SMG 1243.18

FDA staff Guides, Volume 1 – Organizations and Functions

Food and Drug Administration

Center for Veterinary Medicine

Office of New Animal Drug Evaluation

Division of Animal Bioengineering and Cellular Therapies

(Effective: December 14, 2018)

1. Division of Animal Bioengineering and Cellular Therapies (DCGCI)

A. Evaluates the molecular characterization of intentional genetic alterations to animals, and the safety, effectiveness, and durability of these alterations.

B. Evaluates the product characterization, donor eligibility, product comparability, and safety and effectiveness of animal cell- and tissue-based and gene therapy products.

C. Participates in the jurisdictional determination of novel therapies such as intentionally genetically engineered animals and animal cell and gene therapies, and the determination of the appropriate level and type of regulatory oversight of these products.

D. Provides scientific and regulatory expertise in the development and implementation of regulation, guidance, policy, and review processes for animal bioengineering and cell and gene therapy new animal drugs.

E. Participates in the development of post-approval monitoring and reporting requirements and enforcement strategies for animal bioengineering and animal cell and gene therapy new animal drugs.

F. Evaluates and makes recommendations concerning manufacturing related changes to animal bioengineering and animal cell and gene therapy new animal drugs.

G. Determines the adequacy of information submitted to support proposed investigational use of animal bioengineering and animal cell and gene therapy new animal drugs.

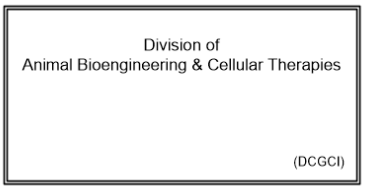
H. Recommends and may participate in research projects conducted by the Center's Office of Research to gain further information supporting regulation of animal bioengineering and animal cell and gene therapy drugs.

I. Evaluates division activities to ensure compliance with the National Environmental Policy Act (NEPA).

2. Authority and Effective Date

The functional statements for the Division of Animal Bioengineering and Cellular Therapies 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
Center for Veterinary Medicine
Office of New Animal Drug Evaluation
Division of Animal Bioengineering and Cellular Therapies



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Effective Date: December 14, 2018

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 Animal Bioengineering and Cellular Therapies organization structure depicting all the organizational structures reporting to the Division of Animal Bioengineering and Cellular Therapies:

Division of Animal Bioengineering and Cellular Therapies (DCGCI)