

SMG 1243.16

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND
FUNCTIONS**

FOOD AND DRUG ADMINISTRATION

OFFICE OF FOODS AND VETERINARY MEDICINE

CENTER FOR VETERINARY MEDICINE

OFFICE OF NEW ANIMAL DRUG EVALUATION

DIVISION OF GENERIC ANIMAL DRUGS

Effective: October 1, 2012

1. DIVISION OF GENERIC ANIMAL DRUGS (DJJVCG).

- A. Evaluates, for animal safety and effectiveness, abbreviated new animal drug applications; evaluates proposed labeling to assure that it clearly indicates the use and limitations of the product and provides other required information; recommends procedures to establish the safety and effectiveness of drugs and feed additives for food and non-food animals.
- B. Determines the adequacy of information submitted to support proposed use of investigational generic drugs.
- C. Evaluates Division activities to ensure compliance with the National Environmental Policy Act (NEPA).
- D. Recommends, and may participate in, intramural and extramural research projects to be conducted or coordinated by the Center's Office of Research to gain further information on drugs for animals.
- E. Participates in the development and implementation of regulations, guidance and policies pertaining to generic drugs.
- F. Provides technical support and expert testimony in legal proceedings relative to the approval of generic new animal drugs.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Secretary for Health and Human Services, effective October 1, 2012.

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The following is the Food and Drug Administration, Office of Foods and Veterinary Medicine, Center for Veterinary Medicine, Office of New Animal Drug Evaluation, Division of Generic Animal Drugs organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR