

(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 Pharmaceutical 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), and the Director and Deputy Director, Office of Surveillance and Biometrics, CDRH, are authorized to approve electronic reporting under § 803.14 of this chapter.

(b) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Surveillance and Biometrics, CDRH, are authorized to request the submission of additional information under § 803.15 of this chapter.

(c) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Surveillance and Biometrics, CDRH, are authorized to grant or revoke exemptions and variances from reporting requirements under § 803.19 of this chapter.

[60 FR 63607, Dec. 11, 1995]

§ 5.99 Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.

The Director and Deputy Director, Center for Drug Evaluation and Research (CDER), the Director and Deputy Director, Center for Veterinary Medicine (CVM), and the Director and Associate Director for Policy Coordination and Public Relations, Center for Biologics Evaluation and Research

(CBER) are authorized to issue the following notices under section 306 of the Federal Food, Drug, and Cosmetic Act (the act) which relate to the assigned functions of their organizations:

(a) Notices of opportunity for hearing on proposals for mandatory or permissive debarment.

(b) Notices ordering debarment when opportunity for a hearing has been waived.

(c) Notices ordering debarment where the person notifies the agency that the person acquiesces to debarment under section 306(c)(2)(B) of the act.

(d) Notices of opportunity for hearing on proposals denying an application to terminate debarment under section 306(d)(3) of the act.

(e) Orders denying an application to terminate debarment under section 306(d)(3) of the act when opportunity for a hearing has been waived.

[61 FR 8215, Mar. 4, 1996; 61 FR 11545, Mar. 21, 1996; 61 FR 14375, Apr. 1, 1996]

Subpart C—Organization

§ 5.100 Officials authorized to make certification under 5 U.S.C. 605(b) for any proposed and final rules.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to decisions made under the Regulatory Flexibility Act (5 U.S.C. 605(b)), to certify that a proposed or final rule, if issued, will not have a significant economic impact on a substantial number of small entities:

(a) The Associate Commissioner for Regulatory Affairs (ACRA).

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

(c) The Director, Center for Drug Evaluation and Research (CDER).

(d) The Director, Center for Devices and Radiological Health (CDRH).

(e) The Director, Center for Food Safety and Applied Nutrition (CFSAN).

(f) The Director, Center for Veterinary Medicine (CVM).

(g) Other FDA Officials authorized to issue FEDERAL REGISTER documents.

[62 FR 48757, Sept. 17, 1997]

§ 5.200 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER.¹

OFFICE OF THE ADMINISTRATIVE LAW JUDGE.

OFFICE OF EXECUTIVE SECRETARIAT.

OFFICE OF EQUAL EMPLOYMENT AND CIVIL RIGHTS.

OFFICE OF THE CHIEF COUNSEL.

OFFICE OF INTERNAL AFFAIRS.

OFFICE OF EXTERNAL AFFAIRS.

Industry and Small Business Liaison Staff.

Office of Special Health Issues.

Office of Consumer Affairs.

Office of Health Affairs.

Office of Legislative Affairs.

Office of Public Affairs.

Office of Women's Health.

Office of International Affairs.

OFFICE OF MANAGEMENT AND SYSTEMS.

Office of Planning and Evaluation.

Office of Human Resources and Management Services.

Office of Facilities, Acquisitions, and Central Services.

Office of Information Resources Management.

Office of Financial Management.

OFFICE OF POLICY.

Regulations Policy and Management Staff.

Policy Development and Coordination Staff.

Policy Research Staff.

International Policy Staff.

OFFICE OF OPERATIONS.

OFFICE OF SCIENCE.

OFFICE OF ORPHAN PRODUCTS DEVELOPMENT.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH.²

Office of the Center Director

Environmental Health and Program Assurance Staff.

Equal Employment Opportunity Staff.

Scientific Coordination Staff.

Technology Advancement Staff.

Office of Planning and Resource Management

Planning Staff.

¹Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

²Mailing address: Jefferson, AR 72079-9502.