SMG 1410.24

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - GENERAL REDELEGATIONS OF AUTHORITY

DISCLOSURE OF OFFICIAL RECORDS AND AUTHORIZATION OF TESTIMONY

Effective Date: 04/27/2007

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED AND REDELEGATION.

A. The following officials are authorized to make determinations to disclose official records and information under part 20 off Title 21, Code of Federal Regulations, (21 CFR), except that only the officials, listed in subparagraphs 1.A.2. through 1.A.8. of this SMG, have the authority under specific sections of 21 CFR, part 20.

1.a. 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.

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

c. The Director, Office of the Executive Secretariat, Office of the Senior Associate Commissioner, OC.

d. 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, Dockets Management Branch, DMP, OHRMS, OMS, OC.

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

f. Regional Food and Drug Directors and District Directors.

g. Director, Winchester Engineering and Analytical Center.

h. Chiefs of branches Field/District Offices and Centers.

i. Freedom of Information Officers and other employees engaged in Freedom of Information activities.

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

k. 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.

l. The Director and Deputy Director, the Directors, Office of New Drugs and Office of Pharmaceutical Science, the Associate Director for Medical Policy, and the Associate Director for Policy, Center for Drug Evaluation and Research (CDER).

m. The Director and Deputy Director Center for Devices and Radiological Health (CDRH).

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

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

p. 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.

q. 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 Sec. 20.1 of 21 CFR. 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 Sec. 20.82 of 21 CFR. 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 Sec. 20.85 of 21 CFR. 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 Sec. 20.88(d) of 21 CFR and the ACRA and the Center Directors may further redelegate this authority.

    a. The ACRA, the Deputy ACRA, ORA and the Director, OE, ORA.

    b. 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.

    c. The Director and Deputy Director, CDER; the Directors, Office of New Drugs and Office of Pharmaceutical Science, CDER; the Associate Director for Policy, CDER.

    d. The Director and Deputy Director CDRH, and the Director, Office of Health and Industry Programs, CDRH.

    e. The Director and Deputy Director, CFSAN.

    f. The Director and Deputy Director, CVM.

    g. 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 Secs. 20.88(e) and 20.89(d) of 21 CFR and they may not further redelegate this authority.

    a. 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).

    b. 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 Secs. 20.88(e) and 20.89(d) of 21 CFR. These officials may not further redelegate this authority.

8. The following officials are authorized to disclose confidential commercial information to foreign government officials under Sec. 20.89(c) of 21 CFR; and they may not further redelegate it:

    a. The Deputy ACRA, ORA; and the Director, OE, ORA.

    b. 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.

    c. The Director and Deputy Director, CDER; the Directors, Office of New Drugs and Office of Pharmaceutical Science, CDER; the Associate Director for Medical Policy, CDER; the Associate Director for Policy, CDER, and the Director, Division of Information Disclosure Policy, Office of Regulatory Policy, CDER.

    d. The Director and Deputy Director, CDRH

    e. The Director and Deputy Director, CFSAN.

    f. The Director and Deputy Director, CVM.

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

B. The Director, Division of Records Management, Office of Business Process Support, 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 and Deputy Director, 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.

2. REDELEGATION.

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on April 27, 2007.