SMG 1218.3

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 CLINICAL EVALUATION AND PHARMACOLOGY/TOXICOLOGY

Effective Date: September 24, 2016

1. DIVISION OF CLINICAL EVALUATION AND PHARMACOLOGY/TOXICOLOGY (DKKBLB).

A. Develops and maintains the Office's Clinical, Clinical Pharmacology, and Pharmacology/Toxicology Review Programs.

B. Provides clinical, clinical pharmacology and non-clinical review and recommends appropriate action on Investigational New Drug Applications (INDs), Biologics License Applications (BLAs), New Drug Applications (NDAs), Investigational Device Exemptions (IDEs), Pre-Market Approval Applications (PMAs), and 510(k) submissions pertinent to products within the Office's purview.

C. Provides recommendations on clinical, clinical pharmacology, and non-clinical programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

D. Contributes to the interpretation of clinical, clinical pharmacology, and non-clinical data submitted in support of INDs, BLAs, and amendments, NDAs and supplements, including data submitted for postmarketing surveillance.

E. Develops regulatory policies and documents concerning clinical, clinical pharmacology, and non-clinical aspects of products regulated in the Office.

F. Provides clinical, clinical pharmacology and non-clinical consultation and serves as a source of clinical, clinical pharmacology, and non-clinical information within the Center on products regulated in the Office.

G. Cooperates with other Agency components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others on clinical, clinical pharmacology, and non-clinical issues related to products regulated in the Office.

H. Performs consultative reviews of clinical, clinical pharmacology, and non-clinical data in response to request from other Agency components.

I. Evaluates clinical experience and adverse reaction reports relating to products regulated in the Office.

J. Develops and pursues research programs in clinical trial design and analysis and pharmacology/toxicology.

2. GENERAL MEDICINE BRANCH 1 (DKKBLB1).

A. Provides clinical review and recommends appropriate action on Investigational New Drug Applications (INDs), Biologics License Applications (BLAs), New Drug Applications (NDAs), Investigational Device Exemptions (IDEs), Pre-Market Approval Applications (PMAs), and 510(k) submissions pertinent to products within the Office's purview.

B. Provides recommendations on clinical and clinical pharmacology programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

C. Provides clinical consultation and serves as a source of clinical information within the Center on products regulated in the Office.

D. Cooperates with other Agency components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others on clinical issues related to products regulated in the Office.

E. Performs consultative reviews of clinical data in response to request from other Agency components.

F. Evaluates clinical experience and adverse reaction reports relating to products regulated in the Office.

G. Develops and pursues research programs in clinical trial design and analysis.

3. PHARMACOLOGY/TOXICOLOGY BRANCH 1 (DKKBLB2).

A. Provides non-clinical review and recommends appropriate action on Investigational New Drug Applications (INDs), Biologics License Applications (BLAs), New Drug Applications (NDAs), Investigational Device Exemptions (IDEs), Pre-Market Approval Applications (PMAs), and 510(k) submissions pertinent to products within the Office's purview.

B. Provides recommendations on non-clinical programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

C. Provides non-clinical consultation and serves as a source of non-clinical information within the Center on products regulated in the Office.

D. Cooperates with other Agency components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others on non-clinical issues related to products regulated in the Office.

E. Performs consultative reviews of non-clinical data in response to request from other Agency components.

F. Develops and pursues research programs in pharmacology/toxicology.

4. ONCOLOGY BRANCH (DKKBLB3).

A. Provides oncology clinical review and recommends appropriate action on Investigational New Drug Applications (INDs), Biologics License Applications (BLAs), New Drug Applications (NDAs), Investigational Device Exemptions (IDEs), Pre-Market Approval Applications (PMAs), and 510(k) submissions pertinent to products within the Office's purview.

B. Provides recommendations on oncology clinical programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

C. Provides oncology clinical consultation and serves as a source of clinical information within the Center on products regulated in the Office.

D. Cooperates with other Agency components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others on oncology clinical issues related to products regulated in the Office.

E. Performs consultative reviews of oncology clinical data in response to request from other Agency components.

F. Evaluates clinical experience and adverse reaction reports relating to oncology products regulated in the Office.

G. Develops and pursues research programs in clinical trial design and analysis.

5. GENERAL MEDICINE BRANCH II (DKKBLB4).

A. Provides clinical and clinical pharmacology review and recommends appropriate action on Investigational New Drug Applications (INDs), Biologics License Applications (BLAs), New Drug Applications (NDAs), Investigational Device Exemptions (IDEs), Pre-Market Approval Applications (PMAs), and 510(k) submissions pertinent to products within the Office's purview.

B. Provides recommendations on clinical and clinical pharmacology programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

C. Provides clinical and clinical pharmacology consultation and serves as a source of clinical information within the Center on products regulated in the Office.

D. Cooperates with other Agency components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others on clinical issues related to products regulated in the Office.

E. Performs consultative reviews of clinical and clinical pharmacology data in response to request from other Agency components.

F. Evaluates clinical experience and adverse reaction reports relating to products regulated in the Office.

G. Develops and pursues research programs in clinical trial design and analysis.

6. PHARMACOLOGY/TOXICOLOGY BRANCH II (DKKBLB5).

A. Provides non-clinical review and recommends appropriate action on Investigational New Drug Applications (INDs), Biologics License Applications (BLAs), New Drug Applications (NDAs), Investigational Device Exemptions (IDEs), Pre-Market Approval Applications (PMAs), and 510(k) submissions pertinent to products within the Office's purview.

B. Provides recommendations on non-clinical programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

C. Provides non-clinical consultation and serves as a source of non-clinical information within the Center on products regulated in the Office.

D. Cooperates with other Agency components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others on non-clinical issues related to products regulated in the Office.

E. Performs consultative reviews of non-clinical data in response to request from other Agency components.

F. Develops and pursues research programs in pharmacology/toxicology.

7. CLINICAL HEMATOLOGY BRANCH (DKKBLB6).

A. Provides hematology clinical review and recommends appropriate action on Investigational New Drug Applications (INDs), Biologics License Applications (BLAs), New Drug Applications (NDAs), Investigational Device Exemptions (IDEs), Pre-Market Approval Applications (PMAs), and 510(k) submissions pertinent to products within the Office's purview.

B. Provides recommendations on hematology clinical programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

C. Provides hematology clinical consultation and serves as a source of clinical information within the Center on products regulated in the Office.

D. Cooperates with other Agency components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others on hematology clinical issues related to products regulated in the Office.

E. Performs consultative reviews of hematology clinical data in response to request from other Agency components.

F. Evaluates clinical experience and adverse reaction reports relating to hematology products regulated in the Office.

G. Develops and pursues research programs in clinical trial design and analysis.

8. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Commissioner for Food and Drugs on July 28, 2016, and effective on September 24, 2016.

Back to Organizations and Functions, Volume I (1000-1300)

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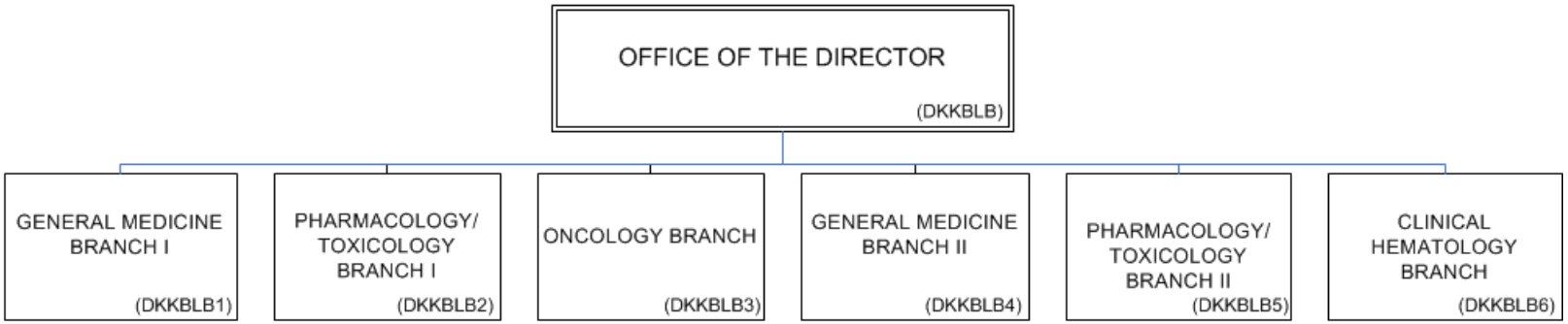

STAFF MANUAL GUIDE 1218.3
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 24, 2016

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

OFFICE OF THE DIRECTOR (DKKBLB):

- General Medicine Branch I (DKKBLB1)
- Pharmacology/Toxicology Branch I (DKKBLB2)
- Oncology Branch (DKKBLB3)
- General Medicine Branch II (DKKBLB4)
- Pharmacology/Toxicology Branch II (DKKBLB5)
- Clinical Hematology Branch (DKKBLB6)