

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Center for Veterinary Medicine**

**Office of New Animal Drug Evaluation**

**Division of Scientific Support**

Effective Date: December 14, 2018

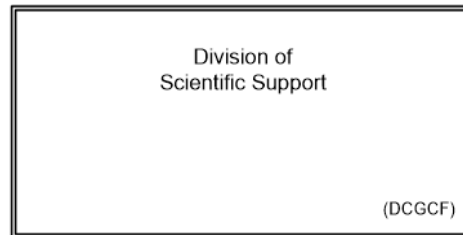
**1. Division of Scientific Support (DCGCF)**

- 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 and Center 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 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.
- 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 the Division of Scientific Support were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services  
Food and Drug Administration  
Center for Veterinary Medicine  
Office of New Animal Drug Evaluation  
Division of Scientific Support**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Office of New Animal Drug Evaluation, Division of Scientific Support organization structure depicting all the organizational structures reporting to the Division of Scientific Support:

Division of Scientific Support (DCGCF)