SMG 1218.2

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

OFFICE OF TISSUES AND ADVANCED THERAPIES

DIVISION OF CELLULAR AND GENE THERAPIES

Effective Date: July 8, 2011

1. DIVISION OF CELLULAR AND GENE THERAPIES (DKKBLA).

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, HDEs, and 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 Agency 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, and 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.

I. Initiates and conducts mission relevant scientific research on molecular and cellular biology, tumor biology, virology, immunology, tissue safety, tissue engineering, and cell biology related to cellular, tissue engineering, gene therapy, and therapeutic vaccine products.

J. Assists in collaborative research and management of contract-supported activities.

2. CELL THERAPIES BRANCH (DKKBLA1).

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, HDEs, and 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 Agency 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, and 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 THERAPIES BRANCH (DKKBLA2).

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, HDEs, and 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 Agency 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, and 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 TRANSFER AND IMMUNOGENICITY BRANCH (DKKBLA4).

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, HDEs, and 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 Agency 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, and 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.

I. Initiates and conducts mission relevant scientific research on molecular and cellular biology, virology, immunology, related to cellular, gene therapy, and therapeutic vaccine products.

J. Assists in collaborative research and management of contract-supported activities.

5. CELLULAR AND TISSUE THERAPY BRANCH (DKKBLA6).

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, HDEs, and 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 Agency 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, and 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.

I. Initiates and conducts mission relevant scientific research on molecular and cell biology, developmental biology, immunology, tissue engineering, related to cellular, tissue engineering, gene therapy, and therapeutic vaccine products.

J. Assists in collaborative research and management of contract-supported activities.

6. TUMOR VACCINE AND BIOTECHNOLOGY BRANCH (DKKBLA5).

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, HDEs, and 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 Agency 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, and 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.

I. Initiates and conducts mission relevant scientific research on tumor biology, tissue safety, cell biology, and immunology related to cancer vaccines, cellular, tissues, tissue engineering and gene therapy and related products.

J. Assists in collaborative research and management of contract-supported activities.

7. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Secretary of the Department of Health and Human Services on July 8, 2011.

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FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO
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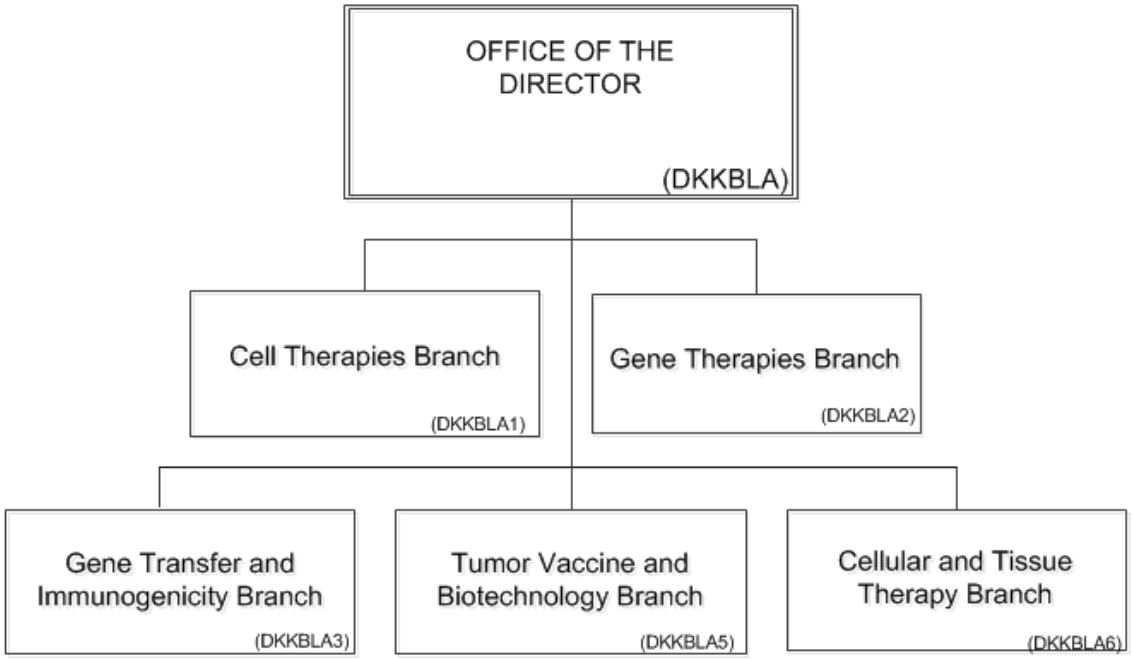

Staff Manual Guide 1218.2
Organizations and Functions
Effective Date: September 24, 2016

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Center for Biologics Evaluation and Research, Office of Tissues and Advanced Therapies, Division of Cellular and Gene Therapies organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DKKBLA):

- Cell Therapies Branch (DKKBLA1)
- Gene Therapies Branch (DKKBLA2)
- Gene Transfer and Immunogenicity Branch (DKKBLA3)
- Tumor Vaccine and Biotechnology Branch (DKKBLA5)
- Cellular and Tissue Therapy Branch (DKKBLA6)