

Commissioner for International and Constituent Relations; the Senior Associate Commissioner for Management and Systems; the Senior Associate Commissioner for Policy, Planning, and Legislation; the Associate and Deputy Associate Commissioners; the Chief Counsel and Deputy Chief Counsels; the Directors and Deputy Directors for CBER, CFSAN, CDRH, CVM, CDER, and NCTR; the Director, Office of Executive Operations, OSAC, OC; the Directors of the Offices of Management, CBER and CDER; the Director, Office of Management Systems, CFSAN; the Director, Office of Systems and Management, CDRH; the Director, Office of Management and Communications, CVM; the Associate Director, Office of Management Services, NCTR; the Director, Office of Resource Management, ORA; and the Director, OHRMS, OMS, OC. The other officials delegated authority by this section may not further redelegate it.

(d) The Chief, Regulations Editorial Section (RES), Regulations Policy and Management Staff (RPMS), Office of Policy, Planning, and Legislation (OPPL), OC, and his or her alternates are authorized to certify true copies of FEDERAL REGISTER documents. The Chief, RES, RPMS, OPPL, OC may designate alternates as required.

§ 5.23 Disclosure of official records and authorization of testimony.

(a) The following officials are authorized to make determinations to disclose official records and information under part 20 of this chapter, except that only the officials, listed in paragraphs (a)(2) through (a)(8) of this section, have the authority under specific sections of part 20 of this chapter.

(1)(i) Deputy Commissioner, the Senior Associate Commissioner, the Deputy Commissioner for International and Constituent Relations, the Senior Associate Commissioner for Management and Systems, the Senior Associate Commissioner for Policy, Planning, and Legislation, and the Associate and Deputy Associate Commissioners.

(ii) The Director, Office of Executive Operations, Office of the Senior Associate Commissioner, Office of the Commissioner (OC).

(iii) The Director, Office of the Executive Secretariat, Office of the Senior Associate Commissioner, OC.

(iv) The Director, Office of Human Resources and Management Services (OHRMS), Office of Management and Systems (OMS), OC; the Director, Division of Management Programs (DMP), OHRMS, OMS, OC; and the Chief, Division of Dockets Management, DMP, OHRMS, OMS, OC.

(v) Program officials at all organizational levels down to and including branch level for all Headquarters organizations.

(vi) Regional Food and Drug Directors and District Directors.

(vii) Director, Winchester Engineering and Analytical Center.

(viii) Chiefs of branches Field/District Offices and Centers.

(ix) Freedom of Information Officers and other employees engaged in Freedom of Information activities.

(x) The Director, Office of Enforcement (OE), Office of Regulatory Affairs (ORA); Deputy Director, OE, ORA; and Director, Division of Compliance Policy, OE, ORA.

(xi) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER); and the Director and Deputy Director, Office of Communication, Training, and Manufacturer's Assistance (OCTMA), CBER.

(xii) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, the Associate Director for Medical Policy, and the Associate Director for Regulatory Policy, Center for Drug Evaluation and Research (CDER).

(xiii) The Director, Center for Devices and Radiological Health (CDRH), the Deputy Director for Regulations and Policy, and the Deputy Director for Science, CDRH.

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

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

(xvi) The Director, National Center for Toxicological Research (NCTR); the Deputy Center Directors, Offices of Research and Management, respectively,

NCTR; and the Deputy Director for Washington Operations, NCTR.

(xvii) These officials may not further redelegate this authority.

(2) The Deputy Associate Commissioner for Regulatory Affairs (Deputy ACRA), ORA; the Director and Deputy Director, Office of Enforcement OE, ORA; and the Director, Division of Compliance Policy, OE, ORA are delegated the authority to grant requests for testimony or to authorize the giving of testimony under § 20.1 of this chapter. These officials may not further redelegate this authority.

(3) The Associate and Deputy Associate Commissioners are delegated the authority to disclose official records and information under § 20.82 of this chapter. These officials may not further redelegate this authority.

(4) The Associate and Deputy Associate Commissioners; the Director and Deputy Director, OE, ORA; and the Director, Division of Compliance Policy, OE, ORA are delegated the authority to disclose official records and information under § 20.85 of this chapter. These officials may not further redelegate this authority.

(5) The following officials are delegated the authority to disclose confidential commercial information to State government officials under § 20.88(d) of this chapter and the ACRA and the Center Directors may further redelegate this authority.

(i) The ACRA, the Deputy ACRA, ORA and the Director, OE, ORA.

(ii) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER); and the Director and Deputy Director, Office of Communication, Training, and Manufacturer's Assistance (OCTMA), CBER.

(iii) The Director and Deputy Director, CDER; the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER; the Associate Director for Regulatory Policy, CDER.

(iv) The Director, CDRH, the Deputy Director for Regulations and Policy, the Deputy Director for Science, and the Director, Office of Health and Industry Programs, CDRH.

(v) The Director and Deputy Director, CFSAN.

(vi) The Director and Deputy Director, CVM.

(vii) The Director, the Deputy Center Directors, Offices of Research and Management, respectively, NCTR, and the Deputy Director for Washington Operations, NCTR.

(6) The following officials are delegated the authority to disclose nonpublic, predecisional documents to State and foreign government officials under §§ 20.88(e) and 20.89(d) of this chapter and they may not further redelegate this authority.

(i) The Associate Commissioner for Policy, Office of Policy, Planning and Legislation (OPPL); and the Director, Office of International Programs, Office of International and Constituent Relations (OICR).

(ii) For level 2 nonpublic, predecisional guidance documents, any Center Director or Deputy Director, and any Director for an OC office having program responsibilities.

(7) The Associate Commissioner for Policy, OPPL; and the Director, Office of International Programs, OICR are delegated the authority to receive nonpublic, predecisional documents from State and foreign government officials under §§ 20.88(e) and 20.89(d) of this chapter. These officials may not further redelegate this authority.

(8) The following officials are authorized to disclose confidential commercial information to foreign government officials under § 20.89(c) of this chapter; and they may not further redelegate it:

(i) The Deputy ACRA, ORA; and the Director, OE, ORA.

(ii) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER); and the Director and Deputy Director, Office of Communication, Training, and Manufacturer's Assistance (OCTMA), CBER.

(iii) The Director and Deputy Director, CDER; the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER; the Associate Director for Medical Policy, CDER; the Associate Director for Regulatory Policy, CDER; and the Director, Division of Information Disclosure Policy, Office of Regulatory Policy, CDER.

(iv) The Director, CDRH, the Deputy Director for Regulations and Policy

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and the Deputy Director for Science, CDRH.

(v) The Director and Deputy Director, CFSAN.

(vi) The Director and Deputy Director, CVM.

(vii) The Director, the Deputy Center Directors, Offices of Research and Management, respectively, and the Deputy Director for Washington Operations, NCTR.

(b) The Chief, Information Management Team, Division of Data Management and Services, Office of Information Technology, CDER, is authorized to sign affidavits regarding the presence or absence of records of Registration of Drug Establishments. This official may not further redelegate this authority.

(c) The following officials are authorized to sign affidavits regarding the presence or absence of medical device establishment registration records and these officials may not further redelegate this authority:

(1) The Director, the Deputy Director for Regulations and Policy, and the Deputy Director for Science, CDRH.

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

(3) The Director and Deputy Director, Division of Program Operations, Office of Compliance, CDRH.

(4) The Chief, Information Processing and Office Automation Branch, Division of Program Operations, Office of Compliance, CDRH.

(d) The Director, Office of Resource Management, Office of Regulatory Affairs is authorized to sign affidavits regarding the presence or absence of records in the files of that office and this official may not further redelegate this authority.

(e) The Director and Deputy Directors, CBER, the Director and Deputy Director, Office of Blood Research and Review (OBRR), and the Director and Deputy Director, Division of Blood Applications, OBRR, CBER, are authorized to sign affidavits regarding the presence or absence of records of registration of blood product establishments. These officials may not further redelegate this authority.

§ 5.24 Authority relating to technology transfer.

(a) The Associate Commissioner for Regulatory Affairs is authorized to perform the functions of the Commissioner of Food and Drugs as requested by the Commissioner regarding the authority to disapprove or require modification of cooperative research and development agreements and licensing agreements and transmit written explanation of such approval or disapproval to the head of the laboratory concerned under section 11(c)(5)(A) and (B) of the Stevenson-Wydler Technology Innovation Act of 1980 (the Act) (15 U.S.C. 3710a(c)(5) (A) and (B)), as amended.

(b) The following officials are authorized to perform the functions of the Commissioner of Food and Drugs (Commissioner) requested by the Commissioner under the Act (15 U.S.C. 3701 *et seq.*), as amended, and Executive Order 12591 of April 10, 1987 (except to the extent that redelegation of those functions is specifically limited in § 5.10(a)(26)), as they pertain to the functions of their respective organizations, including the authority to perform the functions of laboratory directors under the Act as the heads of their respective Federal laboratories, subject to the discretion of the Commissioner to require that agreements entered into under section 11(a) of the Act (15 U.S.C. 3710a(a)) include provisions in accordance with section 11(c)(5)(A) of the Act (15 U.S.C. 3710a(c)(5)(A)):

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

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

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

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

(5) The Director, Center for Veterinary Medicine.

(6) The Director, National Center for Toxicological Research.

(7) The Associate Commissioner for Regulatory Affairs.

(c) These officials may not further redelegate these authorities.