Order Code RL32568

Senate Prescription Drug Importation Legislation: A Side-by-Side Comparison of Current Law, S. 2307, S. 2328, and S. 2493

September 7, 2004

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Summary

Senators Grassley, Dorgan, and Gregg have each introduced bills that address Congressional concerns with prescription drug importation that were not resolved by the provisions in the Medicare Prescription Drug, Improvement, and Modernization Act (the MMA, P.L. 108-173).

- S. 2307, the Reliable Entry for Medicines at Everyday Discounts through Importation with Effective Safeguards Act of 2004, introduced by Senator Grassley on April 8, 2004 [the Grassley bill];
- S. 2328, the Pharmaceutical Market Access and Drug Safety Act of 2004, introduced by Senator Dorgan on April 21, 2004 [the Dorgan bill]; and
- S. 2493, the Safe Importation of Medical Products and Other Rx Therapies Act of 2004, introduced by Senator Gregg on June 2, 2004 [the Gregg bill].

By continuing the major legal obstacle to importation — the requirement that the Secretary of Health and Human Services first certify that imports are safe and offer cost savings to U.S. consumers, something no Secretary has been willing to do — the MMA effectively does not allow the commercial or personal-use importation of prescription drugs. This report briefly discusses major differences among current law and the bills introduced in April and June 2004 and presents a side-by-side comparison of the provisions.

Although all three bills seek to make lower-priced prescription drugs available to U.S. consumers by allowing importation while also ensuring that the drugs are safe and effective, they take different approaches. The three Senate bills use extensive registration, licensing, facility inspection, and records requirements to document an imported shipment's chain-of-custody requirements rather than the MMA's mandated laboratory testing of imported drugs to verify their content, potency, and labeling. Current law and the bills each have different lists of countries from which imports could be imported, and they provide the Secretary with different time frames and criteria for determining whether to permit commercial or personal-use importation. Secretarial reporting requirements vary as do mechanisms to fund the import activities: the MMA relies on appropriations, and the Senate bills each create specific user fee provisions. Only the Gregg bill requires the regulation of Internet pharmacies. The Grassley and Dorgan bills propose links to antitrust, patent, and internal revenue titles of the U.S. Code to influence industry behavior. The MMA does not specify when importation could begin. For commercial imports from Canada, the Grassley and Dorgan bills start 90 days from enactment, later for other countries; the Gregg bill allows imports from Canada only, beginning one year from enactment. The Grassley and Gregg bills allow personal-use imports from Canada upon enactment, with the Grassley bill's allowing other countries later; the Dorgan bill allows personal-use imports from Canada only, beginning 90 days after enactment.

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Introduction

This report compares the provisions of three Senate prescription drug importation bills with current law provisions on the subject.[1] The law on the importation of prescription drugs was recently amended by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA, P.L. 108-173). The three bills[2] with provisions compared to current law are:

- S. 2307, introduced by Senator Grassley on April 8, 2004 [the Grassley bill];
- S. 2328, introduced by Senator Dorgan[3] on April 21, 2004 [the Dorgan bill]; and
- S. 2493, introduced by Senator Gregg[4] on June 2, 2004 [the Gregg bill].

The new law and the three bills all seek to balance the availability of imported prescription drugs — both for commercial and personal use — and the assurance that those imports would be safe and effective. The underlying goal is to reduce or restrain the growth of the financial burden that prescription drugs place on U.S. consumers. They all would act primarily by replacing or amending Section 804 of

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[1] This report replaces the CRS Congressional Distribution Memorandum, *Senate Prescription Drug Importation Legislation [updated]*, by (name redacted) and (name redacted), dated June 25, 2004. For a detailed comparison of changes in Section 804 made by the MMA to the preexisting law (as established by the 2000 MEDS Act), see CRS Report RL32271, *Importation of Prescription Drugs Provisions in P.L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, by (name redacted) and (name redacted). For an analysis of the issues involved in drug importation, see CRS Report RL32511, *Importing Prescription Drugs: Objectives, Options, and Outlook*, by (name redacted) and (name redacted).

[2] The House passed H.R. 2427 (introduced by Rep. Gil Gutknecht) on July 25, 2003, before passage of the MMA. The conferees did not, however, include its provisions in their final agreement. No Senate version was introduced.

[3] Co-sponsors of S. 2328 at its introduction were Sens. Snowe, Kennedy, McCain, Daschle, Lott, Stabenow, Chafee, Johnson, Pryor, and Feingold; by Sept. 1, 2004, it had 30 co-sponsors.

[4] Co-sponsors of S. 2493 at its introduction were Sens. Smith, Collins, Coleman, Sessions, Lott, and Enzi; by Sept. 1, 2004, Sen. Voinovich had joined as a co-sponsor.

the Federal Food, Drug, and Cosmetic Act (FFDCA) that had been initially added to the FFDCA by the Medicine Equity and Drug Safety (MEDS) Act of 2000. Individual bills would amend other laws.

Impetus for developing new importation legislation so soon after enactment of the MMA is the result of the new law's retaining the MEDS Act provision that importation not be allowed unless the Secretary of Health and Human Services (HHS) certifies that imports are safe and offer cost savings to U.S. consumers. The three bills each eliminate this requirement and, instead, include other potential safeguards regarding drug safety and effectiveness.

Differences Among the Bills

Some of the major areas of difference among the bills are the following:

Monitoring

While the MMA relies on laboratory testing of samples of every shipment of imported drugs to verify their content, potency, and labeling, the three proposed Senate bills focus on documentation of a monitored, uninterrupted chain of custody from manufacturing facility to importer. The MMA requires Canadian exporters to register with the Secretary. The Grassley and Dorgan bills specify extensive requirements for that registration, and the Dorgan bill extends similar registration requirements to importers as well as exporters. To do so, they require ongoing and onsite physical monitoring of the facilities of a drug's manufacturer, registered exporter, and registered importer, including inspection, if the Secretary determines it necessary, of any facility that handles the product along the chain of custody. The Gregg bill has extensive registration requirements for importers and dispensers of imported prescription drugs, including providing to the commercial purchaser identifying information on all preceding transactions that transferred the drug since it left the manufacturer's control.

FDA Approval

The MMA and the Gregg bill explicitly require that an imported drug be approved for U.S. sale by the Food and Drug Administration (FDA). The Grassley and Dorgan bills allow different administrative requirements for importation while maintaining the substantive elements of FDA approval. The Grassley bill also requires that the imported drug be manufactured in the same facility as the equivalent FDA-approved drug.

Permitted Countries

The three Senate bills[5] and current law vary in the countries from which they would permit drug importation. The Grassley bill includes Australia, Canada, Japan, New Zealand, Switzerland, members of the European Union, Iceland, Liechtenstein, and Norway; it also allows the Secretary to designate additional countries that have equivalent regulatory requirements regarding safety and effectiveness. For commercial imports, the Dorgan bill differs in that it excludes Iceland, Liechtenstein, and Norway, and specifies European Union countries as of January 2003, thereby excluding the 10 admitted to membership in May 2004. The Dorgan bill, alone, distinguishes between commercial and personal-use imports regarding permitted countries, allowing only Canada for the latter. The Gregg bill includes Canada and allows the Secretary, three years after enactment, to designate as eligible any members of the European Union as of December 2003. Current law, the MMA, includes only Canada, although it allows the Secretary to grant waivers permitting personal-use importation from other countries.

Logistics

The Grassley bill would allow the manufacturer of an FDA-approved drug distributed in the United States to petition the Secretary to stop the importation of that drug when it has been manufactured in or exported to another country. The petition would have to assert that the imported drug differs from the U.S. drug enough that it would require a supplemental application to FDA if the manufacturer wanted to introduce it to the U.S. market. The manufacturer would, through fees similar to those established for supplemental applications under the Prescription Drug User Fee Act (PDUFA, P.L. 102-571), pay the expense of the Secretary's review. The Dorgan bill would require the manufacturer of any drug that "may be imported" to submit a notice with extensive documentation of the differences, if any, between a drug it produces for commercial marketing in a permitted country and the drug it produces for the U.S. market. Here, too, the manufacturer would pay for the review of these materials with fees similar to those required for supplemental or new drug applications under PDUFA. The Gregg bill does not require the manufacturer to document differences between its U.S.-marketed and foreign-marketed products.

Reports

The MMA and the Grassley bills require the HHS Secretary to submit reports to Congress. The MMA also requires a report from the Commerce Secretary and others. The Dorgan bill requires no report. The Gregg bill requires three reports to Congress, covering which countries the Secretary has designated as permitted for imports and the reasons why, the implementation of registration fees and the use of those fees, and the commissioning of federal and state officials to conduct inspections.

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[5] The most inclusive list is in H.R. 2427 [not included in this report's table], the Gutknecht bill, which follows the language in the MEDS Act of 2000. Permitted countries would be Australia, Canada, Israel, Japan, New Zealand, South Africa, Switzerland, members of the European Union, Iceland, Liechtenstein, and Norway.

Funding

The MMA includes no explicit funding mechanism other than authorizing appropriations of such sums as necessary to implement the provisions. The Grassley bill calls for exporter fees that, in the aggregate, would cover the cost of administering the import provisions. The Dorgan bill includes exporter and importer fees based on the share of volume of imports, adjusted annually, to not exceed 1% of the price of drug imports. The Gregg bill sets a $5,000 first-time registration fee and requires the Secretary to set annually a fee, based on anticipated costs, to enforce the Act without further appropriation.

Incentives

Implementation of the MMA is restricted by the requirement that the Secretary certify safety and cost savings. Criticism of the MMA cites anticipated manufacturer resistance. The Grassley and Dorgan bills propose links to antitrust, patent, and internal revenue titles of the U.S. Code to influence industry behavior. The Grassley bill includes tax incentives and penalties to minimize manufacturer interference. The Dorgan bill creates an antitrust provision to compel manufacturer participation and amends patent law to remove obstacles to importation. The Gregg bill includes neither positive nor negative incentives to influence manufacturer behavior.

Internet Pharmacies

Neither current law, the MMA, nor the Grassley and Dorgan bills, as introduced, address Internet sales.[6] The Gregg bill presents an extensive statutory and regulatory structure for Internet pharmacies, placing it in the FFDCA, although set apart from the importation sections. In addition to registration, the bill requires that Internet pharmacies provide specific professional services including confidential patient medication profiles, "interactive and meaningful consultation by a licensed pharmacist," and verification of prescription validity. It requires advance notice of commercial shipments of prescription drug shipments and includes a licensing fee. Providers of interactive computer services are liable if they accept advertising for a prescription drug from an unlicensed Internet pharmacy or accept advertising stating a physician's prescription is not needed to obtain a prescription drug; the bill requires policies and procedures to prevent payments for unlawful Internet pharmacy requests.

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[6] Pending bills in the 108th Congress that address Internet pharmacies include H.R. 4598, H.R. 4612, H.R. 3880, H.R. 3870, H.R. 2652, H.R. 725, S. 2464, and S. 2288. The July 21, 2004 online newsletter, *Inside Health Policy*, reported that the Dorgan bill sponsors have added an Internet sales provision that covers U.S. Internet pharmacies. The report adds that the addition is based on a bill that Sens. Feinstein and Coleman introduced (S. 2464) as a companion bill to H.R. 3880, introduced by Reps. Davis and Waxman ("Dorgan Rx Import Bill Guards Against Fake U.S. Internet Pharmacies," July 21, 2004 at [http://insidehealthpolicy.com].

Effective Dates

The MMA does not specify when importation could begin other than linking it to the required safety and cost certification by the Secretary. The three Senate bills stipulate various time frames for commercial and personal-use importation, with varying times for different countries.

Commercial Imports. The Grassley bill requires that the Secretary promulgate and make effective an interim final rule not later than 90 days after enactment for commercial imports from Canada; it allows imports from other countries, approximately two years later, if the Secretary designates them based on a report required by the bill. The Dorgan bill would allow registered importers to import from Canada beginning when the Secretary promulgates an interim rule, which is required within 90 days of enactment; the Secretary could add other countries one year later. The Gregg bill would allow pharmacy and wholesaler importation from Canada one year after enactment, even if the Secretary has not issued regulations; the Secretary could allow imports from pre-2004 members of the European Union in three years, following a required study.

Personal-Use Imports. The Grassley bill would allow a 90-day supply from Canada immediately until 45-days after promulgation of an interim final rule, which is required within 90 days of enactment. Following a report to Congress due 18 months after enactment, the Secretary may designate other countries from which to allow personal-use imports. The Dorgan bill allows personal-use imports from Canada beginning when the interim rule is promulgated, which is 90 days after enactment; it does not provide for personal-use imports from any other country. The Gregg bill allows personal-use imports from enactment, even if the Secretary has not issued regulations. It also requires the Secretary to promulgate interim final regulations regarding Internet pharmacy certification within one year of enactment, with licensing to take effect 90 days after that promulgation.

Side-by-Side Comparison

The following table arrays the prescription drug importation provisions of current law and the three Senate bills, with the columns ordered chronologically based on date of enactment or introduction. Organized by topic, the rows do not directly follow the order of provisions in any one of the compared documents.

Comparison of Prescription Drug Importation Provisions in Current Law, S. 2307, S. 2328, and S. 2493

Topic	Current law: Medicare Prescription Drug, Improvement, and Modernization Act of 2003, enacted 12/8/2003 as P.L. 108-173 [117 Stat. 2464]	S. 2307 (Grassley 4/8/04) Reliable Entry for Medicines at Everyday Discounts through Importation with Effective Safeguards (REMEDIES) Act of 2004	S. 2328 (Dorgan 4/21/04) Pharmaceutical Market Access and Drug Safety Act of 2004	S. 2493 (Gregg 6/2/04) Safe Importation of Medical Products and Other Rx Therapies (IMPORT) Act of 2004
Legislation	Section 804 of the Federal Food, Drug, and Cosmetic Act — Importation of Covered Products — was first established under the Medicine Equity and Drug Safety Act of 2000 (P.L. 106-387). Section 1121(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173) replaced Section 804 entirely.	Section 2. Repeals Section 804 of the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by Section 1121(a) of P.L. 108-173. Section 3. Inserts a new Section 804. Also amends, deletes, or adds provisions in other sections of the FFDCA; and the Internal Revenue Code of 1986 [31 USC 26]; and the Controlled Substances Import and Export Act [21 USC 956].	Section 3. Repeals Section 804 of the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by Section 1121(a) of P.L. 108-173. Section 4. Inserts a new Section 804. Also amends, deletes, or adds provisions in other sections of the FFDCA; and the Clayton Antitrust Act [15 USC 12 et seq.]; the Controlled Substances Import and Export Act [21 USC 956]; Section 271 [Infringement of Patent] of Title 35 [Patents]; and Section 351 of the Public Health Service Act [42 USC 262].	Section 2. Adds a new Subchapter B — "Importation of Prescription Drugs" — to Chapter VIII of the Federal Food, Drug, and Cosmetic Act (FFDCA), adding Sections 811-817. Section 16. Repeals Section 804 of the FFDCA. Also amends, deletes, or adds provisions in other sections of the FFDCA; and the Controlled Substances Import and Export Act [21 USC 956].
Findings	No provision.	No provision.	Section 2. *Findings*. Includes findings that, although the United States is the largest market for prescription drugs, U.S. prices are "unjustly" higher than in other countries, and that allowing the importation of prescription drugs would save American consumers money and ensure access to safe and effective FDA-approved drugs.	No provision.
Direction to regulate	804(b). *Regulations.* Section 801 of the FFDCA allows only a drug's manufacturer to import that drug. Section 804(b) requires the Secretary of Health and Human Services	804(a). *Waivers Regarding Commercial and Personal Importation of Prescription Drugs.* The HHS Secretary shall provide, in regulations, a waiver of Section	804(a). *Importation of Prescription Drugs*. The HHS Secretary shall provide, in regulations for importing qualifying drugs by registered importers or from registered	Section 2(b). *Regulations*. Authorizes the HHS Secretary to promulgate regulations to carry out Section 812 [personal importation] and directs the Secretary to

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	(HHS), after consultation with the United States Trade Representative and the Commissioner of Customs, to promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States. 804(j)(2). *Waiver Authority.* The Secretary is authorized to grant waivers, either through rule-making or on a case-by-case basis, of the law that allows only manufacturers to import FDA-approved drugs, to allow individuals to bring in pharmaceuticals under conditions the Secretary determines appropriate. The Secretary must publish guidance describing the consistent circumstances in which waivers would be granted to individuals.	801(d)(1) as long as the drug complies with the standards of Section 801(a), which allows only certain drugs to be imported. A qualifying drug may not be imported unless the drug meets certain conditions [stated in 804(h)] or the imported drug is for personal use or for use by a family member and not for resale and meets the conditions in Section 804(i), as below.	exporters, a waiver of Section 801(d)(1) as long as the drug complies with the standards of Section 801(a), which allows only certain drugs to be imported. A qualifying drug may not be imported unless the drug is imported by a pharmacy or a wholesaler who is a registered importer, or a by an individual for personal or family-member use (and not for resale) from a registered exporter.	promulgate interim final regulations to carry out Section 813 [pharmacy and wholesaler importation of prescription drugs] of the FFDCA (as added by this section). Even if the Secretary has not promulgated regulations, Section 812 shall take effect on the date of enactment of this Act and Section 813 shall take effect one year after enactment. 813. *Pharmacy and Wholesaler Importation of Prescription Drugs.* A drug importation facility, pharmacy, Internet pharmacy, or wholesaler may import a prescription drug from Canada or a permitted country into the United States.
Permitted countries	Stipulates that the Secretary's regulations would include only Canada for imports by pharmacists and wholesalers; does not specify country for individual imports.	804(a)(4)(B). A "permitted country" is Canada and, 180 days after the publication of a report (see below), Australia, a member country of the European Union[*] or the European Free Trade Association,[***] Japan, and New Zealand. The Secretary may designate any additional country that has equivalent regulatory requirements to ensure the safety and effectiveness of drugs.	804(a)(4)(D). [For commercial importation,] A "permitted country" means Australia, Canada, a member country of the European Union as of January 1, 2003,[*] Japan, New Zealand, and Switzerland. 804(i)(1). For personal-use importation, includes Canada only.	811*(4)(A). [Note: Section 811 does not have a letter designating the beginning of this subsection, which an asterisk notes here.] Defines "permitted country" as a member of the European Union as of December 31, 2003,[*] that is designated by the Secretary based on a report due to the Senate HELP Committee and the House Energy and Commerce Committee three years after enactment (see under "Study and report," below).

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				813(d). Prohibits the importation of a prescription drug that had entered any country other than Canada or another permitted country after leaving the control of the manufacturer. Even when a drug comes from a permitted country, if it had been outside the manufacturer's control, the Secretary may prohibit its import if the Secretary determines that allowing it would present a risk to the public health.
[*]The European Union as of January 1, 2003 consisted of the following 15 member states: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxemburg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom. On May 1, 2004, 10 countries joined the European Union: Cyprus, the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia, and the Slovak Republic. [**]The European Economic Area consists of the European Union plus Iceland, Liechtenstein, and Norway. [***]The European Free Trade Association consists of Iceland, Liechtenstein, Norway, Switzerland, and the member states of the European Union.				
Definitions	804(a). *Definitions.* Defines "*importer*" to mean a pharmacist or a wholesaler; "*pharmacist*" to mean a person licensed by a state to practice pharmacy, including the dispensing and selling of prescription drugs; and "*wholesaler*" to mean a person licensed as a wholesaler or distributor of prescription drugs in the United States, but does not include the manufacturer of the drug being imported.	804(a)(4). *Definitions.* Defines "*importer*," "*pharmacist*," and "*wholesaler*" the same as current law. Defines "*exporter*" to mean a person who is (or seeks to be) in the business of exporting a drug to the United States after submitting a registration; "*registered exporter*" to mean an exporter with an approved registration in effect; and "*registration condition*" to mean a condition that must exist for a registration to be approved.	804(a)(4). *Definitions.* Defines "*registered exporter*," "*registration condition*," "*pharmacist*," and "*wholesaler*" the same as S. 2307. Defines "*exporter*" to mean a person who is in the business of exporting a drug from Canada to individuals in the United States or that seeks to be in such a business pursuant to submitting a registration; "*pharmacy*" to mean a person licensed by a state to engage in the business of selling prescription drugs at retail and employs 1 or more pharmacists; "*importer*" to mean a pharmacy, a group of pharmacies, or a wholesaler that is in drug importing business or that seeks an approved registration to do so; and "*registered*	811. *Definitions.* Defines "*drug importation facility*" as a "person, other than an individual importing a prescription drug under Section 812, located outside the United States (other than a transporter) that engages in the distribution or dispensing of a prescription drug that is imported or offered for importation into the United States." Defines "*Internet pharmacy*" as a person that offers to dispense a prescription drug through an Internet website in interstate commerce, regardless of whether its physical location is in the United States. Defines "*pharmacy*" as a person licensed by a state to dispense prescription drugs or to provide pharmaceutical care. Defines

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			importer" to mean a pharmacy, a group of pharmacies, or a wholesaler with an approved and in effect registration.	"*treating provider*" as "a licensed health care provider that (A) performs a documented patient evaluation (including a patient history and physical examination) of an individual to establish the diagnosis for which a prescription drug is prescribed; discusses with the individual the treatment options of the individual and the risks and benefits of treatment; and maintains contemporaneous medical records concerning the individual; or (B) provides care to an individual as part of an on-call or cross-coverage arrangement with a health care provider described in subparagraph (A)." Defines "*wholesaler*" as a person licensed as a wholesaler or distributor of prescription drugs in the United States, but does not include the manufacturer of the drug being imported or an individual importing for personal use. Section 15(c). *Anticounterfeiting Provisions; Distributors of Record.* Amends Section 503(e) of the FFDCA as follows. Defines "*distributor of record*" as a person that takes title to or possession of a drug from manufacture; this includes a person that manufacturers, processes, packs, distributes, receives, holds, imports, or offers for importation, and this does not include a transporter. Defines "*transporter*"

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				as the United States Postal Service, foreign government postal service, or a private carrier in the business of transporting packages. Defines "*wholesale distribution*" as the distribution of a drug to other than the consumer or patient but not including an intracompany sale or distribution by a transporter.
	Defines "*prescription drug*" as a drug subject to Section 503(b) [a drug intended for use by man that is not safe for use except under the supervision of a licensed practitioner] other than a controlled substance, a biological product, an infused drug, an intravenously injected drug, a drug that is inhaled during surgery, or a parenteral drug that the Secretary determines poses a threat to the public health. "*Qualifying laboratory*" is defined as a laboratory in the United States that has been approved by the Secretary for the purposes of this section.	Defines "*covered prescription drug*" as an approved drug under Section 505(b)(1) [an FDA-approved drug] that is subject to Section 503(b)(1) [a drug requiring a prescription]. Defines "*qualifying drug*" as a covered prescription drug other than a controlled substance, a biological product, an infused drug, an intravenously injected drug, or a drug that is inhaled during surgery. 804(g)(2)(A). A "*U.S. label drug*" is a drug approved for commercial distribution in the United States. 804(g)(2)(B)(i, iii). A "*petition drug*" is a drug named in a manufacturer's petition to the Secretary to stop its import. [See 804(g), below, regarding petitions.]	Defines "*prescription drug*" as a drug described in FFDCA Section 503(b)(1). Has the same definition for "*qualifying drug*" as S. 2307.	811*(5). Defines "*prescription drug*" similarly to current law [an FDA-approved drug], with additional exceptions: a drug manufactured through any biotechnology process, including a therapeutic DNA plasmid product, a therapeutic synthetic peptide product of not more than 40 amino acids, a monoclonal antibody product for in vivo use, and a therapeutic recombinant DNA-derived product; a drug requiring refrigeration at any time; or a photoreactive drug.

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Qualifying drugs	804(c). *Limitation.* Regulations must ensure that all imported prescription drugs meet the same safety and efficacy standards as drugs approved in the United States and that the importer comply with all information, reporting, and testing requirements. The Secretary is permitted to adopt such rules as necessary to safeguard public health or as a means to facilitate the importation of prescription drugs.	804(c). *Sources of Exporting Qualifying Drugs*. An exporter must only export a drug that has a verified chain of custody from the manufacturer to the exporter. The exporter must comply with the following: the drug must have been manufactured in an FDA-registered establishment [registered under (h) or (i) of Section 510], which is located in the U.S. or any foreign country, and the establishment manufactured the drug for distribution in the U.S. **and** for distribution in a permitted country; the drug came directly from the manufacturing establishment or from an entity that, by contract with the exporter, provides the exporter a chain of custody statement from the manufacturing establishment, identifying each prior sale, purchase, or trade with dates, names and addresses of all parties to the transaction; exporter agrees to permit the Secretary to inspect the statements and related records to determine accuracy; and agrees to allow the Secretary to inspect all facilities involved and all the contracting chain of custody parties; the foreign country from which the exporter will export the drug is a permitted country, and exporter ensures that during any period in which the drug was not in the drug manufacturer's control, the drug did not enter a non-permitted country.	804(c). *Sources of Qualifying Drugs.* Same as S. 2307 except that the manufacturing establishment must be either inspected by the Secretary or registered under Section 510. The manufacturing establishment can be in the United States or any foreign country, as in S. 2307, but the establishment can manufacture the drug either for distribution in the US **or** for distribution in a permitted country. Canada is the only foreign country from which the exporter can export the drug; the importer can import from a permitted country only. The exporter or importer must retain a sample of each lot of the drug sufficient for testing by the Secretary.	No explicitly comparable provision; however, requires that an imported prescription drug must be FDA-approved.

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Relationship to FDA approval	No explicitly comparable provision; however, the law requires that all imported drugs be FDA-approved.	804(g)(1). *Compliance with Section 801(a)* [Imports and Exports]. For each exported qualifying drug, the exporter must comply with Section 801(a) FFDCA standards subject to the import approval status, labeling, and standards for refused admission criteria under this Act [Sections 804(g)(2,3) and 804(j)]. 804(g)(2)(A). *Approval Status; Importation*. A drug may be imported into the United States if (1) the Secretary has verified the source of the exported drug, including that the drug is approved for commercial distribution in a specified foreign country and that the establishment that manufactures the drug also manufactures the drug for distribution in the United States (referred to as a "U.S. label drug"); and (2) it has the same active ingredients, route of administration, dosage form, and strength as the U.S. label drug, according to the label of the drug. [Section 804(g)(2)(B) is described later in this document.]	804(g)(1). *Compliance with Section 801(a)*. Similar to S. 2307. Each qualifying drug exported or imported by the registered exporter or importer must be in compliance with Section 801(a) standards regarding admission of the drug into the United States, subject to paragraphs (2), (3), and (4) [see below]. 804(g)(2)(A,B). *Section 505; Approval Status.* There is a general presumption that a drug proposed for export or import is an FDA-approved drug if it complies with 804(c) and if it has the same active ingredient or ingredients, route of administration, dosage form, and strength, according to the labeling information (referred to in this subsection as a 'U.S. label drug') as an FDA-approved drug that is manufactured by or for the person that manufactures the drug proposed for export or import. A drug that meets the criteria stated above may be imported into the United States.	813(b). *Requirements.* Requires that each imported prescription drug be FDA-approved [Section 505] and comply with FDA requirements regarding adulteration [Section 501] and misbranding [Section 502]. Requires that the container have a prominent and conspicuous label with the following items: the lot number; the name, address, and phone number of the drug importation facility; a statement that the drug was imported, naming the country from which it came; and a unique identifier, indicating that the drug has been imported, based on the national drug code of the prescription drug. Requires that the drug comply with any other FFDCA requirements.
Testing	804(e). *Testing*. The importer or the manufacturer must conduct the required authenticity testing at a qualified laboratory. If the importer conducts these tests, the manufacturer must give the importing pharmacist or	No provision.	No provision.	No provision.

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	wholesaler the information needed to authenticate the product and confirm its labeling. Also, testing information must be kept in confidence and used only for testing or to otherwise comply with this Act. The Secretary may adopt rules to protect trade secrets and commercial or financial information that is privileged or confidential.			
Monitoring and inspections	No provision.	804(d)(1). *Monitoring of Facilities.* The exporter must agree to assist the Secretary to determine exporter compliance with all required conditions. The exporter must permit the Secretary to assign one or more employees to conduct day-to-day on-site continuous monitoring of warehouses or other exporter owned, controlled, or operated facility that relate to qualifying drugs; to have day-to-day access to records including financial records; to verify the chain of custody of each qualifying drug, monitor markings, and sample the exported drugs to assure compliance; and to carry out other functions that the Secretary determines necessary regarding compliance. The Secretary may allow periodic, rather than day-to-day, inspections of a business with sufficient history of compliance.	804(d)(1). *Inspection of Facilities.* Similar to S. 2307 except it also allows the Secretary to have on-site, day-to-day access to samples of such drugs. Also, any employee assigned by the Secretary must carry out the functions of the section not less than every three weeks and that such an assignment remains in effect on a continuous basis.	Section 10. *Advance Notice of Imported Prescription Drug Shipments.* Amends FFDCA Section 801 to allow the Secretary to inspect drug imports at ports of entry. The person importing or offering for importation the prescription drug must give the Secretary advance (between 24 hours and five days) notice of: the established name, dosage form, and quantity of the prescription drug; the name of the shipper; the name of the country from which the prescription drug originates; the country from which it is shipped; the name of the port of entry; documentation of the original source of the prescription drug; the quantity of each lot of the prescription drug originally received by the facility from that source; the lot or control number assigned to the prescription drug by the manufacturer of the prescription drug; the name,

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				address, telephone number, and professional license number of the drug importation facility located in Canada or a permitted country; and certification from the drug importation facility located in a foreign country or from the manufacturer of the prescription drug that the prescription drug is approved for marketing in the United States and is not adulterated or misbranded and meets all labeling requirements under this Act. Failure to provide notice results in holding of drug at the point of entry. Section 13. *Authority to Commission Other Federal and State Officials to Conduct Inspections.* Amends the FFDCA to permit the Secretary to sign a memorandum of understanding with another federal agency or a state for its employees to conduct examinations and investigations for the purposes of enforcing compliance with this Act. The memorandum is to include provisions for ensuring adequate training and reimbursement. Reporting to the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce is required on the joint activities. The Secretary may contract with a state to use State Board of Pharmacy personnel to

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				conduct examinations and inspections required by this Act. Agreements with a state are effective only in that state and for facilities located in that state; and agreements are effective only at facilities that are jointly regulated by the Secretary and the other agency.
Records of chain of custody	No provision.	804(d)(3). *Certain Duties*. The Secretary shall verify the chain of custody of each qualifying drug from the drug manufacturer to the exporter. If the qualifying drug is exported to individuals for personal use, the Secretary is directed to randomly select samples of the exports to determine whether the conditions required for individual imports are being met. The sampling process must allow a statistically significant determination of compliance. The Secretary is directed to monitor the required markings of exports. 804(h). *Importers; Conditions for Importation*. An importer may import a drug if it receives the drug directly from the mail, a common carrier, or a	804(d)(3). *Certain Duties Relating to Exporters*. Similar to S. 2307 except that these duties involve verifying the chain of custody of a statistically significant sample of qualifying drugs from the manufacturing establishment, which may be accomplished by the use of anti-counterfeiting or track-and-trace technologies, if available. Record review is the same as S. 2307. However, the employees shall inspect, as the Secretary determines is necessary, the warehouses and other facilities of other parties in the chain of custody of qualifying drugs, and determine whether the exporter is in compliance with all other registration conditions. 804(d)(4). *Certain Duties Relating to Importers*. The Secretary must inspect not less than every three weeks the importer's places of	Section 15(a). *Anticounterfeiting Provisions; Required Records*. Amends Section 503(e) of the FFDCA by requiring the wholesale distributor of record, for each distribution, to provide to the recipient the identity of the immediately previous distributor of record from which the prescription drug was purchased; and, for each wholesale distribution of an imported drug, to provide the purchaser with identifying information, such as dates and the names and addresses of all parties to each transaction. Requires the distributor to keep the records available for two years for Secretarial inspection, including the immediately previous and subsequent distributors of all distributions, and, for imports, each previous and subsequent distributor, to the extent feasible.

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		vehicle or aircraft owned by the importer or a business organization of which the importer is a part. The personnel of the transporting entities must have had exclusive custody of the drug without the involvement of any other entity including a wholesale distributor. Although the wholesale distributor, or any entity not the importer, cannot at any point have custody of the drug, the wholesaler could negotiate price and other processes for purchasing drugs from exporters.	business that relate to the receipt and distribution of a qualifying drug, including each warehouse or other facility owned or controlled by, or operated for, the importer at which qualifying drugs are received or from which they are distributed to pharmacies. During these inspections, the Secretary (1) shall verify the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the importer, which may be accomplished by the use of anticounterfeiting or track-and-trace technologies; (2) may inspect, if necessary, the warehouses and other facilities of other parties in the chain of custody of qualifying drugs; and shall determine whether the importer is in compliance with all other registration conditions.	
		Section 7. *Wholesale Distribution of Drugs; Statements Regarding Prior Sale, Purchase, or Trade*. Section 503(e) of the FFDCA gives requirements of wholesale distributors (guidelines). This bill would change the exclusion of the manufacturer and authorized distributor to an exclusion of a registered exporter. It would also insert the requirement that a wholesale distributor is not exempt	Section 8. *Wholesale Distribution of Drugs; Statements Regarding Prior Sale, Purchase, or Trade*. Same as S. 2307. It also removes the reference to manufacturer and authorized distributor, but does not insert registered exporter.	

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		from providing to the person who receives the drug after export a statement identifying each prior sale, purchase, or trade of such drug including the date of the transaction and the names and addresses of all parties to the transaction. The Secretary may establish "alternative requirements" to identify the chain of custody of the drug through the wholesale distribution chain if the alternatives provide greater certainty and alternatives are economically and technically feasible. If the Secretary does promulgate final rules for "alternative requirements" then other conditions are amended. Each manufacturer distributing FDA approved drugs shall maintain records of authorized distributors who are distributors with an ongoing relationship with them to distribute the manufacturer's products.		
Charitable contributions	804(i). *Charitable Contributions.* Section 801(d)(1) of the Act, which allows only the U.S. manufacturer of a drug to import it into the United States, will continue to apply to a product donated by a manufacturer of a drug to a charitable or humanitarian organization or foreign government.	804(k). *Charitable Contributions.* Similar to MMA.	No provision.	813(g). *Charitable Contributions.* Similar to current law.

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Repeal of controlled substances exemption	No provision.	Section 8. *Repeal of Importation Exemption Under Controlled Substances Import and Export Act.* This section repeals the exemption authority of the Attorney General to allow imports of controlled substances for personal use under certain conditions.	Section 9. *Repeal of Importation Exemption Under Controlled Substances Import and Export Act*. Same as S. 2307.	Section 16(a). *Conforming Amendments.* Repeals Section 1006 of the Controlled Substances Import and Export Act. (Same as S. 2307.)
Registration of importers and exporters	804(f). *Registration of Foreign Sellers.* Requires any Canadian establishment engaged in the distribution of a prescription drug imported or offered for importation into the United States to register its name and place of business with the Secretary. Also requires that the Canadian establishment register the name of its U.S. agent.	804(b)(1). *Registration of Foreign Exporters*. To register, an exporter must submit to the Secretary: the name and addresses of every place of business of the exporter that relates to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter; and	804(b)(1). *Registration of Importers and Exporters.* To register, the importer or the exporter (referred to as the registrant) must submit to the Secretary: the name and addresses of every place of business of the registrant including each warehouse or other facility owned or controlled by, or operated for, the registrant; and	Section 8. *Registration of Prescription Drug Importation Facilities.* Adds to the FFDCA a new Section 814, *Registration of Certain Importers*, to require a drug importation facility, pharmacy, Internet pharmacy, or wholesaler engaged in the importation or offering for importation of prescription drugs into the United States, or in the dispensing of such drugs, to register with the Secretary. To register, the person must submit: [814(b)(1)(A)] the name and address of each drug importation facility, pharmacy, Internet pharmacy, or wholesaler at which, and all trade names under which, the registrant conducts business; and [814(b)(1)(B)] the name of each prescription drug to be imported into the United States.

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		information necessary to demonstrate compliance with the conditions relating to the sources of exported drug; the monitoring of foreign facilities; the marking of compliant shipments; fee payment; being licensed as a pharmacy; and compliance with Section 801(a) standards [federal government can sample and inspect to prevent the importation of adulterated, misbranded, or non-FDA-approved drugs];	information necessary to demonstrate that the *importer* is in compliance with registration conditions relating to the sources of exported drugs; the inspection of facilities of the importer; the payment of fees; compliance with the standards referred to in Section 801(a); and maintenance of records and samples; and information necessary to demonstrate that the *exporter* is in compliance with registration conditions relating to the sources of exported drugs; the inspection of facilities of the exporter and the marking of compliant shipments; the payment of fees; compliance with Section 801(a) standards; being licensed as a pharmacist; conditions for individual importation from Canada; and maintenance of records and samples.	
		The exporter must agree to export only qualified drugs;	The importer or the exporter must agree to not import or export any nonqualifying drug.	
		to export only to persons authorized to import the drug;	The exporter must agree to not export a qualifying drug to anyone who is not a registered importer, and to post a bond payable to the Treasury of the United States if, after opportunity for an informal hearing, the Secretary decides that the exporter has exported a drug to the United States that is not a qualifying drug or that is not in compliance with subsections (g). The	

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			bond amount is the lesser of the value of drugs exported by the exporter to the United States in a typical four-week period over the course of a year under this section; or $1,000,000.	
		to submit to the jurisdiction of U.S. courts and supply the name and address of its U.S. agent for service of process;		[814(b)(1)(C)] the name and address of an agent for service of process in the United States.
		to monitor compliance with all registration conditions, and correct and promptly report any noncompliance conditions to the Secretary;	The registrant agrees to ensure and monitor compliance with each registration condition, to promptly correct any noncompliance, and to promptly report to the Secretary any such noncompliance; and	
		to submit a compliance plan that shows how the exporter will correct any violation;	to submit a plan as to how the registrant will comply with this agreement.	
		to notify the Secretary of any changes in information provided in the registration or in the compliance plan; and	The exporter must agree to update any information provided in the registration or in the compliance plan.	[814(b)(2)] timely notification of any change in the information.
		to comply with any other conditions for registration that the Secretary requires to protect the public health while permitting imports.	The Secretary may require other conditions for registration that would protect the public health while permitting imports of qualifying drugs by pharmacies, groups of pharmacies, wholesalers as registered importers, and individuals.	

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			The registrant must agree to notify the Secretary of a recall or withdrawal of a drug distributed in a permitted country that the registrant has or intends to export or import; provide for the return to the registrant of such a drug; and cease or not begin the exportation or importation of such a drug unless the Secretary has notified the registrant that imports may proceed; and	
			to enforce a contract under subsection (c)(3)(B) (records of chain-of-custody of a drug) against a party in the chain of custody of a qualifying drug and under the authority of the Secretary to inspect such statements to determine their accuracy and agree to inspections.	814(d)(1). *Authority.* "Nothing in this section authorizes the Secretary to require an application, review, or licensing process for a drug importation facility, pharmacy, or wholesaler." 814(d)(2). *Importation by Individuals.* This section does not apply to a prescription drug imported by an individual for personal use or to a commercial transaction conducted between an Internet pharmacy and an individual.

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				813(h). *Jurisdiction*. The district courts of the United States shall have jurisdiction in an action brought by the United States against a person importing or offering for importation a prescription drug in violation of the requirements of this section. Section 8(c). *Importation; Failure to Register*. Prohibits delivery of a prescription drug until the drug importation facility, pharmacy, Internet pharmacy, or wholesaler is registered. Requires that the drug be held in a secure facility and not be transferred.
Licensing as pharmacies and pharmacists	No provision.	804(f). *Licensing as a Pharmacy*. The Secretary must determine that the exporter intending to export a qualifying drug for personal use is (1) authorized under foreign law to dispense prescription drugs, and (2) that the foreign country's programs to regulate pharmacists are comparable to U.S. state programs; or, if the exporter is not a licensed pharmacist, that the exporter employs a sufficient number of pharmacists licensed by one of the states and assigns to those pharmacists responsibility for dispensing drugs that individuals will import into the United States for personal use.	804(h). *Licensing as Pharmacist.* A condition of registration is that the exporter agrees that a qualifying drug will be exported to an individual only if the Secretary has verified that the exporter is authorized under Canadian law to dispense prescription drugs; and the exporter employs enough persons licensed under Canadian law to dispense prescription drugs to dispense safely the qualifying drugs exported by the exporter to individuals, and the exporter assigns to those persons responsibility for dispensing such qualifying drugs to individuals.	No provision.

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Fees	No provision.	804(e). *Fees*. As a condition of registration, an exporter must pay a semi-annual fee with the first payment included with the registration. The aggregate fee total for each fiscal year must cover the costs of administering this program. These costs are for monitoring foreign facilities; developing, implementing, and maintaining a system to mark shipments to indicate registration compliance; and conducting inspections within the United States to determine compliance with required conditions for importers and for imports for personal use. The Secretary may use these fees only for these costs. For the first year, however, the Secretary may collect a lesser aggregate total of fees taking into account the lesser number of registered exporters and the capacity of that group to pay the administrative costs. Authorizes the collection of a semi-annual fee from each exporter set by the Secretary as a pro rata share of the aggregate costs, including the number of employees that the Secretary has assigned to that exporter.	804(e). *Importer Fees*. An importer must pay the Secretary a $10,000 fee along with the registration submission. In addition, the importer must pay the Secretary a semiannual fee. The Secretary shall ensure that the aggregate total of fees collected for a fiscal year from all importers is sufficient, and no more than necessary, to pay the costs of administering this section with respect to registered importers for a fiscal year. These are costs for inspecting the facilities of importers; reviewing qualifying drugs offered for import to importers; and determining the compliance of importers with registration conditions. The aggregate total of fees collected shall not exceed **1%** of the total price of drugs imported annually to the United States by registered importers under this section. The fee for an individual importer shall be a reasonable estimate by the Secretary of the semiannual share of the importer of the volume of drugs imported by importers. The Secretary must annually adjust the fees to accurately reflect the actual costs, and to not exceed, in the aggregate, 1% of the total price of drugs imported	Section 14. Adds to the FFDCA a new Section 740A, *Fees Relating to Prescription Drug Importation*. Requires the Secretary to establish a user fee program under which a drug importation facility, pharmacy, Internet pharmacy, or wholesaler registering with the Secretary under Section 814 shall be required to pay the Secretary a fee beginning for FY2005. Directs the Secretary to determine the amount annually based on anticipated costs of enforcing this Act, publish the fee 60 days in advance of each fiscal year, hold a public meeting and provide time for public comment. Directs the Secretary to use the collected fees, without further appropriation, to enforce the Act. The fee shall be payable annually and only once for each facility. From 30 days after the due date, a registered facility may not import a prescription drug until all fees are paid. Requires the Secretary, 60 days after the end of FY2005 and annually thereafter, to submit a report to the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce describing implementation of the user fee authority during the

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			annually to the United States by registered importers under this section. Subject to appropriations acts, the fees collected by the Secretary are available only to the Secretary and are for the sole purpose of paying the costs of administering this program. 804(f). *Exporter Fees*. Requirements for exporters are similar to the requirements for importers, as above, except that the aggregate exporter fees must cover the cost of monitoring foreign facilities; developing, implementing, and sustaining a system to mark shipments to indicate compliance with all registration conditions; and conducting inspections within the United States to determine compliance with conditions for licensing exporting pharmacists and for importation from Canada.	fiscal year and the use by the Secretary of the fees.
Packaging	No explicitly comparable provision; however, the law requires that all imported drugs be FDA-approved and carry the FDA-approved labeling.	804(d)(2). *Marking of Compliant Shipments*. The exporter must agree to mark each shipping container of drugs identifying that the shipment is in compliance with all registration conditions. The markings may include anti-counterfeiting or track-and-trace technologies and shall be designed to prevent unauthorized affixation.	804(d)(2). *Marking of Compliant Shipments*. Same as S. 2307.	Section 15(b). *Anticounterfeiting Provisions; Electronic Track and Trace Technology*. Directs the Secretary to require, no later than December 31, 2007, the adoption and use of electronic track and trace technology for a prescription drug at the case and pallet level that will identify each sale, purchase, or trade of that case or pallet (including the date of transmission and the names

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				and addresses of all parties to the transaction).
	804(h). *Approved Labeling.* Requires a drug manufacturer to give the importer written authorization to use, at no cost, the approved labeling for the prescription drug.	804(g)(3)(A). *Labeling; Importation by Importer.* If a qualifying drug is offered to a pharmacist or wholesaler for import or is imported, it must bear a copy of the labeling approved by FDA, whether or not the copy bears the trademark involved. The Secretary shall provide a copy of the approved labeling to the registered exporters upon request.	804(g)(3)(A). *Section 502; Labeling; Importation by Registered Importer*. If an importer imports a qualifying drug, the drug must bear the labeling approved for the drug by FDA, without regard to whether the copy bears the trademark. The label must include the name and location of the manufacturer, the lot number assigned by the manufacturer; and the name, location, and registration number of the importer. The Secretary shall provide a copy to the registered importer involved, upon request of the importer.	813(c). *Approved Labeling.* Requires that a drug importation facility demonstrate to the Secretary that the labeling of the prescription drug to be imported into the United States complies with the requirements of Sections 502 [adulteration] and 503 [misbranding]. Requires that the Secretary approve or deny the application within 60 days of receipt and notify the applicant of the decision and, if the application is denied, provide the reason for the denial. Requires the Secretary to maintain an up-to-date list of application status. 813(e). *Prohibition of Commingling.* Prohibits a drug importation facility, pharmacy, Internet pharmacy, or wholesaler from commingling imported and not imported prescription drugs. Requires that a pharmacy or Internet pharmacy that dispenses a prescription drug imported from Canada or a permitted country affix on each dispensed container of the drug the label required by FDA unless such a label is already affixed to the container.
		804(g)(3)(B). *Labeling; Importation by Individual*. If a drug is imported	804(g)(3)(B). *Section 502; Labeling; Importation by Individual*. If a drug	

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		by an individual, it must bear a label providing the directions for use by the consumer, and 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.	is imported by a registered exporter to an individual, the drug must bear a label providing the directions for use by the consumer, and bear 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.	
Records	804(d)(1). *Information and Records.* Drug importers must provide information that includes: the name and amount of the active ingredient of the drug, the dosage form of the drug, the date the drug is shipped, the quantity shipped, information about its origin and destination, the price paid by the importer, the original source of the drug, the amount of each lot received from that source, the manufacturer's lot or control number, and the importer's name, address, and license number. For a prescription drug imported directly from the first foreign recipient from the manufacturer, there must be documentation indicating that the drug came directly from the manufacturer and was subsequently	Section 804(c) requires, among other criteria, the manufacturer to provide a chain-of-custody statement to the exporter.	804(j). *Maintenance of Records and Samples.* Both importers and exporters must maintain records required under this section for not less than two years; and maintain samples of each lot of a drug required under this section for not less than two years.	Section 15(a). *Anticounterfeiting Provisions; Required Records.* Requires the wholesale distributor to create and maintain for two years available to the Secretary, for each wholesale distribution, records of the immediately previous and immediately subsequent distributors of record; and, for each imported drug, records of each previous and each subsequent distributor, as feasible. Section 9. Adds to the FFDCA a new Section 815, *Maintenance and Inspection of Records for Prescription Drugs*. Authorizes the Secretary to establish, by regulation, requirements relating to the establishment and maintenance, for not longer than two years, of records by a drug

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	shipped by that recipient to the importer; that the amount being imported is not greater than the quantity that was originally received; and verification that each batch of the drug has been statistically sampled and tested for authenticity and degradation prior to importation. Samples of subsequent shipments of these drugs must also be tested for authenticity and degradation. For a prescription drug not imported directly from the first recipient in the foreign country, there must be documentation demonstrating that each batch in each shipment of the drug has been statistically sampled and tested for authenticity and degradation prior to importation. Also, the importer or manufacturer must certify that the drug is FDA-approved, properly labeled, not adulterated, and not misbranded, provide laboratory records of authenticity testing, including data, and evidence that testing was conducted in an approved U.S. laboratory. The importer is required to provide any other information that the Secretary determines is necessary to ensure the public health.			importation facility, pharmacy, Internet pharmacy, or wholesaler engaged in the importation of prescription drugs into the United States, or in the dispensing of such drugs; and any person that processes, packages, distributes, receives, holds, or transports a prescription drug imported under this subchapter. If the Secretary has reason to believe that an imported prescription drug presents a risk to the public health, requires that the drug importation facility, pharmacy, Internet pharmacy, or wholesaler that imports the prescription drug, and each person that processes, packages, distributes, receives, holds, or transports the prescription drug permit the Secretary's officer or employee, with appropriate credentials and a written notice, "at reasonable times, within reasonable limits and in a reasonable manner," to have access to and copy all records, in any format, at any location, needed to determine whether the prescription drug presents a risk to the public health. Requires the Secretary to prevent the unauthorized disclosure of any trade secret, confidential, or privileged information. The Secretary's requirements do not apply to personal-use imports.

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	804(d)(2). *Maintenance by the Secretary*. Records regarding imported prescription drugs "covered products" must be provided to the Secretary, and then kept for such time as the Secretary determines to be appropriate.			Importers of drugs are to maintain records for two years.
Manufacturer requirements	No provision.	804(g)(2)(B). *Approval Status; Petition by Manufacturer; General Provisions.* A drug manufacturer may file a petition with the Secretary requesting that a drug's import cease. The petition must claim that the drug is changed from the U.S. label drug in a manner that, if made to the U.S. label drug in the United States, would need a supplemental application. The petition must also state whether, under FDA regulations, the change could be made pending an application's approval or whether, in consideration of a bioequivalence matter, the changed drug could not be sold before such an approval. The manufacturer's chief executive officer, chief legal counsel, and chief medical officer must each certify that the information in the petition is complete and true. Unless the petition makes a nonequivalence claim, the petitioner pays a fee that is equivalent to the PDUFA fee established for a human drug application for which clinical data on safety or effectiveness is required for approval. Subject to	804(g)(2)(C). *Section 505; Approval Status; Notice by Manufacturer; General Provisions.* A manufacturer of any drug that may be imported must submit to the Secretary a notice that includes each difference in the drug from a condition established in the approved application for the U.S. label drug beyond the variations provided for in the application; any difference in labeling; the date on which the drug with such difference was, or will be, introduced for commercial distribution in a permitted country; and such additional information as the Secretary may require; or states that there is no difference in the drug from a condition established in the approved application for the U.S. label drug beyond the variations provided for in the application and differences in labeling. The manufacturer must notify the government of the permitted country that has approved (or has an application pending) the drug's	No provision.

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		appropriations acts, the collected fees are available to the Secretary to pay for administering this section. The Secretary must grant or deny a petition within 180 days of its filing.	commercial distribution that it is filing this notice. The notice must include the material (with verified English translation, if necessary) that the manufacturer submitted to the permitted country in seeking marketing approval. The chief executive officer and the chief medical officer of the manufacturer involved must each certify in the notice that the information provided is complete and true; and provide a copy of the notice to the Federal Trade Commission and to the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice. If a notice submitted shows that the difference would require the submission of a supplemental application if made as a change to the U.S. label drug, the person that submits the notice shall pay to the Secretary a fee in the same amount as would apply if the person were paying a PDUFA fee for a supplemental application. Subject to appropriations Acts, fees collected by the Secretary are available only to the Secretary and are for the sole purpose of paying the costs of reviewing notices. Timing of notice submission to the Secretary:	

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			For a notice regarding drug differences that would require approval before being marketed, the notice must be submitted to the Secretary at least 120 days before the changed drug is introduced for commercial distribution in a permitted country, unless the country requires that earlier distribution, in which case the notice must be submitted no later than the day the drug is commercially introduced in that country, and annually thereafter. For a notice regarding drug differences that would require a supplemental application but not require pre-market approval or for a drug that would not require a supplemental application, the notice must be submitted no later than the day the drug is commercially introduced in that country. The Secretary shall treat these notices as if they related to a manufacturing change to the U.S. label drug under Section 506A of the FFDCA; and shall review and approve or disapprove the notice within 120 days of its submission. If the review would require an inspection by the Secretary of the manufacturing establishment, such inspection shall be authorized. Through the Internet website of the Food and Drug Administration, the Secretary shall readily make available	

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			to the public a list of notices submitted and the status of the Secretary's review, including determinations. The Secretary shall promptly update the Internet website with any changes to the list.	
		804(g)(2)(D). *Approval Status; Petition; Drug Changes Requiring Prior Approval*. A petition raising a "bioequivalence consideration" claims either a "possible nonequivalence claim" or a "nonequivalence claim." If the petition raises a possible nonequivalence claim, the petitioning manufacturer must notify the foreign country that approved the drug for commercial distribution in writing that there is a claim submitted to the Secretary and that the petition has with it the information submitted to the foreign country to obtain an approval there. The drug may continue to be imported and receivers are notified that there is a possible nonequivalence claim. If the Secretary decides that the petition drug is not bioequivalent, then the Secretary may grant the petition and imports may cease. If the petition makes a nonequivalence claim, the Secretary must order imports to cease during the petition review, and if the finding is	804(g)(2)(D). *Notice; Drug Difference Requiring Prior Approval*. If the notice regarding an imported drug shows that it requires the approval of a supplemental application before the difference could be make to the U.S. label drug, the Secretary must notify registered exporters, registered importers, the Federal Trade Commission, and the Assistant Attorney General that the notice has been submitted with respect to the drug involved. If the Secretary has not made a determination whether a supplemental application regarding the U.S. label drug would be approved or disapproved by the date on which the drug involved is to be introduced for commercial distribution in a permitted country, the Secretary must order that the importation of the drug involved from the permitted country cease during the period in which the Secretary completes review of the notice; and promptly notify registered exporters, registered importers, the Federal Trade Commission, and the Attorney General of the order. If the	

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		that the drug is not bioequivalent, then the order to cease imports continues. If a petition makes a possible-nonequivalence claim or a nonequivalence claim and if the petition drug was approved for commercial distribution by FDA and/or a foreign government on or after January 1, 2004, the Secretary may not accept the petition unless the petitioner submits information showing that: (1) the drugs differ due to a difference in the legal approval requirements between the U.S. and the foreign country; or (2) the petitioner has submitted a supplemental application to the Secretary or to the foreign government to remove the difference between the petition drug and the U.S. label drug. If the Secretary ceased imports of a drug, the Secretary shall rescind the order promptly after a supplemental application is approved. The Secretary must rescind any order if false, fictitious, or fraudulent statements in the petition influenced the Secretary's decision. 804(g)(2)(C). *Approval Status; Petition; Drug Changes Not Requiring Prior Approval.* For a petition drug which would have been allowed to be sold pending the	Secretary decides that such a supplemental application regarding the U.S. label drug would not be approved, the Secretary shall stop all importation of the drug involved from the permitted country, and notify the permitted country that approved the drug for commercial distribution of the determination; and promptly notify registered exporters, registered importers, the Federal Trade Commission, and the Assistant Attorney General of the determination. If the Secretary determines that the supplemental application regarding the U.S. label drug would be approved, the Secretary shall vacate the order to cease trade, if any, and permit importation of the drug and promptly notify registered exporters, registered importers, the Federal Trade Commission, and the Assistant Attorney General of the determination. 804(g)(2)(E). *Notice; Drug Difference Not Requiring Prior Approval.* If the imported drug does not require the approval of a supplemental application before the	

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		supplemental application approval, the importation may continue while the Secretary considers the manufacturer's petition to cease importation. For importation to continue, the importer must inform all purchasers that the manufacturer is making a claim that the drug is different than the U.S. label drug and the registered exporter must notify all individuals importing the drug from the exporter for individual personal use that the manufacturer is making the claim. If the Secretary decides that the supplemental application regarding the U.S. label drug would not be approved, the Secretary shall grant the petition and order that imports of that drug cease.	difference could be made to the U.S. label drug the following shall occur: During the period in which the notice is being reviewed by the Secretary, the authority under this subsection to import the drug involved continues in effect. If the Secretary determines that such a supplemental application regarding the U.S. label drug would not be approved, the Secretary shall order that the importation of the drug involved from the permitted country cease, shall notify the permitted country that approved the drug for commercial distribution of the determination, and shall promptly notify registered exporters, registered importers, the Federal Trade Commission, and the Assistant Attorney General of the determination. 804(g)(2)(F). *Notice; Drug Difference Not Requiring Approval; No Difference.* If the differences between the U.S. label drug and the drug to be commercially distributed in a permitted country would not require a supplemental application, the Secretary may not stop the importation and shall promptly notify registered exporters and registered importers.	

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			804(g)(2)(G). *Differences in Active Ingredients, Route of Administration, Dosage Form, or Strength.* A manufacturer of a U.S. label drug must submit an application under Section 505(b) [new drug approval] of the FFDCA for a drug that it manufactures for distribution in a permitted country when each active ingredient of the drug is related to an active ingredient of the U.S. label drug [for purposes of this application, active ingredients are related if they are "the same; or different salts, esters, or complexes of the same moiety."], and there is no drug for export from at least half of the permitted countries with the same active ingredients, route of administration, dosage form, and strength as the U.S. label drug. The application must request approval of the drug for the indications for which the U.S. label drug is approved and include the information [with a verified English translation, if necessary] that the manufacturer submitted to the government of the permitted country for purposes of obtaining approval for that drug's commercial distribution; include a right of reference to the application under Section 505(b) for the U.S. label drug; and include such additional information as the Secretary may require. This	

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			application shall be submitted to the Secretary not later than the day on which the previous information is submitted to the government of the permitted country. The Secretary shall promptly notify registered exporters, registered importers, the Federal Trade Commission, and the Assistant Attorney General of a determination to approve or to disapprove an application.	
Secretary's actions	804(l)(1). *Commencement of Program.* The drug import program can begin only if the Secretary first certifies to Congress that its implementation would pose no additional risk to public health and safety, and would result in a significant reduction in the cost of covered products to American consumers.	No provision.	No provision.	No provision.
	804(l)(2). *Termination of Program.* The authority of the Secretary to terminate the program is restricted to the procedure in this section. Between 12 and 18 months after the regulations are implemented, if the Secretary certifies to Congress that, based on substantial evidence, in the opinion of the Secretary, the benefits of the implementation of the import program do not outweigh any detriment, drug imports under the section would cease 30 days after the	No provision.	No provision.	No provision.

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	certification is submitted. However, the certification may not be submitted unless, after a public hearing, the Secretary finds it is more likely than not that implementation will result in an increased risk to the public health; identifies, in qualitative and quantitative terms, the nature and causes of the increased risk; considers whether measures can be taken to avoid, reduce, or mitigate the increased risk and, if those measures would require additional statutory authority, to report to Congress describing needed legislation; identifies, in qualitative and quantitative terms, the benefits that would result from the program, including reductions in the cost of drugs to U.S. consumers, which would allow them to obtain needed medications without foregoing other necessities of life; and, in specific terms, compares the detriment with those benefits and determines the benefits do not outweigh the detriment.			
	804(g). *Suspension of Importations.* If the Secretary discovers a pattern of counterfeit or violative products, the agency must suspend importation of that specific prescription drug or that specific importer. The suspension must stay in effect until the Secretary investigates and determines whether	804(b)(4). *Suspension and Termination.* The Secretary may *suspend* a registration if, after notice and opportunity for a hearing, the exporter fails to maintain substantial compliance with registration conditions. In addition, the Secretary shall suspend immediately, without	804(b)(4). *Suspension and Termination.* Same as S. 2307, except it refers to the importer as well as the exporter.	Section 6. Adds new Section 817, *Suspension of Importation.* Allows the Secretary to immediately order the suspension of the importation of a particular prescription drug or a particular dosage form by a drug importation facility, pharmacy, Internet pharmacy, or wholesaler or a

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	the public is being adequately protected from counterfeit and violative drug products under existing regulations.	prior notice, the exporter's registration if the exporter has exported a non-qualifying drug, not met the requirements relating to a U.S. label drug, or exported a drug to an individual who did not meet the conditions under law. The Secretary must give the exporter a hearing within 10 days of the suspension. If the Secretary determines that there would be no further violations, the Secretary may reinstate the suspended registration. After notice and the opportunity for a hearing, the Secretary may *terminate* a registration if the exporter has a pattern or practice of violating one or more registration condition. The Secretary may terminate a registration permanently or for a fixed period of not less than one year. A registration will have no legal effect if, during the period in which a registration is terminated, the exporter or a partner or principal officer of the enterprise assisted in the preparation of the registration.		country (but not an individual importing for personal use or an individual engaged in an Internet pharmacy transaction) if the Secretary determines it presents a risk to the public health. Allows this action to be appealed; requires that the Secretary, after providing opportunity for an informal hearing, confirm or terminate the order within 30 days. An order under this section shall not be subject to judicial review. If the Secretary determines that a drug importation facility, pharmacy, Internet pharmacy, or wholesaler, or a country (but not an individual importing for personal use or an individual engaged in an Internet pharmacy transaction) is engaged in a pattern of importation that violates the Act's requirements, the Secretary may immediately order suspension of importation of prescription drugs from that person or country. Allows that this action be appealed; and requires the Secretary, after providing opportunity for an informal hearing, to confirm or terminate the order within 30 days. An order under this section shall not be subject to judicial review.

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	804(k). *Construction.* Nothing in this section limits the Secretary's authority relating to the importation of prescription drugs, other than with respect to Section 801(d)(1), which allows only the manufacturer to import a prescription drug.			813(i). *Effect of Section.* Similar to current law. Nothing in this section [*Pharmacy and Wholesaler Importation of Prescription Drugs*] limits the authority of the Secretary relating to the importation of prescription drugs (including the interdiction of prescription drugs that are unapproved, adulterated, or misbranded), other than with respect to the banning of anyone other than the manufacturer from importing a prescription drug that had been supplied as a charitable contribution.
		804(b)(2). *Approval or disapproval of registration.* The Secretary must approve or disapprove a registration within 90-days of its submission. If the registration is disapproved, the Secretary must notify the exporter as to why. After a registration has been denied, if and when the exporter is in compliance, the Secretary must notify the exporter. Within 30 days of receiving an exporter's compliance plan, described above, the Secretary must decide if the change affects the exporter's registration approval and inform the exporter.	804(b)(2). *Approval or disapproval of registration.* Same as S. 2307.	814(b)(3). Requires the Secretary, not later than 60 days after receipt of a completed registration, to assign a registration number to each registered drug importation facility, pharmacy, Internet pharmacy, and wholesaler, and notify the registrant of the receipt of the registration. 814(c). Requires that the Secretary provide for and require electronic filing of registrations, with adequate authentication protocols to allow identification of the registrant and validation of the data.
		804(b)(3). *Publication of Contact Information for Registered Exporters.* The Secretary shall post publicly on the FDA website a list of registered exporters, including contact	804(b)(3). *Publication of Contact Information for Registered Exporters.* Same as S. 2307 except it does not require a requested link on the FDA website to the Internet site of the	Requires that the Secretary keep an up-to-date list of registrants and make it available to the public on an Internet website and through a toll-free telephone number.

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		information; update this information; and provide, if requested by the exporter, a link to the exporter's website.	exporter.	
Studies and reports	Section 1122. *Study and Report on Importation of Drugs.* The law requires the Secretary, in consultation with appropriate government agencies, to conduct a study on the importation of drugs in the United States pursuant to Section 804 of the Federal Food, Drug, and Cosmetic Act (as added by Section 1121 of P.L. 108-173). The Secretary shall submit the report to Congress not later than 12 months after the enactment of this Act. Section 1123. *Study and Report on Trade in Pharmaceuticals.* The law requires the President's designees to conduct a study and report on issues related to trade and pharmaceuticals. [The conference report on H.R. 1, which became P.L. 108-173, provides detail regarding the reports required by Sections 1122 and 1123.]	804(a)(4)(B)(ii). *Report*. Within 18 months after enactment, the Secretary must submit to Congress a report that describes the impact of the new drug import program on the safety and integrity of the U.S. prescription drug distribution system, the prevalence in the United States of counterfeit, adulterated, or misbranded drugs, and patient drug therapy; describes the potential impact of permitting imports from additional countries; includes proposed legislation to improve the safety, efficiency, and efficacy of the drug importation program. Requires the Secretary also, in consultation with the Federal Trade Commission, to evaluate the extent to which the new import program achieves lower prices through competition in the U.S. prescription drug market, and to identify how the import program could be improved to meet that objective.	No provision.	811*(4)(B). *Report*. Requires that the Secretary, three years after enactment, submit to the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce a report that includes a list of permitted countries and why the Secretary determined that drug imports from such countries would not increase risk to the public health. Requires the Secretary to list those countries from which prescription drug imports are not permitted and why and what possible actions those countries might take to avoid, reduce, or mitigate increased risk. Authorizes the Secretary to determine whether to designate as permitted other countries at any time after submission of the report. Adds [in Sec. 4 and Sec. 14] new FFDCA sections 511(f) and 740A to require the Secretary to report to Congress annually on the implementation of the user fee authority and the use of those fees.
Enforcement	No provision.	Section 3(b). *Prohibited Acts*. Amends Section 301 of the FFDCA,	Section 4(b). *Prohibited Acts.* Similar to S. 2307, but refers to sale	Section 2(c). *Prohibited Act.* Amends Section 301 of the FFDCA

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		as amended by Section 1121(b) of P.L. 108-173, to prohibit the importer of a qualifying drug, imported for commercial purposes, to sell that drug unless the drug is sold at retail as it is dispensed to a customer of the importer, or is sold or traded to the registered exporter from which the importer imported the drug. It also prohibits an individual who imports the drug for personal use from selling or trading that drug. Prohibits making false, fictitious, or fraudulent statements in filing a petition to stop a drug's importation; if made, requires the maker to be imprisoned not more than 10 years, fined, or both. Section 3(c). *Civil Penalty*. Amends Section 303 of the FFDCA to make technical corrections to the numbering of the provision. A person who knowingly violates the revised Act by providing false statements that were a material factor in the Secretary's decision to issue an order to cease importation is liable for a civil penalty not to exceed a reasonable estimate of the gross revenue that would have been collected from sales of qualifying drugs by the registered exporter during the period for which the order was in effect. Section 3(e). *Amendment of Certain Provision*. The Secretary may not	by a pharmacist rather than an importer.	by prohibiting the dispensing or offering to dispense a prescription drug imported into the United States in violation of the requirements of the new Section 813 (relating to pharmacy and wholesaler importation).

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		send a warning notice to an individual who is importing a qualifying drug for personal use unless the importation is not in accordance with Section 804.	Section 4(e)(1). *Anticompetitive Practices Relating to Importing and Exporting Drugs to the United States*. Amends the Clayton Act (15 USC 12 et seq.) to add a new Section: Section 27. *Restraint of Trade Regarding Prescription Drugs*. Section 27(a) makes it "unlawful for any person engaged in commerce ..." to charge a price to, deny or restrict supplies to, or refuse to do business with a registered exporter, other person that exports prescription drugs to the United States, a registered importer, or other person that distributes, sells, or uses prescription drugs imported to the United States under Section 804 of the FFDCA more than to others who do not export or import under Section 804. It is also unlawful to fail to submit a required manufacturer notice in the required time or provide information requested by the Secretary; to submit a notice with "a materially false, fictitious, or fraudulent statement;" fail to submit a timely application regarding differences between the drug that may be imported and another drug; to fail to provide a copy	

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			to the permitted country; to make false statements; or to fail to timely provide information requested by the Secretary; to "cause there to be a difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and a prescription drug for distribution in Australia, Canada, a member country of the European Union as of January 1, 2003, Japan, New Zealand, or Switzerland for the purpose of restricting importation of the drug to the United States ..."; to refuse to allow a required inspection or fail to conform to good manufacturing practice; or to "engage in any other action that the Federal Trade Commission determines to unfairly restrict competition under Section 804 ...." Section 27(b). Presumption. "A difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and a	

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			prescription drug for distribution in" a permitted country in Section 804 of the FFDCA "made after January 1, 2004, shall be presumed to be for the purpose of restricting importation of the drug to the United States unless (1) ... the difference was required by the country in which the drug is distributed; (2) the Secretary ... determines that the difference was necessary to improve the safety or efficacy of the drug; or (3) the person manufacturing the drug for distribution in the United States has given notice to the Secretary ... that the drug for distribution in the United States is not different from a drug for distribution in ..." at least half of the permitted countries. Section 27(c). *Affirmative Defense*. "It shall be an affirmative defense to a charge that a person has violated paragraph (1), (2), (3), (4), or (5) of subsection (a) that the higher prices charged for prescription drugs sold to a person, the denial of supplies of prescription drugs to a person, the refusal to do business with a person, or the specific restriction or delay of supplies to a person is not based, in whole or in part, on (1) the person exporting or importing prescription drugs to the United States ...; or (2) the person distributing, selling, or using prescription drugs imported to the United States...."	

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			Section 27(d). *Definitions*. Applies the definitions in Section 503(b)(1) of the FFDCA for prescription drug, and in new Section 804 for registered importer and registered exporter. Section 4(e)(2). *Applicability of Amendments to Importation Under the Pharmaceutical Market Access and Fair Trade Act of 2004*. [*sic*; S. 2328 was renamed the *Pharmaceutical Market Access and Drug Safety Act of 2004* before it was introduced.] Section 27 of the Clayton Act shall apply to personal-use importation from Canada. A notice filed under paragraph 6 above will apply to notices required in new Section 804(g)(2)(C)(i) that are not submitted by the dates required under (c)(1)(C,D). Section 4(f). *Exhaustion*. Amends Section 271 of Title 35 USC by inserting a new subsection that would reverse judicial precedent holding that sales of patented goods outside the United States do not exhaust the U.S. patent. Under this provision, goods that were the subject of authorized foreign sales by the U.S. patent holder may be imported in the United States without regard to the U.S. patent.	
		Section 6. *Civil Actions Regarding Property*. Amends Section 303 of the FFDCA: *Penalties* by adding (g)(1) to	Section 7. *Civil Actions Regarding Property*. Same as S. 2307.	Section 7. *Debarment for Repeated or Serious Drug Importation Violations.* Amends Section 306(b)

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		authorize the Attorney General to commence civil action in any federal court if a person is importing a drug that violates the Act. The court action may enjoin the alienation or disposition of property or issue a restraining order to prohibit any person from withdrawing, transferring, removing, dissipating, or disposing of such property or property of equivalent value; and to appoint a temporary receiver to administer the order. Such proceedings must be carried out in the same manner as applies under Section 1345 of Title 18 USC [regarding injunctions against mail fraud].		of the FFDCA to allow the Secretary to debar a person (other than an individual importing for personal use or an individual engaged in an Internet pharmacy transaction) from importing a prescription drug for up to five years if the person "has been convicted of a felony for conduct relating to the importation into the United States of any prescription drug; or ... has engaged in a pattern of importing or offering for import a prescription drug that presents a risk to the public health." Allows the Secretary to withdraw the debarment if the conviction on which it was based is reversed or if it "serves the interests of justice and adequately protects the integrity of the ... prescription drug importation process." Section 7(e). Amends Section 801 by adding a subsection (s), *Importation of Prescription Drugs by Debarred Persons.* Requires that a prescription drug imported by a debarred person be held at its port of entry or moved to a secure facility, if appropriate, and not otherwise be transferred. While the prescription drug is held under a bond, it may not be delivered. While the drug is being held, prohibits its transfer by any person from the port of entry or the secure facility where it is held. Allows for the delivery of a prescription drug to a non-debarred

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				person if that person shows, at their own expense, that the drug complies with FFDCA requirements.
		Section 9. *Enforcement Through Denial of Deduction for Certain Advertising Expenses*. Amends the Internal Revenue Code of 1986 by adding a new section: Section 280L. *Advertising Expenditures of Taxpayers Who Discriminate Against Foreign Sellers of Prescription Drugs to Domestic Consumers*. In general, no tax deduction is allowed unless the taxpayer certifies that it took no direct or indirect action to prevent or place conditions on the authorized importation of a qualifying drug into the United States from a registered exporter to a pharmacy or an individual. The Secretary will decide how the certification must be made and what fees to charge to cover the cost of confirming the certification. Advertising includes direct-to-consumer advertising and any activity designed to promote the use of the drug directed to providers or others who may make decisions about a drug's use (other than the provision of free samples). The amendment will apply to taxable years beginning after enactment of this Act. Section 10. *Compliance Through Allowance of Research and Development Tax Credit*. Amends		

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		Section 41 of the Internal Revenue Code of 1986 to increase the amount of credit by 20% if the taxpayer certifies that it has taken no direct or indirect action to prevent the authorized importation of qualifying drugs into the United States from a registered exporter to a pharmacy or individual, and has not set conditions on import terms. The Secretary will decide how the certification is made and what fees should be charged to cover the costs of confirming the certification. 804(j). *Standards for Refusing Admission*. A qualifying drug from a registered exporter may be refused entry into the United States only if: the shipping container does not bear the required markings; the container or markings appear to be counterfeit or appear to have been tampered with; the container appears damaged in a way that could affect the strength, quality, or purity of the drug; the Secretary becomes aware that the drug may be counterfeit, been prepared, packed, or held under insanitary conditions, or if the drug was not made or stored under good manufacturing processes; the Secretary has obtained an injunction against the drug, prohibiting distribution in commerce, or has withdrawn the approval of the drug; or	804(g)(4). *Section 501; Standards for Refusing Admission*. Similar to S. 2307. Numbers (1) through (4) apply if the import is from a registered exporter to an individual. 804(i)(2). *Notice Regarding Drug Refused Admission*. If a registered exporter ships a drug to an individual and the drug is refused admission to the United States, a written notice shall be sent to the individual and to the exporter that informs them of the refusal and the reason for the refusal.	Section 11. *Authority to Mark Prescription Drugs Refused Admission into the United States.* Amends Section 801 of the FFDCA (as amended by Section 10(a) of this Act) to allow the Secretary to require the owner or consignee of the drug to label any prescription drug refused admission indicating that, with the owner or consignee responsible for all labeling expenses, until the Secretary determines that the prescription drug has been brought into compliance with this Act. Amends Section 502 of the FFDCA so that if the prescription drug does not carry the label after the Secretary has informed the owner, it shall be considered misbranded. This does not apply to a personal-use import or a commercial transaction between an Internet pharmacy and an individual. This section does not limit

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				the authority of the [HHS] Secretary or the Secretary of the Treasury to require the marking of prescription drugs refused admission under any other provision of law.
		if the manufacturer has instituted a recall of the drug.	804(k). *Drug Recalls*. A manufacturer of a drug imported from a permitted country shall promptly inform the Secretary if the drug is recalled or withdrawn from the market in a permitted country; how the drug may be identified, including lot number; and the reason for the recall or withdrawal. The Secretary shall enter into an agreement with the government of each permitted country to receive information about recalls and withdrawals of prescription drugs in the country; or monitor recalls and withdrawals of prescription drugs in the country using any information that is available to the public. The Secretary may notify registered exporters, registered importers, wholesalers, pharmacies, or the public of a recall or withdrawal of a prescription drug.	813(f). *Drug Recalls.* Requires that a drug importation facility promptly provide the Secretary and any person to whom the prescription drug was distributed a notice that the drug has been recalled or withdrawn from the market. Requires that the notification include identifying information (including the lot number) and the reason for the recall or withdrawal.
		Section 5(a). Creates a new Section 805 in the FFDCA, *Disposition of Certain Drugs Denied Admission*, to establish that any import shipment of drugs valued at less than $10,000 in violation of standards set in Sections 801(a) or 801(d)(1) shall be refused admission. These standards are	Section 6. Creates in the FFDCA a new Section 805. *Disposition of Certain Drugs Denied Admission.* Similar to S. 2307 except it (1) refers to the Secretary of Homeland Security as the refuser of admission; (2) does not state that this section does not transfer to the Secretary responsibility	Section 5(a). Creates in the FFDCA a new Section 816, *Administrative Detention*. An officer or qualified employee of the FDA may order the detention of any prescription drug that it believes to present a risk to the public health. If the Secretary approves, requires that the drug be

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		referred to in Section 804(j) and mean that the drugs are not sufficiently marked. Drugs refused admission must be destroyed unless the U.S. Attorney General determines they are needed as evidence or potential evidence. In general, refused admission and destruction of drugs may be done without notice to the importer, owner, or consignee of the drugs, with receipts and record keeping done on a summary basis to efficiently utilize federal resources. This section has no effect on laws regarding shipments of drugs that are valued equal to or greater than $10,000, nor does this section transfer to the Secretary responsibility for carrying out this section. Procedures to carry out this section must be established within 30 days of enactment of this Act.	for carrying out this section; and states that procedures for carrying out this section shall be established within 90, rather than 30, days of enactment of this Act.	detained for up to 30 days, labeled as detained and in a secure facility. Until the Secretary releases the drug or the detention period expires, prohibits the transfer of the drug from detention, including delivery pursuant to the execution of a bond. Allows the claimant to appeal the detention and the Secretary must confirm within five days or the order will be terminated. Section 5(b) amends Section 801 of the FFDCA by adding a paragraph (r), *Temporary Hold at Port of Entry*. With approval by the Secretary or a designated official (director of the district in which the drug is located, or a senior official of the director), directs an FDA officer or qualified employee who believes there is a risk to public health and was unable to inspect to request the Secretary of the Treasury to detain the prescription drug for 24 hours to allow inspection. Directs FDA, when detaining a drug, to notify the state of the port of entry. Prohibits the transfer of a detained drug or its removal or alteration of the detention label. Prohibits delivery of the prescription drug being held pursuant to the execution of a bond. This subsection does not apply to a drug imported by an individual for personal use or to a commercial transaction between an Internet pharmacy and an individual.

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Personal use	804(j). *Waiver Authority for Importation by Individuals.* 804(j)(1). *Declaration.* Congress declares that the Secretary should use discretion when enforcing the current legal prohibition against persons importing drugs or devices. The Secretary should focus enforcement on cases where the importing may pose a significant threat to public health. When the importation is clearly for personal use and the prescription drug or device does not appear to present an unreasonable risk to the individual, the Secretary should exercise discretion to permit the importation by the individual. 804(j)(3). The Secretary is required to grant waivers, by regulation, so persons can import for personal use up to a 90-day supply of an FDA-approved prescription drug from a licensed pharmacy in Canada, so long as the drug's final dosage form was made in an FDA-registered facility, came from a registered Canadian seller, was accompanied by a valid prescription, and was imported under conditions the Secretary determines were necessary to ensure public safety.	804(i)(1). *Personal Use; Conditions for Importation*. Individuals can import up to a 90-day supply of a qualifying drug if the drug is accompanied by: a copy of a prescription that is valid under federal and state laws and was issued by a practitioner who, under the state law of which the individual resides, is authorized to administer drugs; a statement that provides sufficient information for the Secretary to determine whether the prescription meets those regulations, including the prescriber's licensure; and the documentation required by the exporting country to dispense a drug. All prescriptions must be marked to indicate they have been filled to prevent duplicative filling by another pharmacist. The Secretary can prohibit from import drugs that were approved under accelerated procedures for serious or life-threatening illness. 804(i)(2). The exporter must notify the individual carrying a qualifying drug into the United States for personal use that the shipping container must be intact and be marked as in compliance with requirements that the drug is approved for distribution in a permitted country and is manufactured in a facility that also manufactures it for U.S. distribution;	804(i)(1). *Individuals; Conditions for Importation From Canada*. Similar to S. 2307 except it also allows the prescribing practitioner to be licensed where the individual receives care; refers to Canada specifically, rather than "the exporting country;" and requires that the Canadian document, in addition to the U.S. prescription, be marked as filled. The individual must have given the registered exporter a complete list of all drugs used by the individual for review by those who dispense the drug. Section 4(c)(3). Not less than 15 days after the enactment of this Act and until 60 days from promulgation of the interim rule, the Secretary shall, through the Internet website of the Food and Drug Administration, make readily available to the public a list of persons licensed in Canada to dispense prescription drugs who are willing to export drugs to individuals in the United States. Section 4(c)(4). The provisions on disposal of drugs denied admission and civil action regarding property (Sections 6 and 7 of this bill) do not apply to personal-use imports by individuals. Section 4(d). *Amendment of Certain Provision [Section 801]*. If a drug is imported by a person not in the	812. *Personal Importation.* Allows an individual to import a prescription drug from Canada or a permitted country into the United States for personal use (not for resale) if the prescription drug is purchased from a licensed pharmacy in Canada or a permitted country and dispensed in compliance with that country's applicable laws; it is imported for personal use (not for resale) by the individual; it is imported physically by the individual; it does not exceed a 90-day supply during any 90-day period; and the prescription drug is accompanied by a copy of a prescription valid in a state and cosigned by a prescribing physician in Canada or the permitted country or, if the prescription drug is available in Canada or the permitted country without a prescription, a copy of the valid prescription signed by a pharmacist licensed in that country. *Compassionate Use.* Authorizes the Secretary to permit an individual to import up to a 90-day supply of a drug that is not approved by the Secretary under FFDCA 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.

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		and the drug has the same ingredients, route of administration, dosage form, and strength as the U.S. label drug. 804(i)(3). There is a presumption that the drug imported is "an approved drug under Section 505(b)(1) if the criteria described in subsection (g)(A)(i-ii) are met." [*sic*; probably should be (g)(2)(A)(i-ii)] Section 4. *Additional Waivers Regarding Personal Importation; Enforcement Policies of Secretary*. Amends Section 801 by establishing a new category of waivers for individuals and allows the Secretary to establish by regulation a waiver of the requirement that only manufacturers import drugs if the drug was dispensed in the United States by a licensed pharmacist or practitioner and the individual traveled from the United States with the drug, and the individual returns to the United States with the drug. The drug cannot appear adulterated, and not be more than a 30-day supply. It must be accompanied by a statement that the individual seeks to import the drug under a personal import waiver, and complies with such additional standards the Secretary decides are needed to protect the public health. The Secretary may, by regulation, waive standards for personal use	importation business or shipped by an unregistered exporter and is refused admission, the Secretary shall notify the individual of the refusal, that the import is not subject to a waiver, and that the individual may legally import certain prescription drugs from registered Canadian exporters, a list of which is posted on the FDA website. Section 5. *Additional Waivers Regarding Personal Importation; Enforcement Policies of Secretary*. Similar to S. 2307, except that it requires that the Secretary establish by regulation a waiver of standards for personal use imports if the drug was dispensed to the individual while that person was in a foreign country and met that country's laws and regulations. In addition, the quantity of the imported drug may not exceed a 90-day supply if the drug is dispensed in Australia, Canada, a member country of the European Union as of January 1, 2003, Japan, New Zealand, or Switzerland; otherwise, the limit is a 14-day supply.	

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		imports if the drug was dispensed to the individual while that person was in a foreign country, met that country's laws and regulations, and was approved for commercial distribution in the foreign country in which the drug was obtained. The drug is entering with the individual and does not appear adulterated, does not exceed a 10-day supply, has a statement from the individual seeking to import the drug under a personal waiver, and complies with such additional standards that the Secretary determines to be appropriate to protect the public health. The Secretary may not administer any enforcement policy that permits imports of drugs in violation of this act or Section 351 of the Public Health Service Act. The Secretary's authority to establish waivers of the standards in Section 801(a) of the FFDCA for personal use imports is not limited by this Act; waivers must not, however, be more permissive than current FDA regulatory guidance.[#]		

[#]"In deciding whether to exercise discretion to allow personal shipments of drugs or devices, FDA personnel may consider a more permissive policy in the following situations: (1) when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; or (2) when (a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; (b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; (c) the product is considered not to represent an unreasonable risk; and (d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than three month supply)and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country." *FDA Regulatory Procedures Manual* at [http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html].

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Rulemaking deadlines	No provision.	Section 3(d)(1). *Implementation; Rulemaking.* The Secretary must publish, within 90 days of enactment and without notice and comment, an interim final rule for implementing Section 804; and publish a final rule by one year after the interim rule.	Section 4(c)(1)(A)(i). *Implementation; Rulemaking; Promulgation by Secretary.* Same as S. 2307.	Section 8(b). Requires that the Secretary, not later than one year after enactment, promulgate regulations to carry out Section 814 [to register prescription drug importation facilities].
Effective dates	No provision.	Section 3(d)(2). *Implementation; Personal Importation from Canada.* Until 45-days after the promulgation of the interim final rule, an individual may import up to a 90-day supply of a qualifying drug from Canada, for personal or family-member use, according to conditions in this act.	Section 4(c)(1)(A)(ii). *Effect of Rules.* An individual may import a prescription drug for personal or family-member use from a registered exporter beginning when the interim rule is promulgated. A registered importer may import a prescription drug from Canada beginning when the interim rule is promulgated. A registered importer may import a prescription drug from the other permitted countries beginning one year after enactment. Section 4(c)(1)(B). Registrations submitted by entities in Canada that are significant exporters of prescription drugs to individuals in the United States as of the date of the enactment of this Act will have review priority during the period in which the interim rule is in effect. The Secretary must approve or disapprove of the registration within	Section 2(b)(1)(B). Directs that personal-use importation be allowed from enactment of this Act, even if the Secretary has not issued regulations. Section 2(b)(2)(B). Directs that pharmacy and wholesaler importation be allowed one year after enactment of this Act even if the Secretary has not issued regulations. Section 8(b). Directs that registration of prescription drug importation facilities requirements take effect on the effective date of the final regulations or, if the final regulations have not been made effective, one year after enactment.

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			30 days, rather than the 90-day limit that this bill sets for approval or disapproval of registration in general. Section 4(c)(1)(C). Regarding drugs to be imported from Canada, (1) a manufacturer's notice that, because of differences from the U.S. label drug, requires prior approval from the Secretary must be submitted to the Secretary within 30 days of enactment; (2) a notice regarding a drug that does not require prior approval must be submitted to the Secretary within 90 days of enactment. Section 4(c)(1)(D). For drugs to be imported from Australia, a member country of the European Union as of January 1, 2003, Japan, New Zealand, or Switzerland, (1) a manufacturer's notice that, because of differences from the U.S. label drug, requires prior approval from the Secretary, must be submitted to the Secretary within 180 days of enactment; (2) a notice regarding a drug that does not require prior approval must be submitted to the Secretary within 270 days of enactment. Section 4(c)(2). *Implementation; Personal Importation from Canada*. For the 60 days after the interim rule is promulgated, an individual may import a prescription drug from	

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			Canada for personal or family-member use (rather than for resale), according to conditions in this act.	
Appropriations	804(m). *Authorization of Appropriations.* Authorizes to be appropriated such sums as are necessary to carry out this section.	No provision.	No provision.	No provision.
Protection against adulterated prescription drugs	No provision.	No provision.	No provision.	Section 3. *Protection Against Adulterated Prescription Drugs.* Amends Section 801(h) of the FFDCA [as added by P.L. 107-188] to include prescription drugs along with food, as follows. Directs the Secretary to give high priority to improving FDA information management systems to allow the Secretary to better allocate resources, detect the intentional adulteration, and facilitate the importation of prescription drugs. Also requires the Secretary to improve linkages with other federal regulatory agencies, states and Indian tribes to ensure the safety of imported prescription drugs.
Internet pharmacies	No provision.	No provision.	No provision.	Section 4. Adds to the FFDCA a new Section 511, *Internet Pharmacies*. 511(a). *Definitions*. Defines the terms "*advertising service provider*," "*designated payment system*," "*federal functional regulator*," "*restricted transaction*," "*unlawful Internet pharmacy request*," "*credit*," "*creditor*," "*credit card*," "*electronic*

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				fund transfer," "*financial institution*," "*money transmitting business*," and "*money transmitting service*." Includes references to the Communications Act of 1934 [47 USC 230(f)], the Gramm-Leach-Bliley Act [15 USC 6809; note: the bill also cites 21 USC 6805(a), perhaps in error], the Truth in Lending Act [15 USC 1602], the Electronic Fund Transfer Act [15 USC 1693a], and the Uniform Commercial Code [Article 4A]. In particular, defines "*Internet pharmacy*" as "a person that dispenses or offers to dispense a prescription drug through an Internet website in interstate commerce in the United States regardless of whether the physical location of the principal place of business of the Internet pharmacy is in the United States or in another country." Defines "*unlawful Internet pharmacy request*" as "the request, or transmittal of a request, made to an unlicensed Internet pharmacy for a prescription drug by mail (including a private carrier), facsimile, phone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet." 511(b,c). *Licensing of Internet Pharmacies*. To dispense a prescription drug to a person in the United States, requires that an Internet

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				pharmacy be licensed with the Secretary and have its principal place of business in the United States, Canada, or a permitted country. Requires that the license application include verification of compliance, in each state in which the Internet pharmacies seeks to dispense prescription drugs, with all federal and state laws regarding the practice of pharmacy and the manufacturing and distribution of controlled substances and, for an Internet pharmacy in Canada or a permitted country, verification regarding compliance with applicable laws of that country. Also requires the application to include verification that the Secretary has not terminated a previous Internet pharmacy license of the owner, that the owner will permit inspections by the Secretary, and that any agreement between the Internet pharmacy and a patient releasing liability for negligence is null and void. *Identification Requirements.* Requires that the Internet pharmacy website include the street address and telephone number of each place of business; the names of the supervising and Internet service pharmacists; names of all states or countries where the pharmacy and pharmacists are licensed or otherwise authorized to

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				dispense prescription drugs; name, address, telephone number, and state of licensure of any health care practitioner to whom the Internet pharmacy makes referrals; and a statement that it will dispense prescription drugs only after receipt of a valid prescription. *Professional Services Requirements*. Requires an Internet pharmacy to maintain patient medication profiles, conduct prospective drug use reviews, ensure patient confidentiality in accordance with the Health Insurance Portability and Accountability Act of 1996, offer "interactive and meaningful consultation by a licensed pharmacist," establish a mechanism to report errors and suspected adverse reactions and to document responses, develop system to inform about drug recalls, educate about disposal of medications, assure sale "is in accordance with a prescription from the treating provider of the individual," and verify prescription validity by mail or electronic mail receipt from the treating provider. If the prescription is for a controlled substance, the Internet pharmacy must confirm with the treating provider that the prescription is accurate and must provide the individual's name and address, identity and quantity of the drug, date prescription was presented to the Internet pharmacy, date and

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				time of the verification request, and the name, telephone, fax, and e-mail contacts of the Internet pharmacy contact person. If the treating provider does not respond within 72 hours or informs the pharmacy that prescription is inaccurate or expired, the Internet pharmacy may not fill prescription. The Internet pharmacy must maintain records of direct communications with treating providers. *Licensure Procedure*. Requires that the Secretary assign an ID number and notify applicant of license application receipt and issue a license within 60 days if pharmacy complies with all required conditions. Directs the Secretary to require electronic submission of application and to ensure adequate authentication protocols. Requires that the Secretary keep an up-to-date list of licensees and make the list available to the public by an Internet website and a toll-free telephone number. *Licensing Fee*. The licensing fee for the year in which an Internet pharmacy first submits an application is $5,000. Requires that the Secretary publish, at least 60 days before the start of each fiscal year, and allow 30 days for comment, the licensing fee

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				based on anticipated costs of enforcing requirements of this section in the subsequent year. Requires that the Secretary use, without further appropriation, the fees to carry out this section. The fee is due October 1 of each year and payable only once for each Internet pharmacy. If the Internet pharmacy has not paid the fee 30 days after the due date, prohibits it from dispensing drugs until it pays. Requires the Secretary, in 2005 and each subsequent year, to submit a report to Congress describing the implementation of the licensing fee authority and the use of the fees collected. Allows the Secretary to terminate a license if the Internet pharmacy has a pattern of noncompliance, made an untrue statement in the license application, or is in violation of an applicable federal or state law. Requires that, before renewing a license, the Secretary conduct an evaluation of compliance that may include testing of the website and other systems and a physical inspection of the records and premises. Authorizes the Secretary to award a renewable five-year contract to operate the licensing program, with annual performance reviews. 511(d). *Providers of Interactive Computer Services or Advertising Services.* Establishes that these providers are liable if they accept

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				advertising for a prescription drug from an unlicensed Internet pharmacy or accept advertising stating a physician's prescription is not needed to obtain a prescription drug. 511(e). *Policies and Procedures Required To Prevent Payments for Unlawful Internet Pharmacy Requests.* Requires regulations within a year of enactment regarding design (using, for example, authorization codes) of the payment system (with system participant participation, if feasible) to prevent or block restricted transactions. Establishes that there be no liability for blocking or refusing to honor a restricted transaction. Requires that the Federal Trade Commission and other federal functional regulators (as defined in the Gramm-Leach-Bliley Act, 15 USC 6809) enforce this section taking into consideration the person's history and extent of compliance, the extent to which the person knew the transaction related to an unlawful Internet pharmacy request, and the feasibility of any specific remedy. 511(f). *Reports Regarding Internet-Related Violations of Federal and State Laws on Dispensing of Drugs.* Directs the Secretary to award a grant or contract to develop and maintain a system of identifying unlicensed Internet pharmacy websites or those

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				in violation of federal or state laws; reporting these to state medical and pharmacy licensing boards, the Attorney General, and the Secretary; and submitting reports each fiscal year to the Secretary. Section 4(b). *Prohibited Acts.* Amends FFDCA Section 301, adding violations of Section 511 including drug sale or Internet pharmacy ownership, representing that a prescription drug may be obtained without a prescription, or accepting advertising from an Internet pharmacy without having a copy of the pharmacy's license on file. Section 4(c). *Links to Illegal Internet Pharmacies.* Amends FFDCA Section 302, stating that U.S. district courts and courts of the territories shall have jurisdiction to order an interactive computer service to remove or disable access to a website that violates this section. States that relief shall be available after notice and opportunity to appear; shall not oblige the provider to actively or passively monitory activity for violations; and shall specify the provider to which the relief applies. Section 4(d). Requires that the Secretary, within one year of enactment, promulgate interim final regulations consistent with the

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				Verified Internet Pharmacy Sites certification program developed by the National Association of Boards of Pharmacy. States that the licensure requirement will take effect no later than 90 days after the publication of interim regulations. Section 4(e). *Return to Sender*. Requires that a shipment of a prescription drug from an unlicensed Internet pharmacy be refused admission and that the Secretary return it to the pharmacy at the pharmacy's expense. Directs the Secretary to return to the pharmacy at the pharmacy's expense a refused shipment from a licensed Internet pharmacy and to notify the individual and the Internet pharmacy along with the reason. Prohibits the return of a prescription drug that is required to be destroyed.
Prohibition of port shopping	No provision.	No provision.	No provision.	813(a)(2). *Limitation to Certain Ports.* Allows the Secretary to limit to a reasonable number the ports of entry in the United States through which a prescription drug may be imported under this section. 813(c)(3)(B). *Lists; Ports.* Requires the Secretary to maintain an updated list of ports through which a prescription drug may be imported under this section and to make the list

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				available to the public on an Internet website. Section 12. *Prohibition of Port Shopping.* Prohibits entry of the prescription drug if it has previously been refused admission under Section 801(a), unless the person reoffering the prescription drug affirmatively establishes, at the expense of the owner or consignee of the prescription drug, that the prescription drug complies with the applicable requirements of this Act, as determined by the Secretary. This section does not apply to a personal-use import or to a commercial transaction between an Internet pharmacy and an individual.
Anti-counterfeiting programs				Section 15(d). *Anticounterfeiting Programs.* Requires the Secretary to establish a "Counterfeit Alert Network" to notify health professionals and the public of counterfeit drugs; develop, publish, and keep up-to-date (quarterly) an Internet accessible reference document to identify prescription drugs marketed in the United States, Canada, and other countries as the Secretary permits. Directs the Secretary to develop and publish a range of materials, including those to help the identification and reporting of counterfeit drugs, practice guidelines (in cooperation with drug

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				supply chain members) for the sale and distribution of drugs, and revised model rules (in cooperation with the National Association of Boards of Pharmacy) for state licensure of wholesalers.