SMG 1410.402

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - MEDICAL DEVICES AND RADIOLOGICAL HEALTH

ISSUANCE OF FEDERAL REGISTER DOCUMENTS PERTAINING TO PREMARKET SUBMISSION REQUIREMENTS AND EXEMPTION FROM PREMARKET NOTIFICATION

Effective Date: July 3, 2014

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The following officials are authorized to make determinations and issue Federal Register notices and rules under section 510(m) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360(m)) concerning exemptions from premarket notification.

1. Director and Deputy Directors, Center for Devices and Radiological Health, Office of Medical Products (OMPT).

2. Director and Deputy Director, Center for Biologics Evaluation and Research, OMPT.

3. Director and Deputy Directors, Center for Drug Evaluation and Research, 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 July 3, 2014.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/23/2009	N/a	OC/OO/ 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
Revision	07/03/2014	N/a	CDRH/OMO/ DEMO/AMB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs