

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

constitutionality of the remainder of the chapter and the applicability thereof to other persons and circumstances shall not be affected thereby.

(June 25, 1938, ch. 675, §901, 52 Stat. 1059.)

§ 392. Exemption of meats and meat food products

(a) Law determinative of exemption

Meats and meat food products shall be exempt from the provisions of this chapter to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended [21 U.S.C. 601 et seq.].

(b) Laws unaffected

Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of section 351 of Public Health Service Act [42 U.S.C. 262] (relating to viruses, serums, toxins, and analogous products applicable to man); the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913 (37 Stat. 832-833) [21 U.S.C. 151 et seq.]; the Filled Cheese Act of June 6, 1896 (U.S.C., 1934 ed., title 26, ch. 10), the Filled Milk Act of March 4, 1923 [21 U.S.C. 61 et seq.]; or the Import Milk Act of February 15, 1927 [21 U.S.C. 141 et seq.].

(June 25, 1938, ch. 675, §902(b), (c), 52 Stat. 1059; Pub. L. 90-399, §107, July 13, 1968, 82 Stat. 353.)

REFERENCES IN TEXT

The Meat Inspection Act, approved March 4, 1907, as amended, referred to in subsec. (a), is act Mar. 4, 1907, ch. 2907, titles I to IV, as added Dec. 15, 1967, Pub. L. 90-201, 81 Stat. 584, which are classified generally to subchapters I to IV (§601 et seq.) of chapter 12 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables.

Act of March 4, 1913, referred to in subsec. (b), is act Mar. 4, 1913, ch. 145, 37 Stat. 828, as amended. The provisions of such act referred to relating to viruses, etc., applicable to domestic animals, are contained in the eighth paragraph under the heading “Bureau of Animal Industry”, 37 Stat. 832, as amended, popularly known as the Virus-Serum-Toxin Act, which is classified generally to chapter 5 (§151 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 151 of this title and Tables.

The Filled Cheese Act of June 6, 1896 (U.S.C., 1934 ed., title 26, ch. 10), referred to in subsec. (b), is act June 6, 1896, ch. 337, 29 Stat. 253, as amended, which had been classified to chapter 10 (§1000 et seq.) of Title 26, Internal Revenue, and included as chapter 17 (§2350 et seq.) of Title 26, Internal Revenue Code of 1939. Such chapter 17 was covered by section 4831 et seq. of Title 26, Internal Revenue Code, prior to the repeal of section 4831 et seq. of Title 26 by Pub. L. 93-490, §3(a)(1), Oct. 26, 1974, 88 Stat. 1466.

The Filled Milk Act of March 4, 1923, referred to in subsec. (b), is act Mar. 4, 1923, ch. 262, 42 Stat. 1486, as amended, which is classified generally to chapter 3 (§61 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 61 of this title and Tables.

The Import Milk Act of February 15, 1927, referred to in subsec. (b), is act Feb. 15, 1927, ch. 155, 44 Stat. 1101, as amended, which is classified generally to subchapter IV (§141 et seq.) of chapter 4 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 141 of this title and Tables.

CODIFICATION

Subsecs. (a) and (b) of this section comprise respectively subsecs. (b) and (c) of section 902 of act June 25, 1938. Subsecs. (a) and (d) of section 902 of act June 25, 1938, which prescribed the effective date of this chapter and made appropriations available, are set out as notes under section 301 of this title and this section, respectively.

AMENDMENTS

1968—Subsec. (b). Pub. L. 90-399 substituted “section 262 of title 42 (relating to viruses, serums, toxins, and analogous products applicable to man)” for “the virus serum, and toxin Act of July 1, 1902” and inserted reference to “the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913”.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90-399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90-399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

AVAILABILITY OF APPROPRIATIONS

Section 902(d) of act June 25, 1938, provided that: “In order to carry out the provisions of this Act which take effect [see section 902(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title] prior to the repeal of the Food and Drugs Act of June 30, 1906, as amended [sections 1 to 15 of this title], appropriations available for the enforcement of such Act of June 30, 1906, are also authorized to be made available to carry out such provisions.”

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 679 of this title.

§ 393. Food and Drug Administration

(a) In general

There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the “Administration”).

(b) Mission

The Administration shall—

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that—

(A) foods are safe, wholesome, sanitary, and properly labeled;

(B) human and veterinary drugs are safe and effective;

(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;

(D) cosmetics are safe and properly labeled; and

(E) public health and safety are protected from electronic product radiation;

(3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and

(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medi-