

§ 5.93 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.

The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs with regard to decisions made under section 505 (c)(3)(D), (j)(4)(B)(iv), and (j)(4)(D) of the Federal Food, Drug and Cosmetic Act (the act) concerning the date of submission or the date of effective approval of abbreviated new drug applications including supplements thereto submitted under section 505(j) of the act and of new drug applications including supplements thereto submitted under section 505(b)(1) of the act and described under section 505(b)(2) of the 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, Division of Bioequivalence, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

[53 FR 18274, May 23, 1988, as amended at 55 FR 6247, Feb. 22, 1990; 62 FR 2558, Jan. 17, 1997]

§ 5.94 Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.

The following officials are authorized to extend or stay an effective date in § 201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

(a) For drugs assigned to their organizations:

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

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

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

(b) For drugs assigned to their organizations:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharma-

ceutical Science, Center for Drug Evaluation and Research (CDER).

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

(3) 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.

[52 FR 2514, Jan. 23, 1987, as amended at 54 FR 8320, Feb. 28, 1989; 55 FR 51688, Dec. 17, 1990; 62 FR 2558, Jan. 17, 1997]

§ 5.95 Submission of and effective approval dates for abbreviated new animal drug applications and certain new animal drug applications.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to decisions made under section 512(c)(2)(D)(iv) and (c)(2)(F) of the Federal Food, Drug, and Cosmetic Act (the act) concerning the date of submission and the date of effective approval of abbreviated new animal drug applications including supplements thereto, submitted under section 512(b)(2) of the act, and of new animal drug applications including supplements thereto, submitted under section 512(b)(1) of the act:

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(b) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

[56 FR 6263, Feb. 15, 1991]

§ 5.98 Authority relating to medical device reporting procedures.

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Surveillance and Biometrics, (OSB), CDRH and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH, are authorized to approve electronic reporting under § 803.14 of this chapter.

(b) The Director and Deputy Directors, CDRH, the Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH, are authorized to request the submission of additional information under § 803.15 of this chapter.