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determine whether such products are in compliance with the PHSA.

(2) Refuse admission of noncomplying products and notify the Secretary of the Treasury of such refusal.

(3) Supervise operations to bring noncomplying products into compliance under the PHSA.

(4) Refuse or grant permission and time extensions to bring noncomplying products into compliance with the PHSA in accordance with a corrective action plan approved by the Director, Office of Compliance and Surveillance, CDRH.

(c) The following officials are authorized, under section 360B(b) of the PHSA, to exempt persons from issuing a certification, as required by section 358(h) of the PHSA, for electronic products imported into the United States for testing, evaluation, demonstrations, or training, which will not be introduced into commerce and upon completion of their function will be destroyed or exported in accord with U.S. Customs Service's regulations:

(1) The Director and Deputy Directors, CDRH.

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) Regional Food and Drug Directors.

(4) District Directors.

(5) The Director, St. Louis Branch.

(d) The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to exercise all of the functions of the Commissioner of Food and Drugs under section 362 of the PHSA that refers to the prohibition of the introduction of foods, drugs, devices, cosmetics, and electronic products and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health, and such functions relate to the law enforcement functions of the Food and Drug Administration.

(e) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to exportation of medical devices under section 801(e) of the FFDCA:

(1) For medical devices assigned to their respective organization:

(i) The Director and Deputy Directors, CDRH.

(ii) The Director and Deputy Director, Office of Compliance, CDRH.

(iii) The Director and Deputy Director, Division of Program Operations, Office of Compliance, CDRH.

(iv) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(v) The Director and Deputy Director, Office of Compliance, CBER.

(2) Regional Food and Drug Directors.

(3) District Directors.

(4) The Director, St. Louis Branch.

(f) The following officials are authorized to perform the functions of the Commissioner of Food and Drugs, for drugs under their jurisdiction, pertaining to authorizing the reimportation of prescription drugs under section 801(d)(2) of the FFDCA for emergency medical care:

(1) The Director, Center for Biologics Evaluation and Research (CBER) and the Director, Office of Compliance, CBER.

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER) and the Director and Deputy Director, Office of Compliance, CDER.

[48 FR 8441, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 572, Jan. 5, 1984; 49 FR 14933, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 6518, Feb. 13, 1989; 54 FR 8317, Feb. 28, 1989; 54 FR 9034, Mar. 3, 1989; 55 FR 47053, Nov. 9, 1990; 57 FR 40318, Sept. 3, 1992; 62 FR 2555, Jan. 17, 1997; 62 FR 67271, Dec. 24, 1997]

§5.46 Manufacturer's resident import agents.

The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to reject manufacturer's designation of import agents under §1005.25(b) of this chapter.

[62 FR 67271, Dec. 24, 1997]

§5.47 Detention of adulterated or misbranded medical devices.

The following officials are authorized to perform all the functions of the