

**FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY**

**REGULATORY - GENERAL REDELEGATIONS OF AUTHORITY**

**HEARINGS**

Effective Date: 09/29/2011

**1. AUTHORITY DELEGATED AND TO WHOM DELEGATED**

A. The following officials are authorized to designate officials to hold informal hearings that relate to their assigned functions under Sections 305, 404(b), and 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335, 344(b), and 381(a)); Section 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1455) (21 U.S.C. 145); Section 9(b) of the Federal Caustic Poison Act (44 Stat. 1406; see also Public Law 86-613, Section 19 formerly Section 18); and Section 5 of the Federal Import Milk Act. Officials so designated are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer to or to take from any person an oath, affirmation, affidavit, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in 21 CFR or this delegation:

1. Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), Office of Foods, (OF); and Director, Office of Regulations, Policy and Social Sciences, CFSAN, OF
2. Director and Deputy Directors, Center for Drug Evaluation and Research (CDER), Office of Medical Products and Tobacco, (OMPT); Directors, Office of New Drugs (OND) and Office of Pharmaceutical Science (OPS); Associate Director for Policy and the Associate Director for Medical Policy, CDER, OMPT; Directors, Offices of Drug Evaluation (ODE) I, II, III, and IV; Office of Antimicrobial Products (OAP) and Office of Hematology and Oncology Products (OHOP), OND, CDER, OMPT; and the Director and Deputy Director, Office of Compliance (OC), CDER, OMPT
3. Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), OMPT
4. Director and Deputy Director, Center for Tobacco Products (CTP), OMPT

5. Director, Deputy Director and the Senior Advisor for Science Policy, Center for Veterinary Medicine (CVM), OF
  6. Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), OMPT; and the Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVR), Office of Cellular, Tissue and Gene Therapies (OCTGT), and Office of Compliance and Biologics Quality (OCBQ), CBER, OMPT
  7. Director, Office of Enforcement (OE), Office of Regulatory Affairs (ORA), Office of Global Regulatory Operations and Policy, (OGROP); and Director of Compliance, OE, ORA, OGROP
  8. Regional Food and Drug Directors, ORA, OGROP
  9. District Directors, ORA, OGROP
  10. Regional Laboratory Directors, ORA, OGROP
- B. The following officials are authorized to serve as the presiding officer, and to designate other officials to serve as the presiding officer, at a regulatory hearing and to conduct such a hearing under the provisions of 21 CFR, Part 16. An official can serve as the presiding officer in a particular hearing only if he or she satisfies the requirements of 21 CFR, Part 16, Section 16.42(b) with respect to the action that is the subject of the hearing. Such officials are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer or to take from any person an oath, affirmation, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this delegation:
1. Ombudsman, Office of Scientific Integrity, Office of the Chief Scientist, Office of the Commissioner (OC)
  2. Director and Deputy Directors, CFSAN, OF
  3. Director and Deputy Directors, CDER, OMPT; Directors, OND and OPS, CDER, OMPT; Associate Director for Policy and Associate Director for Medical Policy, CDER, OMPT; Directors, ODE I, II, III, and IV; OAP and OHOP, OND, CDER, OMPT; and Director and Deputy Director, OC, CDER, OMPT
  4. Director and Deputy Directors, CDRH, OMPT
  5. Director and Deputy Director, CTP, OMPT

6. Director, Deputy Director, and Senior Advisor for Science Policy, CVM, OF
7. Director and Deputy Director, CBER, OMPT; Directors and Deputy Directors, OBRR, OVR, OCTGT; and OCBQ, CBER, OMPT
8. Director, OE, ORA, OGROP; and Director of Compliance, OE, ORA, OGROP
9. Regional Food and Drug Directors, ORA, OGROP
10. District Directors, ORA, OGROP
11. Regional Laboratory Directors, ORA, OGROP
12. Director, Office of Good Clinical Practice, Office of Special Medical Programs, OMPT
13. An Administrative Law Judge
14. Such other FDA Official as is designated by the Commissioner by memorandum in the proceeding

**2. REDELEGATION**

These Officials may not further redelegate these authorities.

**3. EFFECTIVE DATE**

The Commissioner of Food and Drugs approved this delegation, via memorandum, on September 29, 2011.

<b>STATUS (I, R, C)</b>	<b>DATE APPROVED</b>	<b>LOCATION OF CHANGE HISTORY</b>	<b>CONTACT</b>	<b>APPROVING OFFICIAL</b>
Initial	06/04/2010	N/a	OC/OA/OM/OMP	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	03/07/2011	N/a	OC/OA/OM/OMP	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	09/29/2011	N/a	OO/OM	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs