

FDA STAFF MANUAL GUIDES, VOLUME I – ORGANIZATIONS AND FUNCTIONS

**Department of Health and Human
Services Food and Drug Administration
Office of New Animal Product Evaluation
Division of Companion Animal Drugs**

Effective Date: August 23, 2024

1. DIVISION OF COMPANION ANIMAL DRUGS (DCGCC).

- A. Manages the evaluation of animal safety and effectiveness under new animal drug applications for wildlife and companion animals; oversees proposed labeling reviews to assure that it clearly indicates the use and limitations of the product and provides other required information; establishes procedures to evaluate the safety and effectiveness of drugs for wildlife and companion animals; and provides such information to investigators and developers.
- B. Verifies the adequacy of information submitted to support proposed use of investigational food animal drugs.
- C. Verifies the adequacy of information submitted to support proposed use of investigational drugs in wildlife and companion animals.
- D. Manages intramural and extramural research projects to gain further information on drugs for wildlife and companion animals.
- E. Manages the development and implementation of regulations, guidance, and policies pertaining to drugs intended for use in wildlife and companion animals.
- F. Provides technical support and expert testimony in legal proceedings relative to the approval of new animal drugs for wildlife and companion animals.
- G. Develops short and long-range work plans and staffing need proposals for the Division.

2. COMPANION ANIMAL BRANCH 1 (DCGCC1).

- A. Evaluates, for animal safety and effectiveness, new animal drug applications for wildlife and companion animals; 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 for wildlife and companion animals; and provides such information to investigators and developers.
- B. Determines the adequacy of information submitted to support proposed use of investigational drugs in wildlife and companion animals.

- C. Recommends, and may participate in, intramural and extramural research projects to gain further information on drugs for wildlife and companion animals.
- D. Participates in the development and implementation of regulations, guidance, and policies pertaining to drugs intended for use in wildlife and companion animals.
- E. Provides technical support and expert testimony in legal proceedings relative to the approval of new animal drugs for wildlife and companion animals.

3. COMPANION ANIMAL BRANCH 2 (DCGCC2).

- A. Evaluates, for animal safety and effectiveness, new animal drug applications for wildlife and companion animals; 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 for wildlife and companion animals; and provides such information to investigators and developers.
- B. Determines the adequacy of information submitted to support proposed use of investigational drugs in wildlife and companion animals.
- C. Recommends, and may participate in, intramural and extramural research projects to gain further information on drugs for wildlife and companion animals.
- D. Participates in the development and implementation of regulations, guidance, and policies pertaining to drugs intended for use in wildlife and companion animals.
- E. Provides technical support and expert testimony in legal proceedings relative to the approval of new animal drugs for wildlife and companion animals.

4. COMPANION ANIMAL BRANCH 3 (DCGCC3).

- A. Evaluates, for animal safety and effectiveness, new animal drug applications for wildlife and companion animals; 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 for wildlife and companion animals; and provides such information to investigators and developers.
- B. Determines the adequacy of information submitted to support proposed use of investigational drugs in wildlife and companion animals.
- C. Recommends, and may participate in, intramural and extramural research projects to gain further information on drugs for wildlife and companion animals.
- D. Participates in the development and implementation of regulations, guidance, and policies pertaining to drugs intended for use in wildlife and companion animals.
- E. Provides technical support and expert testimony in legal proceedings relative to the approval of new animal drugs for wildlife and companion animals.

5. AUTHORITY AND EFFECTIVE DATE.

The functional statements for the Division of Companion Animal Drugs were approved by the Secretary of Health and Human Services on July 22, 2024, and effective on August 23, 2024.