

TITLE 21 - FOOD AND DRUGS
CHAPTER 9 - FEDERAL FOOD, DRUG, AND COSMETIC ACT
SUBCHAPTER VIII - IMPORTS AND EXPORTS

§ 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 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.