

**SMG 1410.504**

**FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY**

**REGULATORY - ANIMAL DRUGS**

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

Effective Date: October 16, 2014

**1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED.**

A. The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to decisions made under sections 512(c)(2)(D)(iv) and (c)(2)(F) of the Federal, Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(c)(2)(D)(iv) and (c)(2)(F) concerning the date of submission and the date of effective approval of abbreviated new animal drug applications including supplements thereto, submitted under section 512(b)(2) of the FD&C Act (21 U.S.C. 360b(b)(2)), and of new animal drug applications including supplements thereto, submitted under section 512(b)(1) of the FD&C Act (21 U.S.C. 360b(b)(1)):

1. Director and Deputy Directors, Center for Veterinary Medicine (CVM), Office of Foods and Veterinary Medicine (OFVM).
2. Director and Deputy Director, Office of New Animal Drug Evaluation, CVM, OFVM.

**2. REDELEGATION.**

These officials may not further re-delegate this authority.

**3. EFFECTIVE DATE.**

The Commissioner of Food and Drugs approved this delegation on October 16, 2014.

<b>STATUS (I, R, C)</b>	<b>DATE APPROVED</b>	<b>LOCATION OF CHANGE HISTORY</b>	<b>CONTACT</b>	<b>APPROVING OFFICIAL</b>
Initial	02/24/2011	N/a	CVM/OM	Commissioner of Food and Drugs
Revision	10/16/2014	N/a	CVM/OM	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs