SMG 1410.111

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - HUMAN DRUGS

PERMIT OR DENY USE OF AN INVESTIGATIONAL DRUG FOR TREATMENT USE

Effective Date: 06/20/2012

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED

The following officials are authorized to permit or deny expanded access to an investigational drug or an approved drug where availability is limited by a risk evaluation and mitigation strategy, for treatment use, under a protocol or investigational new drug application (IND) submitted under 21 CFR, Part 312, subpart I:

A. Director and Deputy Directors, Center for Drug Evaluation and Research (CDER), Office of Medical Products and Tobacco (OMPT)

B. Director, Office of New Drugs (OND), CDER, OMPT

C. Directors, Offices of Drug Evaluation I, II, III, and IV, Office of Antimicrobial Products and Office of Hematology and Oncology Products, OND, CDER, OMPT

D. Director, Deputy Director, and Associate Director for Review Management, Center for Biologics Evaluation and Research (CBER), OMPT

E. Directors, Offices 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 these authorities.

3. EFFECTIVE DATE

The Commissioner of Food and Drugs approved this delegation, via memorandum, on June 20, 2012.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	11/02/2010	N/a	CDER/OM	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	06/20/2012	N/a	OO/OBS	Commissioner of Food and Drugs