108TH CONGRESS
2D SESSION

S. 2307

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.

IN THE SENATE OF THE UNITED STATES

APRIL 8, 2004

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

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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.

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 ''Reliable Entry for Medicines at Everyday Discounts through Importation with Effective Safeguards Act of 2004''.

SEC. 2. 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.), as amended by section 1121(a) of Public Law 108–173 (117 Stat. 2464), is amended by striking section 804.

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

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

"SEC. 804. WAIVERS REGARDING COMMERCIAL AND PERSONAL IMPORTATION OF PRESCRIPTION DRUGS; REGISTERED FOREIGN EXPORTERS.

''(a) WAIVERS.—

''(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—

''(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 (includ-

ing 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 an importer and the importation is in accordance with subsection (h); or

''(B) the drug is imported by an individual for personal use or for the use of a family member of the individual (rather than for resale), and the importation is in accordance with subsection (i).

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

''(4) DEFINITIONS.—

''(A) IMPORTER.—The term 'importer' means a pharmacist or wholesaler.

''(B) PERMITTED COUNTRY.—

''(i) IN GENERAL.—For purposes of this section, the term 'permitted country' means—

''(I) Canada;

"(II) 180 days after the date of publication of the report under clause (ii)—

"(aa) Australia;

"(bb) a member country of the European Union or the European Free Trade Association;

"(cc) Japan; and

"(dd) New Zealand; and

"(III) any country designated as a permitted country under clause (iii).

"(ii) REPORT.—

"(I) IN GENERAL.—Not later than 18 months after the date of enactment of this section, the Secretary shall submit to Congress a report subject to subclauses (II) and (III).

"(II) CONTENTS OF REPORT.—The report under subclause (I) shall—

"(aa) describe the impact of the drug importation system established under this section on—

"(AA) the safety and integrity of the Nation's pre-

scription drug distribution system;

"(BB) the prevalence of counterfeit, adulterated, or misbranded drugs in the United States; and

"(CC) patient drug therapy;

"(bb) describe the potential impact of expanding the system to allow importation from additional countries; and

"(cc) include proposed legislation to improve the safety, efficiency, and efficacy of the drug reimportation system;

"(III) CONSULTATION WITH THE FEDERAL TRADE COMMISSION.—The Secretary, in consultation with the Chairman of the Federal Trade Commission, shall include in the report under subclause (I)—

"(aa) an evaluation of the extent to which this section advances the objective of intro-

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

''(bb) recommendations for improving the operation and effectiveness of this section to meet that objective.

''(iii) ADDITIONAL COUNTRIES.—The Secretary may designate an additional country as a permitted country if the country meets the requirements of section 802(b)(1)(B) as that section relates to drugs.

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

''(D) REGISTERED EXPORTER.—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 'registration condition' means a condition for a registration under subsection (b) to be approved.

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

''(i) A controlled substance, as defined in section 102 of the Controlled Substances Act.

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

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

''(iv) An intravenously injected drug.

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

''(F) WHOLESALER.—

''(i) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).

''(ii) EXCLUSION.—The term 'wholesaler' does not include a person authorized to import drugs under section 801(d)(1).

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

''(i) The term 'covered prescription drug' means an approved drug under section 505(b)(1) that is subject to section 503(b)(1).

''(ii) The term 'exporter' means a person who is in the business of exporting a drug to the United States or who, pursuant to submitting a registration under subsection (b), seeks to be in such business.

''(b) REGISTRATION OF FOREIGN EXPORTERS.—

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

''(A) The name of the exporter and an identification of all 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.

''(B) Such information as the Secretary determines to be necessary to demonstrate that

the exporter is in compliance with registration conditions under subsections (c), (d), (e), (f), and (g) (relating to the sources of exported drugs; the monitoring of foreign facilities and the marking of compliant shipments; the payment of fees; being licensed as a pharmacy (in the case of importation by individuals); and compliance with the standards referred to in section 801(a)).

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

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

''(E) An agreement by the exporter that the exporter submits to the jurisdiction of the courts of the United States for the purpose of adjudication of any action arising out of the activities of the exporter under this section with the name and address of an agent in the United States for service of process.

"(F) An agreement by the exporter 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.

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

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

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

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

"(I) Such other provisions as the Secretary may require to protect the public health while permitting the importation 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 an exporter sub-

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

''(3) PUBLICATION OF CONTACT INFORMATION FOR REGISTERED EXPORTERS.—Through the Internet site of the Food and Drug Administration, the Secretary shall make available to the public a list of registered exporters, including contact information

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

''(4) SUSPENSION AND TERMINATION.—

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

''(i) Subject to clause (ii), if the Secretary determines, after notice and opportunity for a hearing, that the exporter 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 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)(E), the Secretary shall imme-

diately 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 exporter involved 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 exporter 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 an exporter if the Secretary determines that the exporter has engaged in a pattern or practice of violating one or more registration conditions, or if on one or more occasions the Secretary has under subparagraph (A)(ii) suspended the registration of the exporter. The Secretary may make the termination permanent, or for a fixed period of not less than one year. During the pe-

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

''(c) SOURCES OF EXPORTED QUALIFYING DRUGS.—A registration condition is that the exporter involved agrees that a qualifying drug will under subsection (a) be exported to the United States only if, as verified by the Secretary under subsection (d)(3)(A), there is compliance with the following:

''(1) The drug was manufactured in an establishment required to register under subsection (h) or (i) of section 510.

''(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 and for distribution in one or more foreign countries specified in paragraph (4) (without regard to whether in addition the drug was manufactured for distribution in foreign countries not so specified).

''(3) The exporter obtained the drug—

''(A) directly from the establishment; or

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

''(i) provides to the exporter 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 any of the States; and

''(iv) has ensured, through such contractual relationships as may be necessary, that the Secretary has the same authorities

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 exporter will export the drug is a permitted country.

''(5) 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.

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

''(1) MONITORING 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 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, on a day-to-day basis, to records of the exporter that relate to the export of such drugs, including financial records;

"(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, with the permission of the exporter, has assigned one or more employees of the Secretary to carry out the functions described in this subsection for the Secretary—

"(i) on a day-to-day basis on the premises of places of businesses referred to in subparagraph (A)(i), and such an assignment remains in effect on a continuous basis; or

"(ii) on a periodic basis on the premises of places of businesses referred to in subparagraph (A)(i), if the Secretary determines that the exporter has a sufficient history of compliance with the registration conditions.

''(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.—Duties of the Secretary under paragraphs (1) and (2) regarding an exporter include the following:

''(A) Verifying the chain of custody of each qualifying drug from the manufacturer of the drug to the exporter.

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

section (i). Such sampling 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).

''(e) FEES.—

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

''(2) AMOUNT OF FEE.—

''(A) AGGREGATE TOTAL OF FEES.—The Secretary shall ensure that the aggregate total of fees collected under paragraph (1) for a fiscal year from all exporters is sufficient to pay the costs of administering this section for a fiscal year, including monitoring foreign facilities under subsection (d); developing, implementing, and maintaining under such subsection a system to mark shipments to indicate compliance with all registration conditions; and conducting under such subsection inspections within the

United States to determine compliance with conditions under subsections (h) and (i); except that, during the 12-month period beginning on the date of the promulgation of the interim final rule for implementing this section, the Secretary may collect a lesser aggregate total of fees, taking into account the number of registered exporters and the capacity of such exporters as a group to pay such administrative costs.

''(B) INDIVIDUAL EXPORTER FEE.—Subject to the exception described in subparagraph (A), a fee under paragraph (1) for an exporter shall be an amount that is a reasonable estimate by the Secretary of the semiannual pro rata share of the exporter of the costs referred to in subparagraph (A). Such pro rata share shall take into account the number of employees that the Secretary has under subsection (d)(1)(B) assigned to the exporter.

''(3) USE OF FEES.—Subject to appropriations Acts, fees collected by the Secretary under paragraph (1) are available to the Secretary for paying the costs referred to in paragraph (2)(A).

''(f) LICENSING AS A PHARMACY.—A registration condition is that the exporter involved agrees that a qualifying drug will under subsection (a)(2)(B) be exported to an individual only if the Secretary has determined that—

''(1) (A) the exporter is authorized under foreign law to dispense drugs that are only safe for use under the supervision of a practitioner authorized by law to administer such drugs; and

''(B) the foreign country that issued such authorization for the exporter did so under a regulatory program that, with respect to the training of persons who dispense such drugs but do not administer the drugs, protects the public health in a manner comparable to programs of the States that regulate pharmacists; or

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

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

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

(a) by the exporter 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) and (3) and subsection (j).

''(2) APPROVAL STATUS.—

''(A) IMPORTATION.—Subject to subparagraphs (C) and (D), a drug may, in accordance with the other subsections of this section, be imported into the United States if the following criteria are met:

''(i) The Secretary has with respect to the drug verified compliance with subsection (c), including verifying that the drug is approved for commercial distribution in a foreign country specified in paragraph (4) of such subsection, and that the establishment that manufactured the drug also manufactures the drug for distribution in the United States (referred to in this paragraph as a 'U.S. label drug').

''(ii) As compared to the U.S. label drug, the drug has the same active ingredient or ingredients, route of administration, dosage form, and strength, according

to information provided by the labeling of the drug.

''(B) PETITION BY MANUFACTURER; GENERAL PROVISIONS.—

''(i) IN GENERAL.—A person who manufactures a drug imported under subsection (a) may in accordance with this paragraph file with the Secretary a petition that requests the Secretary to order that importation of the drug under such subsection cease. Such a petition may be accepted for filing only if the petition claims that the drug is changed from the U.S. label drug and the change would require the submission of a supplemental application if made to the U.S. label drug, and only if the petition claims that—

''(I) the change could, under section 314.70 of title 21, Code of Federal Regulations, be made before the approval of such application; or

''(II) (aa) the change could not, under such section 314.70, be made before the approval of such application; and

''(bb) the change raises a bioequivalence consideration described in subparagraph (E)(i).

''(ii) CERTIFICATIONS.—The Secretary may not accept a petition under clause (i) for filing unless the chief executive officer, the chief legal counsel, and the chief medical officer of the manufacturer involved each certifies in the petition that the information provided in the petition is complete and true.

''(iii) CERTAIN CLAIMS.—With respect to a drug being imported under subsection (a) for which a claim is made in a petition under clause (i) (referred to in this paragraph as a 'petition drug'), the Secretary may not accept the petition for filing under clause (i) if the Secretary determines that any of the changes from the U.S. label drug described in the petition is—

''(I) a variation provided for in the approved application under section 505(b)(1) for the U.S. label drug; or

''(II) a change for which, under section 314.70 of title 21, Code of

Federal Regulations, a supplemental application would not be required.

"(iv) FEE.—The Secretary may not accept a petition under clause (i) for filing unless the person submitting the petition pays 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), except that the fee may not be required for a petition that, under clause (i)(II)(bb), makes a nonequivalence claim (as defined in subparagraph (E)(i)). Subject to appropriations Acts, fees collected by the Secretary under the preceding sentence are available to the Secretary for paying the costs referred to in subsection (e)(2)(A).

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

"(C) PETITION; DRUG CHANGES NOT REQUIRING PRIOR APPROVAL.—In the case of a petition under subparagraph (B)(i)(I):

''(i) During the period in which the petition is being reviewed by the Secretary, the authority under subsection (a) to import the petition drug involved continues in effect, subject to clause (ii).

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

''(I) any importer importing the petition drug under subsection (a)(2)(A) inform individuals to whom the importer sells or dispenses the drug that the manufacturer is making a claim that the drug is different than the U.S. label drug; and

''(II) the registered exporter involved notify any individuals importing the petition drug from the exporter under subsection (a)(2)(B) that the manufacturer is making such a claim.

''(iii) If the Secretary determines that the supplemental application referred to in subparagraph (C)(i)(I) regarding the U.S. label drug would not be approved, the Secretary shall grant the petition and order

that importation of the petition drug under subsection (a) cease.

"(D) PETITION; DRUG CHANGES REQUIRING PRIOR APPROVAL.—

"(i) BIOEQUIVALENCE CONSIDERATIONS.—For purposes of subparagraph (B)(i)(II)(bb), a claim that a change in a petition drug raises a bioequivalence consideration is a claim that—

"(I) the change creates the possibility that such drug is not bioequivalent to the U.S. label drug (in this paragraph referred to as a 'possible-nonequivalence claim'); or

"(II) the petition drug is not bioequivalent to the U.S. label drug (referred to in this paragraph as a 'nonequivalence claim').

"(ii) INFORMATION REGARDING FOREIGN GOVERNMENT.—The Secretary may not accept a petition for filing under subparagraph (B)(i) that makes a possible-nonequivalence claim or a nonequivalence claim unless the following conditions are met with respect to the foreign country

that approved the petition drug for commercial distribution:

"(I) The person filing the petition submits with the petition information demonstrating that the person has notified the government of the foreign country in writing that the person is submitting to the Secretary a claim under clause (i), which notice describes the claim.

"(II) Such person submits with the petition the information the person submitted to the government of the foreign country for purposes of obtaining approval for commercial distribution of the petition drug in the country.

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

"(I) Clauses (i) and (ii) of subparagraph (C) apply to the same extent and in the same manner as such clauses apply to a petition under sub-

paragraph (B)(i) that makes a claim described in subclause (I) of such subparagraph.

''(II) If the Secretary determines that the petition drug is not bioequivalent to the U.S. label drug, the Secretary shall grant the petition and order that importation of the petition drug under subsection (a) cease.

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

''(I) Promptly after the petition is filed, the Secretary shall order that the importation of the petition drug involved cease during the period in which the petition is under review by the Secretary.

''(II) If the Secretary determines that the petition drug is not bioequivalent to the U.S. label drug, the Secretary shall grant the petition and provide that the order under subclause (I) remains in effect.

"(v) DRUGS APPROVED ON OR AFTER JANUARY 1, 2004.—In the case of a petition under subparagraph (C)(i) that makes a possible-nonequivalence claim or a non-equivalence claim, if the petition drug involved for commercial distribution was approved by the foreign government on or after January 1, 2004, or if the U.S. label drug was approved by the Secretary on or after such date:

"(I) The Secretary may not accept the petition for filing unless the person submitting the petition submits with the petition information demonstrating that—

"(aa) the difference between the petition drug and the U.S. label drug is due to a difference between the legal requirements for approval of the drug in the foreign country and for approval by the Secretary; or

"(bb) the person has submitted a supplemental application to the government of the foreign

country, or to the Secretary, that will, if approved, remove the difference between the petition drug and the U.S. label drug.

''(II) If under clause (iii)(II) or (iv)(II) the Secretary has ordered that importation of the petition drug under subsection (a) cease, the Secretary shall rescind the order promptly after the approval of a supplemental application referred to in subclause (I)(bb) of this clause.

''(vi) FALSE STATEMENTS.—The Secretary shall rescind an order under clause (iii)(II) or (iv)(II) promptly after determining that a materially false, fictitious, or fraudulent statement or representation in the petition involved was a material factor in the decision of the Secretary to grant the petition.

''(3) LABELING.—

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

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

''(B) IMPORTATION BY INDIVIDUAL.—In the case of a qualifying drug that under subsection (a)(2)(B) is imported or offered for import with respect 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 registered exporter involved a copy of the special labeling, upon request of the exporter.

''(h) IMPORTERS; CONDITIONS FOR IMPORTATION.—

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

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

''(A) The importer, or a business organization of which the importer is a part, takes delivery directly from the mail, from a common carrier, or from a vehicle or aircraft owned by the importer or such business organization.

''(B) From the port of entry for the drug to the delivery of the drug to the importer or such business organization—

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

''(ii) personnel of the transporting entities involved had exclusive custody of the drug, without the custodial involvement of any other type of entity, including a person in the business of the wholesale distribution of drugs.

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

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

''(i) PERSONAL USE; CONDITIONS FOR IMPORTATION.—

''(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—

''(i) 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, is authorized to administer prescription drugs; and

''(ii) a statement that provides information sufficient for the Secretary to determine whether the prescription meets the requirement of clause (i), including with

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

''(B) With respect to the foreign country from which the registered exporter involved dispensed the drug, the drug is accompanied by a copy of the documentation that was required under the law or regulations of such country 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 the foreign country involved, have been filled; and

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

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

''(E) 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 PERSONAL ENTRY.—A registration condition is that the exporter involved agrees that, in providing a qualifying drug to an individual under subsection (a)(2)(B) in circumstances in which the drug will accompany the individual as the individual enters the United States, the exporter will notify the individual that the drug is authorized to be imported under such subsection only if the shipping container for the drug is intact and bears the marking affixed under subsection (d)(2).

''(3) PRESUMPTION.—In the case of importation under this subsection, for purposes of judicial and administrative procedure, there is a presumption that a drug proposed for export under subsection (a) is an approved drug under section 505(b)(1) if the criteria described in subsection (g)(A)(i) and (ii) are met.

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

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

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

''(2) Such markings appear to be counterfeit.

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

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

''(5) After the shipment leaves the custody of the registered exporter, the Secretary becomes aware that—

''(A) the drug may be counterfeit;

''(B) the drug may have been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth; or

''(C) 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.

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

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

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

''(k) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, this section does not authorize the importation into the United States of a qualifying drug donated or otherwise supplied for free or at nominal cost by the manufacturer of the drug to a charitable or humanitarian organization, including the United Nations and affiliates, or to a government of a foreign country.''

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

(1) in section 301 (21 U.S.C. 331), by amending paragraph (aa) to read as follows:

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

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

''(B) a sale or trade of the drug to the registered exporter from which the importer imported the drug.

''(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 knowing making of a materially false, fictitious, or fraudulent statement or representation in a petition under clause (i) of section 804(g)(2)(C). Such a petition that is not accepted for filing by reason of clause (iii) of such section shall be considered to contain such a statement or representation.''; and

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

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

(c) CIVIL PENALTY.—

(1) TECHNICAL AMENDMENTS.—

(A) IN GENERAL.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended in the last subsection by striking the subsection designation and all that fol-

lows through ''Except as provided'' in paragraph (1)(A) and inserting the following:

''(f)(1)(A) Except as provided''.

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

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

(ii) section 201(c) of the Medical Device User Fee and Modernization Act of 2002 (116 Stat. 1609).

(2) CIVIL PENALTIES.—

(A) IN GENERAL.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as amended by paragraph (1) of this subsection, is amended in subsection (f)—

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

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

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

(B) CONFORMING AMENDMENTS.—Section 303(f) of the Federal Food, Drug, and Cosmetic Act, as amended by subparagraph (A), is amended—

(i) in paragraph 5 (as redesignated) by striking ''paragraph (3)(A)'' and inserting ''paragraph (4)(A)''; and

(ii) in paragraph 6 (as redesignated) by striking ''paragraph (4)'' each place it appears and inserting ''paragraph (5)''.

(d) IMPLEMENTATION.—

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

retary of Health and Human Services shall promulgate an interim final 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, and the rule may be made effective immediately upon promulgation of the rule. Not later than one year after the date on which the interim final 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 final rule, to the extent that such provisions are not modified.

(2) PERSONAL IMPORTATION FROM CANADA.—Until the expiration of the 45-day period beginning on the date on which the interim final 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 each of the following conditions:

(A) The drug is not—

(i) a controlled substance, as defined in section 102 of the Controlled Substances Act;

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

(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, 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.

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

(1) in the matter preceding clause (i), by striking ''With respect to'' and all that follows through ''may not send'' and inserting the following: ''With respect to a qualifying drug that is imported or of-

fered for import in the United States by an individual pursuant to section 804(a)(2)(B), the Secretary may not send'';

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

(3) in clause (iii), by striking ''or'' at the end; and

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

''(iv) importation is not in accordance with section 804; or''.

SEC. 4. 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 subsections:

''(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 may 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 30-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) The importation complies with 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 may 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 a 10-day supply.

''(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) The importation complies with 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 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. 5. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION INTO UNITED STATES.

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

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

''(a) IN GENERAL.—A shipment of drugs that is imported or offered for import into the United States shall be refused admission 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(j).

''(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. 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.

''(g) ADMINISTRATION.—This section may be not be construed as transferring to the Secretary responsibility for carrying out this section.''.

(b) PROCEDURES.—Procedures for carrying out section 805 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) of this subsection, shall be established not later than 30 days after the date of the enactment of this Act.

SEC. 6. 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 subsection (a) or (d) of section 801 or section 804, 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. 7. 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'' and inserting '', other than a registered exporter under section 804,'';

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

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

''(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 who is engaged in the business of the wholesale distribution of the drug from providing the statement described in subparagraph (A) to the person who 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 an importer who intends to sell the drug at retail if the Secretary determines that the alternative requirements will identify such chain of custody or the identity of the drug with greater certainty than 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 established 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 paragraphs:

''(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. 8. 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.

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

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

''SEC. 280L. ADVERTISING EXPENDITURES OF TAXPAYERS WHO DISCRIMINATE AGAINST FOREIGN SELLERS OF PRESCRIPTION DRUGS TO DOMESTIC CONSUMERS.

''(a) IN GENERAL.—No deduction otherwise allowable under this chapter shall be allowed for any amount paid or incurred for advertising for the taxable year by any taxpayer unless the taxpayer certifies that the taxpayer has not taken any action, directly or indirectly, during such taxable year to prevent the authorized importation of a qualifying drug into the United States from a registered exporter to a pharmacy or individual pursuant to section 804(a) of the Federal Food, Drug, and Cosmetic Act or has otherwise conditioned the terms by which a qualifying drug is imported into the United States from a registered exporter under such section. Such certification shall be made in such manner as the Secretary determines and shall be accompanied by such fees as the Secretary determines necessary to cover the costs of confirming such certification.

''(b) ADVERTISING.—For purposes of this section, the term 'advertising' includes direct to consumer advertising and any activity designed to promote the use of a prescription drug directed to providers or others who may make decisions about the use of prescription drugs (other than the provision of free samples).''.

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

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

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

SEC. 10. COMPLIANCE THROUGH ALLOWANCE OF RESEARCH AND DEVELOPMENT TAX CREDIT.

(a) IN GENERAL.—Section 41 of the Internal Revenue Code of 1986 (relating to credit for increasing research activities) is amended by adding at the end the following new subsection:

"(i) INCREASE IN CREDIT FOR CERTAIN TAXPAYERS.—The amount of the credit otherwise determined under this section for any taxable year shall be increased by 20 percent if the taxpayer certifies that the taxpayer has not taken any action, directly or indirectly, during such taxable year to prevent the authorized importation of a qualifying drug into the United States from a registered exporter to a pharmacy or individual pursuant to section 804(a) of the Federal Food, Drug, and Cosmetic Act or has otherwise conditioned the terms by which a qualifying drug is imported into the United States from

a registered exporter under such section. Such certification shall be made in such manner as the Secretary determines and shall be accompanied by such fees as the Secretary determines necessary to cover the costs of confirming such certification.''.

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

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