SMG 1410.103

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - HUMAN DRUGS

AUTHORITY TO APPROVE AND TO WITHDRAW APPROVAL OF A CHARGE FOR INVESTIGATIONAL NEW DRUGS

Effective Date: 06/11/2012

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED

The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs to approve a charge and to withdraw approval to charge for investigational drugs in a clinical trial under an investigational new drug application under 21 CFR, Part 300, Section 312.8:

A. Director and the Deputy Directors, Center for Drug Evaluation and Research (CDER), Office of Medical Products and Tobacco (OMPT), and the Directors, Office of New Drugs (OND) and Office of Pharmaceutical Science, CDER, OMPT, and the Directors, Offices of Drug Evaluation I, II, III, and IV, Office of Antimicrobial Products, and Office of Hematology and Oncology Drug Products, OND, CDER, OMPT

B. Director, Deputy Director, and Associate Director for Review Management, Center for Biologics Evaluation and Research (CBER), OMPT, and the Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, and Office of Cellular, Tissue and Gene Therapies, CBER, OMPT

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 11, 2012.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	10/20/2010	N/a	CDER/OM/DMB/MAB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Revision	06/11/2012	N/a	OO/OBS	Commissioner of Food and Drugs