

tifying the drug or device when the exporter first begins to export such drug or device to any country listed in clause (i) or (ii) of subsection (b)(1)(A) of this section. When an exporter of a drug or device first begins to export a drug or device to a country which is not listed in clause (i) or (ii) of subsection (b)(1)(A)<sup>1</sup> of this section, the exporter shall provide a simple notification to the Secretary identifying the drug or device and the country to which such drug or device is being exported. Any exporter of a drug or device shall maintain records of all drugs or devices exported and the countries to which they were exported.

**(h) References to Secretary and term “drug”**

For purposes of this section—

(1) a reference to the Secretary shall in the case of a biological product which is required to be licensed under the Act of March 4, 1913 [21 U.S.C. 151 et seq.] (37 Stat. 832–833) (commonly known as the Virus-Serum Toxin Act) be considered to be a reference to the Secretary of Agriculture, and

(2) the term “drug” includes drugs for human use as well as biologicals under section 262 of title 42 or the Act of March 4, 1913 (37 Stat. 832–833) (commonly known as the Virus-Serum Toxin Act).

**(i) Exportation**

Insulin and antibiotic drugs may be exported without regard to the requirements in this section if the insulin and antibiotic drugs meet the requirements of section 381(e)(1) of this title.

(June 25, 1938, ch. 675, §802, as added Pub. L. 99-660, title I, §102(2), Nov. 14, 1986, 100 Stat. 3743; amended Pub. L. 104-134, title III, §2102(d)(1), Apr. 26, 1996, 110 Stat. 1321-315; Pub. L. 104-180, title VI, §603(c), Aug. 6, 1996, 110 Stat. 1595; Pub. L. 105-115, title I, §125(c), Nov. 21, 1997, 111 Stat. 2326.)

REFERENCES IN TEXT

Act of March 4, 1913 (known as the Virus-Serum Toxin Act), referred to in subsecs. (a)(1)(A)(ii), (C), (2)(C) and (h), is the eighth paragraph under the heading “Bureau of Animal Industry” of act Mar. 4, 1913, ch. 145, 37 Stat. 832, as amended, 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.

AMENDMENTS

1997—Subsec. (i). Pub. L. 105-115 added subsec. (i).

1996—Pub. L. 104-134 reenacted section catchline without change and amended text generally. Prior to amendment, text related to exports of certain unapproved products, including provisions relating to drugs intended for human or animal use which required approval or licensing, conditions for export, active pursuit of drug approval or licensing, application for export, contents, approval or disapproval, list of eligible countries for export, and criteria for list change, report to Secretary by holder of approved application, events requiring report, and annual report to Secretary on pursuit of approval of drug, export of drug under approved application prohibited under certain conditions, determination by Secretary of noncompliance, failure of active pursuit of drug approval, imminent hazard of drug to public health, or exportation of drug to non-

eligible country, notices, hearings, and prohibition on exportation of drug under certain circumstances, drugs used in prevention or treatment of tropical disease, and reference to Secretary and holder of application.

Subsec. (f)(5). Pub. L. 104-180 substituted “if the labeling of the drug or device is not” for “if the drug or device is not labeled”.

**§ 383. Office of International Relations**

**(a) Establishment**

There is established in the Department of Health and Human Services an Office of International Relations.

**(b) Agreements with foreign countries**

In carrying out the functions of the office under subsection (a) of this section, the Secretary may enter into agreements with foreign countries to facilitate commerce in devices between the United States and such countries consistent with the requirements of this chapter. In such agreements, the Secretary shall encourage the mutual recognition of—

(1) good manufacturing practice regulations promulgated under section 360j(f) of this title, and

(2) other regulations and testing protocols as the Secretary determines to be appropriate.

**(c) Harmonizing regulatory requirements**

(1) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this chapter.

(2) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States.

(3) The Secretary shall regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements.

(4) The Secretary shall, not later than 180 days after November 21, 1997, make public a plan that 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

<sup>1</sup> So in original. Probably should be subsection “(b)(1)(A)”.

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 prescription drugs**

**(a) Definitions**

In this section:

**(1) Importer**

The term “importer” means a pharmacist or wholesaler.

**(2) Pharmacist**

The term “pharmacist” means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

**(3) Prescription drug**

The term “prescription drug” means a drug subject to section 353(b) of this title, other than—

(A) a controlled substance (as defined in section 802 of this title);

(B) a biological product (as defined in section 262 of title 42);

(C) an infused drug (including a peritoneal dialysis solution);

(D) an intravenously injected drug;

(E) a drug that is inhaled during surgery; or

(F) a drug which is a parenteral drug, the importation of which pursuant to subsection (b) of this section is determined by the Secretary to pose a threat to the public health, in which case section 381(d)(1) of this title shall continue to apply.

**(4) Qualifying laboratory**

The term “qualifying laboratory” means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

**(5) Wholesaler**

**(A) In general**

The term “wholesaler” means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 353(e)(2)(A) of this title.

**(B) Exclusion**

The term “wholesaler” does not include a person authorized to import drugs under section 381(d)(1) of this title.

**(b) 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 prescription drugs from Canada into the United States.

**(c) Limitation**

The regulations under subsection (b) of this section shall—

(1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 355 of this title (including with respect to being safe and effective for the intended use of the prescription drug), with sections 351 and 352 of this title, and with other applicable requirements of this chapter;

(2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e) 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 prescription drugs.

**(d) Information and records**

**(1) In general**

The regulations under subsection (b) of this section shall require an importer of a prescription drug under subsection (b) of this section to submit to the Secretary the following information and documentation:

(A) The name and quantity of the active ingredient of the prescription drug.

(B) A description of the dosage form of the prescription drug.

(C) The date on which the prescription drug is shipped.

(D) The quantity of the prescription drug that is shipped.

(E) The point of origin and destination of the prescription drug.

(F) The price paid by the importer for the prescription drug.

(G) Documentation from the foreign seller specifying—

(i) the original source of the prescription drug; and

(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

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

(J)(i) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

(I) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

(II) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

(III)(aa) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.