

name, a color photograph, the signature of the holder, his or her special authority under 21 U.S.C. 334 and 372 and other duties as assigned by the Commissioner, an identification number, the Commissioner's or his designee's signature, the names of the Department of Health and Human Services, the Public Health Service, and the Food and Drug Administration. Part 1 of the form is superimposed with the symbol FDA with blue imprint, and part 2 is superimposed with the FDA criminal investigator's badge with blue imprint.

(4) Form FDA-200E, entitled "Special Authority for Criminal Investigative Specialists," is in two parts and bears the holder's name, a color photograph, the signature of the holder, his or her special authority under the act, and other duties under the law, as assigned by the Commissioner, an identification number, the Commissioner's or his designee's signature, the names of the Department of Health and Human Services, the Public Health Service, and the Food and Drug Administration. Part 1 of the form is superimposed with the symbol FDA with blue imprint, and part 2 is superimposed with the FDA criminal investigative specialist's badge with blue imprint.

[49 FR 19973, May 11, 1984, as amended at 53 FR 22293, June 15, 1988; 56 FR 23788, May 24, 1991; 58 FR 494, Jan. 6, 1993; 58 FR 42496, Aug. 10, 1993; 59 FR 47799, Sept. 19, 1994]

§ 5.36 Certification following inspections.

Regional Food and Drug Directors and District Directors are authorized to issue certificates of sanitation under § 1240.20 of this chapter.

[60 FR 15871, Mar. 28, 1995]

§ 5.37 Issuance of reports of minor violations.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 309 of the Federal Food, Drug, and Cosmetic Act regarding the issuance of written notices or warnings:

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

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

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

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

(iii) For medical devices assigned to their respective divisions, the Division Directors, Office of Compliance, CDRH.

(iv) 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.

(3)(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition, (CFSAN).

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Field Programs, CFSAN.

(iv) The Director, Division of Enforcement, Office of Field Programs, CFSAN.

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

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

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

(5)(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 Director and Deputy Director, Office of Compliance, CDER.

(iii) The Associate Director for Medical Policy, CDER.

(iv) The Director, Division of Drug Marketing, Advertising, and Communications, Office of Drug Evaluation I, Office of Review Management, CDER.

(6)(i) Regional Food and Drug Directors.

(ii) District Directors.

(iii) Chiefs of District Compliance Branches.

(iv) The Director, St. Louis Branch.

(v) The Director, Northeast Regional Laboratory, Northeast Region.

(vi) The Director, Southeast Regional Laboratory, Southeast Region.

(vii) The Director, Winchester Engineering and Analytical Center.

(viii) The Director, National Forensic Chemistry Center.

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 539(d) of the Federal Food, Drug, and Cosmetic Act regarding the issuance of written notices or warnings:

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

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

(3) For medical devices assigned to their respective divisions, the Division Directors, Office of Compliance, CDRH.

(4) The Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH.

(5) Regional Food and Drug Directors; District Directors; the Director, St. Louis Branch; the Director, Northeast Regional Laboratory, Northeast Region; the Director, Southeast Regional Laboratory, Southeast Region; the Director, Winchester Engineering and Analytical Center; and the Director, National Forensic Chemistry Center, when such functions relate to:

(i) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter; and

(ii) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product as defined in § 1040.20(b) of this chapter.

[48 FR 8441, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14933, 14936, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8317, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990; 57 FR 40318, Sept. 3, 1992; 59 FR 42491, Aug. 18, 1994; 60 FR 15871, Mar. 28, 1995; 62 FR 2555, Jan. 17, 1997; 62 FR 67271, Dec. 24, 1997; 64 FR 4965, Feb. 2, 1999]

§ 5.38 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs, new animal drugs, and feeds bearing or containing new animal drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 505(e) of the Federal Food,

Drug, and Cosmetic Act (the act) regarding the issuance of written notices.

(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 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 Redlegation 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]