

SMG 1410.401

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - MEDICAL DEVICES AND RADIOLOGICAL HEALTH

ISSUANCE OF FEDERAL REGISTER DOCUMENTS TO RECOGNIZE OR TO WITHDRAW RECOGNITION OF A STANDARD TO MEET PREMARKET SUBMISSION REQUIREMENTS

Effective Date: 02/10/2011

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

The following officials are authorized to issue Federal Register documents under Section 514(c) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360d(c)) recognizing or withdrawing recognition of a standard for which a person may submit a declaration of conformity in order to meet a premarket submission requirement.

1. Director and Deputy Directors, Center for Devices and Radiological Health
2. Director and Deputy Director, Center for Biologics Evaluation and Research
3. Director and Deputy Directors, Center for Drug Evaluation and Research

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 February 10, 2011.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/23/2009	N/a	OC/OA/OM/OMP	Commissioner of Food and Drugs
Revision	02/10/2011	N/a	CDRH/OMO/DEMO/AMB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs