

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - GENERAL REDELEGATIONS OF AUTHORITY

**OFFICIALS AUTHORIZED TO MAKE CERTIFICATION UNDER 5 U.S.C.
605(B) FOR ANY PROPOSED AND FINAL RULES**

Effective Date: May 6, 2013

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

- A. The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to decisions made under the Regulatory Flexibility Act (5 U.S.C. 605(B)), to certify that a proposed or final rule, if issued, will not have a significant economic impact on a substantial number of small entities:
1. Deputy Commissioners for Office of Medical Products and Tobacco (OMPT), Office of Global Regulatory Operations and Policy (OGROP), and the Office of Foods and Veterinary Medicine (OFVM).
 2. Associate Commissioner for Regulatory Affairs, OGROP.
 3. Director, Center for Biologics Evaluation and Research, OMPT.
 4. Director, Center for Drug Evaluation and Research, OMPT.
 5. Director, Center for Devices and Radiological Health, OMPT.
 6. Director, Center for Tobacco Products, OMPT.
 7. Director, Center for Food Safety and Applied Nutrition, OFVM.
 8. Director and Deputy Director, Center for Veterinary Medicine, OFVM.
- B. The following officials, who are authorized to issue Federal Register documents:
1. Associate Commissioner for Special Medical Programs (OSMP), OMPT.
 2. Assistant Commissioner for Policy, Office of Policy (OP), Office of Policy and Planning (OPP), Office of the Commissioner (OC).

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 May 6, 2013.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	12/07/2009	N/a	FDA/OC/OA /OM/OMP	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	05/06/2013	N/a	OGROP/ ORA/ORM	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs