

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 Biotechnology

Effective Date: August 23, 2024

1. Division of Biotechnology (DCGCI).

- A. Manages the evaluation of product characterization, molecular characterization, durability, donor eligibility, product comparability, and safety and effectiveness of biotechnology products such as intentional genomic alterations in animals, animal cells, tissues, and cell- and tissue-based products, cell-based gene therapies, and other biotechnology innovations.
- B. Manages the jurisdictional determination of novel biotechnology products, and the determination of the appropriate level and type of regulatory oversight of these products.
- C. Oversees scientific and regulatory experts in the development and implementation of regulation, guidance, policy, and review processes for biotechnology products.
- D. Allocates resources for the development of post-approval monitoring and reporting requirements and enforcement strategies for biotechnology products.
- E. Manages the evaluation of, and recommendations concerning, manufacturing related changes in biotechnology products.
- F. Verifies the adequacy of information submitted to support proposed investigational use of biotechnology products.
- G. Recommends research projects to gain further information supporting regulation of biotechnology products.

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

2. Animal Biotechnology Branch (DCGCI1).

- A. Evaluates the product characterization, molecular characterization, durability, and safety and effectiveness of animal biotechnology products such as intentional genomic alterations in animals, and other biotechnology innovations.
- B. Participates in the jurisdictional determination of novel biotechnology products, and the determination of the appropriate level and type of regulatory oversight of these products.
- C. Provides scientific and regulatory expertise in the development and implementation of regulation, guidance, policy, and review processes for biotechnology products.
- D. Participates in the development of post-approval monitoring and reporting requirements and enforcement strategies biotechnology products.
- E. Evaluates and makes recommendations concerning manufacturing related changes in biotechnology products.
- F. Verifies the adequacy of information submitted to support proposed investigational use of biotechnology products.
- G. Participates in research projects to gain further information supporting regulation of biotechnology products.

3. Biologic Products Branch (DCGCI2).

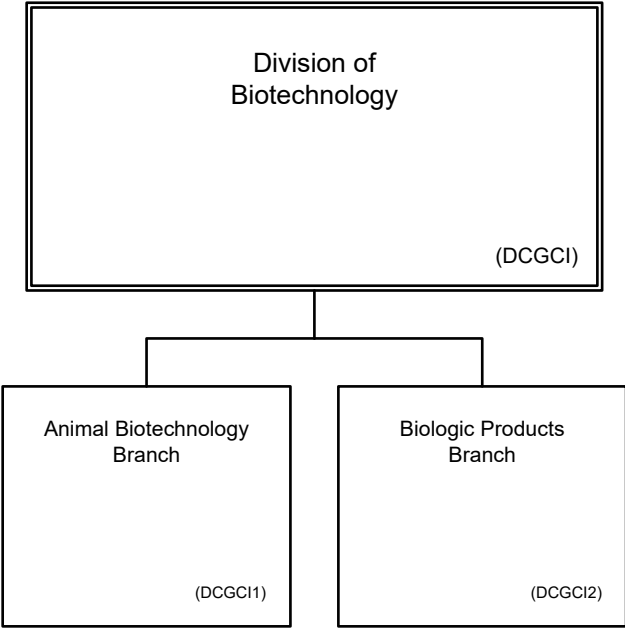
- A. Evaluates the product characterization, donor eligibility, product comparability, and safety and effectiveness of animal cells, tissues, and cell- and tissue-based products, cell-based gene therapies, and other biotechnology innovations.
- B. Participates in the jurisdictional determination of novel biotechnology products, and the determination of the appropriate level and type of regulatory oversight of these products.
- C. Provides scientific and regulatory expertise in the development and implementation of regulation, guidance, policy, and review processes for biotechnology products.
- D. Participates in the development of post-approval monitoring and reporting requirements and enforcement strategies biotechnology products.

- E. Evaluates and makes recommendations concerning manufacturing related changes in biotechnology products.
- F. Determines the adequacy of information submitted to support proposed investigational use of biotechnology products.
- G. Participates in research projects to gain further information supporting regulation of biotechnology products.

4. Authority and Effective Date.

The functional statements for the Division of Biotechnology 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 Biotechnology**



Staff Manual Guide 1243.18
Organizations and Functions
Effective Date: August 23, 2024

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 Biotechnology organization structure depicting all the organizational structures reporting to the Director:

Division of Biotechnology (DCGCI)
Animal Biotechnology Branch (DCGCI1)
Biologic Products Branch (DCGCI2)