establishes a framework for achieving mutual recognition of good manufacturing practices inspections.

(5) Paragraphs (1) through (4) shall not apply with respect to products defined in section 321(ff) of this title.

(June 25, 1938, ch. 675, § 803, as added Pub. L. 101–629, § 15(a), Nov. 28, 1990, 104 Stat. 4525; amended Pub. L. 105–115, title IV, § 410(b), Nov. 21, 1997, 111 Stat. 2373.)

AMENDMENTS

1997—Subsec. (c). Pub. L. 105–115 added subsec. (c).

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of this title.

REPORT ON ACTIVITIES OF OFFICE OF INTERNATIONAL RELATIONS

Section 15(b) of Pub. L. 101–629 directed Secretary of Health and Human Services, not later than 2 years after Nov. 28, 1990, to prepare and submit to the appropriate committees of Congress a report on the activities of the Office of International Relations under 21 U.S.C. 383.

§ 384. Importation of covered products

(a) Regulations

The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import into the United States covered products.

(b) Limitation

Regulations under subsection (a) of this section shall—

(1) require that safeguards be in place to ensure that each covered product imported pursuant to such subsection complies with section 355 of this title (including with respect to being safe and effective for its intended use), with sections 351 and 352 of this title, and with other applicable requirements of this chapter;

(2) require that an importer of a covered product pursuant to subsection (a) of this section comply with the applicable provisions of this section, including subsection (d) of this section; and

(3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of such products.

(c) Records

Regulations under subsection (a) of this section shall require that records regarding the importation of covered products pursuant to such subsection be provided to and maintained by the Secretary for a period of time determined to be necessary by the Secretary.

(d) Importation

Regulations under subsection (a) of this section shall require an importer of a covered product pursuant to such subsection to provide to the Secretary the following information and records:

(1) The name and amount of the active ingredient of such product and description of the dosage form.

(2) The date that the product is shipped and the quantity of the product that is shipped, points of origin and destination for the product, the price paid for the product by the importer, and (once the product is distributed) the price for which such product is sold by the importer.

(3) Documentation from the foreign seller specifying the original source of the product and the amount of each lot of the product originally received.

(4) The manufacturer's lot or control number of the product imported.

(5) The name, address, and telephone number of the importer, including the professional license number of the importer, if any.

(6) For a product that is coming directly from the first foreign recipient of the product from the manufacturer:

(A) Documentation demonstrating that such product came from such recipient and was received by the recipient from such manufacturer.

(B) Documentation of the amount of each lot of the product received by such recipient to demonstrate that the amount being imported into the United States is not more than the amount that was received by the recipient.

(C) In the case of the initial imported shipment, documentation demonstrating that each batch of such shipment was statistically sampled and tested for authenticity and degradation.

(D) In the case of all subsequent shipments from such recipient, documentation demonstrating that a statistically valid sample of such shipments was tested for authenticity and degradation.

(E) Certification from the importer or manufacturer of such product that the product is approved for marketing in the United States and meets all labeling requirements under this chapter.

(7) For a product that is not coming directly from the first foreign recipient of the product from the manufacturer:

(A) Documentation demonstrating that each batch in all shipments offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

(B) Certification from the importer or manufacturer of such product that the product is approved for marketing in the United States and meets all labeling requirements under this chapter.

(8) Laboratory records, including complete data derived from all tests necessary to assure that the product is in compliance with established specifications and standards.

(9) Documentation demonstrating that the testing required by paragraphs (6) through (8) was performed at a qualifying laboratory (as defined in subsection (k) of this section).

(10) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

(e) Testing

Regulations under subsection (a) of this section—

(1) shall require that testing referred to in paragraphs (6) through (8) of subsection (d) of this section be conducted by the importer of the covered product pursuant to subsection (a) of this section, or the manufacturer of the product;

(2) shall require that if such tests are conducted by the importer, information needed to authenticate the product being tested, and to confirm that the labeling of such product complies with labeling requirements under this chapter, be supplied by the manufacturer of such product to the pharmacist or wholesaler, and shall require that such information be kept in strict confidence and used only for purposes of testing under this chapter; and

(3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

(f) Country limitation

Regulations under subsection (a) of this section shall provide that covered products may be imported pursuant to such subsection only from a country, union, or economic area that is listed in subparagraph (A) of section 382(b)(1) of this title or designated by the Secretary, subject to such limitations as the Secretary determines to be appropriate to protect the public health.

(g) Suspension of importations

The Secretary shall require that importations of specific covered products or importations by specific importers pursuant to subsection (a) of this section be immediately suspended upon discovery of a pattern of importation of such products or by such importers that is counterfeit or in violation of any requirement pursuant to this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative covered products being imported pursuant to subsection (a) of this section.

(h) Prohibited agreements

No manufacturer of a covered product may enter into a contract or agreement that includes a provision to prevent the sale or distribution of covered products imported pursuant to subsection (a) of this section.

(i) Studies; reports

(1) Study by Secretary

(A) In general

The Secretary shall conduct, or contract with an entity to conduct, a study on the imports permitted pursuant to subsection (a) of this section, including consideration of the information received under subsection (d) of this section. In conducting such study, the Secretary or entity shall—

(i) evaluate the compliance of importers with regulations under subsection (a) of this section, and the number of shipments pursuant to such subsection, if any, that have been determined to be counterfeit, misbranded, or adulterated, and determine how such compliance contrasts with the number of shipments of prescription drugs transported within the United States that have been determined to be counterfeit, misbranded, or adulterated; and

(ii) consult with the United States Trade Representative and the Commissioner of Patents and Trademarks to evaluate the effect of importations pursuant to subsection (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.)

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 [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 relating to viruses, etc., applicable to domestic animals, popularly known as the Virus-Serum-Toxin Act, are 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,