SMG 1410.28

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - GENERAL REDELEGATIONS OF AUTHORITY

PATENT TERM EXTENSIONS FOR HUMAN DRUG PRODUCTS, MEDICAL DEVICES, AND FOOD AND COLOR ADDITIVES; AND AUTHORITY TO PERFORM DUE DILIGENCE DETERMINATIONS AND INFORMAL HEARINGS

Effective Date: 06/04/2010

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The Principal Deputy Commissioner is authorized to perform the due diligence, determinations and informal hearings functions under section 156(d)(2)(B)(ii) of title 35 U.S.C. (35 U.S.C. 156), as amended, relative to patent term extensions.

B. The Director, Center for Drug Evaluation and Research (CDER) and the Associate Director for Policy, Office of Regulatory Policy, CDER, are authorized to perform the functions delegated to the Commissioner under title 35 U.S.C. 156, as amended, except for making due diligence determinations and holding of informal hearings under title 35 U.S.C. 156(d)(2)(B).

C. The FDA Ombudsman, Office of Scientific Integrity, Office of the Chief Scientist, OC , is authorized to perform the functions delegated to the Commissioner to make due diligence determinations under title 35 U.S.C. 156 (d)(2)(B), as amended. This delegation does not include the authority to hold informal hearings under title 35 U.S.C. 156(d)(2)(B)(ii).

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 June 4, 2010.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/23/2009	N/a	OC/OA/ OM/OMP	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs