SAFE IMPORTATION OF MEDICAL PRODUCTS AND OTHER RX THERAPIES ACT OF 2004 (SAFE IMPORT ACT)

SECTION-BY-SECTION

SEC. 1. SHORT TITLE.

Provides that the short title of the bill is the ASafe Importation of Medical Products and Other Rx Therapies Act of 2004 or the "Safe IMPORT Act".

SEC. 2. IMPORTATION.

Amends Chapter VIII of the Federal Food, Drug, and Cosmetic Act (FFDCA) by adding two new subchapters: Subchapter A – General Provisions, and Subchapter B – Importation of Prescription Drugs.

Creates a new section 811 that defines the terms used in this subchapter.

- A "drug importation facility" means a person outside of the U.S. (other than a transporter) that distributes or dispenses a prescription drug imported or offered for import into the U.S.
- An "Internet pharmacy" means a person that dispenses or offers to dispense in the U.S. a prescription drug through an Internet website, regardless of whether the business is physically located within or outside of the U.S.
- A "pharmacy" means a person licensed by a State to dispense prescription drugs or provide pharmaceutical care.
- A "permitted country" means a country that was a member of the European Union as of December 31, 2003, and is designated by the Secretary of Health and Human Services ("the Secretary") as a country from which prescription drugs may be imported into the U.S. Three years after the date of enactment, the Secretary is required to submit a report to the Senate Committee on Health, Education, Labor and Pensions (HELP), and the House Committee on Energy and Commerce, that includes an analysis of whether importation of prescription drugs from these 15 countries would present an increased risk to the public health. The report must also identify the specific nature of the increased risk and describe measures that may be taken to avoid, reduce, or mitigate such risk. The Secretary may consider whether to designate a permitted country at any time after submission of the report.
- A "prescription drug" means a described a drug in section 503(b) and approved by the Secretary under section 505 of the FFDCA. The term does not include a controlled substance, a biological product, an infused drug, an intravenously injected drug, a drug inhaled during surgery, a parenteral drug, a drug manufactured through one or more biotechnology processes, a drug required to be refrigerated, or a photoreactive drug.
- A "treating provider" means a licensed health care provider that performs a physical evaluation of an individual; discusses treatment options with that individual; maintains contemporaneous medical records concerning that individual; or provides care to that individual as part of an on-call or cross-coverage arrangement with the health care provider that performed the initial physical evaluation.
- A "wholesaler" means a person licensed as a wholesaler or distributor of prescription drugs in the U.S. as described in section 503(e)(2) of the FFDCA, except a person authorized to import drugs under section 801(d)(1).

Creates a new section 812 that allows an individual to import a prescription drug from Canada or a permitted country into the U.S. for their personal use. The prescription drug must be purchased from a licensed pharmacy in Canada or a permitted country; imported for personal use by the individual and not for resale; imported from Canada or a permitted country into the U.S.; and the quantity of the drug does not exceed a 90-day supply during any 90-day period. The prescription drug must also be accompanied by a copy of a valid prescription cosigned by a prescribing physician in Canada or the permitted country; or, if the drug is available in Canada or the permitted country without a prescription, a copy of the valid prescription signed by a pharmacist licensed in Canada or the permitted country.

The Secretary may continue to permit an individual, under the compassionate use exception, to import a drug that is not approved by the Secretary under section 505, if the importation is for continuation of personal use by the individual for treatment, begun in a foreign country, of a serious medical condition.

Section 812 would take effect on the date of enactment.

Creates an new section 813 that allows a drug importation facility, pharmacy, Internet pharmacy, or wholesaler to import a prescription drug from Canada or a permitted country into the U.S. The Secretary could limit the ports of entry in the U.S. through which a prescription drug could be imported under this Act. The prescription drug must be approved under section 505; comply with sections 501 and 502; bear a label stating, in prominent and conspicuous type, that the drug is imported and the foreign country from which it was imported; and a unique identifier code that modifies the national drug code of the product.

A drug importation facility is required to submit an application to the Secretary to ensure that the that the imported prescription drug's label complies with the requirements of sections 502 and 503. Not later than 60 days after receipt of a completed application, the Secretary shall approve or deny the application consistent with the requirements of sections 502 and 503; notify the applicant of the decision; and, if the application is denied, the reason for the denial. The Secretary is required to compile, maintain, and periodically update a list of applications that are pending, and that have been approved and denied. The Secretary would be required to maintain an updated list of the U.S. ports through which a prescription drug could be imported under this Act and to make the list available to the public through an Internet website.

A prescription drug cannot be imported into the U.S. if, at any time the prescription drug was not in the control of the manufacturer, the drug entered a country other than Canada or a member of the E.U as of December 31, 2003. The Secretary may exclude one or more of the countries that a prescription drug may enter while not in the control of the manufacturer, if the Secretary determines that allowing the drug to enter into that country would present a risk to the public health.

A drug importation facility, pharmacy, Internet pharmacy, or wholesaler cannot commingle a prescription drug imported into the U.S. under this subchapter with a drug that is not imported from Canada or a permitted country. A pharmacy or Internet pharmacy that dispenses an imported prescription drug is required to affix a label on each container identifying it as "reimported," unless such a label is already affixed to the container.

Affirms that section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country. Provides that the district courts of the U.S. shall have jurisdiction in an action brought against a person importing or offering for importation a prescription drug in violation of the requirements of this section.

Affirms that nothing in this section limits the current authority of the Secretary relating to the importation of prescription drugs, including the interdiction of prescription drugs that are or may appear adulterated or misbranded.

Requires the Secretary to promulgate interim final regulations to carry out section 813. However, the section is to take effect upon the expiration of the 1 year period, even if the Secretary does not meet the deadline.

Amends section 301 of the FFDCA, making it a prohibited act to dispense a prescription drug imported into the U.S. in violation of the requirements of this section.

SEC. 3. PROTECTION AGAINST ADULTERATED PRESCRIPTION DRUGS.

Amends section 801(h) by directing the Secretary to give high priority towards improving information management systems relating to the importation of prescription drugs, and to improve our ability to allocate resources, detect adulterated drugs, and facilitate the importation of drugs that are in compliance with the Act. Directs the Secretary to improve linkages with other Federal, State and tribal agencies that share responsibility for the safety of prescription drugs.

SEC. 4. INTERNET PHARMACIES.

Creates a new section 511 that establishes federal licensing requirements for all Internet pharmacies that conduct or solicit business in the U.S.

Paragraph (a) defines the terms used in this section.

- An "advertising service provider" means an advertising company that contracts with an interactive computer service provider (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f)) to provide advertising on the Internet.
- A "designated payment system" means a system used by a creditor, credit card issuer, financial institution, an operator of a terminal at which an electronic fund transfer may be initiated, a money transmitting business, an international, national, regional, or local network or any participant in a network used to effect a credit transaction, electronic fund transfer, or money transmitting service that the Federal functional regulators determine, by regulation or order, could be used in connection with, or to facilitate, a restricted transaction.
- A "prescription drug" means a drug described in section 503(b) that is approved by the Secretary under section 505.
- An "Internet pharmacy" means a person that dispenses or offers to dispense in the U.S. a prescription drug through an Internet website, regardless of whether the business is physically located within or outside of the U.S.
- A "restricted transaction" means a transaction or transmittal, on behalf of any person who places

an unlawful Internet pharmacy request to any person engaged in the operation of an unlicensed Internet pharmacy, of credit, or the proceeds of credit, extended to or on behalf of the person who placed the unlawful internet request; an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the person who placed the unlawful internet request; a check, draft, or similar instrument which is drawn by or on behalf of the person who placed the unlawful internet request and is drawn on or payable at or through any financial institution; or the proceeds of any other form of financial transaction (identified by the Federal functional regulators by regulation) that involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the person who placed the unlawful internet request.

- An "unlawful Internet pharmacy request" means the request, or transmittal of a request made to an unlicensed Internet pharmacy for a prescription drug by mail (including a private carrier), FAX, phone, electronic mail, or by a means that involves the use, in whole or in part, of the Internet.
- The terms 'credit', 'creditor'; and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602)
- An "electronic fund transfer" has the meaning given in section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693); and includes any fund transfer covered under Article 4A of the Uniform Commercial Code, as in effect in any State.
- A "financial institution" has the meaning given the term in section 903 of the Electronic Transfer Fund Act (15 U.S.C. 1693a); and includes a financial institution as defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809).
- A "money transmitting business" or "money transmitting service" have the meaning given the terms in section 5330(d) of title 31, United States Code.

Provides that an Internet pharmacy may dispense or offer to dispense a prescription drug only in accordance with this section. An Internet pharmacy can only be licensed if its principal place of business is in the U.S., Canada, or a permitted country. The Secretary will issue Internet pharmacy applicants an annually renewable license within 60 days of receipt if they are in compliance with the requirements of this subsection. The Secretary will maintain an up-to-date list of all licensed Internet pharmacies and make it available to the public on an Internet website and by means of a toll-free telephone number.

The licensing process requires Internet pharmacies to verify that they are compliant with all State and Federal laws regarding the practice of pharmacy and to make their facilities available to FDA inspection. Among these requirements is an assurance that any agreement between a patient and an Internet pharmacy that releases the Internet pharmacy, or an employee or agent of the Internet pharmacy, from liability arising out of the Internet pharmacy's negligence, shall be null and void.

Internet pharmacies will be required to disclose the street address, city, state, zip code, country, and telephone number of all places of business; the name of the supervising pharmacist and each individual who serves as a pharmacist for purposes of the website; and a list of each State or country, as appropriate, in which the Internet pharmacy and its pharmacists are licensed or otherwise authorized to dispense prescription drugs.

Internet pharmacies will be required to verify the identity of the patient, and that the prescription is from a treating provider as this term is defined in the Act. Internet pharmacies must maintain patient

medication profiles; conduct prospective drug use reviews before dispensing medication; protect patient identity and patient-specific information in accordance with HIPPA, and offer interactive and meaningful consultation by a licensed pharmacist prior and subsequent to the time when the drug is dispensed. They must also establish a system that allows patients to report errors, suspected adverse drug reactions, and that allows the Internet pharmacy to inform patients about drug recalls, and the appropriate means to dispose of expired, damaged, or unusable medications. If a shipment to an individual from a licensed Internet pharmacy is refused admission to the U.S., then the prescription drug must be returned to the Internet pharmacy at the expense of the Internet pharmacy, unless the Secretary is required to destroy the prescription drug. Both the individual and the Internet pharmacy will receive written notice of the reason for refusal.

The initial licensing fee for an Internet pharmacy will be $5,000 and the fee for subsequent years will be determined by the Secretary, based on the anticipated costs of enforcing the requirements of this section. Each licensee will be required to pay only one fee. The fees shall be used to enforce the provisions of this section. Not later than 60 days before the beginning of each fiscal year, the Secretary must establish the license fees that are due for that year. If a licensee fails to pay a fee 30 days after the date on which it is due, the Secretary may prohibit the licensee from engaging in the dispensing of drugs to U.S. consumers until such fee is paid. Not later than 60 days before each fiscal year, the Secretary must publish the licensing fee established under this section, hold a public meeting, and allow for the submission of written comments. Not later than 60 days after the end of each fiscal year during which fees are collected, the Secretary must submit to the Senate HELP Committee, and the House Committee on Energy and Commerce, a report describing the implementation of its licensing fee authority and how the fees were used. The license may be renewed yearly. The license may also be terminated after notice and an opportunity for a hearing, if the Secretary determines that the Internet pharmacy has engaged in a pattern of non-compliance with this section, made untrue statements of material fact on the original license or any subsequent renewal application, or was in violation of any applicable State or Federal law relating to the dispensing of a prescription drug. This section also grants the Secretary the authority to issue a contract for the operation of the licensing program for up to a 5 year term, subject to an annual performance review.

If an Internet pharmacy that imports or offers for importation a prescription drug for subsequent dispensing to an individual, then they must register with the Secretary and comply with subchapter (B) of chapter VIII.

A provider of interactive computer services (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f))) or an advertising service provider shall be liable for dispensing or selling a prescription drug in violation of this section if the provider of the service accepts advertising from an unlicensed Internet pharmacy or allows advertising stating that an individual does not need a physician's prescription to obtain a prescription drug.

Not later than 180 days after the date of enactment of this section, Federal functional regulators shall promulgate regulations requiring a creditor, credit card issuer, financial institution, an operator of a terminal at which an electronic fund transfer may be initiated, a money transmitting business, an international, national, regional, or local network or any participant in a network used to effect a credit transaction, electronic fund transfer, or money transmitting service, to prevent restricted transactions by establishing policies and procedures that are reasonably designed to allow the payment system, and any person involved in the payment system, to identify and block restricted

transactions by means of codes in authorization messages or by other means; and prevent the acceptance of products or services in connection with a restricted transaction. Violations of this subsection of section 511 shall be enforced by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided in section 505(a) of the Gramm-Leach-Bliley Act (21 U.S.C. 6805(a)). In considering an enforcement action, they shall consider the extent and history of the violation; the extent to which the person has established and is maintaining policies and procedures which are in compliance with this subsection; the feasibility that the person can implement the policies and procedures without substantial deviation from normal business practice; and the cost and burdens the remedy will have on the person.

The Secretary shall, pursuant to the submission of an application, make an award of a grant or contract to an entity with experience in developing and maintaining systems that can identify Internet pharmacy websites that are not licensed or appear to be operating in violation of State or Federal laws concerning the dispensing of drugs; report such Internet pharmacy websites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and submit, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken.

Amends section 301 making it a prohibited act to sell a prescription drug, or own or operate an Internet pharmacy, in violation of section 511. The representation by advertisement, sales presentation, direct communication (including telephone, facsimile, or electronic mail), or otherwise by an Internet pharmacy, that prescription drugs may be obtained from the Internet pharmacy without a prescription, is also prohibited. Finally, the acceptance of an advertisement from or provision of links to an Internet pharmacy by an interactive computer service unless they have on file a copy of the license issued to the Internet pharmacy under this section.

Section 302 of the FFDCA is amended by adding that, in the case of a violation of this section, the district courts of the U.S. and the U.S. courts of the Territories shall have jurisdiction to order a provider of an interactive computer service to remove or disable access to a website violating that section, or a link to a website violating that section, that resides on a computer server that such provider controls or operates. A shipment to an individual from an unlicensed Internet pharmacy will be refused admission to the U.S. and returned to the Internet pharmacy at the expense of the Internet pharmacy, unless the Secretary is required to destroy the prescription drug.

SEC. 5. ADMINISTRATIVE DETENTION AND TEMPORARY HOLD.

Creates a new section 816 to the FFDCA, authorizing officers and qualified employees of the FDA to detain a prescription drug being imported into the U.S., if there is credible evidence or information indicating that the drug presents a risk to the public health. The prescription drug could only be detained for 20 days, unless a greater period of time, not to exceed 30 days is required for the Secretary to institute a seizure action or injunction proceeding under section 302. The Secretary may also require that the prescription drug be labeled or marked as detained, and moved to a secure facility.

Creates an administrative appeals process that requires the Secretary, after providing for an informal hearing, to confirm or terminate a detention order within 5 days of an appeal. A confirmation or termination of the detention order is considered a final agency action. If the Secretary fails to comply with the above requirements, the detention order is deemed terminated.

Clarifies that this section is not applicable to a prescription drug imported by an individual under section 812, or to a prescription drug shipped to an individual by an Internet pharmacy.

Amends section 801 to provide for temporary holds at ports of entry. Authorizes an officer or qualified FDA employee to request that the Secretary of the Treasury to hold a prescription drug at the port of entry for a period not to exceed 24 hours. This is to occur when the employee has credible evidence or information that a prescription drug presents a risk to the public health or safety, and the officer needs more time to inspect, examine, or investigate the drug. Directs the Secretary to ask the Secretary of the Treasury to remove a held drug to a secure facility, as appropriate. The drug may not be transferred during the holding period.

Amends section 301, making it a prohibited act to transfer a prescription drug in violation of a detention order or to remove or alter any required mark or label identifying the drug as detained.

SEC. 6. SUSPENSION.

Creates a new section 817 that allows the Secretary to immediately suspend the importation of a particular prescription drug (or dosage form) into the U.S., if such drug presents a risk to the public health. The Secretary may immediately suspend a drug importation facility, pharmacy, Internet pharmacy, or wholesaler from importing or offering for importation a prescription drug into the U.S., if there is a pattern of importing or offering for importation a prescription drug in violation of the FFDCA. The Secretary may immediately suspend the importation or offering for importation of a prescription drug from Canada or any other permitted country if there is a pattern of importing or offering for importation a prescription drug in violation of the FFDCA.

Specifies an appeals process which requires the Secretary, after providing for an informal hearing, to confirm or terminate a suspension order within 30 days of an appeal. If the Secretary fails to comply with the above requirements, the suspension order is deemed terminated. An order under this section shall not, however, be subject to judicial review.

Clarifies that this section is not applicable to a prescription drug imported by an individual under section 812, or to a prescription drug shipped to an individual by an Internet pharmacy.

Amends section 301, making it a prohibited act to import or offering for import a prescription drug in violation of an order of suspension.

SEC. 7. DEBARMENT FOR REPEATED OR SERIOUS PRESCRIPTION DRUG IMPORTATION VIOLATIONS.

Amends section 306(b)(1) to establish debarment for persons convicted of a felony for conduct relating to the importation of any prescription drug or for persons who have engaged in a pattern of importing or offering for import prescription drugs that present a risk to the public health. Amends section 301 to make it a prohibited act the importing or offering for import a prescription drug by, with the assistance of, or at the direction of a debarred person. This section is not applicable to a prescription drug imported by an individual under section 812, or to a prescription drug shipped to an individual by an Internet pharmacy. Amends section 801 to require that a prescription drug being imported or offered for import by a debarred person be held at the port of entry at a secure facility,

and not transferred. The prescription drug may be delivered to a non-debarred person if that person establishes, at their expense, that the drug is in compliance with the FFDCA.

SEC. 8. REGISTRATION OF PRESCRIPTION DRUG IMPORTATION FACILITIES.

Creates a new section 814 that requires the owner, operator, or agent in charge of a drug importation facility, pharmacy, Internet pharmacy or wholesaler engaged in importing or offering for import a prescription drug, to register with the Secretary. For a foreign facility, the registration must include the name of the U.S. agent for the facility. The registration shall contain information necessary to notify the Secretary of the name and address of each registrant; all trade names under which the registrant conducts business; and the name of each prescription drug to be imported into the U.S. Requires the registrant to notify the Secretary in a timely manner of changes to such information. Not later than 60 days after receipt of a completed registration, the Secretary is must notify the registrant of receipt of the registration and assign a registration number. Requires the Secretary to compile and maintain an up-to-date list of registered facilities. Authorizes the Secretary to provide for and require the use of electronic methods of registration. Clarifies that nothing in this section authorizes the Secretary to require an application, review, or licensing process for a drug importation facility, pharmacy, or wholesaler. Also clarifies that this section is not applicable to a prescription drug imported by an individual under section 812, or to a prescription drug shipped to an individual by an Internet pharmacy.

Requires the Secretary to promulgate proposed and final regulations not later than 1 year after enactment. The requirement takes effect upon the expiration of the 1 year period, even if the Secretary does not meet the deadline.

Amends section 801 to require that a prescription drug offered for import from an unregistered foreign facility be held at the port of entry until the facility is registered. Amends section 301 making failure to register a prohibited act.

SEC. 9. MAINTENANCE AND INSPECTION OF RECORDS FOR PRESCRIPTION DRUGS.

Creates a new section 815 that authorizes the Secretary to require the maintenance of records relating to the importation of prescription drugs, and to have access to such records if the Secretary has reason to believe that an imported prescription drug presents a risk to the public health. The Secretary may impose such record requirements on a drug importation facility, pharmacy, Internet pharmacy, or wholesaler engaged in the importation of prescription drug into the U.S., and any person that processes, packages, distributes, receives, holds, or transports such drugs. Limits recordkeeping requirement to two years. Directs the Secretary to take appropriate measures to ensure protection from disclosure of sensitive information. This section is not applicable to a prescription drug imported by an individual under section 812, or to a prescription drug shipped to an individual by an Internet pharmacy.

SEC. 10. ADVANCE NOTICE OF IMPORTED PRESCRIPTION DRUG SHIPMENTS.

Amends section 801 to require prior notice of imported prescription drug shipments. The notice is required to identify the name, dosage form, and quantity of the prescription drug; the shipper; the original country of origin; the country from which the drug is shipped, and the anticipated port of

entry. States that, if notice is not provided, the shipment shall be refused admission. Requires that the period of advance notice shall be not less than 24 hours and not more than 5 days. States that if there is a prescription drug offered for import for which advanced notice has not been provided, such shipment shall be held at the port of entry until the importer, owner, or consignee complies. Clarifies that this section does not limit the Secretary's authority to obtain additional information under other provisions of the FFDCA. Also clarifies that the advanced notice requirement does not apply to a prescription drug imported by an individual under section 812 or to a commercial transaction conducted between an Internet pharmacy and an individual.

Amends section 301 making it a prohibited act to import of offer for import a prescription drug in violation of these requirements.

SEC. 11. AUTHORITY TO MARK PRESCRIPTION DRUGS REFUSED ADMISSION INTO THE UNITED STATES.

Amends section 801 to authorize the Secretary to require the marking of a prescription drug refused entry into the U.S. Marking is to be done at owner's expense. Amends section 502 to make a prescription drug misbranded if it fails to bear the required label when the Secretary has found that the prescription drug presents a risk to the public health and the Secretary has notified the owner or consignee that the label is required and that the drug presents such a threat. Clarifies that this section is not applicable to a prescription drug imported by an individual under section 812, or to a prescription drug shipped to an individual by an Internet pharmacy. Provides a rule of construction stating this does not limit the authority of the HHS Secretary or the Secretary of the Treasury to require the marking of a refused prescription drug under any other provision of law.

SEC. 12. PROHIBITION OF PORT SHOPPING.

Amends section 502 to deem a prescription drug adulterated if it is has previously been refused admission into the U.S., unless the person reoffering the drug establishes that the drug is in compliance with the Act. Clarifies that this section is not applicable to a prescription drug imported by an individual under section 812, or to a prescription drug shipped to an individual by an Internet pharmacy.

SEC. 13. AUTHORITY TO COMMISSION OTHER FEDERAL AND STATE OFFICIALS TO CONDUCT INSPECTIONS.

Amends Section 702 to authorize the Secretary to commission other Federal employees to conduct examinations and inspections. Requires a memorandum of understanding (MOU) between the Secretary and the head of the other Federal agency. The MOU must address training and reimbursement. It is restricted to facilities or other locations that are jointly regulated by the Secretary and the other Federal department or agency. Requires the Secretary and the head of the other Federal department or agency to submit a report to Congress each fiscal year that provides the number of employees that carried out one or more activities, the number of additional drugs that were inspected or examined, and the number of additional examinations or investigations that were carried out pursuant to the MOU.

Authorizes the Secretary to enter into a contract with a State to conduct examinations and investigations. The contract must address the training of State personnel and would only be effective with respect to drug importation facilities, pharmacies, Internet pharmacies, and wholesalers located in the State.

SEC. 14. USER FEES RELATING TO PRESCRIPTION DRUG IMPORTATION.

Amends chapter VII, subchapter C of the FFDCA authorizing the Secretary to establish a user fee program under which a drug importation facility, pharmacy, Internet pharmacy, or wholesaler registered under section 814 shall be required to pay to the Secretary an annual fee. Each registrant would pay only one fee. The amount of the fee shall be determined each year by the Secretary and be based on the anticipated costs to the Secretary of enforcing the provisions of the Safe IMPORT Act. The fees collected under this section shall be used to enforce the provisions of the Safe IMPORT Act. Not later than 60 days before the beginning of each fiscal year, the Secretary must establish the registration fees that are due for that year. If a registrant fails to pay a fee 30 days after the date on which it is due, the Secretary may prohibit the registrant from importing or engaging in the importation of a prescription drug until such fee is paid. Not later than 60 days before each fiscal year, the Secretary must publish the user fees established under this section, hold a public meeting, and allow for the submission of written comments. Not later than 60 days after the end of each fiscal year during which fees are collected under this section, the Secretary must submit to the Senate HELP Committee, and the House Committee on Energy and Commerce, a report describing the implementation of its user fee authority and how the fees were used by the Secretary.

SEC. 15. ANTICOUNTERFEITING PROVISIONS.

Amends section 503(e) to require that a distributor of record create and maintain records identifying the immediate previous source and immediate subsequent recipient of a prescription drug, regardless of whether or not the drug is imported.

Requires that a distributor of record engaged in the importation or offering for importation a prescription drug from Canada or a permitted country create and maintain records identifying all of the previous members of the supply chain. The records must be maintained for a period of two years.

The Secretary shall require the adoption and use of electronic track and trace technology for a prescription drug at the case and pallet level by December 31, 2007.

A "distributor of record" means a person (other than a transporter) that takes title to or possession of a drug from manufacture to retail sale, including a person that manufactures, processes, packs, distributes, receives, holds, imports, or offers for import a prescription drug. A "transporter" means the U.S. Postal Service or equivalent governmental service of a foreign country, or a private carrier engaged in the business of transporting packages for hire.

Requires the Secretary to establish a Counterfeit Alert Network to notify health professionals and the public of counterfeit prescription drugs; develop and publish educational materials to help health professionals and consumers identify and report counterfeit drugs; develop and publish secure business practice guidelines for the sale and distribution of prescription drugs; and in cooperation

with the National Association of Boards of Pharmacy, develop and publish model rules for licensure of wholesalers for adoption by the States.

SEC. 16. CONFORMING AMENDMENTS.

Identifies conforming amendments to the FFDCA.