

Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director, Office of Drug Evaluation II, Office of Review Management, CDER.

(c) The Director and Deputy Director, Division of Metabolism and Endocrine Drug Products, Office of Drug Evaluation II, Office of Review Management, CDER.

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

(e) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(f) The Team Leader and Assistant, Post-Marketing Surveillance Team, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989; 62 FR 2556, Jan. 17, 1997]

§ 5.74 Issuance, amendment, or repeal of regulations pertaining to drugs containing insulin.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 506 of the Federal Food, Drug, and Cosmetic Act regarding the issuance, amendment, or repeal of regulations pertaining to drugs containing insulin:

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

(b) The Director, Office of Drug Evaluation II, Office of Review Management, CDER.

(c) The Director and Deputy Director, Division of Metabolism and Endocrine Drug Products, Office of Drug Evaluation II, Office of Review Management, CDER.

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

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989; 62 FR 2557, Jan. 17, 1997]

§ 5.75 Designation of official master and working standards for antibiotic drugs.

The following officials are authorized to designate official Food and Drug Administration master and working standards for antibiotic drugs under § 430.5 of this chapter:

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

(b) The Director and Deputy Director, Office of Testing and Research, Office of Pharmaceutical Science, CDER.

(c) The Director and Deputy Director, Division of Research and Testing, Office of Testing and Research, Office of Pharmaceutical Science, CDER.

[49 FR 27315, July 3, 1984, as amended at 54 FR 8319, Feb. 28, 1989; 62 FR 2557, Jan. 17, 1997]

§ 5.76 Certification of antibiotic drugs.

The following officials are authorized to certify or reject batches of antibiotic drugs, or any derivative of these drugs, pursuant to sections 507(a) and 512(n) of the Federal Food, Drug, and Cosmetic Act:

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

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

(c) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(d) The Team Leader and Assistant, Post-Marketing Surveillance Team, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989; 62 FR 2557, Jan. 17, 1997]

§ 5.78 Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 507 of the Federal Food, Drug, and Cosmetic Act (the act) regarding

the issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use:

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

(2) The Director, Office of Drug Evaluation I, Office of Review Management, CDER.

(3) The Director, Office of Drug Evaluation IV, Office of Review Management, CDER.

(4) The Director and Deputy Director, Division of Oncologic Drug Products, Office of Drug Evaluation I, Office of Review Management, CDER.

(5) The Director and Deputy Director, Division of Anti-Infective Drug Products, Office of Drug Evaluation IV, Office of Review Management, CDER.

(6) The Director and Deputy Director, Division of Anti-Viral Drug Products, Office of Drug Evaluation IV, Office of Review Management, CDER.

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

(b) The Director and Deputy Directors, Center for Devices and Radiological Health, are authorized to perform all the functions of the Commissioner of Food and Drugs under section 507 of the act regarding the issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use contained in medical devices.

[48 FR 56948, Dec. 27, 1983, as amended at 49 FR 14935, Apr. 16, 1984; 54 FR 8319, Feb. 28, 1989; 62 FR 2557, Jan. 17, 1997; 62 FR 67272, Dec. 24, 1997]

§ 5.80 Approval of new drug applications and their supplements.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act:

(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, for drugs under their jurisdiction.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), for drugs listed in § 314.440(b) of this chapter, are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act.

(b) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction, are authorized to perform all functions of the Commissioner of Food and Drugs with regard to approval of supplemental applications to approved new drug applications for drugs for human use that have been submitted under § 314.70 of this chapter and of new drug applications for drug products other than those that contain new molecular entities (new chemical entities). The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in § 5.10(a) and paragraph (a) of this section.

(c) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of abbreviated new drug applications and supplements thereto for drugs for human use and new drug applications for drugs with a 5S classification whose clinical safety and efficacy may be supported by appropriate literature citations in lieu of submission of data from original proprietary studies, or 505(b)(2) applications under their jurisdiction. The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in § 5.10(a) and paragraph (a) of this section.

(1) For drugs submitted under §§ 314.50, 314.70, and 314.94 of this chapter, except for those drug products listed in § 314.440(b):

(i) The Director and Deputy Director, Office of Generic Drugs (OGD), Office of