

§ 5.57

(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

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Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) For biological products under their jurisdiction:

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

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

(iii) The Directors and Deputy Directors of the divisions in the Office of Biological Product Review, CBER.

[48 FR 40703, Sept. 9, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 49 FR 27489, July 5, 1984; 50 FR 19341, May 8, 1985; 54 FR 8318, Feb. 28, 1989; 55 FR 51688, Dec. 17, 1990; 62 FR 2556, Jan. 17, 1997; 64 FR 56448, Oct. 20, 1999; 65 FR 34962, June 1, 2000]

§ 5.59 Approval, disapproval, or withdrawal of approval of applications for investigational device exemptions.

(a) For medical devices assigned to their respective organizations, the following officials are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act):

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

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

(b) For medical devices assigned to their respective divisions, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the act.

[48 FR 56948, Dec. 27, 1983, as amended at 49 FR 14934, Apr. 16, 1984; 54 FR 8318, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990; 62 FR 67272, Dec. 24, 1997]

§ 5.60 Required and discretionary postmarket surveillance.

(a) For any device (including any device that is or contains a drug or biologic) that was first introduced or delivered for introduction into interstate commerce after January 1, 1991, and that is either a permanent implant, the failure of which may cause serious adverse health consequences or death, a life-sustaining or life-supporting device, or a device that potentially presents a serious risk to human health, any of the following officials is authorized to require a manufacturer of such device to conduct postmarket surveillance:

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

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

(3) The Director and Deputy Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, CDRH.

(4) The Director and Deputy Directors, Division Directors and Associate Division Directors, Office of Device Evaluation, CDRH.

(5) The Chief, Premarket Notification Section; Chief, Premarket Approval Section; Director, Program Operations Staff, Office of Device Evaluation, CDRH.

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

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

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

(9) The Director and Deputy Director, Office of Compliance, CDER.

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

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

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

(b) For any device (including any device that is or contains a drug or biologic), any of the following officials is