SMG 1410.508

FDA STAFF MANUAL GUIDES, VOLUME II- DELEGATIONS OF AUTHORITY

REGULATORY - ANIMAL DRUGS

AUTHORITY UNDER THE MINOR USE AND MINOR SPECIES (MUMS) ANIMAL HEALTH ACT OF 2004

Effective Date: October 16, 2014

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED

A. Director and Deputy Directors, Center for Veterinary Medicine (CVM), Office of Foods and Veterinary Medicine (OFVM) are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under sections 571 (Conditional Approval of New Animal Drugs for Minor Use and Minor Species), 572 (Index of Legally Marketed Unapproved New Animal Drugs for Minor Species), and 573 (Designated New Animal Drugs for Minor Use or Minor Species) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360ccc, 360ccc-1, and 360ccc-2, respectively), as amended by the MUMS Animal Health Act of 2004:

B. Director and Deputy Directors, Office of New Animal Drug Evaluation (ONADE), CVM, OFVM are authorized to perform the following functions under section 571 of the FD&C Act (21 U.S.C. 360ccc), as amended by the MUMS Animal Health Act of 2004:

1. Renew applications for conditional approval of new animal drugs for minor use or minor species

2. Conditionally approve applications for conditional approval of new animal drugs for minor use or species

3. Approve supplements to conditionally approved applications for minor use or minor species

C. Director, Division of Manufacturing Technologies, ONADE, CVM, OFVM is authorized to perform the following functions under section 571 of the FD&C Act (21 U.S.C. 360ccc), as amended by the MUMS Animal Health Act of 2004: approve supplements to conditionally approved applications when such supplements are of the kind described in sections 514.8(a)(4)(iii), (iv), (v), and 514.8(d)(3) of Title 21, Code of Federal Regulations, Part 500:

D. Director and Deputy Director, Office of Surveillance and Compliance (OSC), CVM are authorized to perform the following functions under sections 571 and 572 of

the FD&C Act (21 U.S.C. 360ccc and 360ccc-1, respectively), as amended by the MUMS Animal Health Act of 2004:

1. Approve supplements to conditionally approved applications for minor use or minor species.

2. Approve medicated feed mill license applications under section 512 of the FD&C Act for (21 U.S.C. 360b) the manufacture of animal feeds containing new animal drugs for minor use or minor species conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc).

3. Approve medicated feed mill license applications under section 512 of the FD&C Act for (21 U.S.C. 360b) the manufacture of animal feeds containing new animal drugs for minor species indexed under section 572 of the FD&C Act (21 U.S.C. 360ccc-1).

E. Director, Division of Animal Feeds (DAF), OSC, CVM, OFVM; the Leader, Medicated Feeds Team, DAF, OSC, CVM, OFVM; and the Medicated Feeds Specialist, DAF, OSC, CVM, OFVM are authorized to perform the following functions under sections 571 and 572 of the FD&C Act (21 U.S.C. 360ccc and 360ccc-1, respectively), as amended by the MUMS Animal Health Act of 2004:

1. Approve medicated feed mill license applications under section 512 of the FD&C Act for (21 U.S.C. 360b) the manufacture of animal feeds containing new animal drugs for minor use or minor species conditionally approved under section 571 (21 U.S.C. 360ccc).

2. Approve medicated feed mill license applications under section 512 of the FD&C Act for (21 U.S.C. 360b) the manufacture of animal feeds containing new animal drugs for minor species indexed under section 572 of the FD&C Act (21 U.S.C. 360ccc-1).

F. Director and Deputy Director, Office of Minor Use and Minor Species Animal Drug Development, CVM, OFVM are authorized to perform the following functions under sections 571, 572, and 573 of the FD&C Act (21 U.S.C. 360ccc, 360ccc-1,and 360ccc-2, respectively), as amended by the MUMS Animal Health Act of 2004:

1. Designate new animal drugs for minor use or minor species and terminate such designations.

2. Grant or deny eligibility of a new animal drug for inclusion in an index of legally marketed unapproved new animal drugs.

3. Determine if a qualified expert panel meets the selection criteria provided by implementing regulation.

4. Grant or deny requests for listing of a new animal drug in the index.

5. Remove a new animal drug from the index.

6. Exempt from section 512 of the FD&C Act (21 U.S.C. 360b) minor species new animal drugs and animal feeds bearing or containing new animal drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of minor species animal drugs.

2. REDELEGATION

These officials may not further re-delegate these authorities.

3. EFFECTIVE DATE

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

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
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