

Food and Drug Administration, HHS

§ 5.56

Directors, ODE, CDRH, and the Division Directors, ODE, CDRH.

(ii) The Director and Deputy Director, CBER, and the Director and Deputy Director, Office of Biological Product Review, CBER.

(2) For medical devices assigned to their respective division, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of supplemental premarket applications.

(c) The Director and Deputy Directors, CDRH, for medical devices assigned to their organization, are authorized to issue notices to announce the approval, disapproval, or withdrawal of approval of a device, and to make publicly available a detailed summary of the information on which the decision was based, under sections 515(d), (e), and (g) and 520(h)(1) of the act.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 49 FR 21708, May 23, 1984; 50 FR 9424, Mar. 8, 1985; 54 FR 8317, Feb. 28, 1989; 62 FR 67271, Dec. 24, 1997; 63 FR 27207, May 18, 1998]

§ 5.54 Determinations that medical devices present unreasonable risk of substantial harm.

The following officials, for medical devices assigned to their respective organizations, are authorized to determine that medical devices present an unreasonable risk of substantial harm to the public health, and to order adequate notification thereof, under section 518(a) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH.

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

(c) 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 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 57 FR 40316, Sept. 3, 1992; 62 FR 2556, Jan. 17, 1997; 62 FR 67272, Dec. 24, 1997]

§ 5.55 Orders to repair or replace, or make refunds for, medical devices.

The following officials, for medical devices assigned to their respective organizations, are authorized to order repair or replacement of, or refund for, medical devices under section 518 (b) and (c) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH.

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

(c) 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 56948, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 57 FR 40317, Sept. 3, 1992; 62 FR 2556, Jan. 17, 1997; 62 FR 67272, Dec. 24, 1997]

§ 5.56 Recall authority.

The following officials, for medical devices assigned to their respective organizations, are authorized to perform all of the recall functions under section 518(e) of the Federal Food, Drug, and Cosmetic Act, which have been delegated to the Commissioner of Food and Drugs:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

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

(c) 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.

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

[56 FR 51170, Oct. 10, 1991, as amended at 57 FR 40317, Sept. 3, 1992; 62 FR 2556, Jan. 17, 1997; 62 FR 67272, Dec. 24, 1997]

§ 5.57 Temporary suspension of a medical device application.

The following officials for medical devices assigned to their respective organizations are authorized under section 515(e) of the Federal Food, Drug, and Cosmetic Act, to determine that there is reasonable probability that continuation of the distribution of a device under an approved application would cause serious adverse health consequences or death, and upon making such a determination, to issue an order to temporarily suspend the approval of an application:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

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

(c) The Director and Deputy Directors, Office of Device Evaluation, CDRH.

(d) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; the Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

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

[56 FR 51170, Oct. 10, 1991, as amended at 57 FR 40317, Sept. 3, 1992; 62 FR 2556, Jan. 17, 1997; 62 FR 67272, Dec. 24, 1997]

§ 5.58 Orphan products.

(a) The Director, Office of Orphan Products Development, Office of the Senior Associate Commissioner, Office of the Commissioner, is authorized to

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issue notices, and amendments thereto, inviting sponsorship for orphan products (human and animal drugs, biological products, and medical devices) and submission of:

(1) Notices of claimed investigational exemption for a new drug or new drug applications;

(2) Notices of claimed investigational exemption for a new animal drug or new animal drug applications;

(3) Applications for biologics licenses for biological products; or

(4) Applications for an investigational device exemption or premarket approval applications for medical devices, as appropriate.

(b) The Director, Office of Orphan Products Development, Office of the Senior Associate Commissioner, Office of the Commissioner, is authorized:

(1) To determine whether there is reason to believe that a drug is a drug for a disease or condition that is rare in the United States under section 525(a) of the Federal Food, Drug, and Cosmetic Act (the act) and to designate such drug as a drug for a rare disease or condition under section 526(a) of the act.

(2) To issue holders of approved applications or licenses notice and opportunity for the submission of views under section 527(b)(1) of the act.

(3) To encourage sponsors of an investigational new drug for a rare disease or condition to design protocols for clinical investigations to permit the addition to the investigation of persons with the disease or condition under section 528 of the act.

(c) The following officials are authorized to provide sponsors, under section 525(a) of the act, with recommendations for nonclinical or clinical investigations believed to be necessary for a drug for a rare disease or condition to be approved or licensed:

(1) For drugs under their jurisdiction:

(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of