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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pharmaceutical Market Access and Drug Safety Act of 2004''.

SEC. 2. FINDINGS.

Congress finds that—

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

(2) the United States is the largest market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand pharmaceuticals in the world;

(3) a prescription drug is neither safe nor effective to an individual who cannot afford it;

(4) allowing and structuring the importation of prescription drugs to ensure access to safe and affordable drugs approved by the Food and Drug Administration will provide a level of safety to American consumers that they do not currently enjoy;

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

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

SEC. 3. REPEAL OF CERTAIN SECTION REGARDING IMPORTATION OF PRESCRIPTION DRUGS.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804.

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

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

"SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF PRESCRIPTION DRUGS.

''(a) IMPORTATION OF PRESCRIPTION DRUGS.—

''(1) IN GENERAL.—The Secretary shall in accordance with this section provide by regulation that, in the case of qualifying drugs imported or offered for import into the United States from registered exporters or by registered importers—

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

''(B) the standards referred to in section 801(a) regarding admission of the drugs are subject to subsection (g) of this section (including with respect to qualifying drugs to which section 801(d)(1) does not apply).

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

''(A) the drug is imported by a pharmacy or a wholesaler that is a registered importer; or

''(B) the drug is imported by an individual for personal use or for the use of a family member of the individual (not for resale) from a registered exporter.

''(3) RULE OF CONSTRUCTION.—This section shall apply only with respect to a drug that is imported or offered for import into the United States—

''(A) by a registered importer; or

''(B) from a registered exporter to an individual.

''(4) DEFINITIONS.—

''(A) REGISTERED EXPORTER; REGISTERED IMPORTER.—For purposes of this section:

''(i) The term 'registered exporter' means an exporter for which a registration under subsection (b) has been approved and is in effect.

''(ii) The term 'registered importer' means a pharmacy, group of pharmacies, or a wholesaler for which a registration under subsection (b) has been approved and is in effect.

''(iii) The term 'registration condition' means a condition that must exist for a registration under subsection (b) to be approved.

''(B) QUALIFYING DRUG.—For purposes of this section, the term 'qualifying drug' means a prescription drug, other than any of the following:

''(i) A controlled substance, as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802).

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

''(iii) An infused drug, including a peritoneal dialysis solution.

''(iv) An intravenously injected drug.

''(v) A drug that is inhaled during surgery.

''(C) OTHER DEFINITIONS.—For purposes of this section:

''(i) The term 'exporter' means a person that is in the business of exporting a drug from Canada to individuals in the United States or that, pursuant to submit-

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

''(ii) The term 'importer' means a pharmacy, a group of pharmacies, or a wholesaler that is in the business of importing a drug into the United States or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

''(iii) The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

''(iv) The term 'pharmacy' means a person that—

''(I) is licensed by a State to engage in the business of selling prescription drugs at retail; and

''(II) employs 1 or more pharmacists.

''(v) The term 'prescription drug' means a drug that is described in section 503(b)(1).

''(vi) The term 'wholesaler'—

"(I) means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A); and

"(II) does not include a person authorized to import drugs under section 801(d)(1).

"(D) PERMITTED COUNTRY.—The term 'permitted country' means—

"(i) Australia;

"(ii) Canada;

"(iii) a member country of the European Union as of January 1, 2003;

"(iv) Japan;

"(v) New Zealand; and

"(vi) Switzerland.

"(b) REGISTRATION OF IMPORTERS AND EXPORTERS.—

"(1) REGISTRATION OF IMPORTERS AND EXPORTERS.—A registration condition is that the importer or exporter involved (referred to in this subsection as a 'registrant') submits to the Secretary a registration containing the following:

"(A) The name of the registrant and an identification of all places of business of the

registrant that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the registrant.

''(B) Such information as the Secretary determines to be necessary to demonstrate that the registrant is in compliance with registration conditions under—

''(i) in the case of an importer, subsections (c), (d), (e), (g), and (j) (relating to the sources of exported drugs; the inspection of facilities of the importer; the payment of fees; compliance with the standards referred to in section 801(a); and maintenance of records and samples); or

''(ii) in the case of an exporter, subsections (c), (d), (f), (g), (h), (i), and (j) (relating to the sources of exported drugs; the inspection of facilities of the exporter and the marking of compliant shipments; the payment of fees; and compliance with the standards referred to in section 801(a); being licensed as a pharmacist; conditions for individual importation from Canada; and maintenance of records and samples).

''(C) An agreement by the registrant that the registrant will not under subsection (a) import or export any drug that is not a qualifying drug.

''(D) An agreement by the registrant to—

''(i) notify the Secretary of a recall or withdrawal of a drug distributed in a permitted country that the registrant has exported or imported, or intends to export or import, to the United States under subsection (a);

''(ii) provide for the return to the registrant of such drug; and

''(iii) cease, or not begin, the exportation or importation of such drug unless the Secretary has notified the registrant that exportation or importation of such drug may proceed.

''(E) An agreement by the registrant to ensure and monitor compliance with each registration condition, to promptly correct any noncompliance with such a condition, and to promptly report to the Secretary any such noncompliance.

"(F) A plan describing the manner in which the registrant will comply with the agreement under subparagraph (E).

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

"(H) An agreement by the registrant to notify the Secretary of—

"(i) any change that the registrant intends to make regarding information provided under subparagraph (A) or (B); and

"(ii) any change that the registrant intends to make in the compliance plan under subparagraph (F).

"(I) In the case of an exporter—

"(i) An agreement by the exporter that a qualifying drug will not under subsection (a) be exported to any individual not authorized pursuant to subsection (a)(2)(B) to be an importer of such drug.

"(ii) An agreement to post a bond, payable to the Treasury of the United

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

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

''(II) $1,000,000.

''(J) Such other provisions as the Secretary may require to protect the public health while permitting—

''(i) the importation by pharmacies, groups of pharmacies, wholesalers as registered importers of qualifying drugs under subsection (a); and

''(ii) importation by individuals of qualifying drugs under subsection (a).

''(2) APPROVAL OR DISAPPROVAL OF REGISTRATION.—

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

mits to the Secretary a registration under paragraph (1), the Secretary shall notify the registrant whether the registration is approved or is disapproved. The Secretary shall disapprove a registration if there is reason to believe that the registrant is not in compliance with one or more registration conditions, and shall notify the registrant of such reason. In the case of a disapproved registration, the Secretary shall subsequently notify the registrant that the registration is approved if the Secretary determines that the registrant is in compliance with such conditions.

''(B) CHANGES IN REGISTRATION INFORMATION.—Not later than 30 days after receiving a notice under paragraph (1)(G) from a registrant, the Secretary shall determine whether the change involved affects the approval of the registration of the registrant under paragraph (1), and shall inform the registrant of the determination.

''(3) PUBLICATION OF CONTACT INFORMATION FOR REGISTERED EXPORTERS.—Through the Internet website of the Food and Drug Administration, the Secretary shall make readily available to the

public a list of registered exporters, including contact information for the exporters. Promptly after the approval of a registration submitted under paragraph (1), the Secretary shall update the Internet website accordingly.

''(4) SUSPENSION AND TERMINATION.—

''(A) SUSPENSION.—With respect to the effectiveness of a registration submitted under paragraph (1):

''(i) Subject to clause (ii), if the Secretary determines, after notice and opportunity for a hearing, that the registrant has failed to maintain substantial compliance with all registration conditions, the Secretary may suspend the registration.

''(ii) If the Secretary determines that, under color of the registration, the exporter has exported a drug or the importer has imported a drug that is not a qualifying drug, or a drug that does not meet the criteria under subsection (g)(2)(A), or has exported a qualifying drug to an individual in violation of subsection (i)(1)(F), the Secretary shall immediately suspend the registration. A suspension under the

preceding sentence is not subject to the provision by the Secretary of prior notice, and the Secretary shall provide to the registrant an opportunity for a hearing not later than 10 days after the date on which the registration is suspended.

''(iii) The Secretary may reinstate the registration, whether suspended under clause (i) or (ii), if the Secretary determines that the registrant has demonstrated that further violations of registration conditions will not occur.

''(B) TERMINATION.—The Secretary, after notice and opportunity for a hearing, may terminate the registration under paragraph (1) of a registrant if the Secretary determines that the registrant has engaged in a pattern or practice of violating 1 or more registration conditions, or if on 1 or more occasions the Secretary has under subparagraph (A)(ii) suspended the registration of the registrant. The Secretary may make the termination permanent, or for a fixed period of not less than 1 year. During the period in which the registration is terminated, any registration submitted under paragraph (1)

by the registrant, or a person that is a partner in the export or import enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

''(c) SOURCES OF QUALIFYING DRUGS.—A registration condition is that the exporter or importer involved agrees that a qualifying drug will under subsection (a) be exported or imported to the United States only if there is compliance with the following:

''(1) The drug was manufactured in an establishment—

''(A) required to register under subsection (h) or (i) of section 510; or

''(B) inspected by the Secretary as provided by this section.

''(2) The establishment is located in the United States or in any foreign country, and the establishment manufactured the drug for distribution in the United States or for distribution in 1 or more of the permitted countries (without regard to whether in addition the drug was manufactured for distribution in a foreign country that is not a permitted country).

''(3) The exporter or importer obtained the drug—

''(A) directly from the establishment; or

''(B) directly from an entity that, by contract with the exporter or importer—

''(i) provides to the exporter or importer a statement (in such form and containing such information as the Secretary may require) that, for the chain of custody from the establishment, identifies each prior sale, purchase, or trade of the drug (including the date of the transaction and the names and addresses of all parties to the transaction);

''(ii) agrees to permit the Secretary to inspect such statements and related records to determine their accuracy;

''(iii) agrees, with respect to the qualifying drugs involved, to permit the Secretary to inspect warehouses and other facilities of the entity for purposes of determining whether the facilities are in compliance with any standards under this Act that are applicable to facilities of that type in the United States; and

''(iv) has ensured, through such contractual relationships as may be necessary, that the Secretary has the same authority regarding other parties in the chain of custody from the establishment that the Secretary has under clauses (ii) and (iii) regarding such entity.

''(4) The foreign country from which the importer will import the drug is a permitted country.

''(5) The foreign country from which the exporter will export the drug is Canada.

''(6) During any period in which the drug was not in the control of the manufacturer of the drug, the drug did not enter any country that is not a permitted country.

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

''(d) INSPECTION OF FACILITIES; MARKING OF SHIPMENTS.—

''(1) INSPECTION OF FACILITIES.—A registration condition is that, for the purpose of assisting the Secretary in determining whether the exporter involved is in compliance with all other registration conditions—

''(A) the exporter agrees to permit the Secretary—

''(i) to conduct onsite inspections, including monitoring on a day-to-day basis, of places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter;

''(ii) to have access, including on a day-to-day basis, to—

''(I) records of the exporter that relate to the export of such drugs, including financial records; and

''(II) samples of such drugs;

''(iii) to carry out the duties described in paragraph (3); and

''(iv) to carry out any other functions determined by the Secretary to be necessary regarding the compliance of the exporter; and

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

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

''(2) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the exporter involved agrees to affix to each shipping container of qualifying drugs exported under subsection (a) such markings as the Secretary determines to be necessary to identify the shipment as being in compliance with all registration conditions. Markings under the preceding sentence—

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

''(B) may include anti-counterfeiting or track-and-trace technologies.

''(3) CERTAIN DUTIES RELATING TO EXPORTERS.—Duties of the Secretary with respect to an exporter include the following:

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

"(B) Randomly reviewing records of exports to individuals for the purpose of determining whether the drugs are being imported by the individuals in accordance with the conditions under subsection (i). Such reviews shall be conducted in a manner that will result in a statistically significant determination of compliance with all such conditions.

"(C) Monitoring the affixing of markings under paragraph (2).

"(D) Inspect as the Secretary determines is necessary the warehouses and other facilities of other parties in the chain of custody of qualifying drugs.

"(E) Determine whether the exporter is in compliance with all other registration conditions.

"(4) CERTAIN DUTIES RELATING TO IMPORTERS.—Duties of the Secretary with respect to an importer include the following:

"(A) As authorized under section 704, inspect not less than every 3 weeks, the places of business of the importer that relate to the receipt and distribution of a qualifying drug, including each warehouse or other facility owned

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

''(B) During the inspections under subparagraph (A), verify the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the importer, which may be accomplished by the use of anticounterfeiting or track-and-trace technologies, if available.

''(C) Inspect as the Secretary determines is necessary the warehouses and other facilities of other parties in the chain of custody of qualifying drugs.

''(D) Determine whether the importer is in compliance with all other registration conditions.

''(e) IMPORTER FEES.—

''(1) REGISTRATION FEE.—A registration condition is that the importer involved pays to the Secretary a fee of $10,000 due on the date on which the importer first submits the registration to the Secretary under subsection (b).

''(2) INSPECTION FEE.—A registration condition is that the importer involved pays to the Sec-

retary in accordance with this subsection a fee on a semiannual basis, with the first fee due on the date that is 6 months after the date on which the registration of the importer under subsection (b) is first approved by the Secretary.

''(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—The Secretary shall ensure that the aggregate total of fees collected under paragraph (2) for a fiscal year from all importers is sufficient, and no more than necessary, to pay the costs of administering this section with respect to registered importers for a fiscal year, including—

''(i) inspection of the facilities of importers under subsection (d)(4);

''(ii) reviewing qualifying drugs offered for import to importers; and

''(iii) determining the compliance of importers with registration conditions.

''(B) LIMITATION.—The aggregate total of fees collected under paragraph (2) shall not exceed 1 percent of the total price of drugs imported annually to the United States by registered importers under this section.

"(C) INDIVIDUAL IMPORTER FEE.—Subject to the limitation described in subparagraph (B), a fee under paragraph (2) for an importer shall be an amount that is a reasonable estimate by the Secretary of the semiannual share of the importer of the volume of drugs imported by importers under this section.

"(D) ADJUSTMENT OF FEE.—The Secretary shall annually adjust the fees under paragraph (2) to ensure that the fees accurately reflect the actual costs referred to in subparagraph (A) and do not exceed, in the aggregate, 1 percent of the total price of drugs imported annually to the United States under this section.

"(4) USE OF FEES.—Subject to appropriations Acts, fees collected by the Secretary under paragraphs (1) and (2) are available only to the Secretary and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

"(f) EXPORTER FEES.—

"(1) REGISTRATION FEE.—A registration condition is that the exporter involved pays to the Secretary a fee of $10,000 due on the date on which

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

''(2) INSPECTION FEE.—A registration condition is that the exporter involved pays to the Secretary in accordance with this subsection a fee on a semiannual basis, with the first fee due on the date that is 6 months after the date on which the registration of the exporter under subsection (b) is first approved by the Secretary.

''(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—The Secretary shall ensure that the aggregate total of fees collected under paragraph (2) for a fiscal year from all exporters is sufficient, and not more than necessary, to pay the costs of administering this section with respect to registered exporters for a fiscal year, including—

''(i) monitoring foreign facilities under subsection (d);

''(ii) developing, implementing, and maintaining under such subsection a system to mark shipments to indicate compliance with all registration conditions; and

''(iii) conducting under such subsection inspections within the United

States to determine compliance with conditions under subsections (h) and (i).

''(B) LIMITATION.—The aggregate total of fees collected under paragraph (2) shall not exceed 1 percent of the total price of drugs imported annually to the United States by registered exporters under this section.

''(C) INDIVIDUAL EXPORTER FEE.—Subject to the limitation described in subparagraph (B), a fee under paragraph (2) for an exporter shall be an amount that is a reasonable estimate by the Secretary of the semiannual share of the exporter of the volume of drugs exported by exporters under this section.

''(D) ADJUSTMENT OF FEE.—The Secretary shall annually adjust the fees under paragraph (2) to ensure that the fees accurately reflect the actual costs referred to in subparagraph (A) and do not exceed, in the aggregate, 1 percent of the total price of drugs imported annually to the United States under this section.

''(4) USE OF FEES.—Subject to appropriations Acts, fees collected by the Secretary under paragraphs (1) and (2) are only available to the Sec-

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

''(g) COMPLIANCE WITH SECTION 801(a).—

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

''(2) SECTION 505; APPROVAL STATUS.—

''(A) IN GENERAL.—For purposes of administrative and judicial procedure, there is a presumption that a drug proposed for export or import under subsection (a) is an approved drug under section 505(b) if the following criteria are met:

''(i) The drug proposed for export or import is in compliance with subsection (c).

''(ii) The drug proposed for export or import has the same active ingredient or ingredients, route of administration, dosage form, and strength, according to infor-

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

"(I) is manufactured by or for the person that manufactures the drug proposed for export or import; and

"(II) is approved under section 505(b).

"(B) IMPORTATION.—Subject to subparagraphs (D) and (E), a drug meeting the criteria described in subparagraph (A) may, in accordance with the other subsections of this section, be imported into the United States.

"(C) NOTICE BY MANUFACTURER; GENERAL PROVISIONS.—

"(i) IN GENERAL.—The person that manufactures a drug that may be imported under subsection (a) shall in accordance with this paragraph submit to the Secretary a notice that—

"(I) includes each difference in the drug from a condition established in the approved application for the

U.S. label drug beyond the variations provided for in the application, any difference in labeling, the date on which the drug with such difference was, or will be, introduced for commercial distribution in a permitted country, and such additional information as the Secretary may require; or

''(II) states that there is no difference in the drug from a condition established in the approved application for the U.S. label drug beyond the variations provided for in the application and differences in labeling.

''(ii) INFORMATION REGARDING FOREIGN GOVERNMENT.—A notice under clause (i)(I) shall with respect to the permitted country that approved the drug for commercial distribution, or with respect to which such approval is sought, include the following:

''(I) Information demonstrating that the person submitting the notice has also notified the government of the permitted country in writing that

the person is submitting to the Secretary a notice under clause (i)(I), which notice describes the difference in the drug from a condition established in the approved application for the U.S. label drug.

''(II) The information that the person submitted or will submit to the government of the permitted country for purposes of obtaining approval for commercial distribution of the drug in the country which, if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation.

''(iii) CERTIFICATIONS.—The chief executive officer and the chief medical officer of the manufacturer involved shall each certify in the notice under clause (i) that—

''(I) the information provided in the notice is complete and true; and

"(II) a copy of the notice has been provided to the Federal Trade Commission and to the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice (referred to in this subsection as the 'Assistant Attorney General').

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

"(v) TIMING OF SUBMISSION OF NOTICES.—

"(I) PRIOR APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (D) applies shall be submitted to the Secretary not later than 120 days before the drug with the difference is introduced for commercial distribution in a permitted country, unless the country requires that distribution of the drug with the difference begin less than 120 days after the country requires the difference.

"(II) OTHER APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (E) applies shall be submitted to the Secretary not later than the day on which the drug with the difference is introduced for commercial distribution in a permitted country.

"(III) OTHER NOTICES.—A notice under clause (i) to which subparagraph (F) applies shall be submitted to the Secretary on the date that the drug is first introduced for commer-

cial distribution in a permitted country and annually thereafter.

''(vi) REVIEW BY SECRETARY.—

''(I) IN GENERAL.—In this paragraph, the difference in a drug that may be imported under subsection (a) from the U.S. label drug shall be treated by the Secretary as if it was a manufacturing change to the U.S. label drug under section 506A.

''(II) REVIEW BY THE SECRETARY.—The Secretary shall review and approve or disapprove the difference in a notice submitted under clause (i), if required under section 506A, not later than 120 days after the date on which the notice is submitted.

''(III) ESTABLISHMENT INSPECTION.—If review of such difference would require an inspection by the Secretary of the establishment in which the drug is manufactured, such inspection shall be authorized by section 704.

"(vii) PUBLICATION OF INFORMATION ON NOTICES.—

"(I) IN GENERAL.—Through the Internet website of the Food and Drug Administration, the Secretary shall readily make available to the public a list of notices submitted under clause (i).

"(II) CONTENTS.—The list under subclause (I) shall include the date on which a notice is submitted and whether—

"(aa) a notice is under review;

"(bb) the Secretary has ordered that importation of the drug from a permitted country cease; or

"(cc) the importation of the drug is permitted under subsection (a).

"(III) UPDATE.—The Secretary shall promptly update the Internet website with any changes to the list.

"(D) NOTICE; DRUG DIFFERENCE REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (C)(i) that includes a difference that would, under section 506A(c) or (d)(3)(B)(i), require the approval of a supplemental application before the difference could be made to the U.S. label drug the following shall occur:

"(i) Promptly after the notice is submitted, the Secretary shall notify registered exporters, registered importers, the Federal Trade Commission, and the Assistant Attorney General that the notice has been submitted with respect to the drug involved.

"(ii) If the Secretary has not made a determination whether a supplemental application regarding the U.S. label drug would be approved or disapproved by the date on which the drug involved is to be introduced for commercial distribution in a permitted country, the Secretary shall—

"(I) order that the importation of the drug involved from the permitted country cease for the period in which

the Secretary completes review of the notice; and

''(II) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the Attorney General of the order.

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

''(I) order that the importation of the drug involved from the permitted country cease, or provide that an order under clause (ii), if any, remains in effect;

''(II) notify the permitted country that approved the drug for commercial distribution of the determination; and

''(III) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the Assistant Attorney General of the determination.

''(iv) If the Secretary determines that such a supplemental application regarding the U.S. label drug would be approved, the Secretary shall vacate the order under clause (ii), if any, permit importation of the drug under subsection (a), and promptly notify registered exporters, registered importers, the Federal Trade Commission, and the Assistant Attorney General of the determination.

''(E) NOTICE; DRUG DIFFERENCE NOT REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (C)(i) that includes a difference that would, under section 506A(d)(3)(B)(ii), not require the approval of a supplemental application before the difference could be made to the U.S. label drug the following shall occur:

''(i) During the period in which the notice is being reviewed by the Secretary, the authority under this subsection to import the drug involved continues in effect.

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

the Secretary shall order that the importation of the drug involved from the permitted country cease, shall notify the permitted country that approved the drug for commercial distribution of the determination, and shall promptly notify registered exporters, registered importers, the Federal Trade Commission, and the Assistant Attorney General of the determination.

''(F) NOTICE; DRUG DIFFERENCE NOT REQUIRING APPROVAL; NO DIFFERENCE.—In the case of a notice under subparagraph (C)(i) that includes a difference for which, under section 506A(d)(1)(A), a supplemental application would not be required for the difference to be made to the U.S. label drug, or that states that there is no difference, the Secretary—

''(i) may not order that the importation of the drug involved cease; and

''(ii) shall promptly notify registered exporters and registered importers.

''(G) DIFFERENCES IN ACTIVE INGREDIENT, ROUTE OF ADMINISTRATION, DOSAGE FORM, OR STRENGTH.—

"(i) IN GENERAL.—A person who manufactures a U.S. label drug shall submit an application under section 505(b) for a drug that is manufactured for distribution in a permitted country by or for the person that manufactures the U.S. label drug if—

"(I) there is no drug for export from at least half of the permitted countries with the same active ingredient or ingredients, route of administration, dosage form, and strength as the U.S. label drug; and

"(II) each active ingredient of the drug is related to an active ingredient of the U.S. label drug, as defined in clause (v).

"(ii) APPLICATION UNDER SECTION 505(b).—The application under section 505(b) required under clause (i) shall—

"(I) request approval of the drug for the indication or indications for which the U.S. label drug is approved under section 505;

"(II) include the information that the person submitted to the government of the permitted country for purposes of obtaining approval for commercial distribution of the drug in that country, which if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation;

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

"(IV) include such additional information as the Secretary may require.

"(iii) TIMING OF SUBMISSION OF APPLICATION.—An application under section 505(b) required under clause (i) shall be submitted to the Secretary not later than the day on which the information referred to in clause (ii)(II) is submitted to the government of the permitted country.

"(iv) NOTICE OF DECISION ON APPLICATION.—The Secretary shall promptly notify registered exporters, registered importers, the Federal Trade Commission, and the Assistant Attorney General of a determination to approve or to disapprove an application under section 505(b) required under clause (i).

"(v) RELATED ACTIVE INGREDIENTS.—For purposes of clause (i)(II), 2 active ingredients are related if they are—

"(I) the same; or

"(II) different salts, esters, or complexes of the same moiety.

"(3) SECTION 502; LABELING.—

"(A) IMPORTATION BY REGISTERED IMPORTER.—

"(i) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by a registered importer, such drug shall be considered to be in compliance with section 502 if the drug bears—

"(I) a copy of the labeling approved for the drug under section

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

"(II) the name of the manufacturer and location of the manufacturer;

"(III) the lot number assigned by the manufacturer; and

"(IV) the name, location, and registration number of the importer.

"(ii) REQUEST FOR COPY OF THE LABELING.—The Secretary shall provide such copy to the registered importer involved, upon request of the importer.

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

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

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

''(A) IN GENERAL.—For purposes of administrative and judicial procedure, there is a presumption that a drug proposed for export or import under subsection (a) is in compliance with section 501 if the drug is in compliance with subsection (c).

''(B) STANDARDS FOR REFUSING ADMISSION.—A qualifying drug exported under subsection (a) from a registered exporter or imported by a registered importer may be refused admission into the United States if 1 or more of the following applies:

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

''(ii) The Secretary becomes aware that—

''(I) the drug may be counterfeit;

''(II) the drug may have been prepared, packed, or held under insanitary conditions; or

''(III) the methods used in, or the facilities or controls used for, the manufacturing, processing, packing, or holding of the drug do not conform to good manufacturing practice.

''(iii) The Secretary has obtained an injunction under section 302 that prohibits the distribution of the drug in interstate commerce.

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

''(v) The manufacturer of the drug has instituted a recall of the drug.

''(vi) If the qualifying drug is exported from a registered exporter to an individual and 1 or more of the following applies:

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

''(II) The markings on the shipping container appear to be counterfeit.

''(III) The shipping container or markings appear to have been tampered with.

''(h) LICENSING AS PHARMACIST.—A registration condition is that the exporter involved agrees that a qualifying drug will be exported to an individual only if the Secretary has verified that—

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

''(2) the exporter employs persons that are licensed under Canadian law to dispense prescription drugs in sufficient number to dispense safely the qualifying drugs exported by the exporter to individuals, and the exporter assigns to those persons responsibility for dispensing such qualifying drugs to individuals.

''(i) INDIVIDUALS; CONDITIONS FOR IMPORTATION FROM CANADA.—

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

''(A) The drug is accompanied by a copy of a prescription for the drug, which prescription—

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

''(ii) was issued by a practitioner who, under the law of a State of which the individual is a resident, or in which the individual receives care from the practitioner who issues the prescription, is authorized to administer prescription drugs.

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

''(C) The copies referred to in subparagraphs (A)(i) and (B) are marked in a manner sufficient—

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

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

''(D) The individual has provided to the registered exporter a complete list of all drugs used by the individual for review by the individuals who dispense the drug.

"(E) The quantity of the drug does not exceed a 90-day supply.

"(F) The drug is not an ineligible subpart H drug. For purposes of this section, a prescription drug is an 'ineligible subpart H drug' if the drug was approved by the Secretary under subpart H of part 314 of title 21, Code of Federal Regulations (relating to accelerated approval), with restrictions under section 520 of such part to assure safe use, and the Secretary has published in the Federal Register a notice that the Secretary has determined that good cause exists to prohibit the drug from being imported pursuant to this subsection.

"(2) NOTICE REGARDING DRUG REFUSED ADMISSION.—If a registered exporter ships a drug to an individual pursuant to subsection (a)(2)(B) and the drug is refused admission to the United States, a written notice shall be sent to the individual and to the exporter that informs the individual and the exporter of such refusal and the reason for the refusal.

"(j) MAINTENANCE OF RECORDS AND SAMPLES.—A registration condition is that the importer or exporter involved shall—

''(1) maintain records required under this section for not less than 2 years; and

''(2) maintain samples of each lot of a drug required under this section for not less than 2 years.

''(k) DRUG RECALLS.—

''(1) MANUFACTURERS.—A person that manufactures a prescription drug imported from a permitted country under this section shall promptly inform the Secretary—

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

''(B) how the drug may be identified, including lot number; and

''(C) the reason for the recall or withdrawal.

''(2) SECRETARY.—With respect to each permitted country, the Secretary shall—

''(A) enter into an agreement with the government of the country to receive information about recalls and withdrawals of prescription drugs in the country; or

''(B) monitor recalls and withdrawals of prescription drugs in the country using any information that is available to the public in any media.

''(3) NOTICE.—The Secretary may notify, as appropriate, registered exporters, registered importers, wholesalers, pharmacies, or the public of a recall or withdrawal of a prescription drug in a permitted country.''.

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

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

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

''(A) a sale at retail made pursuant to dispensing the drug to a customer of the pharmacist or organization; or

''(B) a sale or trade of the drug to a pharmacy or a wholesaler registered to import drugs under section 804.

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

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

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

''(4) The importation of a drug in violation of a requirement under section 804.''; and

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

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

(c) IMPLEMENTATION.—

(1) RULEMAKING.—

(A) IN GENERAL.—

(i) PROMULGATION BY SECRETARY.—Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate an interim rule for implementing section 804 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) of this section. Such rule shall be developed and promulgated by the Secretary without providing general notice of proposed rulemaking. Not later than 1 year

after the date on which the interim rule is promulgated, the Secretary shall, in accordance with procedures under section 553 of title 5, United States Code, promulgate a final rule for implementing such section 804, which may incorporate by reference provisions of the interim rule, to the extent that such provisions are not modified.

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

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

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

(III) from Australia, a member country of the European Union as of January 1, 2003, Japan, New Zealand, or Switzerland by registered importers on the date that is 1 year after the date of the enactment of this Act.

(B) CERTAIN EXPORTERS.—The interim rule under subparagraph (A) shall provide that, in the review of registrations submitted under subsection (b) of the section 804 referred to in such subparagraph, registrations submitted by entities in Canada that are significant exporters of prescription drugs to individuals in the United States as of the date of the enactment of this Act will have priority during the period in which the interim rule under subparagraph (A) is in effect. During such period, the reference in subsection (b)(2)(A) of such section 804 to 90 days (relating to approval or disapproval of registrations) is, as applied to such entities, deemed to be 30 days.

(C) DRUGS FOR IMPORT FROM CANADA.—The notices with respect to drugs to be imported from Canada that are required under subsection (g)(2)(C)(i)(I) of such section 804 and that require approval under subsection (g)(2)(D) or (E) of such section 804 shall be submitted to the Secretary not later than 30 days after the date of enactment of this Act. The notices with respect to drugs to be imported from Canada that are required under

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

(D) DRUGS FOR IMPORT FROM OTHER COUNTRIES.—The notices with respect to drugs to be imported from Australia, a member country of the European Union as of January 1, 2003, Japan, New Zealand, or Switzerland that are required under subsection (g)(2)(C)(i)(I) of such section 804 and that require approval under subsection (g)(2)(D) or (E) of such section 804 shall be submitted to the Secretary not later than 180 days after the date of enactment of this Act. The notices with respect to drugs to be imported from such countries that are required under subsection (g)(2)(C)(i)(II) of such section 804 and that do not require approval under subsection (g)(2)(D) or (E) of such section 804 shall be submitted to the Secretary not later than 270 days after the date of enactment of this Act.

(2) PERSONAL IMPORTATION FROM CANADA.—Until the expiration of the 60-day period beginning

on the date on which the interim rule under paragraph (1)(A) is promulgated, an individual may import a prescription drug from Canada for personal use or for the use of a family member of the individual (rather than for resale), subject to compliance with the following conditions:

(A) The drug is not—

(i) a controlled substance, as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802);

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

(iii) an infused drug, including a peritoneal dialysis solution;

(iv) an intravenously injected drug;

(v) a drug that is inhaled during surgery; or

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

(B) The drug is dispensed by a person licensed in Canada to dispense such drugs.

(C) The drug is accompanied by a copy of the prescription for the drug, which prescription—

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

(ii) was issued by a practitioner who, under the law of a State of which the individual is a resident, or in which the individual receives care from the practitioner who issues the prescription, is authorized to administer prescription drugs.

(D) The drug is accompanied by a copy of the document that was required in Canada as a condition of dispensing the drug to the individual.

(E) The copies referred to in subparagraphs (C) and (D) are marked in a manner sufficient—

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

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

(F) The quantity of the drug does not exceed a 90-day supply.

(3) FACILITATION OF CANADIAN IMPORTS.—Not less than 15 days after the enactment of this Act and until the expiration of the 60-day period that begins on the date on which the interim rule under paragraph (1)(A) is promulgated, the Secretary shall, through the Internet website of the Food and Drug Administration, make readily available to the public a list of persons licensed in Canada to dispense prescription drugs who are willing to export drugs under paragraph (2) to individuals in the United States.

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

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

''(g) With respect to a prescription drug that is imported or offered for import into the United States by an individual who is not in the business of such importation, that is not shipped by a registered exporter under section

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

''(1) the drug has been refused admission because the drug was not a lawful import under section 804;

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

''(3) the individual may under section 804 lawfully import certain prescription drugs from Canadian exporters registered with the Secretary; and

''(4) the individual can find information about such importation, including a list of registered exporters, on the Internet website of the Food and Drug Administration.''.

(e) ANTICOMPETITIVE PRACTICES RELATING TO IMPORTING AND EXPORTING DRUGS TO THE UNITED STATES.—

(1) IN GENERAL.—The Clayton Act (15 U.S.C. 12 et seq.) is amended by adding at the end the following:

''SEC. 27. RESTRAINT OF TRADE REGARDING PRESCRIPTION DRUGS.

''(a) IN GENERAL.—It shall be unlawful for any person engaged in commerce, directly or indirectly to—

''(1) charge a higher price for prescription drugs sold to a registered exporter or other person that exports prescription drugs to the United States under section 804 of the Federal Food, Drug, and Cosmetic Act than the price that is charged to another person that is in the same country and that does not export prescription drugs into the United States under section 804 of such Act;

''(2) charge a higher price for prescription drugs sold to a registered importer or other person that distributes, sells, or uses prescription drugs imported to the United States under section 804 of such Act than the price that is charged to another person in the United States that does not import prescription drugs under section 804 of such Act, or that does not distribute, sell, or use such drugs;

''(3) deny supplies of prescription drugs to a registered exporter or other person that exports prescription drugs to the United States under section 804 of such Act or to a registered importer or other person that distributes, sells, or uses prescription drugs imported to the United States under section 804 of such Act;

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

son that exports prescription drugs to the United States under section 804 of such Act or with a registered importer or other person that distributes, sells, or uses prescription drugs imported to the United States under section 804 of such Act;

''(5) specifically restrict supplies of prescription drugs to a registered exporter or other person that exports prescription drugs to the United States under section 804 of such Act or to a registered importer or other person that distributes, sells, or uses prescription drugs imported to the United States under section 804 of such Act;

''(6) fail to submit a notice under subsection (g)(2)(C)(i) of section 804 of such Act, fail to submit such a notice on or before the date specified in subsection (g)(2)(C)(v) of section 804 of such Act, submit such a notice that makes a materially false, fictitious, or fraudulent statement, or fail to provide promptly any information requested by the Secretary of Health and Human Services to review such a notice;

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

tion 804 of such Act, submit such an application that makes a materially false, fictitious, or fraudulent statement, or fail to provide promptly any information requested by the Secretary of Health and Human Services to review such an application;

''(8) cause there to be a difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and a prescription drug for distribution in Australia, Canada, a member country of the European Union as of January 1, 2003, Japan, New Zealand, or Switzerland for the purpose of restricting importation of the drug to the United States under section 804 of such Act;

''(9) refuse to allow an inspection authorized under section 804 of such Act of an establishment that manufactures a prescription drug that is offered for import under such section;

''(10) fail to conform to the methods used in, or the facilities used for, the manufacturing, processing, packing, or holding of a prescription drug of-

fered for import under section 804 to good manufacturing practice under such Act; or

''(11) engage in any other action that the Federal Trade Commission determines to unfairly restrict competition under section 804 of such Act.

''(b) PRESUMPTION.—A difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and a prescription drug for distribution in Australia, Canada, a member country of the European Union as of January 1, 2003, Japan, New Zealand, or Switzerland made after January 1, 2004, shall be presumed to be for the purpose of restricting importation of the drug to the United States under section 804 of the Federal Food, Drug, and Cosmetic Act unless—

''(1) the person manufacturing the drug for distribution in the United States proves that the difference was required by the country in which the drug is distributed;

''(2) the Secretary of Health and Human Services, acting through the Commissioner of Food and Drug, determines that the difference was necessary to improve the safety or efficacy of the drug; or

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

''(c) AFFIRMATIVE DEFENSE.—It shall be an affirmative defense to a charge that a person has violated paragraph (1), (2), (3), (4), or (5) of subsection (a) that the higher prices charged for prescription drugs sold to a person, the denial of supplies of prescription drugs to a person, the refusal to do business with a person, or the specific restriction or delay of supplies to a person is not based, in whole or in part, on—

''(1) the person exporting or importing prescription drugs to the United States under section 804 of the Federal Food, Drug, and Cosmetic Act; or

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

''(d) DEFINITIONS.—In this section:

''(1) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug that is described in

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

''(2) REGISTERED IMPORTER.—The term 'registered importer' has the meaning given such term in section 804 of the Federal Food, Drug, and Cosmetic Act.

''(3) REGISTERED EXPORTER.—The term 'registered exporter' has the same meaning as in section 804 of the Federal Food, Drug, and Cosmetic Act.''.

(2) APPLICABILITY OF AMENDMENTS TO IMPORTATION UNDER THE PHARMACEUTICAL MARKET ACCESS AND FAIR TRADE ACT OF 2004.—

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

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

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

(f) EXHAUSTION.—

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

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

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

''(h) It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention under section 804 of the Federal Food, Drug, and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent.''.

(2) RULE OF CONSTRUCTION.—Nothing in the amendment made by paragraph (1) shall be construed to affect the ability of a patent owner or licensee to enforce their patent, subject to such amendment.

SEC. 5. ADDITIONAL WAIVERS REGARDING PERSONAL IMPORTATION; ENFORCEMENT POLICIES OF SECRETARY.

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

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

''(2) With respect to the standards referred to in subsection (d)(1), the Secretary shall establish by regulation a waiver of such standards in the case of the importation by an individual of a drug into the United States in the following circumstances:

''(A) The drug was dispensed to the individual while the individual was in the United States, the drug was dispensed by a pharmacist or by a practitioner licensed by law to administer the drug, and the individual traveled from the United States with the drug.

''(B) The individual is entering the United States and the drug accompanies the individual at the time of entry.

''(C) The drug does not appear to the Secretary to be adulterated.

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

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

''(F) Such additional standards as the Secretary determines to be appropriate to protect the public health.

''(3) With respect to the standards referred to in subsections (a) and (d)(1), the Secretary shall establish by regulation a waiver of such standards in the case of the importation by an individual of a drug into the United States in the following circumstances:

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

''(B) The individual is entering the United States and the drug accompanies the individual at the time of entry.

''(C) The drug is approved for commercial distribution in the foreign country in which the drug was obtained.

''(D) The drug does not appear to the Secretary to be adulterated.

''(E) The quantity of the drug does not exceed—

''(i) a 90-day supply if the drug is dispensed in Australia, Canada, a member country of the European Union as of January 1, 2003, Japan, New Zealand, or Switzerland; or

''(ii) a 14-day supply otherwise.

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

''(G) Such additional standards as the Secretary determines to be appropriate to protect the public health.

''(q) The Secretary may not administer any enforcement policy that has the effect of permitting the importation of a prescription drug into the United States in violation of this Act or section 351 of the Public Health Service Act.''.

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

not meet such standards, provided that such waiver is no more permissive than the guidance, as in effect on January 1, 2004, that is provided in the item numbered 2 (relating to a specific situation, consisting of conditions (a) through (d)) under the heading ''Drugs, Biologics, and Devices'' in chapter 9 of the FDA/ORA Regulatory Procedures Manual (relating to import operations/actions), in the subchapter relating to coverage of personal importations.

SEC. 6. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION INTO UNITED STATES.

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

''SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION.

''(a) IN GENERAL.—The Secretary of Homeland Security shall refuse admission to a shipment of drugs that is imported or offered for import into the United States if the shipment has a declared value of less than $10,000 and the drugs are in violation of any standard referred to in section 801(a) or 801(d)(1), including any drugs imported or offered for import under enforcement policies prohibited under section 801(q).

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

''(c) DESTRUCTION OF VIOLATIVE SHIPMENTS.—Drugs refused admission under subsection (a) or (b) shall be destroyed, subject to subsection (e). Section 801(b) does not authorize the delivery of the drugs pursuant to the execution of a bond, and the drugs may not be exported.

''(d) CERTAIN PROCEDURES.—

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

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

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

''(e) EVIDENCE EXCEPTION.—Drugs may not be destroyed under subsection (c) to the extent that the Attorney General of the United States determines that the drugs should be preserved as evidence or potential evidence with respect to an offense against the United States.

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

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

SEC. 7. CIVIL ACTIONS REGARDING PROPERTY.

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

''(g)(1) If a person is alienating or disposing of property, or intends to alienate or dispose of property, that is obtained as a result of or is traceable to a drug imported in violation of section 801(a) or 801(d), the Attorney General may commence a civil action in any Federal court—

''(A) to enjoin such alienation or disposition of property; or

''(B) for a restraining order to—

''(i) prohibit any person from withdrawing, transferring, removing, dissipating, or disposing of any such property or property of equivalent value; and

''(ii) appoint a temporary receiver to administer such restraining order.

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

SEC. 8. WHOLESALE DISTRIBUTION OF DRUGS; STATEMENTS REGARDING PRIOR SALE, PURCHASE, OR TRADE.

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

(1) in paragraph (1)—

(A) by striking ''and who is not the manufacturer or an authorized distributor of record of such drug'';

(B) by striking ''to an authorized distributor of record or''; and

(C) by striking subparagraph (B) and inserting the following:

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

''(C)(i) The Secretary may by regulation establish requirements that supersede subparagraph (A) (referred to in this subparagraph as 'alternative requirements') to identify the chain of custody of a drug subject to subsection (b) from the manufacturer of the drug throughout the wholesale distribution of the drug to a pharmacist who intends to sell the drug at retail if the Secretary determines that the alternative requirements, which may include anti-counterfeiting or track-and-trace technologies, will identify such chain of custody or the identity of the drug with equal certainty to the requirements of subparagraph (A), and that the alternative requirements are economically and technically feasible.

''(ii) If the Secretary promulgates a final rule to establish such alternative requirements, the final rule in addition shall, with respect to the registration condition es-

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

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

(3) in paragraph (3), by striking ''and subsection (d)—'' in the matter preceding subparagraph (A) and all that follows through ''the term 'wholesale distribution' means'' in subparagraph (B) and inserting the following: ''and subsection (d), the term 'wholesale distribution' means''.

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

''(4) Each manufacturer of a drug subject to subsection (b) shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

''(5) For purposes of this subsection, the term 'authorized distributors of record' means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.''.

SEC. 9. REPEAL OF IMPORTATION EXEMPTION UNDER CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.

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

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