SMG 1410.107

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - HUMAN DRUGS

SUBMISSION OF AND EFFECTIVE APPROVAL DATES FOR ABBREVIATED NEW DRUG APPLICATIONS AND CERTAIN NEW DRUG APPLICATIONS

Effective Date: 06/04/2004

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs with regard to decisions made under section 505 (c)(3)(D), (j)(4)(B)(iv), and (j)(4)(D) and section 505A of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 355(c)(3)(D), (j)(4)(B)(ii) and (j)(4)(D) and 355a) concerning the date of submission or the date of effective approval of abbreviated new drug applications including supplements thereto submitted under section 505(j) of the act (21 U.S.C. 355(j)) and of new drug applications including supplements thereto submitted under section 505(b)(1) (21 U.S.C. 355 (b)(1)) of the act and described under section 505(b)(2) of the act (21 U.S.C. 355(b)(2)):

1. The Director, the Deputy Director, and the Directors, Office of New Drugs and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

2. The Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

2. REDELEGATION.

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

The Acting Commissioner of Food and Drugs approved this revised delegation via memorandum on June 4, 2004 to reflect updated titles and additional CDER officials.