

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 Generic Animal Drugs

Effective Date: December 14, 2018

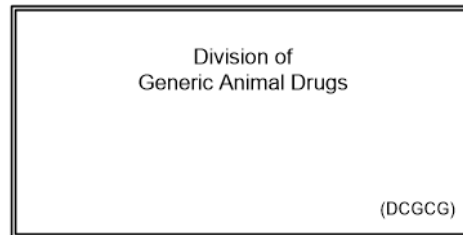
1. Division of Generic Animal Drugs (DCGCG)

- A. Evaluates, for animal safety and effectiveness, abbreviated new animal drug applications; evaluates proposed labeling to assure that it clearly indicates the use and limitations of the product and provides other required information; recommends procedures to establish the safety and effectiveness of drugs and feed additives for food and non-food animals
- B. Determines the adequacy of information submitted to support proposed use of investigational generic drugs.
- C. Evaluates Division activities to ensure compliance with the National Environmental Policy Act (NEPA).
- D. Recommends, and may participate in, intramural and extramural research projects to be conducted or coordinated by the Center's Office of Research to gain further information on drugs for animals.
- E. Participates in the development and implementation of regulations, guidance and policies pertaining to generic drugs.
- F. Provides technical support and expert testimony in legal proceedings relative to the approval of generic new animal drugs.

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
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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 Generic Animal Drugs organization structure depicting all the organizational structures reporting to the Division of Generic Animal Drugs:

Division of Generic Animal Drugs (DCGCG)