

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 Therapeutic Drugs for Food Animals

Effective Date: December 14, 2018

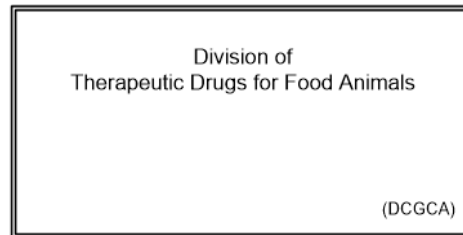
1. Division of Therapeutic Drugs for Food Animals (DCGCA)

- A. Evaluates, for animal safety and effectiveness, new animal drug applications for therapeutic drugs; 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 therapeutic drugs and feed additives for food animals; and, provides consultation on petitions for feed additives in domestic food animals.
- B. Determines the adequacy of information submitted to support proposed use of investigational therapeutic drugs in food animals.
- 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 Science to gain further information on therapeutic drugs for food animals.
- E. Participates in the development and implementation of regulations, guidance and policies pertaining to therapeutic drugs intended for use in food animals.
- F. Provides technical support and expert testimony in legal proceedings relative to the approval of therapeutic new animal drugs for food animals.

2. Authority and Effective Date.

The functional statements for the Division of Therapeutic Drugs for Food Animals 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
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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 Therapeutic Drugs for Food Animals organization structure depicting all the organizational structures reporting to the Division of Therapeutic Drugs for Food Animals:

Division of Therapeutic Drugs for Food Animals (DCGCA)