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 Product Evaluation

Effective Date: August 23, 2024

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

A. Evaluates animal safety and effectiveness, and other criteria as appropriate, of animal products such as drugs in pharmaceutical dosage forms and animal feed; intentional genomic alterations in animals, animal cells, tissues, and cell- and tissue-based products; cell-based gene therapies; and other biotechnology innovations.

B. Evaluates the safety aspects of residues remaining in food produced for human consumption from animals administered these products.

C. Reviews and determines the adequacy of information submitted in support of proposed use of investigational animal products; recommends to the Center Director appropriate action on applications; and acts on investigational use exemption and authorization requests.

D. Evaluates manufacturing methods and procedures for animal products.

E. Coordinates the development and implementation of regulations and policies pertaining to new products intended for animal use.

F. Evaluates office activities to ensure compliance with the National Environmental Policy Act (NEPA).

G. Provides technical support and expert testimony in legal proceedings relative to the approval of new animal products.

H. Participates in international activities designed to harmonize the approval process.

2. **Administrative Staff (DCGC1).**

   A. Provides administrative support for the office.

   B. Manages payroll and operating budgets for the office.

   C. Provides Human Resources support for the office.

   D. Manages contracts, grants, cooperative agreements, and interagency agreements to support the pioneer product pre-approval program.

3. **Regulatory Counsel Staff (DCGC2).**

   A. Advises office leadership and staff on legal, policy and regulatory issues affecting animal products,

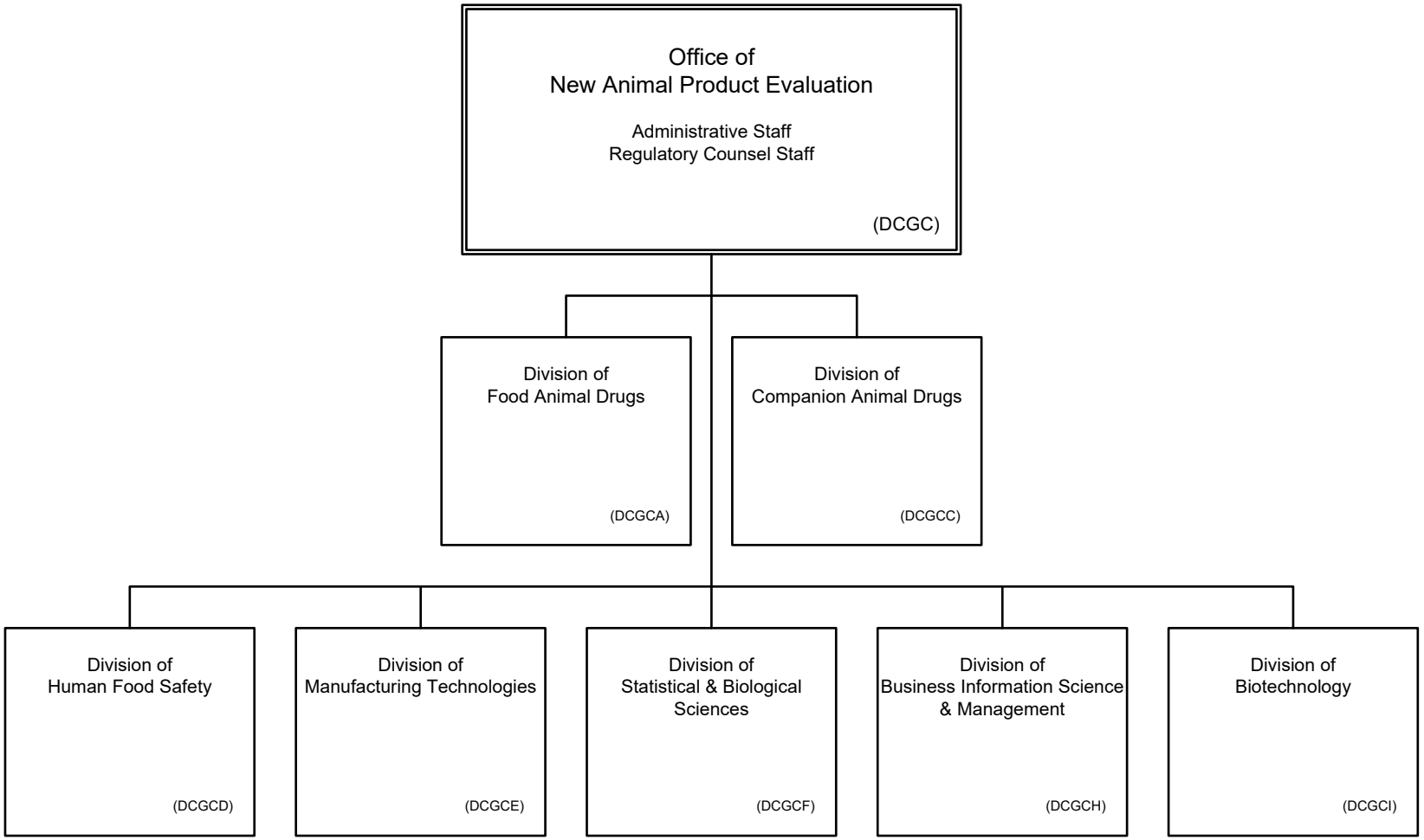
   B. Drafts, and assists in the review and revision of, proposed regulations, guidance documents, and correspondence (e.g., responses to petitions or congressional inquiries), that state or interpret Office, Center, or FDA policy and typically involve industry-wide impact, broad public health implications, or precedent-setting interpretations of FDA policy, to ensure legal sufficiency and compliance with Good Guidance Practices or other requirements.

   C. Represent the Office in crosscutting (affecting multiple offices or Centers) compliance and regulatory policy development initiatives (e.g., working groups, committees, etc.).

4. **Authority and Effective Date.**

   The functional statements for the Office of New Animal Product Evaluation were approved by the Secretary of Health and Human Services on July 22, 2024, and effective on August 23, 2024.

Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
Office of New Animal Product 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 Product Evaluation organization structure depicting all the organizational structures reporting to the Director:

Office of New Animal Product Evaluation (DCGC)
Administrative Staff
Regulatory Counsel Staff
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 Statistical and Biological Sciences (DCGCF)
Division of Business Information Science and Management (DCGCH)
Division of Biotechnology (DCGCI)