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 Generic Animal Drugs

Effective Date: August 23, 2024

1. Office of Generic Animal Drugs (DCGG).

A. Evaluates the bioequivalence of generic new animal drugs in pharmaceutical dosage forms and for use in animal feed, and the safety aspects of drug and food additive residues remaining in food produced for human consumption from animals administered drugs or food additives.

B. Reviews and determines the adequacy of information submitted in support of proposed use of generic investigational new animal drugs (JINADs); recommends to the Center Director appropriate action on abbreviated new animal drug applications; and acts on JINAD notices of exemption and authorization requests.

C. Evaluates manufacturing methods and procedures for generic new animal drug products.

D. Coordinates the development and implementation of regulations and policies pertaining to generic new animal 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 generic new animal drugs.

G. Participates in international activities designed to harmonize the animal drug approval process.

2. Business Management and Operations Staff (DCGG1)

A. Manages the business operations of the office (e.g., administrative support, human resources, payroll, and operational budgets).

B. Provides project management and quality systems support for the office.

C. Advises Office leadership and staff on legal, policy, scientific and regulatory issues affecting generic animal drugs.

3. Authority and Effective Date.

The functional statements for the Office of Generic Animal Drugs 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
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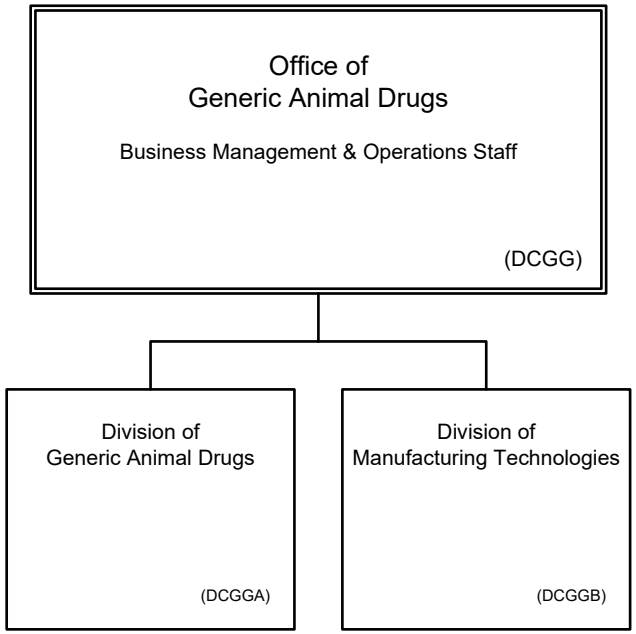

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Office of Generic Animal Drugs organization structure depicting all the organizational structures reporting to the Director:

Office of Generic Animal Drugs (DCGG)
Business Management and Operations Staff
Division of Generic Animal Drugs (DCGGA)
Division of Manufacturing Technologies (DCGGB)