

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - ANIMAL DRUGS

AUTHORITY UNDER THE ANIMAL DRUG USER FEE ACT (ADUFA)

Effective Date: October 16, 2014

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED.

A. Director, Center for Veterinary Medicine (CVM), Office of Foods and Veterinary Medicine is authorized to take actions necessary to implement and administer section 740 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379j-12(d)), as amended by ADUFA, which includes, but is not limited to, the authority to:

1. Assess animal drug user fees.
2. Under section 740(d) of the FD&C Act (21 U.S.C. 379j-12(d)), waive or reduce animal drug user fees, except for waivers and reductions under section 740(d)(1)(B) of the FD&C Act, pertaining to situations where the fees assessed exceed the costs to FDA for reviewing applications; and,
3. Decide appeals of CVM's initial animal drug user fee waiver and reduction decisions and reconsideration of those decisions.*

(*NOTE: Agency-level appeals are to be made to the Chief Scientist and Deputy Commissioner for Science and Public Health delegated authority under SMG 1410.21, whose decision will constitute final Agency action).

2. REDELEGATION.

This official may 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