SMG 1410.509

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - ANIMAL DRUGS

IMPORT TOLERANCES UNDER SECTION 512(a) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Effective Date: October 16, 2014

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED AND REDELEGATION.

A. The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under section 512(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(a)), as amended by the Animal Drug Availability Act of 1996, regarding import tolerances of drug residues found in the edible tissue of imported food products of animal origin:

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

2. Director and Deputy Director, Office of Surveillance and Compliance, CVM, OFVM, the same authority under section 512(a) of the FD&C Act (21 U.S.C. 360b(a)) regarding import tolerances of drug residues found in the edible tissue of imported food products of animal origin. Specifically, the authority to:

   a. Establish tolerances of drug residues of animal drugs that are not approved in the United States that are found in the edible tissue of imported food products of animal origin.

   b. Revoke tolerances if information demonstrates that the use of the new animal drug under actual use conditions results in food being imported into the United States with residues exceeding the tolerance or if scientific evidence shows the tolerance to be unsafe.

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