

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - HUMAN DRUGS AND ANIMAL DRUGS

**REQUESTS FOR RECORDS OR OTHER INFORMATION FROM ESTABLISHMENTS
ENGAGED IN MANUFACTURING, PREPARING, PROPAGATING, COMPOUNDING,
OR PROCESSING OF DRUGS**

Effective Date: 09/08/2014

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED.

- A. The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to requesting and confirming receipt of records or other information from establishments under section 704(a)(4) of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 374(a)(4)).
1. Director and Deputy Directors, Center for Drug Evaluation and Research (CDER), Office of Medical Products and Tobacco (OMPT).
 2. Director, Deputy Directors, and Division Directors, Office of Pharmaceutical Science, and Office of Compliance, Center for Drug Evaluation and Research (CDER), Office of Medical Products and Tobacco (OMPT).
 3. Deputy Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs (ORA).
 4. District Directors, Office of Regulatory Affairs (ORA), Office of Global Regulatory Operations and Policy (OGROP).
 5. Director and Deputy Directors, Center for Veterinary Medicine (CVM), Office of Foods and Veterinary Medicine, (OFVM).
 6. Director and Deputy Director, Office of Surveillance and Compliance, CVM, OFVM.
 7. Director and Deputy Director, Office of New Animal Drug Evaluation (ONADE), CVM, OFVM.
 8. Director, Division of Manufacturing Technologies, ONADE, CVM, OFVM.
 9. Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), OMPT.

10. Director and Deputy Director, Office of Compliance and Biologics Quality (OCBQ), CBER, OMPT.

11. Division Directors and Deputy Division Directors, OCBQ, CBER, OMPT.

2. REDELEGATION.

These officials may not further re-delegate these authorities.

3. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation on 09/08/2014.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	09/08/2014	N/a	CDER/OM	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs