

108TH CONGRESS
2D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

Mr. GRASSLEY introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs by importers, and by individuals for personal use, 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 “Reliable Entry for
5 Medicines at Everyday Discounts through Importation
6 with Effective Safeguards Act of 2004”.

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

3 Chapter VIII of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 381 et seq.), as amended by section
5 1121(a) of Public Law 108–173 (117 Stat. 2464), is
6 amended by striking section 804.

7 **SEC. 3. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER**
8 **OF CERTAIN IMPORT RESTRICTIONS.**

9 (a) IN GENERAL.—Chapter VIII of the Federal
10 Food, Drug, and Cosmetic Act, as amended by section 2
11 of this Act, is amended by inserting after section 803 the
12 following section:

13 **“SEC. 804. WAIVERS REGARDING COMMERCIAL AND PER-**
14 **SONAL IMPORTATION OF PRESCRIPTION**
15 **DRUGS; REGISTERED FOREIGN EXPORTERS.**

16 “(a) WAIVERS.—

17 “(1) IN GENERAL.—The Secretary shall in ac-
18 cordance with this section provide by regulation
19 that, in the case of qualifying drugs imported or of-
20 fered for import into the United States from reg-
21 istered exporters—

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

24 “(B) the standards referred to in section
25 801(a) regarding admission of the drugs are
26 subject to subsection (g) of this section (includ-

1 ing with respect to qualifying drugs to which
2 section 801(d)(1) does not apply).

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

5 “(A) the drug is imported by an importer
6 and the importation is in accordance with sub-
7 section (h); or

8 “(B) the drug is imported by an individual
9 for personal use or for the use of a family mem-
10 ber of the individual (rather than for resale),
11 and the importation is in accordance with sub-
12 section (i).

13 “(3) RULE OF CONSTRUCTION.—This section
14 has legal effect only with respect to a drug that is
15 imported or offered for import into the United
16 States from a registered exporter.

17 “(4) DEFINITIONS.—

18 “(A) IMPORTER.—The term ‘importer’
19 means a pharmacist or wholesaler.

20 “(B) PERMITTED COUNTRY.—

21 “(i) IN GENERAL.—For purposes of
22 this section, the term ‘permitted country’
23 means—

24 “(I) Canada;

1 “(II) 180 days after the date of
2 publication of the report under clause
3 (ii)—

4 “(aa) Australia;

5 “(bb) a member country of
6 the European Union or the Euro-
7 pean Free Trade Association;

8 “(cc) Japan; and

9 “(dd) New Zealand; and

10 “(III) any country designated as
11 a permitted country under clause (iii).

12 “(ii) REPORT.—

13 “(I) IN GENERAL.—Not later
14 than 18 months after the date of en-
15 actment of this section, the Secretary
16 shall submit to Congress a report sub-
17 ject to subclauses (II) and (III).

18 “(II) CONTENTS OF REPORT.—

19 The report under subclause (I)
20 shall—

21 “(aa) describe the impact of
22 the drug importation system es-
23 tablished under this section on—

24 “(AA) the safety and
25 integrity of the Nation’s pre-

1 description drug distribution
2 system;

3 “(BB) the prevalence of
4 counterfeit, adulterated, or
5 misbranded drugs in the
6 United States; and

7 “(CC) patient drug
8 therapy;

9 “(bb) describe the potential
10 impact of expanding the system
11 to allow importation from addi-
12 tional countries; and

13 “(cc) include proposed legis-
14 lation to improve the safety, effi-
15 ciency, and efficacy of the drug
16 reimportation system;

17 “(III) CONSULTATION WITH THE
18 FEDERAL TRADE COMMISSION.—The
19 Secretary, in consultation with the
20 Chairman of the Federal Trade Com-
21 mission, shall include in the report
22 under subclause (I)—

23 “(aa) an evaluation of the
24 extent to which this section ad-
25 vances the objective of intro-

1 ducing lower-priced competition
2 in the United States market for
3 prescription drugs; and

4 “(bb) recommendations for
5 improving the operation and ef-
6 fectiveness of this section to meet
7 that objective.

8 “(iii) ADDITIONAL COUNTRIES.—The
9 Secretary may designate an additional
10 country as a permitted country if the coun-
11 try meets the requirements of section
12 802(b)(1)(B) as that section relates to
13 drugs.

14 “(C) PHARMACIST.—The term ‘phar-
15 macist’ means a person licensed by a State to
16 practice pharmacy, including the dispensing and
17 selling of prescription drugs.

18 “(D) REGISTERED EXPORTER.—For pur-
19 poses of this section:

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

1 “(ii) the term ‘registration condition’
2 means a condition for a registration under
3 subsection (b) to be approved.

4 “(E) QUALIFYING DRUG.—For purposes of
5 this section, the term ‘qualifying drug’ means a
6 covered prescription drug, other than any of the
7 following:

8 “(i) A controlled substance, as defined
9 in section 102 of the Controlled Sub-
10 stances Act.

11 “(ii) A biological product, as defined
12 in section 351 of the Public Health Service
13 Act.

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

16 “(iv) An intravenously injected drug.

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

19 “(F) WHOLESALER.—

20 “(i) IN GENERAL.—The term ‘whole-
21 saler’ means a person licensed as a whole-
22 saler or distributor of prescription drugs in
23 the United States under section
24 503(e)(2)(A).

1 “(ii) EXCLUSION.—The term ‘whole-
2 saler’ does not include a person authorized
3 to import drugs under section 801(d)(1).

4 “(G) OTHER DEFINITIONS.—For purposes
5 of this section:

6 “(i) The term ‘covered prescription
7 drug’ means an approved drug under sec-
8 tion 505(b)(1) that is subject to section
9 503(b)(1).

10 “(ii) The term ‘exporter’ means a per-
11 son who is in the business of exporting a
12 drug to the United States or who, pursu-
13 ant to submitting a registration under sub-
14 section (b), seeks to be in such business.

15 “(b) REGISTRATION OF FOREIGN EXPORTERS.—

16 “(1) IN GENERAL.—A registration condition is
17 that the exporter involved submits to the Secretary
18 a registration containing the following:

19 “(A) The name of the exporter and an
20 identification of all places of business of the ex-
21 porter that relate to qualifying drugs, including
22 each warehouse or other facility owned or con-
23 trolled by, or operated for, the exporter.

24 “(B) Such information as the Secretary
25 determines to be necessary to demonstrate that

1 the exporter is in compliance with registration
2 conditions under subsections (c), (d), (e), (f),
3 and (g) (relating to the sources of exported
4 drugs; the monitoring of foreign facilities and
5 the marking of compliant shipments; the pay-
6 ment of fees; being licensed as a pharmacy (in
7 the case of importation by individuals); and
8 compliance with the standards referred to in
9 section 801(a)).

10 “(C) An agreement by the exporter that
11 the exporter will not under subsection (a) ex-
12 port any drug that is not a qualifying drug.

13 “(D) An agreement by the exporter that a
14 qualifying drug will not under subsection (a) be
15 exported to any person not authorized pursuant
16 to subsection (a)(2) to be an importer of such
17 drug.

18 “(E) An agreement by the exporter that
19 the exporter submits to the jurisdiction of the
20 courts of the United States for the purpose of
21 adjudication of any action arising out of the ac-
22 tivities of the exporter under this section with
23 the name and address of an agent in the United
24 States for service of process.

1 “(F) An agreement by the exporter to en-
2 sure and monitor compliance with each registra-
3 tion condition, to promptly correct any non-
4 compliance with such a condition, and to
5 promptly report to the Secretary any such non-
6 compliance.

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

10 “(H) An agreement by the exporter to no-
11 tify the Secretary of—

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

15 “(ii) any change that the exporter in-
16 tends to make in the compliance plan
17 under subparagraph (G).

18 “(I) Such other provisions as the Secretary
19 may require to protect the public health while
20 permitting the importation of qualifying drugs
21 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 an exporter sub-

1 mits to the Secretary a registration under para-
2 graph (1), the Secretary shall notify the ex-
3 porter whether the registration is approved or is
4 disapproved. The Secretary shall disapprove a
5 registration if there is reason to believe that the
6 exporter is not in compliance with one or more
7 registration conditions, and shall notify the ex-
8 porter of such reason. In the case of a dis-
9 approved registration, the Secretary shall subse-
10 quently notify the exporter that the registration
11 is approved if the Secretary determines that the
12 exporter is in compliance with such conditions.

13 “(B) CHANGES IN REGISTRATION INFOR-
14 MATION.—Not later than 30 days after receiv-
15 ing a notice under paragraph (1)(G) from a
16 registered exporter, the Secretary shall deter-
17 mine whether the change involved affects the
18 approval of the registration of the exporter
19 under paragraph (1), and shall inform the ex-
20 porter of the determination.

21 “(3) PUBLICATION OF CONTACT INFORMATION
22 FOR REGISTERED EXPORTERS.—Through the Inter-
23 net site of the Food and Drug Administration, the
24 Secretary shall make available to the public a list of
25 registered exporters, including contact information

1 for the exporters. Such list shall be posted on such
2 site in a manner that will assist the public in readily
3 obtaining the list. Promptly after the approval of a
4 registration submitted under paragraph (1), the Sec-
5 retary shall update the site accordingly, including, if
6 requested by the exporter, providing a link to an
7 Internet site of the exporter.

8 “(4) SUSPENSION AND TERMINATION.—

9 “(A) SUSPENSION.—With respect to the
10 effectiveness of a registration submitted under
11 paragraph (1) by an exporter:

12 “(i) Subject to clause (ii), if the Sec-
13 retary determines, after notice and oppor-
14 tunity for a hearing, that the exporter has
15 failed to maintain substantial compliance
16 with all registration conditions, the Sec-
17 retary may suspend the registration.

18 “(ii) If the Secretary determines that,
19 under color of the registration, the ex-
20 porter has exported a drug that is not a
21 qualifying drug, or a drug that does not
22 meet the criteria under subsection
23 (g)(2)(A), or has exported a qualifying
24 drug to an individual in violation of sub-
25 section (i)(1)(E), the Secretary shall imme-

1 diately suspend the registration. A suspen-
2 sion under the preceding sentence is not
3 subject to the provision by the Secretary of
4 prior notice, and the Secretary shall pro-
5 vide to the exporter involved an oppor-
6 tunity for a hearing not later than 10 days
7 after the date on which the registration is
8 suspended.

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

15 “(B) TERMINATION.—The Secretary, after
16 notice and opportunity for a hearing, may ter-
17 minate the registration under paragraph (1) of
18 an exporter if the Secretary determines that the
19 exporter has engaged in a pattern or practice of
20 violating one or more registration conditions, or
21 if on one or more occasions the Secretary has
22 under subparagraph (A)(ii) suspended the reg-
23 istration of the exporter. The Secretary may
24 make the termination permanent, or for a fixed
25 period of not less than one year. During the pe-

1 riod in which the registration is terminated, any
2 registration submitted under paragraph (1) by
3 the exporter or a person who is a partner in the
4 export enterprise or a principal officer in such
5 enterprise, and any registration prepared with
6 the assistance of the exporter or such a person,
7 has no legal effect under this section.

8 “(c) SOURCES OF EXPORTED QUALIFYING DRUGS.—

9 A registration condition is that the exporter involved
10 agrees that a qualifying drug will under subsection (a) be
11 exported to the United States only if, as verified by the
12 Secretary under subsection (d)(3)(A), there is compliance
13 with the following:

14 “(1) The drug was manufactured in an estab-
15 lishment required to register under subsection (h) or
16 (i) of section 510.

17 “(2) The establishment is located in the United
18 States or in any foreign country, and the establish-
19 ment manufactured the drug for distribution in the
20 United States and for distribution in one or more
21 foreign countries specified in paragraph (4) (without
22 regard to whether in addition the drug was manu-
23 factured for distribution in foreign countries not so
24 specified).

25 “(3) The exporter obtained the drug—

1 “(A) directly from the establishment; or

2 “(B) directly from an entity that, by con-
3 tract with the exporter—

4 “(i) provides to the exporter a state-
5 ment (in such form and containing such
6 information as the Secretary may require)
7 that, for the chain of custody from the es-
8 tablishment, identifies each prior sale, pur-
9 chase, or trade of the drug (including the
10 date of the transaction and the names and
11 addresses of all parties to the transaction);

12 “(ii) agrees to permit the Secretary to
13 inspect such statements and related
14 records to determine their accuracy;

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

23 “(iv) has ensured, through such con-
24 tractual relationships as may be necessary,
25 that the Secretary has the same authorities

1 regarding other parties in the chain of cus-
2 tody from the establishment that the Sec-
3 retary has under clauses (ii) and (iii) re-
4 garding such entity.

5 “(4) The foreign country from which the ex-
6 porter will export the drug is a permitted country.

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

11 “(d) MONITORING OF FACILITIES; MARKING OF
12 SHIPMENTS.—

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

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

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

1 “(ii) to have access, on a day-to-day
2 basis, to records of the exporter that relate
3 to the export of such drugs, including fi-
4 nancial records;

5 “(iii) to carry out the duties described
6 in paragraph (3); and

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

11 “(B) the Secretary, with the permission of
12 the exporter, has assigned one or more employ-
13 ees of the Secretary to carry out the functions
14 described in this subsection for the Secretary—

15 “(i) on a day-to-day basis on the
16 premises of places of businesses referred to
17 in subparagraph (A)(i), and such an as-
18 signment remains in effect on a continuous
19 basis; or

20 “(ii) on a periodic basis on the prem-
21 ises of places of businesses referred to in
22 subparagraph (A)(i), if the Secretary de-
23 termines that the exporter has a sufficient
24 history of compliance with the registration
25 conditions.

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

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

12 “(B) may include anti-counterfeiting or
13 track-and-trace technologies.

14 “(3) CERTAIN DUTIES.—Duties of the Sec-
15 retary under paragraphs (1) and (2) regarding an
16 exporter include the following:

17 “(A) Verifying the chain of custody of each
18 qualifying drug from the manufacturer of the
19 drug to the exporter.

20 “(B) If one or more qualifying drugs are
21 exported to individuals under subsection
22 (a)(2)(B), randomly selecting samples of such
23 exports for the purpose of determining whether
24 the drugs are being imported by the individuals
25 in accordance with the conditions under sub-

1 section (i). Such sampling shall be conducted in
2 a manner that will result in a statistically sig-
3 nificant determination of compliance with all
4 such conditions.

5 “(C) Monitoring the affixing of markings
6 under paragraph (2).

7 “(e) FEES.—

8 “(1) IN GENERAL.—A registration condition is
9 that the exporter involved pays to the Secretary in
10 accordance with this subsection a fee on a semi-
11 annual basis, with the first fee due on the date on
12 which the exporter first submits a registration under
13 subsection (b).

14 “(2) AMOUNT OF FEE.—

15 “(A) AGGREGATE TOTAL OF FEES.—The
16 Secretary shall ensure that the aggregate total
17 of fees collected under paragraph (1) for a fis-
18 cal year from all exporters is sufficient to pay
19 the costs of administering this section for a fis-
20 cal year, including monitoring foreign facilities
21 under subsection (d); developing, implementing,
22 and maintaining under such subsection a sys-
23 tem to mark shipments to indicate compliance
24 with all registration conditions; and conducting
25 under such subsection inspections within the

1 United States to determine compliance with
2 conditions under subsections (h) and (i); except
3 that, during the 12-month period beginning on
4 the date of the promulgation of the interim
5 final rule for implementing this section, the
6 Secretary may collect a lesser aggregate total of
7 fees, taking into account the number of reg-
8 istered exporters and the capacity of such ex-
9 porters as a group to pay such administrative
10 costs.

11 “(B) INDIVIDUAL EXPORTER FEE.—Sub-
12 ject to the exception described in subparagraph
13 (A), a fee under paragraph (1) for an exporter
14 shall be an amount that is a reasonable esti-
15 mate by the Secretary of the semiannual pro
16 rata share of the exporter of the costs referred
17 to in subparagraph (A). Such pro rata share
18 shall take into account the number of employees
19 that the Secretary has under subsection
20 (d)(1)(B) assigned to the exporter.

21 “(3) USE OF FEES.—Subject to appropriations
22 Acts, fees collected by the Secretary under para-
23 graph (1) are available to the Secretary for paying
24 the costs referred to in paragraph (2)(A).

1 “(f) LICENSING AS A PHARMACY.—A registration
2 condition is that the exporter involved agrees that a quali-
3 fying drug will under subsection (a)(2)(B) be exported to
4 an individual only if the Secretary has determined that—

5 “(1) (A) the exporter is authorized under for-
6 eign law to dispense drugs that are only safe for use
7 under the supervision of a practitioner authorized by
8 law to administer such drugs; and

9 “(B) the foreign country that issued such au-
10 thORIZATION for the exporter did so under a regu-
11 latory program that, with respect to the training of
12 persons who dispense such drugs but do not admin-
13 ister the drugs, protects the public health in a man-
14 ner comparable to programs of the States that regu-
15 late pharmacists; or

16 “(2) in any case in which the exporter does not
17 meet the condition described in paragraph (1), the
18 exporter employs a sufficient number of individuals
19 that are licensed as a pharmacist under the law of
20 one of the States, and the exporter assigns to such
21 pharmacist responsibility for dispensing qualifying
22 drugs under subsection (a)(2)(B).

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

24 “(1) IN GENERAL.—A registration condition is
25 that each qualifying drug exported under subsection

1 (a) by the exporter involved is in compliance with
2 the standards referred to in section 801(a) regarding
3 admission of the drug into the United States, sub-
4 ject to paragraphs (2) and (3) and subsection (j).

5 “(2) APPROVAL STATUS.—

6 “(A) IMPORTATION.—Subject to subpara-
7 graphs (C) and (D), a drug may, in accordance
8 with the other subsections of this section, be
9 imported into the United States if the following
10 criteria are met:

11 “(i) The Secretary has with respect to
12 the drug verified compliance with sub-
13 section (c), including verifying that the
14 drug is approved for commercial distribu-
15 tion in a foreign country specified in para-
16 graph (4) of such subsection, and that the
17 establishment that manufactured the drug
18 also manufactures the drug for distribution
19 in the United States (referred to in this
20 paragraph as a ‘U.S. label drug’).

21 “(ii) As compared to the U.S. label
22 drug, the drug has the same active ingre-
23 dient or ingredients, route of administra-
24 tion, dosage form, and strength, according

1 to information provided by the labeling of
2 the drug.

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

5 “(i) IN GENERAL.—A person who
6 manufactures a drug imported under sub-
7 section (a) may in accordance with this
8 paragraph file with the Secretary a peti-
9 tion that requests the Secretary to order
10 that importation of the drug under such
11 subsection cease. Such a petition may be
12 accepted for filing only if the petition
13 claims that the drug is changed from the
14 U.S. label drug and the change would re-
15 quire the submission of a supplemental ap-
16 plication if made to the U.S. label drug,
17 and only if the petition claims that—

18 “(I) the change could, under sec-
19 tion 314.70 of title 21, Code of Fed-
20 eral Regulations, be made before the
21 approval of such application; or

22 “(II) (aa) the change could not,
23 under such section 314.70, be made
24 before the approval of such applica-
25 tion; and

1 Federal Regulations, a supplemental
2 application would not be required.

3 “(iv) FEE.—The Secretary may not
4 accept a petition under clause (i) for filing
5 unless the person submitting the petition
6 pays to the Secretary a fee in the same
7 amount as would apply if the person were
8 paying a fee pursuant to section
9 736(a)(1)(A)(ii), except that the fee may
10 not be required for a petition that, under
11 clause (i)(II)(bb), makes a nonequivalence
12 claim (as defined in subparagraph (E)(i)).
13 Subject to appropriations Acts, fees col-
14 lected by the Secretary under the pre-
15 ceding sentence are available to the Sec-
16 retary for paying the costs referred to in
17 subsection (e)(2)(A).

18 “(v) REVIEW BY SECRETARY.—The
19 Secretary shall grant or deny a petition
20 under clause (i) not later than 180 days
21 after the date on which the petition is
22 filed.

23 “(C) PETITION; DRUG CHANGES NOT RE-
24 QUIRING PRIOR APPROVAL.—In the case of a
25 petition under subparagraph (B)(i)(I):

1 “(i) During the period in which the
2 petition is being reviewed by the Secretary,
3 the authority under subsection (a) to im-
4 port the petition drug involved continues in
5 effect, subject to clause (ii).

6 “(ii) Such authority is, during such
7 period, subject to the condition that—

8 “(I) any importer importing the
9 petition drug under subsection
10 (a)(2)(A) inform individuals to whom
11 the importer sells or dispenses the
12 drug that the manufacturer is making
13 a claim that the drug is different than
14 the U.S. label drug; and

15 “(II) the registered exporter in-
16 volved notify any individuals import-
17 ing the petition drug from the ex-
18 porter under subsection (a)(2)(B) that
19 the manufacturer is making such a
20 claim.

21 “(iii) If the Secretary determines that
22 the supplemental application referred to in
23 subparagraph (C)(i)(I) regarding the U.S.
24 label drug would not be approved, the Sec-
25 retary shall grant the petition and order

1 that approved the petition drug for com-
2 mercial distribution:

3 “(I) The person filing the peti-
4 tion submits with the petition infor-
5 mation demonstrating that the person
6 has notified the government of the
7 foreign country in writing that the
8 person is submitting to the Secretary
9 a claim under clause (i), which notice
10 describes the claim.

11 “(II) Such person submits with
12 the petition the information the per-
13 son submitted to the government of
14 the foreign country for purposes of
15 obtaining approval for commercial dis-
16 tribution of the petition drug in the
17 country.

18 “(iii) POSSIBLE-NONEQUIVALENCE
19 CLAIM.—In the case of a petition under
20 subparagraph (C)(i) that makes a possible-
21 nonequivalence claim:

22 “(I) Clauses (i) and (ii) of sub-
23 paragraph (C) apply to the same ex-
24 tent and in the same manner as such
25 clauses apply to a petition under sub-

1 paragraph (B)(i) that makes a claim
2 described in subclause (I) of such sub-
3 paragraph.

4 “(II) If the Secretary determines
5 that the petition drug is not bio-
6 equivalent to the U.S. label drug, the
7 Secretary shall grant the petition and
8 order that importation of the petition
9 drug under subsection (a) cease.

10 “(iv) NONEQUIVALENCE CLAIM.—In
11 the case of a petition under subparagraph
12 (B)(i) that makes a nonequivalence claim:

13 “(I) Promptly after the petition
14 is filed, the Secretary shall order that
15 the importation of the petition drug
16 involved cease during the period in
17 which the petition is under review by
18 the Secretary.

19 “(II) If the Secretary determines
20 that the petition drug is not bio-
21 equivalent to the U.S. label drug, the
22 Secretary shall grant the petition and
23 provide that the order under sub-
24 clause (I) remains in effect.

1 “(v) DRUGS APPROVED ON OR AFTER
2 JANUARY 1, 2004.—In the case of a petition
3 under subparagraph (C)(i) that makes a
4 possible-nonequivalence claim or a non-
5 equivalence claim, if the petition drug in-
6 volved for commercial distribution was ap-
7 proved by the foreign government on or
8 after January 1, 2004, or if the U.S. label
9 drug was approved by the Secretary on or
10 after such date:

11 “(I) The Secretary may not ac-
12 cept the petition for filing unless the
13 person submitting the petition sub-
14 mits with the petition information
15 demonstrating that—

16 “(aa) the difference between
17 the petition drug and the U.S.
18 label drug is due to a difference
19 between the legal requirements
20 for approval of the drug in the
21 foreign country and for approval
22 by the Secretary; or

23 “(bb) the person has sub-
24 mitted a supplemental application
25 to the government of the foreign

1 country, or to the Secretary, that
2 will, if approved, remove the dif-
3 ference between the petition drug
4 and the U.S. label drug.

5 “(II) If under clause (iii)(II) or
6 (iv)(II) the Secretary has ordered that
7 importation of the petition drug under
8 subsection (a) cease, the Secretary
9 shall rescind the order promptly after
10 the approval of a supplemental appli-
11 cation referred to in subclause (I)(bb)
12 of this clause.

13 “(vi) FALSE STATEMENTS.—The Sec-
14 retary shall rescind an order under clause
15 (iii)(II) or (iv)(II) promptly after deter-
16 mining that a materially false, fictitious, or
17 fraudulent statement or representation in
18 the petition involved was a material factor
19 in the decision of the Secretary to grant
20 the petition.

21 “(3) LABELING.—

22 “(A) IMPORTATION BY IMPORTER.—In the
23 case of a qualifying drug that under subsection
24 (a)(2)(A) is imported or offered for import with
25 respect to an importer, such drug shall be con-

1 sidered to be in compliance with section 502 if
2 the drug bears a copy of the labeling approved
3 for the drug under section 505, without regard
4 to whether the copy bears the trademark in-
5 volved. The Secretary shall provide such copy to
6 the registered exporter involved, upon request
7 of the exporter.

8 “(B) IMPORTATION BY INDIVIDUAL.—In
9 the case of a qualifying drug that under sub-
10 section (a)(2)(B) is imported or offered for im-
11 port with respect to an individual, such drug
12 shall be considered to be in compliance with
13 section 502 if the drug bears a label providing
14 the directions for use by the consumer, and
15 bears a copy of any special labeling that would
16 be required by the Secretary had the drug been
17 dispensed by a pharmacist in the United States,
18 without regard to whether the special labeling
19 bears the trademark involved. The Secretary
20 shall provide to the registered exporter involved
21 a copy of the special labeling, upon request of
22 the exporter.

23 “(h) IMPORTERS; CONDITIONS FOR IMPORTATION.—

24 “(1) IN GENERAL.—For purposes of subsection
25 (a)(2)(A), the importation of a qualifying drug by an

1 importer is in accordance with this subsection if the
2 following conditions are met:

3 “(A) The importer, or a business organiza-
4 tion of which the importer is a part, takes deliv-
5 ery directly from the mail, from a common car-
6 rier, or from a vehicle or aircraft owned by the
7 importer or such business organization.

8 “(B) From the port of entry for the drug
9 to the delivery of the drug to the importer or
10 such business organization—

11 “(i) all transport of the drug was by
12 one or more of the modes of transport
13 specified in subparagraph (A); and

14 “(ii) personnel of the transporting en-
15 tities involved had exclusive custody of the
16 drug, without the custodial involvement of
17 any other type of entity, including a person
18 in the business of the wholesale distribu-
19 tion of drugs.

20 “(2) RULE OF CONSTRUCTION.—Paragraph (1)
21 may not be construed as prohibiting a person in the
22 business of the wholesale distribution of drugs, or
23 any other entity that is not an importer, or a busi-
24 ness organization referred to in paragraph (1)(A),
25 from negotiating the purchase price of qualifying

1 drugs from a registered exporter or from otherwise
2 being involved in the process of purchasing such
3 drugs from such exporters, if such person or other
4 entity does not at any point have custody of such
5 drugs.

6 “(i) PERSONAL USE; CONDITIONS FOR IMPORTA-
7 TION.—

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

12 “(A) The drug is accompanied by—

13 “(i) a copy of a prescription for the
14 drug, which prescription—

15 “(I) is valid under applicable
16 Federal and State laws; and

17 “(II) was issued by a practitioner
18 who, under the law of a State of
19 which the individual is a resident, is
20 authorized to administer prescription
21 drugs; and

22 “(ii) a statement that provides infor-
23 mation sufficient for the Secretary to de-
24 termine whether the prescription meets the
25 requirement of clause (i), including with

1 respect to the licensure of the practitioner
2 who issued the prescription.

3 “(B) With respect to the foreign country
4 from which the registered exporter involved dis-
5 pensed the drug, the drug is accompanied by a
6 copy of the documentation that was required
7 under the law or regulations of such country as
8 a condition of dispensing the drug to the indi-
9 vidual.

10 “(C) The copies referred to in subpara-
11 graphs (A)(i) and (B) are marked in a manner
12 sufficient—

13 “(i) to indicate that the prescription,
14 and the equivalent document in the foreign
15 country involved, have been filled; and

16 “(ii) to prevent a duplicative filling by
17 another pharmacist.

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

20 “(E) The drug is not an ineligible subpart
21 H drug. For purposes of this section, a pre-
22 scription drug is an ineligible subpart H drug
23 if the drug was approved by the Secretary
24 under subpart H of part 314 of title 21, Code
25 of Federal Regulations (relating to accelerated

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

7 “(2) NOTICE REGARDING PERSONAL ENTRY.—

8 A registration condition is that the exporter involved
9 agrees that, in providing a qualifying drug to an in-
10 dividual under subsection (a)(2)(B) in circumstances
11 in which the drug will accompany the individual as
12 the individual enters the United States, the exporter
13 will notify the individual that the drug is authorized
14 to be imported under such subsection only if the
15 shipping container for the drug is intact and bears
16 the marking affixed under subsection (d)(2).

17 “(3) PRESUMPTION.—In the case of importa-
18 tion under this subsection, for purposes of judicial
19 and administrative procedure, there is a presumption
20 that a drug proposed for export under subsection (a)
21 is an approved drug under section 505(b)(1) if the
22 criteria described in subsection (g)(A)(i) and (ii) are
23 met.

24 “(j) STANDARDS FOR REFUSING ADMISSION.—A
25 qualifying drug exported under subsection (a) from a reg-

1 istered exporter may be refused admission into the United
2 States only if one or more of the following applies:

3 “(1) The shipping container for such drug does
4 not bear the markings required subsection (d)(2).

5 “(2) Such markings appear to be counterfeit.

6 “(3) The shipping container or markings ap-
7 pear to have been tampered with.

8 “(4) The shipping container appears damaged
9 in a way that may affect the strength, quality, or
10 purity of the drug.

11 “(5) After the shipment leaves the custody of
12 the registered exporter, the Secretary becomes aware
13 that—

14 “(A) the drug may be counterfeit;

15 “(B) the drug may have been prepared,
16 packed, or held under insanitary conditions
17 whereby it may have been contaminated with
18 filth; or

19 “(C) the methods used in, or the facilities
20 or controls used for, the manufacturing, proc-
21 essing, packing, or holding of the drug do not
22 conform to good manufacturing practice.

23 “(6) The Secretary has obtained an injunction
24 under section 302 that prohibits the distribution of
25 the drug in interstate commerce.

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

3 “(8) The manufacturer of the drug has insti-
4 tuted a recall of the drug.

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

13 (b) PROHIBITED ACTS.—The Federal Food, Drug,
14 and Cosmetic Act, as amended by section 1121(b) of Pub-
15 lic Law 108–173 (117 Stat. 2469), is amended—

16 (1) in section 301 (21 U.S.C. 331), by amend-
17 ing paragraph (aa) to read as follows:

18 “(aa)(1) The sale or trade by an importer, or by a
19 business organization of which the importer is a part, of
20 a qualifying drug that under section 804(a)(2)(A) was im-
21 ported by the importer, other than—

22 “(A) a sale at retail made pursuant to dis-
23 pensing the drug to a customer of the importer or
24 organization; or

1 “(B) a sale or trade of the drug to the reg-
2 istered exporter from which the importer imported
3 the drug.

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

7 “(3) The knowing making of a materially false, ficti-
8 tious, or fraudulent statement or representation in a peti-
9 tion under clause (i) of section 804(g)(2)(C). Such a peti-
10 tion that is not accepted for filing by reason of clause (iii)
11 of such section shall be considered to contain such a state-
12 ment or representation.”; and

13 (2) in section 303(a) (21 U.S.C. 333(a)), by
14 amending paragraph (6) to read as follows:

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

19 (c) CIVIL PENALTY.—

20 (1) TECHNICAL AMENDMENTS.—

21 (A) IN GENERAL.—Section 303 of the Fed-
22 eral Food, Drug, and Cosmetic Act (21 U.S.C.
23 333) is amended in the last subsection by strik-
24 ing the subsection designation and all that fol-

1 lows through “Except as provided” in para-
2 graph (1)(A) and inserting the following:

3 “(f)(1)(A) Except as provided”.

4 (B) CERTAIN ACTS.—The amendments
5 made by the following provisions of law are
6 deemed to have been made to subsection (f) of
7 section 303 of the Federal Food, Drug, and
8 Cosmetic Act, as amended by subparagraph (A)
9 of this paragraph:

10 (i) section 407 of the Food Quality
11 Protection Act of 1996 (110 Stat. 1535);
12 and

13 (ii) section 201(c) of the Medical De-
14 vice User Fee and Modernization Act of
15 2002 (116 Stat. 1609).

16 (2) CIVIL PENALTIES.—

17 (A) IN GENERAL.—Section 303 of the Fed-
18 eral Food, Drug, and Cosmetic Act (21 U.S.C.
19 333), as amended by paragraph (1) of this sub-
20 section, is amended in subsection (f)—

21 (i) by redesignating paragraphs (3)
22 through (5) as paragraphs (4) through (6),
23 respectively; and

24 (ii) by inserting after paragraph (2)
25 the following paragraph:

1 “(3) Any person who knowingly violates section
2 301(aa)(3) and whose statement or representation
3 described in such section was a material factor in
4 the decision of the Secretary to issue an order under
5 clause (iii)(II) or (iv)(II) of section 804(g)(2)(E)
6 shall be liable to the United States for a civil penalty
7 in an amount not to exceed a reasonable estimate of
8 the gross revenue that, pursuant to section 804,
9 would have been collected by the register exporter
10 involved for sales of the qualifying drug involved to
11 importers and individuals in the United States dur-
12 ing the period for which the order was in effect.”.

13 (B) CONFORMING AMENDMENTS.—Section
14 303(f) of the Federal Food, Drug, and Cos-
15 metic Act, as amended by subparagraph (A), is
16 amended—

17 (i) in paragraph 5 (as redesignated)
18 by striking “paragraph (3)(A)” and insert-
19 ing “paragraph (4)(A)”; and

20 (ii) in paragraph 6 (as redesignated)
21 by striking “paragraph (4)” each place it
22 appears and inserting “paragraph (5)”.

23 (d) IMPLEMENTATION.—

24 (1) RULEMAKING.—Not later than 90 days
25 after the date of the enactment of this Act, the Sec-

1 retary of Health and Human Services shall promul-
2 gate an interim final rule for implementing section
3 804 of the Federal Food, Drug, and Cosmetic Act,
4 as added by subsection (a) of this section. Such rule
5 shall be developed and promulgated by the Secretary
6 without providing general notice of proposed rule-
7 making, and the rule may be made effective imme-
8 diately upon promulgation of the rule. Not later
9 than one year after the date on which the interim
10 final rule is promulgated, the Secretary shall, in ac-
11 cordance with procedures under section 553 of title
12 5, United States Code, promulgate a final rule for
13 implementing such section 804, which may incor-
14 porate by reference provisions of the interim final
15 rule, to the extent that such provisions are not modi-
16 fied.

17 (2) PERSONAL IMPORTATION FROM CANADA.—
18 Until the expiration of the 45-day period beginning
19 on the date on which the interim final rule under
20 paragraph (1)(A) is promulgated, an individual may
21 import a prescription drug from Canada for personal
22 use or for the use of a family member of the indi-
23 vidual (rather than for resale), subject to compliance
24 with each of the following conditions:

25 (A) The drug is not—

1 (i) a controlled substance, as defined
2 in section 102 of the Controlled Sub-
3 stances Act;

4 (ii) a biological product, as defined in
5 section 351 of the Public Health Service
6 Act;

7 (iii) an infused drug, including a peri-
8 toneal dialysis solution;

9 (iv) an intravenously injected drug;

10 (v) a drug that is inhaled during sur-
11 gery; or

12 (vi) a drug approved by the Secretary
13 under subpart H of part 314 of title 21,
14 Code of Federal Regulations (relating to
15 accelerated approval) with restrictions
16 under section 520 of such part to assure
17 safe use.

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

20 (C) The drug is accompanied by a copy of
21 the prescription for the drug, which prescrip-
22 tion—

23 (i) is valid under applicable Federal
24 and State laws; and

1 (ii) was issued by a practitioner who,
2 under the law of a State of which the indi-
3 vidual is a resident, is authorized to ad-
4 minister prescription drugs.

5 (D) The drug is accompanied by a copy of
6 the document that was required in Canada as
7 a condition of dispensing the drug to the indi-
8 vidual.

9 (E) The copies referred to in subpara-
10 graphs (C) and (D) are marked in a manner
11 sufficient—

12 (i) to indicate that the prescription,
13 and the equivalent document in Canada,
14 have been filled; and

15 (ii) to prevent a duplicative filling by
16 another pharmacist.

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

19 (e) AMENDMENT OF CERTAIN PROVISION.—Section
20 801(g) of the Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 381) is amended—

22 (1) in the matter preceding clause (i), by strik-
23 ing “With respect to” and all that follows through
24 “may not send” and inserting the following: “With
25 respect to a qualifying drug that is imported or of-

1 ferred for import in the United States by an indi-
2 vidual pursuant to section 804(a)(2)(B), the Sec-
3 retary may not send”;

4 (2) by redesignating clause (iv) as clause (v);

5 (3) in clause (iii), by striking “or” at the end;

6 and

7 (4) by inserting after clause (iii) the following:

8 “(iv) importation is not in accordance with
9 section 804; or”.

10 **SEC. 4. ADDITIONAL WAIVERS REGARDING PERSONAL IM-**
11 **PORTATION; ENFORCEMENT POLICIES OF**
12 **SECRETARY.**

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

16 “(p)(1) Waivers under this subsection are in addition
17 to, and independent of, the waiver pursuant to section
18 804(a)(2)(B).

19 “(2) With respect to the standards referred to in sub-
20 section (d)(1), the Secretary may establish by regulation
21 a waiver of such standards in the case of the importation
22 by an individual of a drug into the United States in the
23 following circumstances:

24 “(A) The drug was dispensed to the individual
25 while the individual was in the United States, the

1 drug was dispensed by a pharmacist or by a practi-
2 tioner licensed by law to administer the drug, and
3 the individual traveled from the United States with
4 the drug.

5 “(B) The individual is entering the United
6 States and the drug accompanies the individual at
7 the time of entry.

8 “(C) The drug does not appear to the Secretary
9 to be adulterated.

10 “(D) The quantity of the drug does not exceed
11 a 30-day supply.

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

15 “(F) The importation complies with such addi-
16 tional standards as the Secretary determines to be
17 appropriate to protect the public health.

18 “(3) With respect to the standards referred to in sub-
19 sections (a) and (d)(1), the Secretary may establish by
20 regulation a waiver of such standards in the case of the
21 importation by an individual of a drug into the United
22 States in the following circumstances:

23 “(A) The drug was dispensed to the individual
24 while the individual was in a foreign country, and

1 the drug was dispensed in accordance with the laws
2 and regulations of such country.

3 “(B) The individual is entering the United
4 States and the drug accompanies the individual at
5 the time of entry.

6 “(C) The drug is approved for commercial dis-
7 tribution in the foreign country in which the drug
8 was obtained.

9 “(D) The drug does not appear to the Secretary
10 to be adulterated.

11 “(E) The quantity of the drug does not exceed
12 a 10-day supply.

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

16 “(G) The importation complies with such addi-
17 tional standards as the Secretary determines to be
18 appropriate to protect the public health.

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

24 (b) ADDITIONAL WAIVER.—This Act and the amend-
25 ments made by this Act shall not be construed as limiting

1 the authority of the Secretary of Health and Human Serv-
2 ices to establish a waiver of the standards referred to in
3 section 801(a) of the Federal Food, Drug, and Cosmetic
4 Act with respect to the importation by an individual of
5 a drug into the United States that does not meet such
6 standards, provided that such waiver is no more permis-
7 sive than the guidance, as in effect on January 1, 2004,
8 that is provided in the item numbered 2 (relating to a
9 specific situation, consisting of conditions (a) through (d))
10 under the heading “Drugs, Biologics, and Devices” in
11 chapter 9 of the FDA/ORA Regulatory Procedures Man-
12 ual (relating to import operations/actions), in the sub-
13 chapter relating to coverage of personal importations.

14 **SEC. 5. DISPOSITION OF CERTAIN DRUGS DENIED ADMIS-**
15 **SION INTO UNITED STATES.**

16 (a) IN GENERAL.—Chapter VIII of the Federal
17 Food, Drug, and Cosmetic Act, as amended by section 3
18 of this Act, is amended by adding at the end the following
19 section:

20 **“SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED AD-**
21 **MISSION.**

22 “(a) IN GENERAL.—A shipment of drugs that is im-
23 ported or offered for import into the United States shall
24 be refused admission if the shipment has a declared value
25 of less than \$10,000 and the drugs are in violation of any

1 standard referred to in section 801(a) or 801(d)(1), in-
2 cluding any drugs imported or offered for import under
3 enforcement policies prohibited under section 801(q).

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

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

16 “(d) CERTAIN PROCEDURES.—

17 “(1) IN GENERAL.—The refusal of admission
18 and destruction of drugs under this section may be
19 carried out without notice to the importer, owner, or
20 consignee of the drugs. The issuance of receipts for
21 the drugs, and recordkeeping activities regarding the
22 drugs, may be carried out on a summary basis.

23 “(2) OBJECTIVE OF PROCEDURES.—Procedures
24 promulgated under paragraph (1) shall be designed
25 toward the objective of ensuring that, with respect to

1 efficiently utilizing Federal resources available for
2 carrying out this section, a substantial majority of
3 shipments of drugs subject to subsection (a) or (b)
4 are identified and refused admission and destroyed.

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

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

15 “(g) ADMINISTRATION.—This section may be not be
16 construed as transferring to the Secretary responsibility
17 for carrying out this section.”.

18 (b) PROCEDURES.—Procedures for carrying out sec-
19 tion 805 of the Federal Food, Drug, and Cosmetic Act,
20 as added by subsection (a) of this subsection, shall be es-
21 tablished not later than 30 days after the date of the en-
22 actment of this Act.

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

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

5 “(g)(1) If a person is alienating or disposing of prop-
6 erty, or intends to alienate or dispose of property, that
7 is obtained as a result of or is traceable to a drug imported
8 in violation of subsection (a) or (d) of section 801 or sec-
9 tion 804, the Attorney General may commence a civil ac-
10 tion in any Federal court—

11 “(A) to enjoin such alienation or disposition of
12 property; or

13 “(B) for a restraining order to—

14 “(i) prohibit any person from withdrawing,
15 transferring, removing, dissipating, or disposing
16 of any such property or property of equivalent
17 value; and

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

20 “(2) Proceedings under paragraph (1) shall be
21 carried out in the same manner as applies under
22 section 1345 of title 18, United States Code.”.

1 **SEC. 7. WHOLESALE DISTRIBUTION OF DRUGS; STATE-**
2 **MENTS REGARDING PRIOR SALE, PURCHASE,**
3 **OR TRADE.**

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

8 (1) in paragraph (1)—

9 (A) by striking “and who is not the manu-
10 facturer or an authorized distributor of record
11 of such drug” and inserting “, other than a
12 registered exporter under section 804,”;

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

15 (C) by striking subparagraph (B) and in-
16 serting the following subparagraphs:

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

24 “(C) (i) The Secretary may by regulation establish
25 requirements that supersede subparagraph (A) (referred
26 to in this subparagraph as ‘alternative requirements’) to

1 identify the chain of custody of a drug subject to sub-
2 section (b) from the manufacturer of the drug throughout
3 the wholesale distribution of the drug to an importer who
4 intends to sell the drug at retail if the Secretary deter-
5 mines that the alternative requirements will identify such
6 chain of custody or the identity of the drug with greater
7 certainty than the requirements of subparagraph (A), and
8 that the alternative requirements are economically and
9 technically feasible.

10 “(ii) If the Secretary promulgates a final rule to es-
11 tablish such alternative requirements, the final rule in ad-
12 dition shall, with respect to the registration condition es-
13 tablished in clause (i) of section 804(c)(3)(B), establish
14 a condition equivalent to the alternative requirements, and
15 such equivalent condition supersedes such clause (i).”;

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

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

1 (b) CONFORMING AMENDMENT.—Section 503(d) of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 353(d)) is amended by adding at the end the following
4 paragraphs:

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

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

12 **SEC. 8. REPEAL OF IMPORTATION EXEMPTION UNDER CON-**
13 **TROLLED SUBSTANCES IMPORT AND EXPORT**
14 **ACT.**

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

17 **SEC. 9. ENFORCEMENT THROUGH DENIAL OF DEDUCTION**
18 **FOR CERTAIN ADVERTISING EXPENSES.**

19 (a) IN GENERAL.—Part IX of subchapter B of chap-
20 ter 1 of the Internal Revenue Code of 1986 (relating to
21 items not deductible) is amended by adding at the end
22 the following new section:

1 **“SEC. 280L. ADVERTISING EXPENDITURES OF TAXPAYERS**
2 **WHO DISCRIMINATE AGAINST FOREIGN SELL-**
3 **ERS OF PRESCRIPTION DRUGS TO DOMESTIC**
4 **CONSUMERS.**

5 “(a) IN GENERAL.—No deduction otherwise allow-
6 able under this chapter shall be allowed for any amount
7 paid or incurred for advertising for the taxable year by
8 any taxpayer unless the taxpayer certifies that the tax-
9 payer has not taken any action, directly or indirectly, dur-
10 ing such taxable year to prevent the authorized importa-
11 tion of a qualifying drug into the United States from a
12 registered exporter to a pharmacy or individual pursuant
13 to section 804(a) of the Federal Food, Drug, and Cos-
14 metic Act or has otherwise conditioned the terms by which
15 a qualifying drug is imported into the United States from
16 a registered exporter under such section. Such certifi-
17 cation shall be made in such manner as the Secretary de-
18 termines and shall be accompanied by such fees as the
19 Secretary determines necessary to cover the costs of con-
20 firming such certification.

21 “(b) ADVERTISING.—For purposes of this section,
22 the term ‘advertising’ includes direct to consumer adver-
23 tising and any activity designed to promote the use of a
24 prescription drug directed to providers or others who may
25 make decisions about the use of prescription drugs (other
26 than the provision of free samples).”.

1 (b) CLERICAL AMENDMENT.—The table of sections
2 for part IX of subchapter B of chapter 1 of such Code
3 is amended by adding at the end thereof the following new
4 item:

“Sec. 280L. Advertising expenditures of taxpayers who discriminate against foreign sellers of prescription drugs to domestic consumers.”.

5 (c) EFFECTIVE DATE.—The amendments made by
6 this section shall apply to taxable years beginning after
7 the date of the enactment of this Act.

8 **SEC. 10. COMPLIANCE THROUGH ALLOWANCE OF RE-**
9 **SEARCH AND DEVELOPMENT TAX CREDIT.**

10 (a) IN GENERAL.—Section 41 of the Internal Rev-
11 enue Code of 1986 (relating to credit for increasing re-
12 search activities) is amended by adding at the end the fol-
13 lowing new subsection:

14 “(i) INCREASE IN CREDIT FOR CERTAIN TAX-
15 PAYERS.—The amount of the credit otherwise determined
16 under this section for any taxable year shall be increased
17 by 20 percent if the taxpayer certifies that the taxpayer
18 has not taken any action, directly or indirectly, during
19 such taxable year to prevent the authorized importation
20 of a qualifying drug into the United States from a reg-
21 istered exporter to a pharmacy or individual pursuant to
22 section 804(a) of the Federal Food, Drug, and Cosmetic
23 Act or has otherwise conditioned the terms by which a
24 qualifying drug is imported into the United States from

1 a registered exporter under such section. Such certifi-
2 cation shall be made in such manner as the Secretary de-
3 termines and shall be accompanied by such fees as the
4 Secretary determines necessary to cover the costs of con-
5 firming such certification.”.

6 (b) EFFECTIVE DATE.—The amendment made by
7 this section shall apply to taxable years beginning after
8 the date of the enactment of this Act.