

SMG 1243.1

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

Effective: October 9, 2020

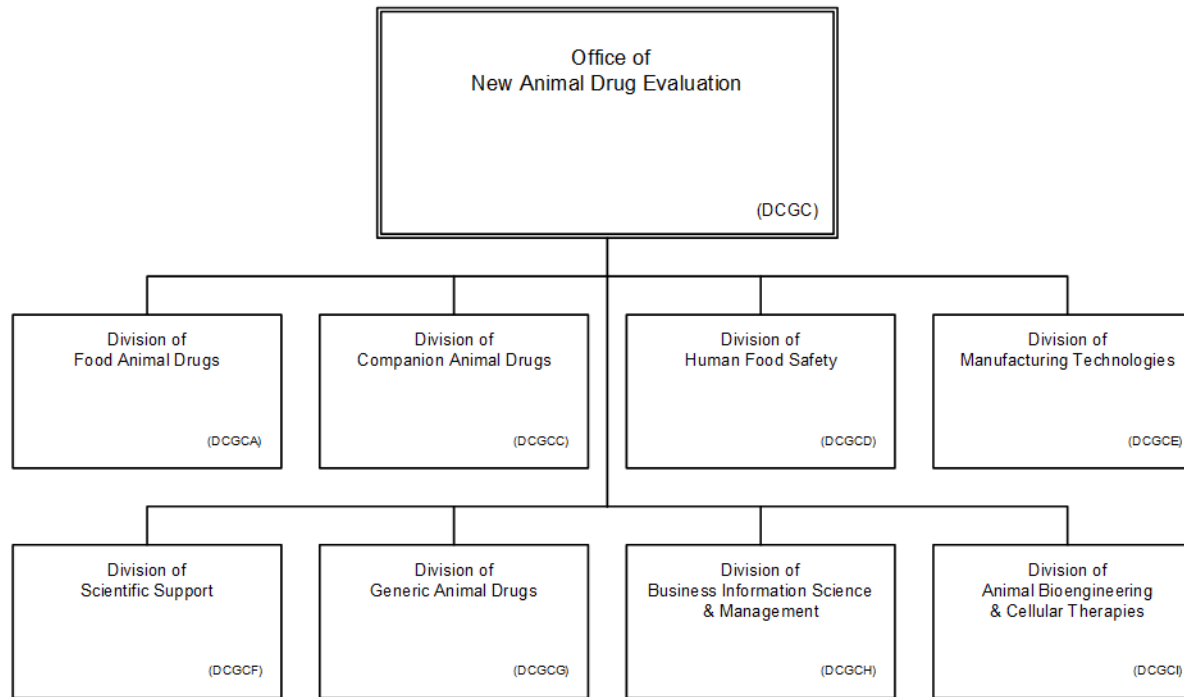
1. Office of New Animal Drug Evaluation (DCGC).

- 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. Provides technical support and expert testimony in legal proceedings relative to the approval of new animal drugs.
- F. Participates in international activities designed to harmonize the drug approval process.
- G. Evaluates office activities to ensure compliance with the National Environmental Policy Act (NEPA).

2. Authority and Effective Date.

The functional statements for this Office were approved by the Commissioner of Food and Drugs on September 8, 2020 and effective on October 9, 2020.

**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 Director of New Animal Drug Evaluation:

Office of New Animal Drug Evaluation (DCGC)

Division of Food Animal Drugs (DCGCA)

Division of Companion Animal Drugs (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)