

**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 Product Evaluation**

**Division of Statistical and Biological Sciences**

Effective Date: August 23, 2024

**1. Division of Statistical and Biological Sciences (DCGCF).**

- A. Serves as the focus for scientific support activities (i.e., environmental impact, clinical pharmacology, and biostatistics) in the Office.
- B. Oversees consulting scientific support to the new animal product review Divisions in the areas of environmental impact, clinical pharmacology, and biostatistics.
- C. Oversees compliance with the National Environmental Policy Act (NEPA).
- D. Manages intramural and extramural research projects to gain further information on issues related to environmental impact, clinical pharmacology, and biostatistics.
- E. Manages the development and implementation of regulations, guidance and policies pertaining to new animal product evaluation specific to environmental impact, clinical pharmacology, and biostatistics.
- F. Provides technical support and expert testimony in legal proceedings pertaining to new animal product evaluation specific to environmental impact, clinical pharmacology, and biostatistics.
- G. Develops short and long-range work plans and staffing need proposals for the Division.

**2. Environmental Branch (DCGCF1).**

- A. Provides environmental impact consulting support to the new animal product review Divisions.

- B. Ensures compliance with the National Environmental Policy Act (NEPA).
- C. Recommends, and may participate in, intramural and extramural research projects to gain further information on issues related to environmental impact.
- D. Participates in the development and implementation of regulations, guidance and policies pertaining to new animal product evaluation specific to environmental impact.
- E. Provides technical support and expert testimony in legal proceedings pertaining to new animal product evaluation specific to environmental impact.

**3. Biostatistics Branch 1 (DCGCF2).**

- A. Provides biostatistics consulting support to the new animal product review Divisions.
- B. Recommends, and may participate in, intramural and extramural research projects to gain further information on issues related to biostatistics.
- C. Participates in the development and implementation of regulations, guidance and policies pertaining to new animal product evaluation specific to biostatistics.
- D. Provides technical support and expert testimony in legal proceedings pertaining to new animal product evaluation specific to biostatistics.

**4. Biostatistics Branch 2 (DCGCF3).**

- A. Provides biostatistics consulting support to the new animal product review Divisions.
- B. Recommends, and may participate in, intramural and extramural research projects to gain further information on issues related to biostatistics.
- C. Participates in the development and implementation of regulations, guidance and policies pertaining to new animal product evaluation specific to biostatistics.
- D. Provides technical support and expert testimony in legal proceedings pertaining to new animal product evaluation specific to biostatistics.

**5. Clinical Pharmacology Branch (DCGCF4).**

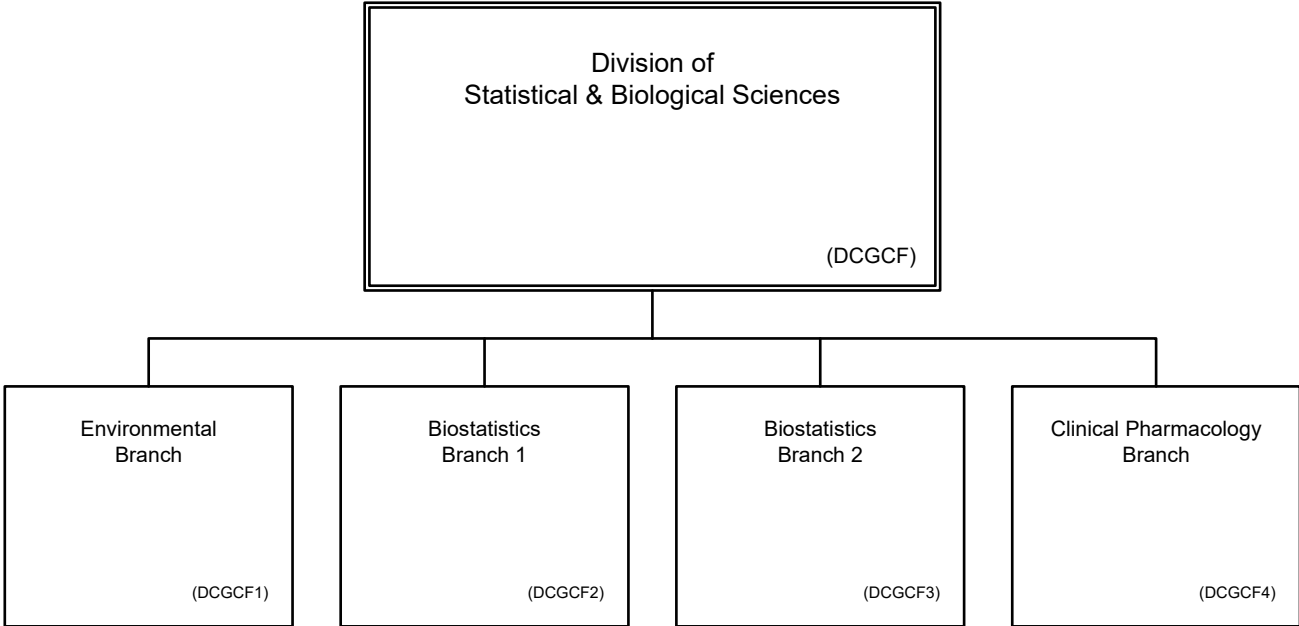
- A. Provides clinical pharmacology consulting support to the new animal product review Divisions.
- B. Recommends, and may participate in, intramural and extramural research projects to gain further information on issues related to clinical pharmacology.

- C. Participates in the development and implementation of regulations, guidance and policies pertaining to new animal product evaluation specific to clinical pharmacology.
- D. Provides technical support and expert testimony in legal proceedings pertaining to new animal product evaluation specific to clinical pharmacology.

**6. Authority and Effective Date.**

The functional statements for the Division of Statistical and Biological Sciences 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 New Animal Product Evaluation  
Division of Statistical and Biological Sciences**



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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 Product Evaluation, Division of Statistical and Biological Sciences organization structure depicting all the organizational structures reporting to the Director:

Division of Statistical and Biological Sciences (DCGCF)  
Environmental Branch (DCGCF1)  
Biostatistics Branch 1 (DCGCF2)  
Biostatistics Branch 2 (DCGCF3)  
Clinical Pharmacology Branch (DCGCF4)