDING PRIOR SALE, PURCHASE,**  
15                   **OR TRADE.**

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

20                   (1) in paragraph (1)—

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

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

1 (C) by striking subparagraph (B) and in-  
2 serting the following:

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

10 “(C)(i) The Secretary may by regulation establish re-  
11 quirements that supersede subparagraph (A) (referred to  
12 in this subparagraph as ‘alternative requirements’) to  
13 identify the chain of custody of a drug subject to sub-  
14 section (b) from the manufacturer of the drug throughout  
15 the wholesale distribution of the drug to a pharmacist who  
16 intends to sell the drug at retail if the Secretary deter-  
17 mines that the alternative requirements, which may in-  
18 clude anti-counterfeiting or track-and-trace technologies,  
19 will identify such chain of custody or the identity of the  
20 drug with equal certainty to the requirements of subpara-  
21 graph (A), and that the alternative requirements are eco-  
22 nomically and technically feasible.

23 “(ii) If the Secretary promulgates a final rule to es-  
24 tablish such alternative requirements, the final rule in ad-  
25 dition shall, with respect to the registration condition es-

1 tablished in clause (i) of section 804(c)(3)(B), establish  
2 a condition equivalent to the alternative requirements, and  
3 such equivalent condition supersedes such clause (i).”;

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

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

14 (b) CONFORMING AMENDMENT.—Section 503(d) of  
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
16 353(d)) is amended by adding at the end the following:

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

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

1 **SEC. 9. REPEAL OF IMPORTATION EXEMPTION UNDER CON-**  
2 **TROLLED SUBSTANCES IMPORT AND EXPORT**  
3 **ACT.**

4 Section 1006 of the Controlled Substances Import  
5 and Export Act (21 U.S.C. 956) is repealed.

○