

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

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

(3) The Director and Deputy Director, Division of Labeling and Nonprescription Drug Compliance, Office of Compliance, CDER.

(4) The Director and Deputy Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER.

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

(6) The Director and Deputy Director, Division of Scientific Investigations, Office of Compliance, CDER.

(7) Regional Food and Drug Directors.

(8) District Directors.

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under sections 512(e) and 512 (m)(4)(B)(ii) and (m)(4)(B)(iii) of the act regarding the issuance of written notices.

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

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(3) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(4) Regional Food and Drug Directors.

(5) District Directors.

[57 FR 18823, May 1, 1992, as amended at 62 FR 2555, Jan. 17, 1997]

§ 5.39 Redelegation of the Center for Biologics Evaluation and Research Director's program authorities.

The following officials are authorized to perform all the functions of the Director, Center for Biologics Evaluation and Research (CBER) with regard to program authorities for their respective areas:

(a) Associate Directors, CBER.

(b) Office Directors, CBER.

(c) Division Directors, CBER.

[58 FR 18346, Apr. 9, 1993]

§ 5.40 Issuance of Federal Register documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use.

The Director and Deputy Director, Center for Veterinary Medicine (CVM) are authorized to issue FEDERAL REGISTER documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use related to implementation of the Animal Medicinal Drug Use Clarification Act of 1994 (the AMDUCA) (Pub. L. 103-396). This authority may be further redelegated by the Director and Deputy Director, CVM.

[62 FR 43471, Aug. 14, 1997]

§ 5.44 Export of unapproved drugs.

(a) The following officials are authorized, under section 802(b) of the Federal Food, Drug, and Cosmetic Act, to approve or disapprove applications to export unapproved new drugs and biological products and to issue notices of receipt of such applications:

(1) For human drugs assigned to their respective organizations:

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

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

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

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

(2) For new animal drugs assigned to their respective organizations:

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

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

(b) The following officials are authorized, under section 802(f) of the Federal Food, Drug, and Cosmetic Act, to approve or disapprove an application to export a drug (including a biological