

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

**REGULATORY - ANIMAL DRUGS**

**APPROVAL OF NEW ANIMAL DRUG APPLICATIONS, MEDICATED FEED MILL  
LICENSE APPLICATIONS, AND THEIR SUPPLEMENTS**

Effective Date: February 18, 2015

**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 the approval of new animal drug applications, and supplements thereto, for new animal drugs submitted under section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b):

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

B. The following officials are authorized to perform all the functions of the Commissioner with regard to the approval of supplemental applications to approved new animal drugs submitted under section 512 of the FD&C Act (21 U.S.C. 360b):

1. Director and Deputy Director, Office of New Animal Drug Evaluation (ONADE), CVM, OFVM.
2. Director and Deputy Director, Office of Surveillance and Compliance (OSC), CVM, OFVM.

C. The following officials are authorized to perform all the functions of the Commissioner with regard to the approval of supplemental applications to new animal drug applications that are described by section 514.8(b) of Title 21, Code of Federal Regulations, Part 500.

1. Director, Division of Manufacturing Technologies, ONADE, CVM, OFVM.
2. Director, Division of Surveillance, OSC, CVM, OFVM.

D. The following officials are authorized to perform all the functions of the Commissioner with regard to the approval of supplemental applications to new

animal drug applications that are described by section 514.8(c)(3) of Title 21, Code of Federal Regulations, Part 500.

1. Director, Division of Therapeutic Drugs for Non-food Animals, ONADE, CVM, OFVM.
  2. Director, Division of Production Drugs, ONADE, CVM, OFVM.
  3. Director, Division of Therapeutic Drugs for Food Animals, ONADE, CVM, OFVM.
  4. Director, Division of Manufacturing Technologies, ONADE, CVM, OFVM.
  5. Director, Division of Generic Animal Drugs, ONADE, CVM, OFVM.
- E. The following officials are authorized to perform all the functions of the Commissioner with regard to the approval of supplemental applications to new animal drug applications that are described by sections 21 CFR 514.8(c)(2)(i)(A) and (D) of Title 21, Code of Federal Regulations, Part 500.
1. Director, Division of Therapeutic Drugs for Non-food Animals, ONADE, CVM, OFVM.
  2. Director, Division of Production Drugs, ONADE, CVM, OFVM.
  3. Director, Division of Therapeutic Drugs for Food Animals, ONADE, CVM, OFVM.
  4. Director, Division of Manufacturing Technologies, ONADE, CVM, OFVM
  5. Director, Division of Generic Animal Drugs, ONADE, CVM, OFVM.
- F. The following officials are authorized to perform all the functions of the Commissioner with regard to the approval of medicated feed mill license applications for the manufacture of animal feeds containing new animal drugs section 512(m) of the FD&C Act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Public Law 104-250):
1. Director and Deputy Directors, CVM, OFVM.
  2. Director and Deputy Director, OSC, CVM, OFVM.
  3. Director, Division of Animal Feeds (DAF), OSC, CVM, OFVM.
  4. Leader, Medicated Feeds Team, DAF, OSC, CVM, OFVM.

5. Medicated Feeds Specialist, Medicated Feeds Team, DAF, OSC, CVM, OFVM.

**2. REDELEGATION.**

These officials may not further re-delegate these authorities.

**3. EFFECTIVE DATE.**

The Commissioner of Food and Drugs approved this delegation on February 18, 2015.

<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
Revision	01/08/2015	N/a	CVM/OM	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	02/18/2015	N/a	CVM/OM	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs