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Importation of Prescription Drugs: A Side-by-Side Comparison of Current Law, S. 109/H.R. 328, S. 184/H.R. 753, and S. 334/H.R. 700

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/name redacted/ and /name redacted/
Specialists in Social Legislation
Domestic Social Policy Division

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Summary

As prices of prescription drugs have risen, many in Congress have sponsored legislation to permit the importation of FDA-approved drugs from less expensive foreign sources. In the 109th Congress, three pairs of bills have been introduced to repeal the existing import restrictions and provide for limited forms of importation of prescription drugs. Current law and the 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. An underlying goal is to reduce or restrain the growth of the financial burden that prescription drugs place on U.S. consumers.

The drug importation provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173) effectively do not allow the commercial or personal-use importation of prescription drugs. Congress, with the MMA, continued 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. This report, which will be updated, briefly discusses major differences among current law and the introduced bills, and presents a side-by-side comparison of their provisions. The bills are the Pharmaceutical Market Access Act of 2005 (S. 109, H.R. 328), the Safe Importation of Medical Products and Other Rx Therapies Act of 2005 (the Safe IMPORT Act of 2005; S. 184, H.R. 753), and the Pharmaceutical Market Access and Drug Safety Act of 2005 (S. 334, H.R. 700).

Although all three pairs of 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 proposed 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 use of 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: current law relies on appropriations alone, while the proposed bills each create specific user-fee provisions. The proposed bills also address the regulation of Internet pharmacies. S. 109/H.R. 328 and S. 334/H.R. 700 propose links to patent law to influence industry behavior. While current law does not specify when importation could begin, S. 109/H.R. 328 requires regulations to allow personal-use and commercial imports 180 days after enactment. S. 184/H.R. 753 provides for personal-use imports at enactment and commercial imports one year later. S. 334/H.R. 7000 begins imports from registered exporters 90 days after enactment and by registered importers one year after enactment.

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Introduction

In recent years, as prices of prescription drugs have risen, many in Congress have sponsored legislation to permit the importation of Food and Drug Administration (FDA) approved drugs from less expensive foreign sources. In the 109th Congress, three pairs of bills have been introduced to repeal the existing import restrictions and provide for limited forms of importation of prescription drugs. Current law and the 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. An underlying goal is to reduce or restrain the growth of the financial burden that prescription drugs place on U.S. consumers.

Current law bars importation unless the Secretary of Health and Human Services (HHS) certifies that imports are safe and offers cost savings to U.S. consumers. Congress reaffirmed this requirement, first established by the Medicine Equity and Drug Safety (MEDS) Act of 2000, most recently in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA, P.L. 108-173) in December 2003. The three bill pairs each would eliminate this requirement and, instead, include other potential safeguards regarding drug safety and effectiveness. They all would act primarily by replacing or amending Section 804 of the Federal Food, Drug, and Cosmetic Act (FFDCA), which had been initially added to the FFDCA by the Medicine Equity and Drug Safety (MEDS) Act of 2000; individual bills would amend other laws.

This report compares the provisions of three approaches to prescription drug importation (represented by three Senate and three House bills) with provisions on the subject in current law.[1] The three bill pairs are:

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[1] 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).

- **The Pharmaceutical Market Access Act of 2005**:
  S. 109, introduced by Senator Vitter on January 24, 2005, and
  H.R. 328, introduced by Representative Gutknecht on January 25, 2005; referred to in this report as the Vitter-Gutknecht bills. No action has been taken.
- **The Safe Importation of Medical Products and Other Rx Therapies Act of 2005, or the Safe IMPORT Act of 2005**:
  S. 184, introduced by Senator Gregg on January 26, 2005, and
  H.R. 753, introduced by Representative Bradley on February 10, 2005; referred to in this report as the Gregg-Bradley bills. No action has been taken.
- **The Pharmaceutical Market Access and Drug Safety Act of 2005**:
  S. 334, introduced by Senator Dorgan on February 9, 2005, and
  H.R. 700, introduced the same day by Representative Emerson; referred to in this report as the Dorgan-Emerson bills. In July 2005, Senator Dorgan successfully offered the drug importation provisions as an amendment to the Federal Trade Commission reauthorization bill (S. 1392) ordered to be reported by the Senate Commerce, Science and Transportation Committee.[2]

The differences in approach across the bills fall into three areas: attempts to ensure that imported drugs are safe and effective; attempts to influence industry behavior so drugs are available for import by U.S. consumers at cost savings to current domestic prices; and administrative arrangements.

Safe and Effective Drugs

Relationship to FDA Approval

Current law and language proposed by the Vitter-Gutknecht and Gregg-Bradley bills explicitly require that an imported drug be approved for U.S. sale by the FDA. The Dorgan-Emerson bills would allow different administrative requirements for importation while maintaining the substantive elements of FDA approval. The Dorgan-Emerson bills require that a manufacturer notify the HHS Secretary when a drug that could be imported differs from the version FDA had approved for sale in the United States (the "U.S. label drug"). The bills require extensive information about whether the difference, if it were to be made to a U.S. label drug, would require a supplemental application to FDA and whether FDA would require that the application be processed before the drug could be marketed.

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[2] Elaine S. Povich, "Drug Importation Tacked to FTC Bill," July 21, 2005, at [http://nationaljournal.com].

Permitted Countries

The three bills and current law vary in the countries from which they would permit drug importation. The most inclusive are the Vitter-Gutknecht bills,[3] which include Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, members of the European Union, Iceland, Liechtenstein, and Norway. These bills also would allow the Secretary to designate additional countries that have equivalent regulatory requirements regarding safety and effectiveness, or to remove a country that does not. The Dorgan-Emerson bills differ from the Vitter-Gutknecht bills by excluding Israel, South Africa, and members of the European Economic Area that are not also members of the European Union (excluded are Iceland, Liechtenstein, and Norway), and, for European Union countries, by adding a reference to their Annex to the Treaty of Accession that essentially disqualifies the 10 countries admitted to membership in May 2004 (excluded are Cyprus, the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia, and the Slovak Republic). The Gregg-Bradley bills would include Canada and allow the Secretary, three years after enactment, to designate as eligible any members of the European Union as of December 2003. Current law includes only Canada, although it allows the Secretary to grant waivers permitting personal-use importation from other countries.

Ensuring Drug Identity

Sponsors of all three pairs of bills are concerned about the potential for entry of adulterated or counterfeit drugs into the U.S. market. Consequently, they call for a variety of procedures covering the registration of exporters or importers; chain-of-custody documentation; inspections of manufacturing, storage, and shipping facilities; laboratory testing of drug samples; packaging; and labeling of shipping containers and consumer products.

Registration. Current law requires that a Canadian establishment involved in importing prescription drugs to the United States register its name and place of business and the name of its U.S. agent with the Secretary. All three bills have extensive registration requirements. The specifics vary and cover extensive recordkeeping, monitoring, inspections, and fees. The Vitter-Gutknecht bills would require all exporters to register; the Gregg-Bradley and Dorgan-Emerson bills require all exporters and all commercial importers to register.

Monitoring, Inspecting, and Testing. While current law relies on laboratory testing of samples of every shipment of imported drugs to verify their content, potency, and labeling, the three proposed bills focus on documentation of a monitored, uninterrupted chain of custody from manufacturing facility to importer. The requirements related to registration involve ongoing and onsite physical monitoring of the facilities of a drug's manufacturer, exporter, or importer. If the Secretary determines it necessary, these would include the inspection of any facility (and its records) that handles the product along the chain of custody.

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[3] In one of the very few differences between S. 109 and H.R. 328, the Gutknecht bill restricts European Union members to those included as of Dec. 31, 2003.

Packaging and Labeling. In addressing counterfeiting and product tampering, all three bills promote measures intended to ensure that the drug dispensed to the individual consumer is the same product that was tested, monitored, or inspected at the manufacturing, shipping, or storage facility. The Vitter-Gutknecht bills would require that the packaging of all prescription drugs (not just those being imported) incorporate overt optically variable counterfeit-resistant technologies that provide visible identification of the product, and be similar to those used to secure U.S. currency. In addition, manufacturers must incorporate the technologies into multiple elements of the packaging (including blister packs, shrink wrap, package labels, package seals, bottles, and boxes). Also, shipping containers of prescription drugs must have labels that incorporate technologies that enable inspectors to verify the authenticity of the shipment. The Gregg-Bradley bills would direct the Secretary to require the use of electronic track-and-trace technology at the case and pallet level that would identify each sale, purchase, or trade of each case or pallet. The Dorgan-Emerson bills require that the exporter and importer agree to mark each shipping container to identify its compliance with all registration conditions. The markings must include anti-counterfeiting or track-and-trace technology, taking into account their economic and technical feasibility, and must be designed to prevent unauthorized affixation.

Internet Pharmacies. Current law does not address use of the Internet to sell or purchase imported prescription drugs. The Vitter-Gutknecht bills have no provisions specifically related to Internet pharmacy procedures, but include qualified Internet pharmacies among other registered exporters and the extensive associated requirements. The Gregg-Bradley and Dorgan-Emerson bills do address Internet sales. Their provisions address registration, posted information, prescriptions, and relationship to medical care.

The Gregg-Bradley bills present an extensive statutory and regulatory structure for Internet pharmacies, placing it in the FFDCA but set apart from the importation sections. In addition to registration, the bills would require 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. They require advance notice of commercial shipments of prescription drugs and include a licensing fee. Providers of interactive computer services would be liable if they accept advertising for a prescription drug from an unlicensed Internet pharmacy or accept advertising stating that a physician's prescription is not needed to obtain a prescription drug. The Gregg-Bradley bills also require policies and procedures to prevent payments for unlawful Internet pharmacy requests.

The Dorgan-Emerson bills would require that detailed information be accessible on the Internet site, covering pharmacist credentials, address and telephone contacts, and the name and professional licensure information of the person, if any, who provides for medical consultations through the site for purposes of providing prescriptions. No one could dispense or sell a drug if the purchaser or patient who communicated through the Internet did not have a valid U.S. prescription. The dispenser of the prescription drug must have a "qualifying medical relationship with the patient."

Cost Savings to U.S. Consumers

Impetus to amend current law goes beyond the concern with drug safety. Even were the Secretary to issue the certification necessary to begin the drug importation section in the FFDCA, many analysts and Members of Congress anticipate manufacturer resistance. The Vitter-Gutknecht and Dorgan-Emerson bills contain specific provisions designed to influence industry behavior; the Gregg-Bradley bills do not.

Discrimination and Unfair Acts

The Vitter-Gutknecht bills and the Dorgan-Emerson bills would make it "unlawful for a manufacturer, directly or indirectly (including being a party to a licensing or other agreement)," to discriminate or act unfairly against an exporter, importer, or person who distributes, sells, or uses an imported prescription drug by charging a higher price; denying, restricting, or delaying supplies; or refusing to do business.

Drug Differences

The Vitter-Gutknecht and Dorgan-Emerson bills would make it unlawful for a manufacturer to make a drug for distribution in a permitted country so that it differs from the drug made for U.S. distribution "for the purpose of restricting importation of the drug.... " Provisions describe involvement of the Federal Trade Commission and the state attorneys general. The extensive notification requirements in the Dorgan-Emerson bills regarding differences between a drug a manufacturer produces for sale in a permitted country and the drug it produces for U.S. distribution could serve, in addition to addressing safety, to influence industry decisions.

Patent Law

The Vitter-Gutknecht and Dorgan-Emerson bills would insert a new subsection in the Patent and Trademark Act 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 into the United States without regard to the U.S. patent.

Administration of Importation Provisions

The timing and funding of importation activities vary across current law and the proposed bills.

Funding

Current law includes no explicit funding mechanism other than authorizing appropriations of such sums as necessary to implement the prescription drug

importation provisions. The Vitter-Gutknecht bills would not only authorize appropriations but also provide for exporter fees to cover the cost of administering the import provisions. The Gregg-Bradley and Dorgan-Emerson bills provide for both exporter and commercial importer fees designed to cover all costs of the program.

All three bills link the aggregate total of all fees to the estimated costs of the importation program, setting a limit of 1% of the total price of drugs imported. The Secretary would collect from each exporter (and importer, except in the Vitter-Gutknecht bills) both a flat registration fee and a proportional registration fee. Each individual importer or exporter would pay the latter fee based on the extent of its own activity and calculated to estimate its proportion of the aggregate amount. The bills would require that these fees be used only for the administration of the importation provisions that the bills would add.

Effective Dates

Current law does not specify when importation could begin, other than linking it to the required safety and cost certification by the Secretary. It directs the Secretary to exercise discretion to permit importation by an individual for personal use, if it does not appear to present an unreasonable risk to the individual. The three proposed bills stipulate various time frames for commercial and personal-use importation, with varying times for different countries.

The Vitter-Gutknecht bills would require that the HHS Secretary, in consultation with the United States Trade Representative and the Commissioner of Customs, issue regulations not later than 180 days after enactment, permitting pharmacists, pharmacies, wholesalers, and individuals to import qualifying drugs from permitted countries. The Gregg-Bradley bills' section on personal importation would take effect on the date of enactment, and their section on commercial importation would take effect one year after enactment, both "without regard to whether the Secretary … has promulgated regulations…. " The Dorgan-Emerson bills would require that the Secretary promulgate a final rule for implementing the importation provisions not later than one year after promulgating an interim rule. It also states that the importation provisions shall "permit the importation of qualifying drugs … without regard to the status of the issuance of implementing regulations" from registered exporters 90 days after enactment and from permitted countries by registered importers one year after enactment.

Side-by-Side Comparison

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

Table 1. Comparison of Prescription Drug Importation Provisions in Current Law, S. 109/H.R. 328, S. 184/H.R. 753, and S. 334/H.R. 700

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. 109 (Vitter 1/24/2005) and H.R. 328 (Gutknecht 1/25/2005) Pharmaceutical Market Access Act of 2005	S. 184 (Gregg 1/26/2005) and H.R. 753 (Bradley 2/10/2005) Safe Importation of Medical Products and Other Rx Therapies Act of 2005 or the Safe IMPORT Act of 2005	S. 334 (Dorgan 2/9/2005) and H.R. 700 (Emerson 2/9/2005) Pharmaceutical Market Access and Drug Safety Act of 2005
Legislation	Section 804 of the Federal Food, Drug, and Cosmetic Act (FFDCA) was first established under the Medicine Equity and Drug Safety Act of 2000 (P.L. 106-387) as Importation of Covered Products. Section 1121(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173) replaced Section 804 entirely, renaming it Importation of Prescription Drugs [21 USC 384].	[Section 4][a] Amends Section 804 of the FFDCA [21 USC 384]. Also amends or adds provisions in other sections of the FFDCA, and in 35 USC 271 [Infringement of Patent].	[Section 2] Adds a new Subchapter B — "Importation of Prescription Drugs" — to Chapter VIII of the 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 in the Controlled Substances Import and Export Act [21 USC 956].	[Sections 3 and 4] Amends Chapter VIII of the FFDCA by replacing Section 804. Also amends, deletes, or adds provisions in other sections of the FFDCA, and in the Controlled Substances Import and Export Act [21 USC 956(a)(2)], and in 35 USC 271 [Infringement of Patent].
	[a]To distinguish between the section numbers of the bills pending in the 109th Congress and the section numbers they would change in the law, this table notes the former in brackets.			
Direction to regulate	804(b). *Regulations.* Section 801(d)(1) of the FFDCA allows only a drug's manufacturer to import that drug. Section 804(b) requires	804(b). *Regulations.* Similar to current law, but (1) adds requirement to publish regulations within 180 days of enactment, (2) would allow	[Section 2(b)] *Regulations.* Authorizes the HHS Secretary to promulgate regulations to carry out Section 812 [personal importation] and directs the	804(a)(1-3). *Importation of prescription drugs.* Waives Section 801(d)(1), which prohibits a drug's importation by any entity other than its

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	the Secretary of 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.	pharmacies and individuals to import in addition to pharmacists and wholesalers, and (3) would allow imports from other permitted countries, not just Canada.	Secretary to 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.	manufacturer, as long as the drug complies with the standards of Section 801(a), which allow only certain drugs to be imported. A qualifying drug may not be imported unless the drug is imported by a pharmacy, a group of pharmacies, or a wholesaler that is a registered importer, or by an individual for personal or family member use (and not for resale) from a registered exporter.
Commencem	804(l)(1). *Commencement of*	No provision.	No provision.	No provision.

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ent of program	*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.			
Termination of program	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 certification is	No provision.	No provision.	No provision.

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	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			

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	detriment with those benefits and determines the benefits do not outweigh the detriment.			
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)(2). The term "*permitted country*" means a country listed in FFDCA Section 802(b)(1)(A); these are Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and a member country of the European Union[b] or a country in the European Economic Area if the drug is marketed in that country or authorized for general marketing in the European Economic Area. The Secretary may add a country, union, or economic area to the list if it has a pharmaceutical infrastructure equivalent or superior to that in the United States; or remove from the list if it does not. In this decision, the Secretary should consider pharmacist qualifications, pharmacy storage procedures,	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,[b] 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). 811*(4)(B). *Report*. Requires that the Secretary, three years after enactment, submit to the Senate HELP Committee and the House Committee on Energy and Commerce a report that includes a list of permitted	804(a)(4)(E). A "*permitted country*" means Australia, Canada, Japan, New Zealand, Switzerland, or a member country of the European Union.[b] Does not include a country whose Annex to the Treaty of Accession to the EU 2003 includes a non-expired transitional measure for the regulation of pharmaceuticals, or a country that does not meet the criteria the Secretary may use to add a country not listed here. Those criteria relate to the country's having statutory or regulatory requirements that require the governmental review of the drug's safety and effectiveness; authorize approval of only those drugs that have been determined to be safe and effective by experts qualified to judge the safety and

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		drug distribution and dispensing systems, and market regulation.	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. 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	effectiveness of the drugs based on adequate and well-controlled investigations, including clinical investigations conducted by experts qualified by scientific training to evaluate the drug; require the methods used in and the facilities and controls used for manufacturing, processing, and packing of drugs be adequate to preserve their identity, quality, purity, and strength; require reporting of adverse reactions to drugs and procedures to withdraw or remove unsafe or ineffective drugs; and require the labeling and promotion of drugs to be in accordance with the drug's approval. The marketing authorization system must be equivalent to systems in the countries that have qualified, and the import of drugs into the United States from the country will not adversely affect U.S. public health.

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			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.	

[b]The European Union (EU), 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 EU: Cyprus, the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia, and the Slovak Republic. [Note: S. 109 refers to EU; H.R. 328 specifies EU as of 12/31/03.] 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.)

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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. "*Qualifying laboratory*" is defined as a laboratory in the United States that has been approved by the Secretary for the purposes of this section.	804(a). "*Pharmacist,*" "*wholesaler,*" and "*qualifying laboratory*" are defined as in current law. Defines "*importer*" to include not only a pharmacist and wholesaler but also a pharmacy, and group of pharmacies. The term "*pharmacy*" means a person licensed by a state to sell prescription drugs at retail who employs 1 or more pharmacists. A "*qualifying Internet pharmacy*" means a registered exporter that dispenses qualifying drugs to individuals over the Internet. Defines "*registered exporter*" to mean an exporter that is exporting or seeking to export a drug to individuals in the United States with an approved registration in effect.	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 "*treating provider*" as a licensed health care provider that (A) performs a documented patient evaluation (including a patient history and physical	804(a)(4). *Definitions.* "*Pharmacist*" and "*wholesaler*" are defined as in current law. Defines "*registered exporter*" to mean an exporter with an approved registration in effect; "*registered importer*" to mean a pharmacy, a group of pharmacies, or a wholesaler with an approved and in effect registration; and a "*registration condition*" to mean a condition that must exist for a registration to be approved. Defines "*exporter*" to mean a person who is in the business of exporting a drug to individuals in the United States from Canada or from a permitted country designated by the Secretary, or that seeks to be in such a business pursuant to submitting a registration. The Secretary shall designate countries (other than Canada) that have statutory or regulatory standards equivalent to U.S. and

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			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. 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.	Canadian standards for pharmacist training and practice, protection of personal medical information privacy, and whose imports will not adversely affect public health. The term "*importer*" to mean a pharmacy, a group of pharmacies, or a wholesaler that is in the drug importing business or that seeks an approved registration to do so; "*pharmacy*" means a person licensed by a state to engage in the business of selling prescription drugs at retail and employs one or more pharmacists.
Qualifying drug	804(a). 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	804(a)(5). Same as current law. 804(a)(6). A "*qualifying drug*" is a drug approved under Section 505(b)(1) and is not a drug manufactured through 1 or	811*(5). Defines "*prescription drug*" similarly to current law [i.e., an FDA-approved drug], with additional exceptions: a drug manufactured through any biotechnology process,	804(a)(4)(B,C). Defines "*prescription drug*" as a drug described in current law (FFDCA Section 503(b)(1)). A "*qualifying drug*" means a

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	practitioner (as approved under Section 505)] 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.	more biotechnology processes, not required to be refrigerated, and not a photoreactive drug. [Section 4(c)] Amends 804(c) by replacing "prescription drug" with "qualifying drug" throughout.	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.	drug for which there is a U.S. label drug. A "*U.S. label drug*" means a drug that has the same active ingredient(s), route of administration, dosage form, and strength as the qualifying drug; is manufactured by or for the person manufacturing the qualifying drug; is approved under Section 505(c) of the FFDCA; and is not a controlled substance, a biological product (including a therapeutic DNA plasmid product, a therapeutic synthetic peptide product, a monoclonal antibody product for in vivo use, and a therapeutic recombinant DNA-derived product), an infused drug, an injected drug, a drug inhaled during surgery, or a drug that is the listed drug referred to in two or more abbreviated new drug applications (ANDAs) under which the drug is commercially marketed.

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				804(c). *Sources of qualifying drugs*. An exporter or importer may export or import a drug only if there is compliance with the following: the drug must have been manufactured in an FDA-registered establishment [registered under Sections 510(h) or 510(i)], and the establishment has been inspected either by the Secretary or by a permitted country whose regulatory system is recognized as equivalent under a mutual recognition agreement as provided in Section 510(i)(3) [cooperative agreements between Secretary and foreign countries regarding means to determine whether a drug shall be refused admission into the United States], Section 803 [agreements between the Secretary and foreign countries regarding mutual recognition of good manufacturing practice regulations], or 21 CFR 26 [mutual recognition of

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				pharmaceutical good manufacturing practice reports, medical device quality system audit reports, and certain medical device product evaluation reports: United States and the European Community] or a successor rule or regulation. The establishment, located in any country, manufactured the drug for distribution in the United States or a permitted country. In addition, the exporter or importer must obtain the drug directly from the manufacturing establishment or directly from an entity that, by contract with the exporter or importer, provides a chain of custody statement from the manufacturing establishment, identifying each prior sale, purchase, or trade with dates and names and

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				addresses of all parties to the transaction; agrees to permit the Secretary to inspect the statements and related records to determine accuracy; and agrees to allow the Secretary to inspect warehouses and other facilities and records involved, including those of all contracting chain of custody parties, through contracts as necessary, to determine whether facilities are in compliance with any FFDCA standards that are applicable to facilities of that type in the United States. The foreign country from which the exporter will export the drug is the permitted country in which the exporter is located, or the foreign country from which the importer will import the drug is a permitted country. The exporter or importer ensures that during any period in which the drug was not in the drug manufacturer's control, the drug

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				did not enter a non-permitted country. The exporter or importer must retain a sample of each lot of the drug, sufficient for testing by the Secretary.
Relationship to FDA approval	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(a)(6). A qualifying drug must be FDA-approved under Section 505(b)(1).	813(b)(1,2). *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].	804(g)(1). *Compliance with section 801(a)* [Imports and Exports]. For each exported or imported qualifying drug, the exporter or importer must comply with FFDCA Section 801(a) standards subject to FFDCA Sections 505 [approval status], 502 [labeling], and 501 [adulteration]. 804(g)(2)(A). *Approval status*. A qualifying drug imported or offered for import must comply with conditions of the approved FDA new drug application under FFDCA Section 505(b) for the U.S. label drug. 804(g)(2)(B)(i). *Approval*

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				status; Notice by manufacturer; General provisions. The manufacturer of the drug for commercial distribution in a permitted country shall submit notice to the Secretary that includes either (a) each difference between the qualifying drug and the U.S. label drug beyond variations provided for in the application and any difference in labeling (other than ingredient labeling), or (b) a statement of no such difference. 804(g)(2)(B)(ii). The notice must include information that the Secretary may require under FFDCA Section 506A [manufacturing changes]; any additional information (which may include data on bioequivalence if not otherwise required under 506A); the date that the qualifying drug with

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				such a difference will be (or was) introduced for commercial distribution in the permitted country; demonstration that the manufacturer also notified the permitted country in writing that it is submitting this notice to the Secretary; and copies, with certified English translation, of all materials the manufacturer submitted to the permitted country for marketing approval in the permitted country. 804(g)(2)(B)(iii). The chief executive officer and the chief medical officer of the manufacturer must certify that the information in the notice is complete and true and has been provided also to the FTC and the state attorneys general. [Section 4(e)(4-5)] For the 100 prescription drugs with the highest dollar volume of sales in

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				the United States in the preceding year (as defined), sets varying time limits for providing notice based on whether drug is for import from Canada (30 days) or from other countries (180 days). [Section 4(e)(6)] *Notice for other drugs for import.* Requires the Secretary to establish a series of notice submission dates for drugs not among the top 100 (see subparagraphs 4-5) in a manner allowing the consistent and efficient use of available resources and staff but to be completed not later than five years after enactment. The Secretary must establish these dates to allow review of notices regarding qualifying drugs with higher dollar volume of sales in the United States before review of notices regarding drugs with lower U.S. sales.

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				[Section 4(e)(7)] *Notices for drugs approved after effective date*. Subparagraphs 4(e)(4-6) do not apply to a qualifying drug first introduced for commercial distribution in a permitted country after enactment of this act. [Section 4(e)(8)] *Report*. The Secretary must submit a report to Congress within 90 days of the end of each fiscal year, beginning with FY2006, concerning the FDA's progress in reviewing notices referred to in paragraphs (4-6) of Section 4(e). 804(g)(4). *Section 501; Adulteration*. A qualified drug imported or offered for import shall be considered in compliance with Section 501 [adulterated drugs] if the drug complies with subsection (c)

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				[sources of qualifying drugs].
Manufacturer requirements	No provision.	804(l)(8). Amends section so that the term "*manufacturer*" in this subsection means any entity, including any affiliate or licensee of that entity, that is engaged in: (A) the production, preparation, propagation, compounding, conversion, or processing of a prescription drug, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or (B) the packaging, repackaging, labeling, relabeling, or distribution of a prescription drug.	No provision.	804(g)(2)(B)(iv). *Fee*. 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 manufacturer submitting the notice must pay to the Secretary a fee in the same amount as would apply if the person were paying a Prescription Drug User Fee Act (PDUFA) fee for a supplemental application. Subject to Appropriations Acts, such fees collected by the Secretary are available only to the Secretary and are for the sole purpose of paying the costs of reviewing notices. 804(g)(2)(B)(v). *Timing of submission of notices*. For a notice regarding drug differences that would require approval

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				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 earlier distribution. For a drug difference that would not require prior approval under Section 506A, the manufacturer must submit notice no later than the day its commercial distribution begins in the permitted country. 804(g)(2)(B)(vi). Review by the Secretary: The Secretary must review the difference between the qualifying drug and the U.S. label drug as if it were a manufacturing change to the U.S. label drug under Section 506A, using the same safe and effective standard for approving

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				or disapproving a change. If the Secretary would approve the difference under 506A and the qualifying drug is not bioequivalent to the U.S. label drug, the Secretary may either: (1) include in the labeling a prominent advisory stating that the qualifying drug is safe and effective but is not bioequivalent to the U.S. label drug, if the Secretary decides an advisory is necessary for health care practitioners and patients to use the qualifying drug safely and effectively; or (2) decline to approve the difference if the Secretary decides that the availability of both the qualifying drug and the U.S. label drug would pose a threat to the public health. The Secretary must review and approve or disapprove the notice

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				of a difference in the qualifying drug that would require prior approval under 506A 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. The Secretary may rely on a satisfactory report from a permitted country of a good manufacturing practice (GMP) inspection of the establishment if the Secretary recognizes such inspections as equivalent under a mutual recognition agreement as provided under Section 510(i)(3), Section 803, or 21 CFR 26. 804(g)(2)(B)(vii). Through FDA's Internet website and a toll-free telephone number, the Secretary shall readily make available to the public a list of notices submitted, dates of

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				submissions, and the status of the Secretary's review, including determinations of whether the import was allowed in. The Secretary shall promptly update the Internet website with any changes to the list. 804(g)(2)(C). *Notice; Drug difference requiring prior approval*. If the notice regarding an imported drug shows that the difference, if made to a U.S. label drug, would require the approval of a supplemental application to FDA, the Secretary must notify registered exporters, registered importers, the Federal Trade Commission (FTC), and the state attorneys general that the notice has been submitted. If, by the date on which the drug involved is to be introduced for commercial distribution in a

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				permitted country, the Secretary has not made a determination whether such a supplemental application would be approved, the Secretary must order that the importation of the involved drug not begin until the Secretary completes review of the notice. The Secretary must also promptly notify registered exporters, registered importers, the FTC, and the state attorneys general. If the Secretary decides that such a supplemental application regarding the U.S. label drug *would not be approved*, the Secretary shall stop its importation or continue the earlier order, if any, to hold until the review had been completed; notify the permitted country that approved the drug for commercial distribution of the determination; and promptly

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				notify registered exporters, registered importers, the FTC, and the state attorneys general of the determination. If the Secretary determines that the supplemental application regarding the U.S. label drug *would be approved*, the Secretary must vacate the hold order, if any, that had been placed on the import pending completion of the review; consider the difference to be a variation provided for in the approved application for the U.S. label drug; permit importation of the drug; and promptly notify registered exporters, registered importers, the FTC, and the state attorneys general of the determination. 804(g)(2)(D). *Notice; Drug difference not requiring prior approval*. If, under Section

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				506(A)(3)(B), the difference described in the notice would not require prior approval before it 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; notify the permitted country that approved the drug for commercial distribution of the determination; and promptly notify registered exporters, registered importers, the FTC, and the state attorneys general of

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				the determination. If the Secretary decides that a supplemental application concerning the U.S. label drug *would be approved*, the difference shall be considered a variation provided for in the approved application for the U.S. label drug. 804(g)(2)(E). *Notice; Drug difference not requiring approval; No difference.* If the difference between the U.S. label drug and the drug to be commercially distributed in a permitted country would not require a supplemental application for the U.S. label drug under Section 506(A)(d)(1)(A), or if the notice states that there is no difference, the Secretary shall consider such difference to be a variation provided for in the approved

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				application for the U.S. label drug, may not stop the importation, and must promptly notify registered exporters and importers. 804(g)(2)(F). *Differences in active ingredient, route of administration, dosage form, or strength.* A manufacturer of a drug approved under Section 505(b) [new drug approval] must submit an application under that section of the FFDCA for approval of a drug that it manufactures for distribution in a permitted country if: "there is no qualifying drug in commercial distribution in permitted countries whose combined population represents at least 50 percent of the total population of all permitted countries with the same active ingredient or ingredients, route of administration, dosage form,

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				and strength as the drug approved under Section 505(b)"; and "each active ingredient of the other drug is related to an active ingredient of the drug approved under section 505(b)...." [For purposes of this paragraph, active ingredients are related if they are "the same; or different salts, esters, or complexes of the same moiety."] The application under Section 505(b) must request approval of the drug for the indication(s) 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;

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				and include such additional information as the Secretary may require. This 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 and importers, the FTC, and the state attorneys general of a determination to approve or to disapprove an application.
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 wholesaler the information needed to authenticate the product and confirm its labeling. Also, testing	804(e). *Testing*. The importer (not the manufacturer) must conduct the testing of qualifying drugs unless the drug is subject to the counterfeit-resistant technologies requirement. (Mention is not made to a qualified laboratory. Nor is mention made here to manufacturer's labeling or protecting trade secrets and information.)	No provision.	No provision.

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	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(f)(5). *Registration of exporters; Inspection of importers and registered exporters*. The Secretary shall inspect warehouses, other facilities, and records of importers and registered exporters as often as the Secretary determines necessary to ensure compliance.	[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 HELP Committee and the House Committee on	804(d)(1). *Inspection of facilities*. To assist the Secretary to determine exporter compliance with all required conditions, the exporter must agree to permit the Secretary: to conduct on-site inspections (including monitoring on a day-to-day basis) of facilities that are exporter owned, controlled or operated that relate to qualifying drugs; to have day-to-day access to records, including financial records, and drug samples; to verify the chain of custody of a statistically significant sample of qualifying drugs, monitor markings, and sample the

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			Energy and Commerce is required on the joint activities. The Secretary may contract with a state to use State Board of Pharmacy personnel to 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.	exported drugs to assure compliance; and to carry out other functions that the Secretary determines necessary regarding compliance. The Secretary is to assign (on a continuous basis) one or more employees to perform these functions randomly, but at least 12 times a year at the exporter's places of business.
Records of chain of custody	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	804(d)(1). *Information and records.* Eliminates section of the law referring to a drug being imported directly from the first foreign recipient; correspondingly renames the list items; and deletes requirement that importer provide the Secretary with its professional license number.	[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	804(d)(3). *Certain duties relating to exporters*. The Secretary shall: randomly inspect at least 12 times annually an exporter's places of business where qualifying drugs are stored and from where they are shipped; and verify the chain of custody of a statistically significant sample of qualifying drugs from the manufacturing establishment, which may be

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	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 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.		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. [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 importation facility,	accomplished or supplemented by the use of anti-counterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of these technologies, except that no drug shall be excluded if it lacks the technologies. If exports are made to individuals for personal use, the Secretary is directed to randomly review records of those exports to determine whether the conditions required for individual imports are being met. That review process must allow a statistically significant determination of compliance. The Secretary is directed to monitor the required markings of exports. The inspectors 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

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	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; and 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		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	determine whether the exporter is in compliance with all other registration conditions.

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	health.		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.	804(d)(6). *Certain duties relating to importers*. The Secretary shall randomly inspect at least 12 times annually an importer's places of business where the qualifying drugs are initially received after importation. During these inspections, the Secretary shall: (1) verify the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the

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				importer, which shall be accomplished by the use of anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except a drug that lacks these technologies from the point of manufacture shall not be excluded from importation by an importer; (2) review prior notices of shipments and inspect, if necessary, the warehouses and other facilities, including records, of other parties in the chain of custody of qualifying drugs; and (3) determine whether the importer is in compliance with all other registration conditions.
	503(e)(1)(A) requires that anyone engaged in the wholesale distribution of a drug and who is not the manufacturer or an authorized			[Section 7(a)] *Wholesale distribution of drugs: Statements regarding prior sale, purchase, or trade; Striking of exemptions; Applicability to registered*

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	distributor of record of such drug must, before each wholesale distribution of such drug, provide to the person who receives the drug 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).			*exporters.* Amends FFDCA Section 503(e) to include an authorized distributor of record along with all wholesale distributors to retail pharmacies to provide to the person who receives the drug a statement identifying each prior sale, purchase, or trade of such drugs. Also, requires the Secretary by regulation to establish alternative requirements to identify the chain of custody through all transactions, which could include standardized anticounterfeiting or track-and-trace technologies that would identify chain-of-custody or the identity of the discrete package of the drug at least as well as the statements required by current law, and be economically and technically feasible. [Section 7(b)] Amends FFDCA Section 503(c) to require that each manufacturer of a

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				prescription drug maintain a list of authorized distributors of record, defining "*authorized distributors of record*" to mean those with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products. [Section 7(c)] Provides effective dates, including a distinction for drugs at high risk of being counterfeited.
Maintenance of Records	804(d)(2). *Maintenance by the Secretary.* Records regarding an imported prescription drug 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.	804(j). *Maintenance of records and samples*. Both importers and exporters must maintain records and samples of each lot of a drug required under this section for not less than two years. The importer shall keep the records at the place of business at which the importer initially received the drug after importation. The exporter shall keep the records at the facility from which the exporter ships

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				the qualifying drug to the United States.
Registration of exporters and importers	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(f). *Registration of exporters; Inspections.* 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 registrant.	[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;	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: for exporters, the name and identification of all places of business of the registrant, including each warehouse or other facility owned or controlled by, or operated for, the exporter; and for importers, the name and identification of up to three places of business (more with permission of the Secretary) at which the importer initially receives the qualifying drug after importation.

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			[814(b)(1)(B)] the name of each prescription drug to be imported into the United States; [814(b)(1)(C)] the name and address of an agent for service of process in the United States; and [814(b)(2)] timely notification of any change in the information.	
		The registrant agrees: to make its places of business and records available to the Secretary for onsite inspections, without prior notice, for the purpose of determining whether the registrant is in compliance with this act's requirements;		Such information as is 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. Such information is necessary to demonstrate that the *exporter* is in compliance with registration conditions relating

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				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.
		to export only qualifying drugs;		The importer or the exporter must agree not to import or export any nonqualifying drug.
		to export only to persons authorized to import the drugs;		The exporter must agree not to export a qualifying drug to anyone who is not a registered importer or an individual importing the drug for personal use or the use of a family member.
		to notify the Secretary of a recall or withdrawal of a qualifying drug in a permitted country to or from which the		The registrant must agree: to notify the Secretary of a recall or withdrawal of a drug distributed in a permitted country that the

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		drug will be imported or exported; to monitor compliance with conditions of registration and report any noncompliance promptly; to submit a compliance plan showing how the registrant will correct violations, if any; and to notify the Secretary promptly of any changes in the registration information.		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. The registrant agrees to ensure and monitor compliance with each registration condition, to promptly correct any noncompliance, to promptly report to the Secretary any such noncompliance; and to submit a plan as to how the registrant will comply with this compliance agreement. The registrant must agree to update any information provided in the registration or in the compliance plan; to notify the Secretary not more than 30 days before the registrant acts to make a change;

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				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 subsection (g). The 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. 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. The registrant must agree to enforce a contract under

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				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 permit the Secretary to inspect chain-of-custody statements to determine their accuracy and agree to facility and record inspections. The exporter agrees to comply with applicable provisions of Canadian law or the laws of the permitted countries that protect the privacy of personal information of each person importing from that exporter. 804(b)(1)(I) and (J). The exporter and importer agree to report to the Secretary not later than August 1 of each fiscal year, the total price and volume of drugs exported/imported by the exporter/importer during January through June of that

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				year; and not later than January 1 of each fiscal year the total price and volume of drugs exported/imported the previous fiscal year.
Secretary's approval or disapproval of registration	No provision.	804(f)(2). *Notice of approval or disapproval*. Within 90 days after receiving a complete registration, the Secretary must notify the registrant of the receipt of the registration, assign a registration number to the registrant, and approve or disapprove the application. The Secretary can disapprove a registration if the registrant is not in compliance with a registration condition, and may reverse the decision if he or she later finds that the registrant does comply. 804(f)(3). *List*. The Secretary shall maintain and update promptly a list of registered	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. Requires that the Secretary	804(b)(2). *Approval or disapproval of registration*. The Secretary must approve or disapprove a registration within 90 days of its submission and notify the registrant. If the registration is disapproved, the Secretary must notify the registrant as to why. After a registration has been denied, if and when the registrant is in compliance, the Secretary must notify the registrant. Within 30 days of receiving a registrant's compliance plan, described above, the Secretary must decide if the change affects the registrant's registration approval and inform the registrant. 804(b)(3). *Publication of*

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		exporters, including qualifying Internet pharmacies, and make the list available to the public on the FDA's website and via a toll-free telephone number. 804(f)(4). *Education of consumers*. The Secretary shall carry out activities (through the website and toll-free telephone number) that educate consumers about the availability of qualifying drugs for import for personal use, including how to verify whether an exporter is registered.	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.	*contact information for registered exporters.* The Secretary shall post publicly on the FDA website and via a toll-free telephone number a list of registered exporters, including the exporters' contact information, and update this information promptly. [Section 4(g)] *Consumer education*. The Secretary must act to educate consumers regarding the availability of qualifying drugs for import for personal use from a registered exporter, including information on how to verify whether an exporter is registered and approved by use of the FDA website and toll-free telephone number. The Secretary must educate consumers that the United States Customs Service (and Border Protection) may seize and destroy drugs

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				otherwise imported, and that drugs from unregistered exporters may be counterfeit, unapproved, unsafe, or ineffective. The Secretary must also educate consumers about the availability of qualifying drugs at registered domestic retail pharmacies. [Section 4(e)(2)] *Review of registration by certain exporters.* In the review of registration submissions, the Secretary must set as a priority within the first 90 days after enactment Canadian entities that are significant exporters of prescription drugs to individuals in the United States as of the date of enactment, allowing a 30-day (rather than a 90-day) review period to approve or disapprove a registration. Whether the Canadian entity exported drugs to U.S.

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				individuals on or before 90-days post enactment shall not serve as a basis for disapproving a registration. During the first year after enactment, the Secretary may limit the number of registered exporters to not less than 50, if the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States. During the second year, the allowed limit is not less than 100. After two years, the Secretary may ask Congress for authority to limit the number of registered exporters if the limitation is necessary for the effective and efficient enforcement of requirements and the limitation will not restrict the ability of individuals to import

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				prescription drugs for personal use from registered exporters. [Section 4(e)(3)] *Limits on number of importers.* During the first year after enactment, the Secretary may limit the number of registered importers to not less than 100 (of which at least a significant number shall be groups of pharmacies, as feasible), giving priority to those importers with demonstrated ability to process a high volume of shipments of drugs imported into the United States. The allowed limit for the second year is not less than 200, giving priority to importers with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States. After three years, the Secretary may ask Congress for authority to limit the number of registered importers if the

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				limitation is necessary for the effective and efficient enforcement of requirements, and the limitation will not restrict the ability of individuals to purchase qualifying imported drugs or restrict the savings available to individuals from those purchases.
			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)] Amends Section 801 by adding 801(t), *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; does not authorize the delivery of the prescription drug pursuant to the execution of a bond while the prescription drug is held under this subsection.	

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Licensing as pharmacist	No provision.	No provision.	No provision.	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 the law of the permitted country in which the exporter is located to dispense prescription drugs; and the exporter employs enough persons licensed under the law of the permitted country in which the exporter is located to dispense safely prescription drugs to individuals, and the exporter assigns to those persons responsibility for dispensing such qualifying drugs to individuals.
Appropriations	804(m). *Authorization of appropriations.* Authorizes to be appropriated such sums as are necessary to carry out this section.	Same as current law.	No provision.	No provision.

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Importer and exporter fees	No provision.	[No importer fee provision.] [Section 5] Adds a new Section 740A to the FFDCA, *Fees relating to prescription drug importation*. 740A(a-c). Requires the Secretary to establish a registration fee program. For the fiscal year in which the registered exporter first submits a registration under Section 804 (or resubmits a registration), the registered exporter will pay a fee of $10,000, payable when the exporter submits the registration. In subsequent years, the fee shall be payable on or before October 1 each year and shall be paid only once for each registered exporter. The Secretary will determine annually the amount of the fee based on the anticipated costs of enforcement of the import	[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	804(e). *Importer fees*. 804(e)(1-2). *Registration fee and inspection fee.* With its registration submission, an importer must pay the Secretary a $10,000 fee. In addition, the importer must pay the Secretary a semiannual inspection fee not later than October 1 and April 1 of each fiscal year. 804(e)(3)(A). *Aggregate total of fees*. The Secretary, in consultation with the Secretaries of Homeland Security and the Treasury and not later than 30 days before the start of each fiscal year, shall establish an aggregate total of fees to be collected for a fiscal year from all importers that is sufficient, and no more than necessary, to pay the costs of administering this section with respect to registered importers for a fiscal

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		program. The total aggregate fee collected shall not exceed 1% of the total price of the drugs exported annually to the U.S. by registered exporters. An exporter's fee shall be based on the Secretary's reasonable estimate of the exporter's annual share of the volume of drugs exported. 740A(d). Requires fees be used only for: administering this section, including the costs associated with inspecting the registered exporter facilities and other entities in the chain of custody of a qualifying drug; and developing, implementing, and maintaining a system to decide if the registered exporters are complying with the registration conditions and when shipments of qualifying drugs are offered for import. The fees shall also pay for	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 FY2006 and annually thereafter, to submit a report to the Senate HELP Committee and the House Committee on Energy and Commerce describing implementation of the user fee authority during the fiscal year and the use of the fees by the Secretary.	year. These are costs for inspecting the facilities of importers and others in the chain of custody of the drug; developing, implementing, and operating an electronic system for the submission and review of prior notices of drug shipments; and inspecting shipments, as necessary, to determine whether a shipment should be refused admission. 804(e)(3)(B). *Amount of inspection fee; Limitation.* The aggregate total of fees collected for a fiscal year shall not exceed 1% of the total price of drugs imported that year by registered importers under this section. 804(e)(3)(C). *Total price of drugs.* To estimate the total price of qualifying drugs imported in the United States by registered importers, the

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		inspecting shipments, when necessary, to determine if any should be refused admission. 740A(e). The Secretary, 60 days prior to each fiscal year (beginning after Sept. 30, 2005), must establish registration fees. 740A(f). If a fee is not paid within 30 days after it is due, the Secretary will not permit the registered exporter to export to the United States or offer drugs for exportation until all fees are paid. 740A(g). *Reports*. Within 60 days of the start of the fiscal year, the Secretary must publish the registration fees, hold a meeting where the public can comment on the recommendation, and provide a 30-day period for written		Secretary shall add the total price of qualifying drugs imported by each registered importer from January 1 to June 30 of the previous fiscal year. By March 1 of the following fiscal year, the Secretary shall calculate the total by adding the totals as reported to the Secretary. If the total price as calculated is less than the aggregate total of fees collected for that fiscal year, the Secretary must, on April 1, provide a pro-rata adjustment to each registered importer of the subsequent fiscal year. 804(e)(3)(D). *Individual importer fee.* The fee to be paid on October 1 and April 1 by an individual importer must be proportional to a reasonable estimate by the Secretary of the semiannual share of the importer of the volume of drugs imported

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		comments. Within 60 days after the end of the fiscal year when fees are collected, the Secretary shall submit to the Senate HELP Committee and the House Energy and Commerce Committee a report that describes how the registration fee authority was implemented and how the fees were used.		by all U.S. importers. 804(e)(4). *Use of fees.* Subject to appropriations acts, the fees collected by the Secretary must be credited to the appropriations account for FDA's salaries and expenses until expended without fiscal year limitation. The Secretary may, in consultation with the Secretaries of Homeland Security and the Treasury, transfer some portion of the fees to the appropriation account for salaries and expenses of the Bureau of Customs and Border Protection until expended. Fees collected by the Secretary are available only to the Secretary (and, if transferred, to the Secretary of Homeland Security) and are for the sole purpose of paying the costs of activities outlined in 804(e)(3)(A).

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				804(e)(5). *Collection of fees.* If the fees are not paid within 30 days after they are due, the fee shall be a claim of the U.S. Government (subject to subchapter II of Chapter 37, Title 31 USC). 804(f). *Exporter fees.* Requirements for exporters are similar to the requirements for importers, as above, except that the aggregate total of exporter fees must cover the costs of inspecting facilities of registered exporters and others in the chain of custody, as necessary; developing, implementing, and operating a system to screen marked shipments offered for import into the United States to indicate compliance with all registration conditions; and screening the markings and inspecting, as necessary, to determine if shipment should be

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				refused admission. [Section 4(e)(9)] *User fees.* To establish the aggregate total of fees from *exporters* for FY2006, directs the Secretary to estimate the total price of drugs imported by registered exporters that year as $1 billion. To establish the aggregate total of fees from *importers*, directs the Secretary to estimate the total price of drugs imported by registered importers as $1 billion for FY2006 and $10 billion for FY2007. Directs the Secretary to allow for reestimates and adjustments for FY2007; and to prepare and submit an annual report on the implementation of the fee authority and the use, by FDA, of those fees. Also directs the Secretary of

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				Homeland Security, in consultation with the Secretary of the Treasury, beginning in FY2006, to prepare and submit a report to Congress on the use of the fees transferred to the Bureau of Customs and Border Protection.
Packaging and anti-counterfeiting programs	Requires that all imported drugs be FDA-approved and carry the FDA-approved labeling.	[Section 6(a)] *Counterfeit-resistant technology.* Amends the FFDCA by adding a new subsection 502(v), stating that if a drug is subject to section 503(b), it shall be deemed to be misbranded unless the drug's packaging complies with requirements of section 505C for counterfeit-resistant technologies. [Section 6(b)] Amends the FFDCA by establishing a new Section 505C, Counterfeit-Resistant Technologies. The Secretary must require that the	[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	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 shall be designed to prevent unauthorized affixation, and shall include anti-counterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies. 804(d)(5). The importer must comply with similar marking

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		packaging of all prescription drugs (not just those being imported) incorporate overt optically variable counterfeit-resistant technologies (as described in (b) according to standards in (c)) or technologies that the Secretary determines to have an equivalent function of security. The technologies employed must provide visible identification of the product (without the need for readers, microscopes, lighting devices, or scanners); be similar to those used by the Bureau of Engraving and Printing to secure U.S. currency; be made and distributed in a secure environment; and should integrate non-visible security features with forensic capability.	agencies, states, and Indian tribes to ensure the safety of imported prescription drugs. [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 and addresses of all parties to the transaction). [Section 15(c)] *Anticounterfeiting provisions; Distributors of record*. Amends Section 503(e) of the FFDCA as follows. Defines	requirements, before wholesale distribution, except the markings or other technology shall not be required on a drug that bears comparable, compatible markings or technology from the manufacturer of the drug.

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		Manufacturers must incorporate the technologies into multiple elements of the packaging for prescription drugs (including blister packs, shrink wrap, package labels, package seals, bottles, and boxes). Also, shipping containers for drugs must have labels that incorporate technologies that enable inspectors to verify the authenticity of the shipment. The labels must have: chain-of-custody procedures according to contractual agreements for the use and distribution of labels; audit methods; and access to databases for government agencies to audit or verify the use of the labels. This section shall take effect 180 days after this act's enactment.	"*distributor of record*" as a person that takes title to or possession of a drug from manufacture; this includes a person that manufactures, processes, packs, distributes, receives, holds, imports, or offers for importation, and this does not include a transporter. Defines "*transporter*" 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. [Section 15(d)] *Anticounterfeiting programs.* Requires the Secretary to establish a Counterfeit Alert Network to notify health	

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			professionals and the public of counterfeit drugs; and to 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 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.	
Labeling	804(h). *Approved labeling.* Requires a drug manufacturer to give the importer written		813(b)(3,4). Requires that the container have a prominent and conspicuous label with the	804(g)(3)(A). *Labeling; Importation by registered importer.* To be considered as

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	authorization to use, at no cost, the approved labeling for the prescription drug.		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. 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	complying with FFDCA Section 502 and the labeling requirements under the U.S. label drug's approved application, a qualifying drug that an importer imports or offers for import must bear: the labeling approved for the U.S. label drug by FDA according to FFDCA Section 505, without regard to whether the copy bears the trademark; the name and location of the manufacturer; the lot number assigned by the manufacturer; the name, location, and registration number of the importer; and the National Drug Code number that the Secretary assigned to the qualifying drug. The Secretary shall provide a copy of the label to the registered importer involved, upon request of the importer. This labeling shall: (1) include

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			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.	the established name (as defined in Section 502(e)(3)) of each active ingredient; (2) not include the brand or proprietary name of the U.S. label drug or its active ingredient(s); (3) if required, include a prominent advisory notice that the qualifying drug is safe and effective but not bioequivalent to the U.S. label drug; and (4) if the inactive ingredients are different from those in the U.S. label drug, include a prominent notice that the ingredients differ. A qualifying drug with different inactive ingredients must be dispensed with an advisory to people with allergies about this difference and with a list of the ingredients of the qualifying drug as would be required under Section 502(e). 804(g)(3)(B). *Labeling;*

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				Importation by individual. A drug imported or offered for import by a registered exporter to an individual shall be considered to be in compliance with Section 502 and labeling requirements under the U.S. label drug's approved application if the packaging and labeling comply with the regulations promulgated under Sections 3 and 4 of the Poison Prevention Packaging Act of 1970 and the labeling includes directions for use by the consumer; the lot number assigned by the manufacturer; the name and registration number of the exporter; if required, a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug; a prominent advisory for persons with allergies if the inactive ingredients differ from those of the U.S. label drug, and

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				a list of the drug's ingredients as would be required under Section 502(e); 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 any trademark involved. The Secretary shall provide to the registered exporter involved a copy of the special labeling, the advisory, and the ingredient list of the drug, upon request of the exporter. The requested labeling and ingredient list shall include the established name for each active ingredient and not include the proprietary name of the U.S. drug or any of its active ingredients. 804(l). *Drug labeling.* When an imported drug is dispensed by a

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				pharmacist to an individual, the pharmacist must provide packaging and labeling that comply with all applicable regulations promulgated under Sections 3 and 4 of the Poison Prevention Packaging Act of 1970 and include with any other labeling to the individual the lot number assigned by the manufacturer, and the name and registration number of the importer. If the inactive ingredients differ from those of the U.S. label drug, the pharmacist must provide a prominent advisory that persons with allergies should check the ingredients, and also provide a list of the ingredients as would be required under FFDCA Section 502(e). If the Secretary had determined that the difference(s) in the qualifying drug would have been treated as a manufacturing change to the

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				U.S. label drug under FFDCA Section 506A, the pharmacist must provide a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug.

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Suspension and termination of importation of a product or by an importer	804(g). *Suspension of importations.* At the time of discovering a pattern of counterfeit or violative products, the Secretary must suspend importation of that specific prescription drug or by that specific importer. The suspension must stay in effect until the Secretary investigates and determines whether the public is being adequately protected from counterfeit and violative drug products under existing importation regulations. 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.	804(g)(A). *Suspension of importation.* Authorizes the Secretary to *suspend* an exporter's registration, after notice and opportunity for a hearing, for failing to maintain compliance with registration conditions. No prior notice is required if the Secretary determines the exporter has exported a non-qualifying drug or exported a qualifying drug to an individual in violation of this section. Allows the Secretary to reinstate a suspended registration if the Secretary determines that the registered exporter has demonstrated that further violations of registration conditions will not occur. 804(g)(2)(B). *Termination.* After notice and the opportunity for a hearing, the Secretary may terminate a registration if the exporter has a pattern or	[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 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.	804(b)(4). *Suspension and termination.* 804(b)(4)(A). *Suspension.* The Secretary may *suspend* a registration if, after notice and opportunity for a hearing, the exporter or importer fails to maintain substantial compliance with registration conditions. In addition, the Secretary shall suspend immediately, without prior notice, the registrant's registration if the exporter/importer has exported/imported 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

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		practice of violating one or more registration conditions, or if the exporter has had its registration suspended on one or more occasions. During the period in which a registration is terminated, any registration will have no legal effect if the exporter or a partner or principal officer of the enterprise assisted in the preparation of the registration. 804(g). *Suspension of importation.* Rather than basing reinstatement on the Secretary's determination that the public is adequately protected, the decision would be based on the Secretary's determination that the violation has been corrected and that the importer has demonstrated that further violations will not occur. It also specifies that this	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.	would be no further violations, the Secretary may reinstate the suspended registration. 804(b)(4)(B). *Termination.* Same as S. 109. 804(b)(5). *Default of bond.* After opportunity for an informal hearing, the exporter's bond shall be defaulted and paid to the U.S. Treasury if the exporter: shipped a non-qualifying drug or a drug not in compliance with FFDCA Section 505(b) for the U.S. label drug [new drug applications], or Section 501 [adulteration]; required conditions for shipment to an individual; or failed to permit an inspection.

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		subsection does not apply to a drug imported by an individual or shipped to an individual by a qualifying Internet pharmacy.	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.	
Prior notice of shipments	No provision.	No provision.	[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	804(d)(4). *Prior notice of shipments*. A condition of registration is that the importer of the prescription drug must give the Secretary advance (between 8 hours and five days) notice of the name and contact person submitting the notice and

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			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, address, telephone number, and professional license number of the drug importation facility located in Canada or a permitted country; and	the importer; the established name of the drug, its quantity, manufacturer lot number, name of manufacturer and production facility; country from which drug will be shipped and shipper's contact information; anticipated arrival information including port of arrival, crossing location, and the date and time; a summary of the chain of custody of the drug from the establishment where manufactured to the importer; and declaration whether the Secretary has ordered that imports cease from the permitted country as a result of review or pending review of differences from the U.S. label drug; and other information that the Secretary may require by regulation.

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			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 the drug at the point of entry.	
Enforcement	FFDCA Section 301(aa) prohibits the importation of a prescription drug in violation of Section 804, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.	[Section 7] *Prohibited acts.* Amends the FFDCA to insert new subsection 301(l), adding failure to register in accordance with Section 804(f) or to import or offer to import a drug in violation of a suspension order under Section 804(g) (relating to being suspended from importation).	[Section 2(c)] *Prohibited act.* Amends Section 301 of the FFDCA 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).	[Section 4(b)] *Prohibited acts.* Amends FFDCA by replacing Section 301(aa) to prohibit the sale or trade by a pharmacist, or by a business organization of which the pharmacist is a part, of a qualifying drug that the pharmacist imported unless the drug sold at retail is dispensed to a customer of the pharmacist or organization or is sold or traded to a pharmacy or wholesaler

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				registered to import drugs; prohibit an individual who imports a drug for personal use from selling or trading that drug; prohibit the making of false, fictitious, or fraudulent statements in filing a notice or application regarding differences between the qualifying and the U.S. label drug, or to fail to submit such notice; and prohibit the falsification of any record required by the Secretary or any registration conditions. Amends FFDCA Section 303(a), by requiring violators of 301(i)(2-3) or 301(aa)(4) to be imprisoned not more than 10 years, fined, or both.
			[Section 7] *Debarment for repeated or serious drug importation violations*. Amends Section 306(b) of the FFDCA to allow the Secretary	

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			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. Amends FFDCA by adding Section 801(s), *Importation of*	

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			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 person if that person shows, at their own expense, that the drug complies with FFDCA requirements.	
Warning notices	801(g). Prohibits the Secretary from sending a warning notice (i.e., a communication from the Secretary notifying or clearly			[Section 4(c)] *Amendment of certain provisions.* Replaces FFDCA Section 801(g). Requires that, if a drug is imported or offered for import

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	suggesting to a person that importing the drug for personal use is or appears to be a violation of this act) to an individual not in the business of importation with respect to a drug being imported or offered for import into the United States unless the import is or appears to be: in violation of Section 801(a) [Imports and Exports] if the drug is or appears to be adulterated, misbranded, or in violation of FFDCA Section 505 [New Drugs]; forbidden or restricted in sale in the country in which it was produced and from which it was exported; in violation of Section 801(d)(1) [regarding insulin]; or otherwise in violation of federal law. The notice must state the reasons underlying the determination made by the Secretary, including a brief			by an individual not in the business of such importation, not shipped by a registered exporter, and refused admission, the Secretary notify the individual that the drug was refused admission because it was not a lawful import and is not otherwise subject to a waiver; and that the individual may lawfully import from a registered exporter and can find information, including a list of registered exporters, on the FDA's website or toll-free telephone number.

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	application of the principal facts involved in the provision of law that is the basis of the determination.			
Unfair and discriminatory acts and practices		[Section 9(a)] Adds subsection 804(l), *Unfair or discriminatory acts and practices*, to make it unlawful for a manufacturer, directly or indirectly (including being a party to a licensing or other agreement) to discriminate or act unfairly against an exporter, importer, or person who distributes, sells, or uses prescription drugs imported to the United States under Section 804 by: charging a higher price; denying, restricting, or delaying supplies; or refusing to do business. It is also unlawful to cause there to be a difference (including a difference in active ingredient, route of administration, dosage form,		804(n)(1). *Unfair and discriminatory acts and practices.* Makes it unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing or other agreement) to: discriminate against a registered exporter or other person in a permitted country that exports a qualifying drug to the United States, a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States by charging a higher price; denying, restricting, or delaying supplies; publicly, privately, or otherwise refusing to do business with a registered

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		strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between the drug for distribution in the United States and the prescription drug for distribution in a permitted country for the purpose of restricting importation of the drug into the United States; to refuse to allow a required inspection or fail to conform to good manufacturing practice; or to become a party to a licensing or other agreement that fails to provide for compliance with all requirements of this section, or that would have the effect of prohibiting the drug's importation; or to engage in any other action that the FTC determines to discriminate against a person that engages in, or to impede, delay, or block the process for, the importation		exporter, registered importer, or other person that distributes, sells, or uses a qualifying imported drug; to knowingly fail to submit notices required by this act regarding differences between the qualifying drug and the U.S. label drug; to fail to submit them by required dates; or to knowingly submit false statements to fail to provide promptly information the Secretary requests to review the notice; to cause there to be a difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment or process, or person that manufactures the drug) between a drug for distribution in the US

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		of the drug under this section.		and in the permitted country; to refuse to allow authorized inspection of an establishment that manufactures the drug for commercial distribution in a permitted country; to fail to conform to good manufacturing practice of methods or facilities used for manufacturing, processing, packing, or holding a drug to be commercially distributed in a permitted country; to be a party to a licensing or other agreement related to a qualifying drug that fails to provide for compliance with all requirements of this section; to enter into a contract that restricts, prohibits, or delays the importation of a qualifying drug; to engage in any other action to restrict, prohibit, or delay the

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				importation of a qualifying drug; or to engage in any other action that the FTC determines to discriminate against a person that engages or attempts to engage in the importation of a qualifying drug under this section.
		[Section 9(a)] The new subsection 804(l)(2,3) addresses *Affirmative defense, and Presumption and affirmative defense*. An entity charged with any of the unfair or discriminatory acts and practices listed in this section has a defense to these charges if its actions are based at least in part on any reason other than a reason relating to the person exporting, importing, distributing, selling, or using an imported drug. An affirmative defense can also be based on the presumption that the		804(n)(2) addresses *Affirmative defense; Discrimination and drug differences*. Similar to S. 109 in that the presumption of affirmative defense is based on the same language. But in addition, the drug differences can also be used as an affirmative defense if the person manufacturing the drug for U.S. distribution has notified the Secretary that the drug for U.S. distribution is not different from a drug for distribution in permitted countries whose combined population represents at least 50% of the total

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		difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, is required by the country in which the drug is distributed; or the Secretary has determined that the difference was necessary to improve the safety or effectiveness of the drug.		population of all permitted countries; or if the difference was not caused, in whole or in part, for the purpose of restricting importation of the drug into the United States.
		804(l)(4)(A). *Sales in other countries.* Specifies that the subsection applies only to the sale or distribution of a prescription drug in a country if the manufacturer of the drug chooses to sell or distribute the drug in the country. Does not compel the manufacturer of a drug to distribute or sell the drug in a country.		804(n)(3)(A). *Sales in other countries*. Same as S. 109.
		804(l)(4)(B). *Discounts to insurers, health plans, pharmacy benefit managers,*		804(n)(3)(B). *Discounts to insurers, health plans, pharmacy benefit managers, and covered*

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		and covered entities. This act does not: (i) prevent or restrict a drug manufacturer from providing discounts to an insurer, health plan, pharmacy benefit manager in the U.S., or a covered entity in the drug discount program under drug pricing agreements authorized in the Public Health Service Act in return for inclusion of the drug on a formulary; (ii) require that such discounts be made available to other prescription drug purchasers; or (iii) prevent or restrict any other measures taken by an insurer, health plan, or pharmacy benefit manager to encourage consumption of a prescription drug. 804(l)(5). *Enforcement; Unfair or discriminatory act or practice; and Actions by the commission*. A violation of this		*entities*. Same as S. 109. 804(n)(4). Same as S. 109. In addition to allowing the FTC to seek monetary relief threefold the damages sustained, allows

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		new subsection shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under Section 18(a)(1)(B) of the Federal Trade Commission (FTC) Act. The FTC must enforce this section as if the same terms and jurisdiction, powers and duties of the FTC under Section 18(a)(1)(B) were incorporated into this section. The FTC may seek threefold damages as monetary relief. 804(l)(6). *Unfair or discriminatory acts and practices; Actions by states*. A state attorney general may bring a civil action in an appropriate U.S. district court to enjoin an unfair or discriminatory act or practice; enforce compliance; obtain damages, restitution, or other compensation on behalf of residents and persons doing		any other remedy available to the FTC under the FTC Act. 804(n)(5-7). *Actions by States.* Similar to S. 109.

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		business in the state, including three-fold damages; or obtain further relief as the court may deem appropriate. The state must provide a written prior notice to the FTC of the civil action and provide the FTC with a copy of the complaint except if it is not feasible to provide prior notice, then the state can serve the notice immediately upon instituting such an action and provide a notice and complaint copy to the FTC at the same time as the attorney general files the action. Once it receives the notice, the FTC has the right to intervene, to be heard on all matters, and to file petitions for appeal. Nothing in this chapter shall prevent a state attorney general from exercising the powers conferred on the attorney general by the		

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		laws of the state to conduct investigations or administer oaths or affirmations or to compel witnesses to attend or to produce documentary or other evidence. A state may not institute an action against the same defendant named in a complaint instituted by or on behalf of the FTC for a violation during the pendency. However, a state attorney general may intervene on behalf of the state's residents in an FTC action and, if so, the attorney general must be heard with respect to any matter that arises in that action and to file a petition for appeal. All civil actions brought before a U.S. district court may be brought where venue is proper under 28 USC §1391. The process may be served in any		

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		district in which the defendant lives or may be found. Any enforcement action taken by the FTC or a state attorney general will be forever barred unless it begins within five years after the FTC or the state attorney general knew that the cause of action accrued. No barred action under the existing law on the effective date of this act shall be revived by this act. If a defendant has been found to have violated a provision, damages may be assessed in the aggregate by statistical or sampling methods, by computing illegal overcharges, or by other systems of estimating aggregate damages as the court may deem appropriate without separately proving the individual claim of or amount of damage to persons on whose behalf the suit was		

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		brought. The district court must exclude from the monetary award any monetary relief that duplicates the amounts already awarded for the same injury. 804(l)(6)(G). *Limitation of actions.* 804(l)(7). *Effect of antitrust laws*. Nothing in this new subsection shall be construed to modify, impair, or supercede the operation of federal antitrust laws. [Section 9(b)] *Regulations.* The FTC shall promulgate regulations to carry out the enforcement program under new Section 804(1) of the FFDCA.		[Section 6] *Civil actions regarding property*. Amends FFDCA Section 303 by adding

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				Section 303(g) that allows the Attorney General to commence civil action in any federal court to stop a person from alienating or disposing of property relating to a drug imported in violation of Section 801(a or d), with proceedings in a manner as applies under 18 USC 1345 and to take effect 90 days after enactment.
Drugs refused admission	FFDCA Section 801 prohibits the importation of a prescription drug by anyone other than its manufacturer. The Secretary works with the Secretary of the Treasury to refuse admission of all other drugs. [Note: The U.S. Customs Service had been part of the Dept. of the Treasury until Congress created the Dept. of Homeland Security, which includes customs functions in its U.S. Customs	740A(d). In listing the allowed uses of collected fees, includes inspections necessary to determine whether a shipment should be refused admission.	[Section 11] *Authority to mark prescription drugs refused admission into the United States.* Further 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 "UNITED STATES: REFUSED ADMISSION" until the Secretary determines that the prescription drug has been	804(g)(5). *Standards for refusing admission.* A drug from a registered exporter may be refused entry into the United States if one or more of the following applies: the drug is not a qualifying drug; a notice for the drug has not been submitted to the Secretary; the Secretary has ordered that imports of the drug from the permitted country cease because differences from the U.S. label drug would not have been

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	and Border Protection component.]		brought into compliance with this act. The owner or consignee shall be responsible for all labeling expenses. 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 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.	approved in a supplemental application; the drug does not comply with the labeling requirements; the shipping 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, may have been prepared, packed, or held under insanitary conditions, or the methods used in or the facilities or controls used for the manufacturing processing, packing, or holding do not conform to good manufacturing processes; the Secretary has obtained an injunction under Section 302 prohibiting the drug's distribution in interstate commerce or has withdrawn the approval of the drug under Section 505(e); the manufacturer has instituted a recall of the drug; the drug is imported or

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				offered for import by a registered importer without submission of a prior notice of shipment; or the drug is imported or offered for import from a registered exporter to an individual and the shipping container does not bear the required markings, the container's markings appear to be counterfeit, or the shipping container or markings appear to have been tampered with. 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 5(a)] Creates in the	[Section 5] *Disposition of*

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			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 detained for up to 30 days, labeled as detained and placed 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	*certain drugs denied admission into United States.* Adds a new FFDCA Section 805. 805(a-c). The Secretary of Homeland Security shall deliver to the HHS Secretary a drug shipment (1) that has a declared value less than $10,000 and whose shipping container does not bear required markings [of compliance], or (2) of which the HHS Secretary has requested delivery. The new section does not authorize delivery pursuant to a bond, nor may the drugs be exported. The HHS Secretary must destroy these shipments if the drugs violate any standard described in Sections 804(g)(5) [standards for refusing admission], 801(a) [imports and exports], or 801(d)(1) [prohibition of importation of an insulin product by other than its manufacturer].

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			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. [Note: The U.S. Customs Service had been part of the Dept. of the Treasury until Congress created the Dept. of Homeland Security, which includes customs functions in its U.S. Customs and Border Protection component.] 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	805(d-f). Sets out procedures to identify and destroy a substantial majority of violative shipments, allowing for preservation of potential evidence, while efficiently using federal resources. [Section 5(b-c)] Requires that procedures to carry out Section 805 be established not later than 90 days after enactment at which time they would take effect.

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			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.	
Drugs recalled	No provision.	No provision.	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.	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 qualifying prescription drugs in the

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				country; or monitor recalls and withdrawals of prescription drugs in permitted countries 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 qualified drug in a permitted country.
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	[Section 4(h)] Amends FFDCA Section 804(j), *Waiver authority for individuals.* Within 180 days of enactment, the Secretary shall by regulation permit an individual to import a drug from a permitted country if it is a qualifying drug; imported from a licensed pharmacy or qualifying Internet pharmacy; for personal use by an	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;	804(i)(1). *Individuals; Conditions for importation.* An individual may import 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 or receives care from the practitioner, is authorized to administer

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	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	individual or family member and not for resale; does not exceed a 90-day supply during any 90-day period; and has with it a copy of a prescription, valid under state and federal laws, that was issued by a practitioner authorized to administer prescription drugs. An individual may import a drug from a non-permitted country if the individual while traveling in the country received the drug with a valid prescription under that country's laws and regulations, enters the United States with the drug, and the drug is approved for commercial distribution in the country where it was obtained, does not appear to be adulterated, and does not exceed a 14-day supply.	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	prescription drugs; the drug is accompanied by documentation required by the permitted country in which the exporter is located to dispense the drug to the individual; copies of the U.S. prescription and the permitted country's documentation must be marked to indicate the prescription has been filled and to prevent duplicative filling by another pharmacist; 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; and the quantity of the drug does not exceed a 90-day supply. Ineligible for importation is a drug approved under accelerated procedures for serious or life-threatening illness with restrictions to assure safe use (21 CFR 314 subpart H) and for which the Secretary has

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	ensure public safety.		continuation of personal use by the individual for treatment, begun in a foreign country, of a serious medical condition.	published a *Federal Register* notice stating there is good cause to refuse the import of this drug.
Rulemaking deadlines	No provision.	No provision.	[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].	[Section 4(e)(f)] The Secretary may promulgate an interim rule for implementing Section 804 and may do so without providing general notice of proposed rulemaking. The Secretary must promulgate a final rule not later than one year after promulgation date of interim rule.
Effective dates	No provision.	804(b). Directs the Secretary to promulgate regulations permitting commercial importation of qualifying drugs from permitted countries not later than 180 days after enactment. 804(j). Directs the Secretary to permit, by regulation, personal-use importation not later than 180 days after enactment.	[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 4(e)(1)] Section 804 shall permit the importation of qualifying drugs without regard to the issuance of implementing regulations (1) from registered exporters 90 days after the act's enactment, and (2) from permitted countries by registered importers one year after the date of enactment.

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			[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.	
Internet pharmacies	No provision.	[Section 4] Includes various references to Internet pharmacies. 804(a)(7). Defines "*qualifying Internet pharmacy*" as a registered exporter that dispenses qualifying drugs to individuals over an Internet website.	[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 fund transfer*," "*financial institution*," "*money transmitting business*," and "*money transmitting service*."	[Section 8] *Internet sales of prescription drugs.* Adds to the FFDCA a new Section 503B. 503B(e). Defines "*practitioner*" and "*prescription drug*" as in Section 503(b)(1), and "*qualifying medical relationship*" as in new Section 503B(b). 503B(f). Defines "*Internet*," "*link*," "*page*," "*site*" and "*address*," "*domain name*," and "*Internet Protocol numbers*" and allows the Secretary to modify

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				any definition to account for changes in technology. 503B(a). *Requirements regarding information on Internet site.* Makes it illegal, in general, for anyone to "dispense a prescription drug pursuant to a sale of the drug by such person" unless the person provides certain required information on each page of the site or a link to a page with that information. These items are: the name of the dispensing person; each state in which that person is authorized by law to dispense drugs; the address and telephone number of each place of business of the person that sells drugs through the Internet; the name of each person who serves as a pharmacist for drugs mailed or shipped from that site's business and each state in which that person is authorized by law to
		804(f)(3). Includes qualifying Internet pharmacies among registered exporters that the Secretary must list. 804(g)(2). Excludes a prescription drug shipped to an individual by a qualifying Internet pharmacy from certain importation suspension authority of the Secretary. 804(j)(1)(B). Includes qualifying Internet pharmacies in directing the Secretary to permit by regulation an individual to import a drug from a permitted country.	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 for a prescription drug made to an unlicensed Internet pharmacy 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.	

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			511(b,c). *Licensing of Internet pharmacies.* To dispense a prescription drug to a person in the United States, requires that an Internet pharmacy be licensed with the Secretary and have its principal place of business in the United States, Canada, or a permitted country. In each state in which an Internet pharmacy seeks to dispense prescription drugs, requires that the license application include verification of compliance 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, requires verification regarding compliance with applicable laws of that country. Also requires the application to	dispense drugs; and, if the person provides for medical consultations through the site for purposes of providing prescriptions, then the name of the person doing the consultations, each state in which that person is authorized by law to do so or practice medicine, and the types of health professions for which the person holds a license or other authorization. The site shall also have the words "licensing and contact information" with a link displayed in a clear and prominent place and manner. 503B(d). Excludes a registered exporter from this section.

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			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; the names of all states or countries where the pharmacy and pharmacists are licensed or otherwise authorized to dispense prescription drugs; the name, address, telephone number, and state of licensure of any health	

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			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. *Licensure procedure*. Requires that the Secretary assign an ID number, notify the 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.	

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			511(c)(5). *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 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	

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			the implementation of the licensing fee authority and the use of the collected fees. 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. *Professional services requirements.* Requires an Internet pharmacy to maintain	503B(b). *Internet sales without appropriate medical relationships.* No one can

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			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 a system to inform about drug recalls, educate about disposal of medications, assure the 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	dispense or sell a drug if: the purchaser or patient communicated through the Internet and did not, when communications began, have a valid U.S. prescription; the dispensing person provided for a practitioner's involvement, or for someone the person represented as a practitioner and that person issued a prescription for the drug that was purchased; and the dispenser knew or had reason to know that the individual referred to as the practitioner did not have a qualifying medical relationship with the patient and the dispenser received payment for dispensing the drug. Such conditions do not apply to dispensing or selling a drug pursuant to telemedicine practices sponsored by a hospital or certain group practices of at

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			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 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 the prescription is inaccurate or expired, the Internet pharmacy may not fill the prescription. The Internet pharmacy must maintain records of direct communications with treating providers.	least 100 physicians with provider agreements under Medicare, or if the Secretary determines the practice promotes the public health. To have a "qualifying medical relationship with the patient," the practitioner must have conducted at least one in-person medical evaluation of the patient, or the practitioner conducts an evaluation as a covering practitioner. An "in-person medical examination" requires the physical presence of the patient as part of the evaluation, without regard to whether other health professionals conduct other portions of the evaluation. Covering practitioners are practitioners who conduct a medical evaluation of the patient at the request of a practitioner who previously has conducted

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				an in-person medical evaluation but is temporarily unavailable to conduct the evaluation of the patient. Someone who is not a practitioner lacks the legal capacity to have a qualifying medical relationship with any patient. This section does not prohibit conduct that is a standard practice of pharmacy. The qualifying medical relationship requirement applies only to this section and does not affect interpretation of state law concerning the practice of medicine.
			511(d). *Providers of interactive computer services or advertising services.* Establishes that these providers are liable if they accept advertising for a prescription drug from an unlicensed	503B(g). *Interactive computer service; Advertising.* If the provider of an interactive computer service (as defined in Communications Act of 1934 [47 USC 230(f)(2)]) or of advertising services does not

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			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 FTC and other federal functional regulators (as defined in the Gramm-Leach-	own or exercise corporate control over a person selling or dispensing drugs in violation of this section, the provider shall not be held liable for that selling or dispensing. [Section 8] Lists dispensing or selling a drug in violation of Section 503B as a prohibited act. It also directs the Secretary to consider practices and procedures of public and private entities that certify as legitimate businesses selling prescription drugs through Internet sites, including practices and procedures regarding disclosure formats and verification programs. Authorizing appropriations of $100,000 for each of FY2005-FY2007, directs the Secretary to make an award or contract to the National Clearinghouse on

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			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 was 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 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	Internet Prescribing (operated by the Federation of State Medical Boards) to identify (and report to state licensing boards, the Attorney General, and the Secretary) Internet sites that appear to violate laws concerning drug dispensing, and to report annually to the Secretary describing investigations.

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			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	

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			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 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	

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			and that the Secretary return it 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 of the reason. Prohibits the return of a prescription drug that is required to be destroyed.	503B(c). *Actions by states.* State attorney general can bring a civil action on if he or she believes that the state's residents have been or were threatened or adversely affected by someone engaging in a pattern or practice that violates Section 301(l), and may obtain reasonable attorneys fees and costs if the state prevails in the civil action or obtain further relief as the court may deem appropriate. The

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				state must serve prior written notice upon the Secretary and provide a copy of the complaint. The Secretary then shall have the right to intervene. Does not prohibit an authorized state official from proceeding in state court.
Prohibition of port shopping	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 available to the public on an Internet website.	No provision.

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			[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.	
Patents	No provision.	[Section 8] *Patents*. Amends the Patent and Trademark Act, Patents and Protection of Patent Rights [35 U.S.C. Section 271], which defines the protection of patent rights and infringement	No provision.	[Section 4(d)] *Exhaustion*. Same as S. 109 Section 8. Patents. [Amends Section 271 of Title 35 USC by inserting a new subsection (h) that would reverse judicial precedent holding that

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		of a patent, by inserting subsection 271(h), stating that it would not be an act of infringement to use, sell, or offer to sell a patented prescription drug under Section 804 of the FFDCA if the drug were first sold abroad by or under the authority of the owner or licensee of such patent.		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 into the United States without regard to the U.S. patent.]
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 prescription drug donated or otherwise supplied at no charge by the manufacturer to a charitable or humanitarian organization or foreign government.	[Section 9(a)] Adds Section 804(l)(4)(C), *Charitable contributions.* Amends current law to include a drug supplied at nominal cost by a manufacturer. Also specifies that this subsection should not prevent a manufacturer from making these transactions.	813(g). *Charitable contributions.* Same as current law.	804(m) and 804(n)(3)(C). *Charitable contributions.* Same as S. 109.

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Controlled substances exemption	No provision.	No provision.	[Section 16(a)] *Conforming amendments.* Repeals Section 1006 of the Controlled Substances Import and Export Act.	[Section 9] *Importation exemption under Controlled Substances Import and Export Act.* Amends Section 1006(a)(2) of the Controlled Substances Import and Export Act by substituting a 10 dosage unit limit for the current 50 dosage unit limit for importation.