

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - ANIMAL DRUGS

ISSUANCE OF NOTICES, PROPOSALS, AND ORDERS RELATING TO NEW ANIMAL DRUGS AND MEDICATED FEED MILL LICENSE APPLICATIONS

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:

1. Issue notices of opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications, and supplements thereto, for drugs for animal use and proposals to refuse approval or to revoke approval of medicated feed mill license applications, and supplements thereto, submitted under Section 512(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Public Law 104-250);
2. Issue notices refusing or withdrawing approval when opportunity for hearing has been waived; and
3. Issue proposals and orders to revoke and amend regulations for new animal drugs for drugs for animal use and medicated feed mill licenses, corresponding to said act on such applications.

B. Director and Deputy Directors, CVM, OFVM, are authorized to issue notices of availability of Public Master Files containing data acceptable for use in applications for new animal drugs for drugs for animal use and feeds bearing or containing new animal drugs.

2. REDELEGATION.

These officials may not further re-delegate these authorities.

3. EFFECTIVE DATE.

The Commissioner of 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