

**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 SCIENTIFIC SUPPORT

Effective: October 1, 2012

1. DIVISION OF SCIENTIFIC SUPPORT (DJJVCF).

- A. Serves as the focus for Scientific Support activities (i.e., environmental science, risk analysis, pharmacokinetic evaluations, and biostatistics) in the Office.
- B. Provides consulting scientific support to the new animal drug review Divisions in the areas of environmental science, risk analysis, pharmacokinetic evaluations, and biostatistics. These activities support the evaluation and approval of New Animal Drug Applications (NADAs).
- C. Represents the Office of New Animal Drug Evaluation and Center for Veterinary Medicine in the areas of risk assessment, environmental assessment and biometrics to other Agencies, outside interested parties, the regulated industry, industry organizations and other national authorities.
- D. Develops and employs the risk analysis methodology for the Center for Veterinary Medicine using state-of-the-art science to identify, assess and recommend Center responses for emerging issues.
- E. Develops risk assessment models to test and develop risk assessment policy for the Center for Veterinary Medicine.
- F. Reviews risk assessments and reviews the work of others who evaluate risk assessments and environmental assessments.
- G. Provides statistical evaluation of animal safety and efficacy studies to the target animal review Divisions.

H. Supports the Performance Goals outlined in the Animal Drug User Fee Act (ADUFA).

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.

Staff Manual Guide 1243.15
Organizations and Functions
Effective Date: October 1 , 2012

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OFFICE OF THE DIRECTOR

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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 Scientific Support organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR