section (a) of this section on trade and patent rights under Federal law.

(B) Report

Not later than 2 years after the effective date of final regulations under subsection (a) of this section, the Secretary shall prepare and submit to the Congress a report describing the findings of the study under subparagraph (A).

(2) Study by General Accounting Office

The Comptroller General of the United States shall conduct a study to determine the effect of this section on the price of covered products sold to consumers at retail. Not later than 18 months after the effective date of final regulations under subsection (a) of this section, the Comptroller General shall prepare and submit to the Congress a report describing the findings of such study.

(j) Construction

Nothing in this section shall be construed to limit the statutory, regulatory, or enforcement authority of the Secretary relating to the importation of covered products, other than with respect to section 381(d)(1) of this title as provided in this section.

(k) Definitions

(1) Covered product

(A) In general

For purposes of this section, the term ''covered product'' means a prescription drug, except that such term does not include a controlled substance in schedule I, II, or III under section 812(c) of this title or a biological product as defined in section 262 of title 42.

(B) Charitable contributions; parenteral drugs

Notwithstanding any other provision of this section, section 381(d)(1) of this title—

(i) continues to apply to a covered product donated or otherwise supplied for free by the manufacturer of the drug to a charitable or humanitarian organization, including the United Nations and affiliates, or to a government of a foreign country; and

(ii) continues to apply to a covered product that is a parenteral drug the importation of which pursuant to subsection (a) of this section is determined by the Secretary to pose a threat to the public health.

(2) Other terms

For purposes of this section:

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

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

(C) The term ''prescription drug'' means a drug subject to section 353(b) of this title.

(D) The term ''qualifying laboratory'' means a laboratory in the United States that has been approved by the Secretary for purposes of this section.

(E) The term ''wholesaler'' means a person licensed as a wholesaler or distributor of prescription drugs in the United States pursuant to section 353(e)(2)(A) of this title. Such term does not include a person authorized to import drugs under section 381(d)(1) of this title.

(*l*) Conditions

This section shall become effective only if the Secretary demonstrates to the Congress that the implementation of this section will—

(1) pose no additional risk to the public's health and safety; and

(2) result in a significant reduction in the cost of covered products to the American consumer.

(m) Sunset

Effective upon the expiration of the 5-year period beginning on the effective date of final regulations under subsection (a) of this section, this section ceases to have any legal effect.

(June 25, 1938, ch. 675, §804, as added Pub. L. 106–387, §1(a) [title VII, §745(c)(2)], Oct. 28, 2000, 114 Stat. 1549, 1549A–36.)

TRANSFER OF FUNCTIONS

For transfer of functions, personnel, assets, and liabilities of the United States Customs Service of the Department of the Treasury, including functions of the Secretary of the Treasury relating thereto, to the Secretary of Homeland Security, and for treatment of related references, see sections 203(1), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

FINDINGS

Pub. L. 106–387, §1(a) [title VII, §745(b)], Oct. 28, 2000, 114 Stat. 1549, 1549A–35, provided that: ''The Congress makes the following findings:

''(1) The cost of prescription drugs for Americans continues to rise at an alarming rate.

''(2) Millions of Americans, including Medicare beneficiaries on fixed incomes, face a daily choice between purchasing life-sustaining prescription drugs, or paying for other necessities, such as food and housing.

''(3) Many life-saving prescription drugs are available in countries other than the United States at substantially lower prices, even though such drugs were developed and are approved for use by patients in the United States.

''(4) Many Americans travel to other countries to purchase prescription drugs because the medicines that they need are unaffordable in the United States.

''(5) Americans should be able to purchase medicines at prices that are comparable to prices for such medicines in other countries, but efforts to enable such purchases should not endanger the gold standard for safety and effectiveness that has been established and maintained in the United States.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 333, 381 of this title.

SUBCHAPTER IX—MISCELLANEOUS

§ 391. Separability clause

If any provision of this chapter is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the