

**SMG 1243.1**

**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**

Effective: December 14, 2018

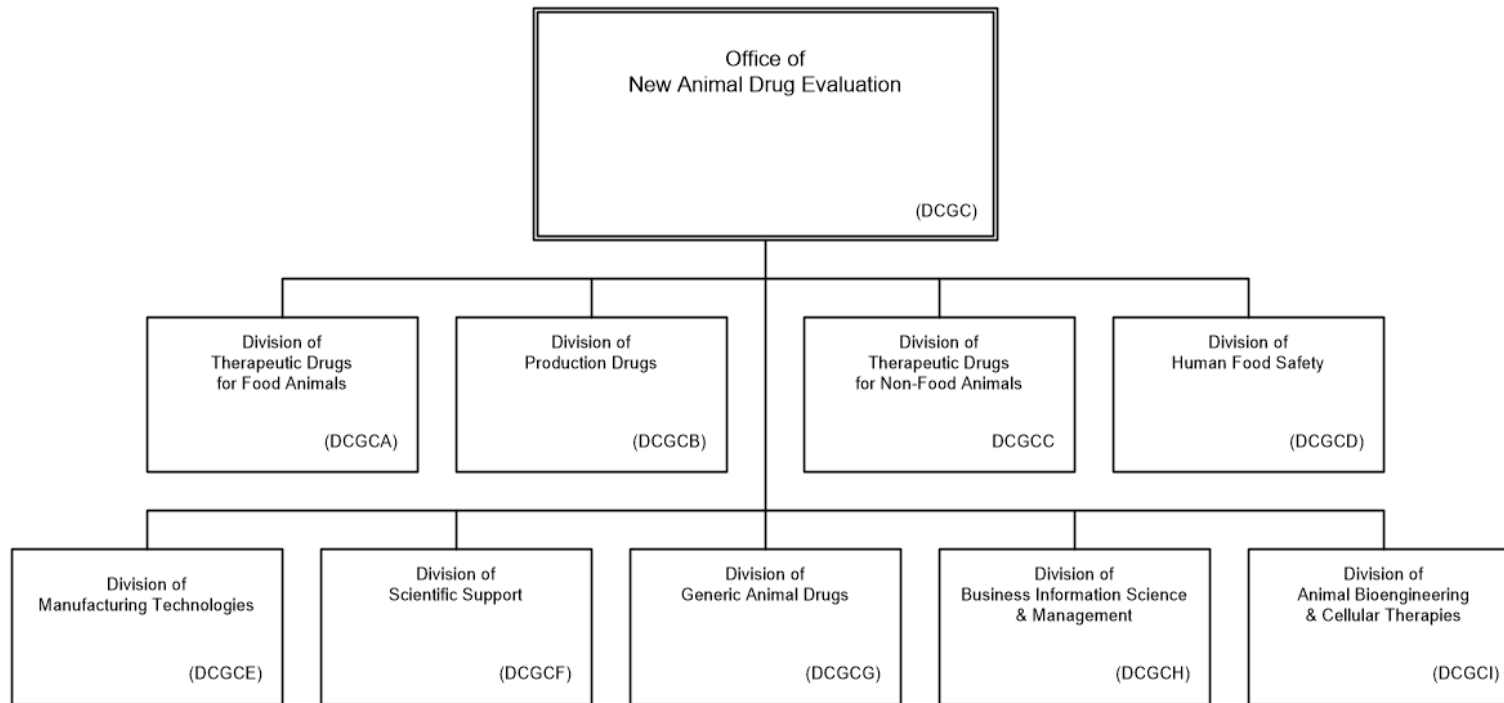
**1. Office of New Animal Drug Evaluation (DCGC).**

- A. Evaluates for animal safety and effectiveness new animal drugs in pharmaceutical dosage forms or for use in animal feed, and the safety aspects of drug and food additive residues remaining in food produced for human consumption from animals, intentionally or otherwise, administered drugs or food additives.
- B. Reviews and determines the adequacy of information submitted in support of proposed use of investigational new animal drugs, and recommends to the Center Director appropriate action on new animal drug applications and acts on investigational new animal drug (INAD) notices of exemption and authorization requests.
- C. Evaluates manufacturing methods and procedures for new animal drug products.
- D. Coordinates the development and implementation of regulations and policies pertaining to new drugs intended for animal use.
- E. Evaluates office activities to ensure compliance with the National Environmental Policy Act (NEPA).
- F. Provides technical support and expert testimony in legal proceedings relative to the approval of new animal drugs.
- G. Participates in international activities designed to harmonize the drug approval process.

**2. Authority and Effective Date**

The functional statements for the Office of New Animal Drug Evaluation 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**



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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 organization structure depicting all the organizational structures reporting to the Office of New Animal Drug Evaluation:

Office of New Animal Drug Evaluation (DCGC)  
Division of Therapeutic Drugs for Food Animals (DCGCA)  
Division of Production Drugs (DCGCB)  
Division of Therapeutic Drugs for Non-Food Animals (DCGCC)  
Division of Human Food Safety (DCGCD)  
Division of Manufacturing Technologies (DCGCE)  
Division of Scientific Support (DCGCF)  
Division of Generic Animal Drugs (DCGCG)  
Division of Business Information Science and Management (DCGCH)  
Division of Animal Bioengineering and Cellular Therapies (DCGCI)