SMG 1247.10

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

Division of Generic Animal Drugs

Effective Date: August 23, 2024

1. Division of Generic Animal Drugs (DCGGA).

A. Manages the evaluation, for bioequivalence, of 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 bioequivalence of generic new animal drugs for food and companion animals.

B. Manages the evaluation of the safety aspects of residues remaining in food produced for human consumption from animals administered generic new animal drugs.

C. Manages the determination of the adequacy of information submitted to support proposed use of investigational generic new animal drugs.

D. Ensures compliance with the National Environmental Policy Act (NEPA).

E. Manages intramural and extramural research projects to gain further information on generic new animal drugs.

F. Manages the development and implementation of regulations, guidance, and policies pertaining to generic new animal drugs.

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

H. Develops short and long-range work plans and staffing need proposals for the Division.

2. **Generics Review Branch 1 (DCGGA1).**

   A. Evaluates, for bioequivalence, 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 bioequivalence of generic new animal drugs for food and companion animals.

   B. Evaluates the safety aspects of residues remaining in food produced for human consumption from animals administered generic new animal drugs.

   C. Determines the adequacy of information submitted to support proposed use of investigational generic new animal drugs.

   D. Recommends steps to comply with NEPA.

   E. Recommends, and may participate in, intramural and extramural research projects to gain further information on generic new animal drugs.

   F. Participates in the development and implementation of regulations, guidance, and policies pertaining to generic new animal drugs.

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

3. **Generics Review Branch 2 (DCGGA2).**

   A. Evaluates, for bioequivalence, 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 bioequivalence of generic new animal drugs for food and companion animals.

   B. Evaluates the safety aspects of residues remaining in food produced for human consumption from animals administered generic new animal drugs.

   C. Determines the adequacy of information submitted to support proposed use of investigational generic new animal drugs.

   D. Recommends steps to comply with NEPA.

   E. Recommends, and may participate in, intramural and extramural research projects to gain further information on generic new animal drugs.

   F. Participates in the development and implementation of regulations, guidance, and policies pertaining to generic new animal drugs.

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

4. **Generics Review Branch 3 (DCGGA3).**

   A. Evaluates, for bioequivalence, 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 bioequivalence of generic new animal drugs for food and companion animals.

   B. Evaluates the safety aspects of residues remaining in food produced for human consumption from animals administered generic new animal drugs.

   C. Determines the adequacy of information submitted to support proposed use of investigational generic new animal drugs.

   D. Recommends steps to comply with NEPA.

   E. Recommends, and may participate in, intramural and extramural research projects to gain further information on generic new animal drugs.

   F. Participates in the development and implementation of regulations, guidance, and policies pertaining to generic new animal drugs.

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

5. **Generics Review Branch 4 (DCGGA4).**

   A. Evaluates, for bioequivalence, 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 bioequivalence of generic new animal drugs for food and companion animals.

   B. Evaluates the safety aspects of residues remaining in food produced for human consumption from animals administered generic new animal drugs.

   C. Determines the adequacy of information submitted to support proposed use of investigational generic new animal drugs.

   D. Recommends steps to comply with NEPA.

   E. Recommends, and may participate in, intramural and extramural research projects to gain further information on generic new animal drugs.

   F. Participates in the development and implementation of regulations, guidance, and policies pertaining to generic new animal drugs.

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

6. Generics Review Branch 5 (DCGGA5).

A. Evaluates, for bioequivalence, 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 bioequivalence of generic new animal drugs for food and companion animals.

B. Evaluates the safety aspects of residues remaining in food produced for human consumption from animals administered generic new animal drugs.

C. Determines the adequacy of information submitted to support proposed use of investigational generic new animal drugs.

D. Recommends steps to comply with NEPA.

E. Recommends, and may participate in, intramural and extramural research projects to gain further information on generic new animal drugs.

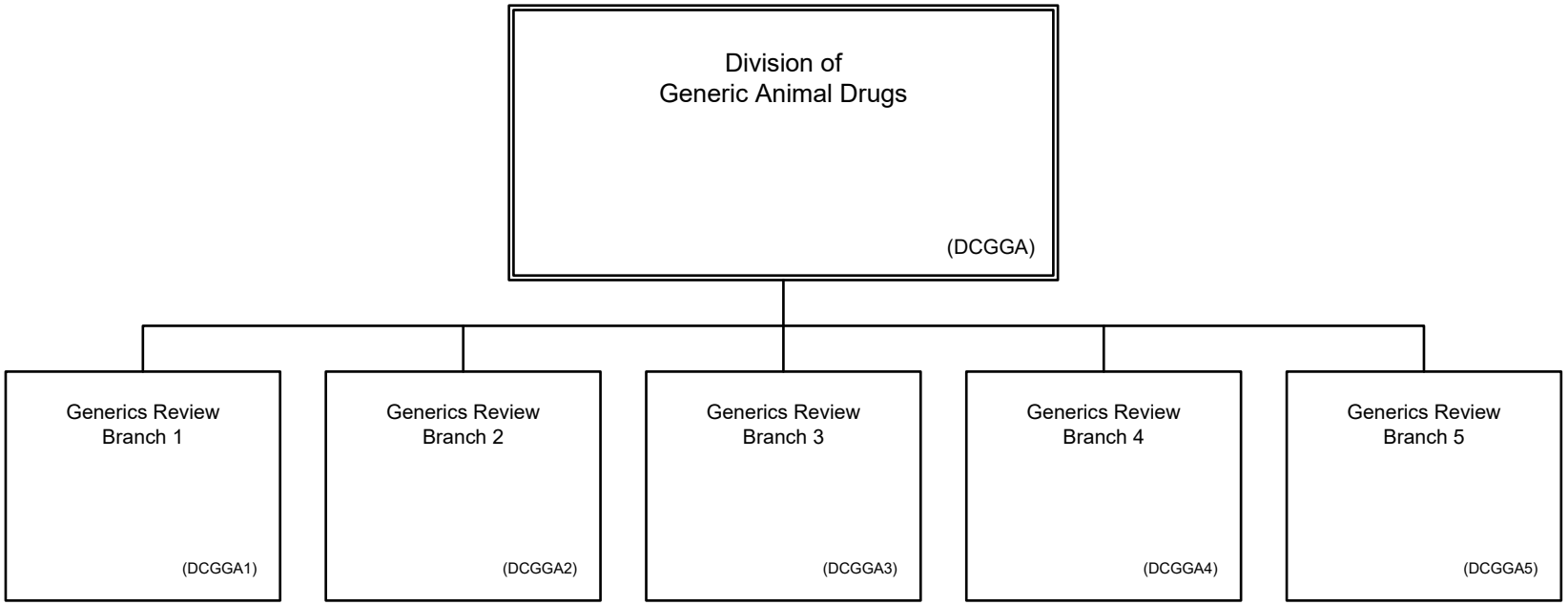
F. Participates in the development and implementation of regulations, guidance, and policies pertaining to generic new animal drugs.

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

7. Authority and Effective Date.

The functional statements for the Division 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
Office of Generic Animal Drugs
Division of Generic Animal Drugs



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

Division of Generic Animal Drugs (DCGGA)
Generics Review Branch 1 (DCGGA1)
Generics Review Branch 2 (DCGGA2)
Generics Review Branch 3 (DCGGA3)
Generics Review Branch 4 (DCGGA4)
Generics Review Branch 5 (DCGGA5)