SMG 1218A.21

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Therapeutic Products

Office of Gene Therapy CMC

Division of Gene Therapy I

Effective Date: September 16, 2022

1. Division of Gene Therapy I (DCBGFA).

A. Evaluates Biologic License Applications (BLAs) and amendments to BLAs for cellular therapy, tissue engineering, gene therapy, and therapeutic vaccine products. Directs BLA review committee activities. Develops policy and formulates recommendations on BLAs consistent with the applicable laws and Center policies.

B. Reviews Investigational New Drug Applications (INDs), Investigational Device Exemptions (IDEs), 510Ks, Humanitarian Device Exemptions (HDEs), and Pre- market Approval Applications (PMAs) for new cellular therapy, tissue engineering, gene therapy, and therapeutic vaccine products.

C. Evaluates biological product deviations and adverse events reported in association with the use of marketed cellular therapy, gene therapy, tissue engineering, and therapeutic vaccine products.

D. Participates in the inspection of manufacturers of cellular therapy, tissue engineering, and gene therapy, and therapeutic vaccine products.

E. Provides expert scientific, medical, and technical advice and assistance to other Center components and to the FDA on cellular therapy, tissue engineering, gene therapy, and therapeutic vaccine products and related issues.

F. Develops policies and procedures applicable to the review and evaluation of INDs, IDEs, 510Ks, HDEs, PMAs, BLAs and products regulated by the Office in the absence of Center-level policies and procedures.

G. Performs consultative reviews of product information and data in BLAs, BLA amendments, INDs, IDEs, 510Ks, HDEs, and PMAs in response to request from other Center components.

H. Initiates and participates in development of reference standards and methods, in conjunction with other Center components governmental and non-governmental organizations and international regulatory agencies.

2. Gene Therapy Branch 1 (DCBGFA1).

A. Evaluates BLAs and amendments to BLAs for cellular therapy, tissue engineering, gene therapy, and therapeutic vaccine products. Directs BLA review committee activities. Develops policy and formulates recommendations on BLAs consistent with the applicable laws and Center policies.

B. Reviews INDs, IDEs, 510Ks, HDEs, and PMAs for new cellular therapy, tissue engineering, gene therapy, and therapeutic vaccine products within the Branch's purview.

C. Evaluates biological product deviations and adverse events reported in association with the use of marketed cellular therapy, gene therapy, tissue engineering, and therapeutic vaccine products.

D. Participates in the inspection of manufacturers of cellular therapy, tissue engineering, and gene therapy, and therapeutic vaccine products.

E. Provides expert scientific, medical, and technical advice and assistance to other Center components and to the FDA on cellular therapy, tissue engineering, gene therapy, and therapeutic vaccine products and related issues.

F. Develops policies and procedures applicable to the review and evaluation of INDs, IDEs, 510Ks, HDEs, PMAs, BLAs and products regulated by the Office in the absence of Center-level policies and procedures.

G. Performs consultative reviews of product information and data in BLAs, BLA amendments, INDs, IDEs, 510Ks, HDEs, and PMAs in response to request from other Center components.

H. Initiates and participates in development of reference standards and methods, in conjunction with other Center components governmental and non-governmental organizations and international regulatory agencies.

3. Gene Therapy Branch 2 (DCBGFA2).

A. Evaluates BLAs and amendments to BLAs for cellular therapy, tissue engineering, gene therapy, and therapeutic vaccine products. Directs BLA review committee activities. Develops policy and formulates recommendations on BLAs consistent with the applicable laws and Center policies.

B. Reviews INDs, IDEs, 510Ks, HDEs, and PMAs for new cellular therapy, tissue engineering, gene therapy, and therapeutic vaccine products within the Branch's purview.

C. Evaluates biological product deviations and adverse events reported in association with the use of marketed cellular therapy, gene therapy, tissue engineering, and therapeutic vaccine products.

D. Participates in the inspection of manufacturers of cellular therapy, tissue engineering, and gene therapy, and therapeutic vaccine products.

E. Provides expert scientific, medical, and technical advice and assistance to other Center components and to the FDA on cellular therapy, tissue engineering, gene therapy, and therapeutic vaccine products and related issues.

F. Develops policies and procedures applicable to the review and evaluation of INDs, IDEs, 510Ks, HDEs, PMAs, BLAs and products regulated by the Office in the absence of Center-level policies and procedures.

G. Performs consultative reviews of product information and data in BLAs, BLA amendments, INDs, IDEs, 510Ks, HDEs, and PMAs in response to request from other Center components.

H. Initiates and participates in development of reference standards and methods, in conjunction with other Center components governmental and non-governmental organizations and international regulatory agencies.

4. Gene Therapy Branch 3 (DCBGFA3).

A. Evaluates BLAs and amendments to BLAs for cellular therapy, tissue engineering, gene therapy, and therapeutic vaccine products. Directs BLA review committee activities. Develops policy and formulates recommendations on BLAs consistent with the applicable laws and Center policies.

B. Reviews INDs, IDEs, 510Ks, HDEs, and PMAs for new cellular therapy, tissue engineering, gene therapy, and therapeutic vaccine products within the Branch's purview.

C. Evaluates biological product deviations and adverse events reported in association with the use of marketed cellular therapy, gene therapy, tissue engineering, and therapeutic vaccine products.

D. Participates in the inspection of manufacturers of cellular therapy, tissue engineering, and gene therapy, and therapeutic vaccine products.

E. Provides expert scientific, medical, and technical advice and assistance to other Center components and to the FDA on cellular therapy, tissue engineering, gene therapy, and therapeutic vaccine products and related issues.

F. Develops policies and procedures applicable to the review and evaluation of INDs, IDEs, 510Ks, HDEs, PMAs, BLAs and products regulated by the Office in the absence of Center-level policies and procedures.

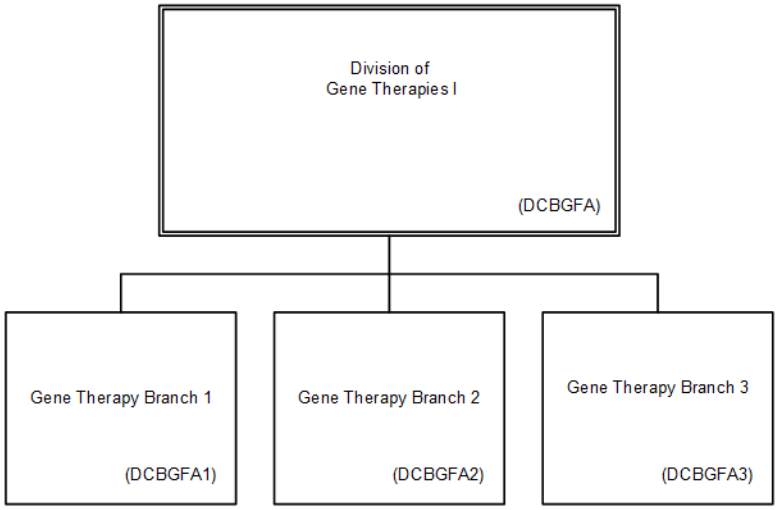
G. Performs consultative reviews of product information and data in BLAs, BLA amendments, INDs, IDEs, 510Ks, HDEs, and PMAs in response to request from other Center components.

H. Initiates and participates in development of reference standards and methods, in conjunction with other Center components governmental and non-governmental organizations and international regulatory agencies.

5. Authority and Effective Date.

The functional statements for the Division of Gene Therapy I were approved by the Secretary of Health and Human Services on August 8, 2022, and effective on September 16, 2022.

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Therapeutic Products
Office of Gene Therapies CMC
Division of Gene Therapies I



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Therapeutic Products, Office of Gene Therapy CMC, Division of Gene Therapy I organization structure depicting all the organizational structures reporting to the Director.

Division of Gene Therapy I (DCBGFA)