SMG 1410.102

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - HUMAN DRUGS

TERMINATION OF EXEMPTIONS FOR NEW DRUGS FOR INVESTIGATIONAL USE IN HUMAN BEINGS

Effective Date: 06/12/2012

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED

A. The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs on the termination of exemptions for new drugs (including those that are biological products which are subject to the licensing provisions of the Public Health Service Act) for investigational use in human beings under 21 CFR, Part, 300, Section 312.44, and in animals under 21 CFR, Part 300, Section 312.160:

1. Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), Office of Medical Products and Tobacco (OMPT)

2. Director and Deputy Directors, Center for Drug Evaluation and Research (CDER), OMPT

3. Directors, Office of New Drugs (OND) and Office of Pharmaceutical Science (OPS), CDER, OMPT

4. Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), OMPT

B. The following officials, for drugs under their jurisdiction, are authorized to terminate exemptions for new drugs for investigational use when sponsors fail to submit an annual progress report under 21 CFR, Part 300, Section 312.44(b)(1)(viii):

1. Directors and Deputy Directors, Offices of Drug Evaluation (ODE) I, II, III, and IV, Office of Antimicrobial Products (OAP), and Office of Oncology Drug Products (OODP), OND, CDER, OMPT

2. Directors and Deputy Directors, Divisions in ODE I, II, III, and IV, OAP, OODP, OND, CDER, OMPT

3. Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), and Office of Cellular, Tissue and Gene Therapies (OCTGT), CBER, OMPT

4. Directors and Deputy Directors, Division of Blood Applications (DBA), OBRR, and Division of Vaccines and Related Products Applications (DVRPA), OVRR, CBER, OMPT

5. Director and Deputy Directors, Office of Device Evaluation (ODE) and Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), CDRH, OMPT

C. The following officials, for drugs under their jurisdiction, are authorized to make the findings set forth in Section 312.44(b) of 21 CFR and to notify sponsors and invite correction before termination action on such exemptions:

1. Directors and Deputy Directors, ODE I, II, III, and IV, OAP, and OODP, OND, CDER, OMPT

2. Directors and Deputy Directors, Divisions in ODE I, II, III, and IV, OAP, OODP, OND, CDER, OMPT

3. Directors and Deputy Directors, OBRR and OVRR, CBER, OMPT

4. Directors and Deputy Directors, DBA, OBRR, and DVRPA, OVRR, CBER, OMPT

5. Director and Deputy Directors, ODE, and OIVD, CDRH, 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 12, 2012.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	07/28/2010	N/a	CDER/OM/DMB/MAB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	03/24/2011	N/a	CDER/OM/DMB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Revision	06/12/2012	N/a	OO/OBS	Commissioner of Food and Drugs