

suit 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), 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)(A) 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.

(B) In carrying out subparagraph (A), the Secretary may participate in appropriate fora, including the International Medical Device Regulators Forum, and may—

(i) provide guidance to such fora on strategies, policies, directions, membership, and other activities of a forum as appropriate;

(ii) to the extent appropriate, solicit, review, and consider comments from industry, aca-

demia, health care professionals, and patient groups regarding the activities of such fora; and

(iii) to the extent appropriate, inform the public of the Secretary's activities within such fora, and share with the public any documentation relating to a forum's strategies, policies, and other activities of such fora.

(4) With respect to devices, the Secretary may, when appropriate, enter into arrangements with nations regarding methods and approaches to harmonizing regulatory requirements for activities, including inspections and common international labeling symbols.

(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; Pub. L. 112-144, title VI, §§609, 610, July 9, 2012, 126 Stat. 1059.)

### Editorial Notes

#### AMENDMENTS

2012—Subsec. (c)(3). Pub. L. 112-144, §610, designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (c)(4). Pub. L. 112-144, §609, amended par. (4) generally. Prior to amendment, par. (4) read as follows: “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.”

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

### Statutory Notes and Related Subsidiaries

#### 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

Pub. L. 101-629, §15(b), Nov. 28, 1990, 104 Stat. 4525, 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);