SMG 1261.18

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF MANAGEMENT

DIVISION OF USER FEE MANAGEMENT AND BUDGET FORMULATION

Effective Date: November 17, 2014

1. DIVISION OF USER FEE MANAGEMENT AND BUDGET FORMULATION (DKKNBD).

A. Provides central oversight and management for Center user fee programs, including Prescription Drug User Fee Amendments (PDUFA), Biosimilar User Fee Act (BsUFA), Generic Drug User Fee Amendments (GDUFA), and Drug Quality and Security Act user fees for pharmacy compounding and track-and-trace programs.

B. Prepares for, supports, and participates in reauthorization negotiations.

C. Supports the Agency's User Fee Management Board.

D. Participates in the annual setting of user fee rates by determining appropriate user fee denominators.

E. Prepares detailed analyses and estimates of annual funding needs for future budget years.

F. Supports the development of the overall Center budget presentation.

G. Analyzes budget trends and funding levels for the Center's programs and activities.

H. Provides estimates and narrative justifications for proposed funding and resources to the Department, Office of Management and Budget (OMB), and Congress.

I. Coordinates with program experts to prepare performance goals, outcomes, and targets for the Center's performance plan.

J. Leads ad-hoc assignments related to the Agency and the Center's priority initiatives.

2. GENERICS BRANCH (DKKNBD1).

A. Processes Generic Drug User Fee Amendments (GDUFA) collections transactions.

B. Evaluates GDUFA user fee obligation status.

C. Resolves GDUFA customer inquiries.

D. Manages the backlog and facility fee arrears lists.

E. Corresponds with industry and processes refunds as needed.

3. POLICY AND OPERATIONS BRANCH (DKKNBD2).

A. Supports the Division of User Fee Management and Budget Formulation by analyzing relevant statutory and regulatory provisions to ensure conformity with applicable law.

B. Counsels the Director and staff on the scope and meaning of relevant regulatory and statutory requirements in general, and in respect to particular members of the Industry as necessary.

C. Drafts decision memoranda, memoranda to file, and correspondence with the Industry to support, catalog, and communicate the decisions or interpretations rendered by the Division.

D. Reviews and evaluates evidence for legal and administrative actions and recommendations, and prepares documentation to support the Agency's action.

E. Catalogs Agency decisions rendered by the Division to ensure equity and continuity in the decision-making process.

F. Partners with Director to define Division's mission, scope, and strategic plan.

G. Establishes and manages processes supporting the business needs of the Division's front-line programs.

H. Works with stakeholders to mitigate operational risks through analysis of management practices, processes, and policies.

I. Facilitates communications with internal and external stakeholders to meet statutory requirements.

J. Collaborates with the Brands and Generics branches to clearly communi¬cate decisions on applicants' compliance with applicable user fee obligations.

4. BRANDS BRANCH (DKKNBD3).

A. Manages and implements administrative and business processes for Prescription Drug User Fee Amendments (PDUFA) and Biosimilar User Fee Act (BsUFA) including: issuing annual bills for product and establishment fees; advising on applicable fees for applications and supplements; and addressing industry requests for waivers, exemptions, refunds, and patent term extensions.

B. Supports user fee collection activities for PDUFA and BsUFA user fee programs.

C. Evaluates applicants' user fee obligation status for PDUFA and BsUFA applications.

D. Resolves customer inquiries on user fee obligations under the PDUFA and BsUFA user fee programs.

E. Collaborates with review divisions to determine appropriate PDUFA and BsUFA user fees for applications and supplements.

F. Serves as the liaison between the financial and review Offices.

G. Provides support for reporting requirements, statutory updates, and the annual fee setting process.

5. AUTHORITY AND EFFECTIVE DATE.

This Division was approved by the Director, Center for Drug Evaluation and Research, and effective on November 17, 2014.

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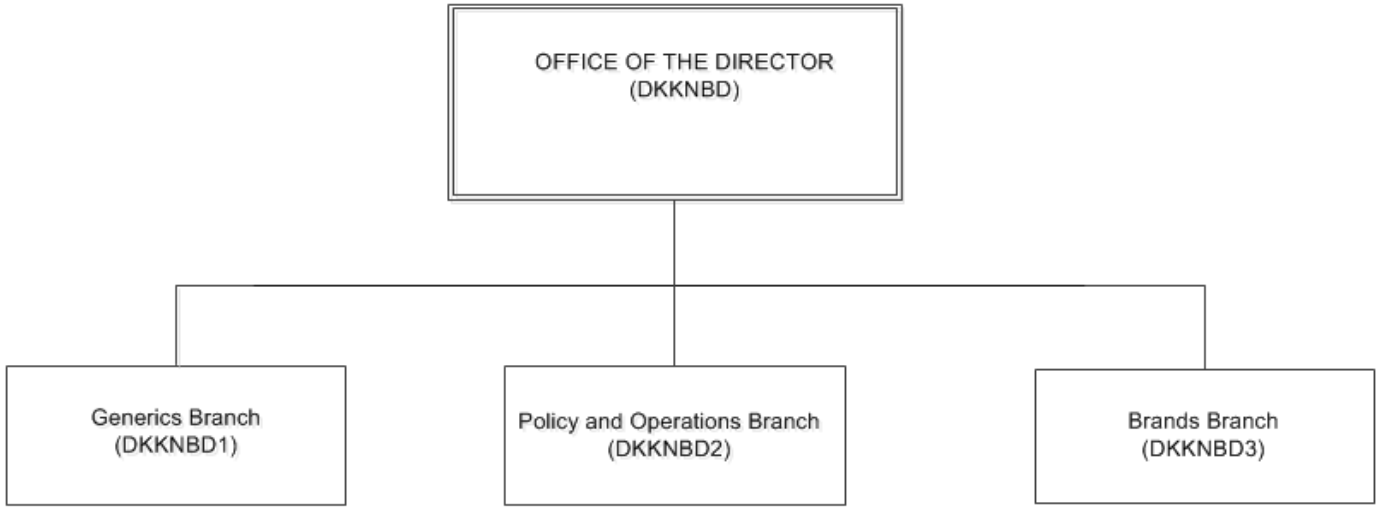

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Management, Division of User Fee Management and Budget Formulation organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Generics Branch
- Policy and Operations Branch
- Brands Branch