SMG 2010.14

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FDA OFFICIAL COUNCILS AND COMMITTEES

FDA USER FEE COUNCIL

Effective Date: August 13, 2015

1. PURPOSE

This charter describes the duties and responsibilities of the Food and Drug Administration (FDA) User Fee (UF) Council, the organization of its membership, and its operating procedures. The Council will lead a variety of oversight and analysis activities and make recommendations to FDA Management Council regarding FDA-wide user fee management issues. This charter also explains the method for establishing expert working groups that report to the Council and their responsibilities, organization, and operating procedures.

2. OWNERSHIP

Process and Document Owners

This document will be maintained by the following parties:

- Change Management Process Owners: Chairpersons, as described in *Membership* below
- Document Owner: Chief Financial Officer
- Key Partners: Office of Operations, Executive Secretariat

Review Schedule and Sign-Off Procedure

This document will be reviewed for content and accuracy semi-annually by the Office of Operations, Executive Secretariat and Chairpersons.

Version Control

Initial approval by the Commissioner will result in the creation of version 1.0. Future approvals will always be whole numbers (version 2.0, 3.0, etc.). Any changes will result in a change of version number as well. For example, should a new objective/process be added after initial approval, this would result in draft version 1.1. Once this change is approved by the Commissioner, the document would become version 2.0.

Version #	Date	Modified by	Description of Modification
1.0	02/13/2013	M. Ellerbe	Version 1.0 submitted for signature
1.1	12/16/2014	J. Johnson	Additional non-voting members added, sub-committees added, and conforming updates made.
2.0	02/18/2015	E. Mitchell	Version 1.1 submitted for signature

3. BACKGROUND AND SCOPE

FDA has the authority to collect fees or funds to support or enhance various programs, including the Animal Drug User Fee Act (ADUFA), Animal Generic Drug User Fee Act (AGDUFA), Medical Device User Fee Amendments (MDUFA), Prescription Drug User Fee Act (PDUFA), Tobacco Control Act, Food Safety Modernization Act (FSMA), Export Certifications, Mammography Quality Standards Act (MQSA) Color Certifications, the Generic Drug User Fee Amendments (GDUFA) and the Biosimilars User Fee Act (BsUFA). Collectively, these user fee programs represent an estimated $2 billion – or nearly 45 percent -- of FDA's total budget request in FY 2014. The agency's expanding level of user fees, the reporting of agency performance commitments associated with these fees, and the need for FDA to convey how these fees are executed calls for strong financial governance. This includes a wider understanding of the design of these programs, clear financial plans, data-driven decisions on resource allocation, consistency and transparency about assumptions, and accountability for resources spent.

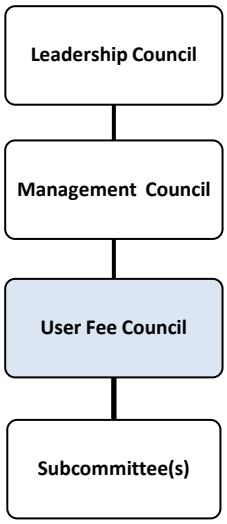
The UF Council recognizes that governance is currently in place for the user fee programs including annual reports to Congress (financial and performance), oversight from the FDA user fee teams, both at the Centers and in the Office of Financial Management, as well as an established fiduciary infrastructure created to assure the necessary firewalls between non-user fee and user fee activities.

The Council will work to support the appropriate standards and policies to ensure FDA compliance with statutory provisions that authorize FDA to collect and spend user fee funds, and require, as directed by law, the financial and performance reporting to Congress. The UF Council will ensure the development of consistent financial plans.

4. ORGANIZATIONAL STRUCTURE

The UFC is a component of the Operations Management Councils (OMC). Each OMC is subordinate to the MC; the Chief Financial Officer will serve as Chair of the User Fee Council.

A diagram of the organizational structure is provided below.



5. RESPONSIBILITIES

The following are the responsibilities of the Council:

- Responsibilities related to allocation of projected user fee collections to ensure a data-driven approach based on the tasks specified in the user fee commitments and distribution of associated projected workload across FDA components.

  - Considers impacts on budget formulation activities and analyses.

  - Ensures that there is a transparent and collaborative process for allocating and tracking resources to support the accomplishment of all negotiated user fee performance commitments and statutory requirements.

  - Reviews and approves the user fee program's five-year financial plans and ensures the annual allocations are aligned.

  - Reviews program financial status, including actual fee collections compared to estimates and actual workload compared to estimates;

analyzes deviations from expected levels; and recommends adjustments to allocations.

- Responsibilities related to setting standards and definitions for clear and consistent metrics and accounting for user fee workload and associated costs across all FDA components engaged in or supported by a given user fee program.

  - Sets minimum standards for the quality and performance of internal workload tracking and financial tracking systems to be used by agency programs.

  - Reviews the calculation of standard costs for FDA user fees programs, including developing an algorithm to adjust for changes in workload.

  - Ensures usage of reporting capabilities by FDA user fee program managers.

- Responsibilities related to preparation and positioning for future rounds of user fee negotiations. A comprehensive understanding of user fee program costs and cost drivers enables the most strategic and successful positioning for future user fee negotiations.

  - Conducts analysis to determine what factors drive performance-based goal-committed workload to inform and justify any future revisions or addition of a workload adjuster to a given user fee program.

  - Conducts analysis to examine and justify FDA indirect costs, including non-review staff, administrative staff and other indirect costs (such as rent and rent related) allocated to user fee programs.

  - Conducts analysis to examine and justify IT systems costs that are or should be allocated to user fee programs

- Serves as the reporting body for designated subcommittees of the UF Council.

Membership

The UF Council will be organized as follows:

Chairpersons

The Chief Financial Officer will serve as the Chairperson. The Chairperson is responsible for the following activities:

- Direct the activities of the Council

- Develop highest priority issues and agenda; presented to and ratified by FDA senior staff

- Prepare briefings for FDA senior staff as requested – including quarterly updates to the Management Council and a Monthly calendar of events

- Ensure UF Council activities including recommendations, decisions, issues, action items, meeting summaries, and other pertinent materials attributable to the UF Council are documented and communicated to FDA senior staff in a timely manner

- Coordinate the collection, management, and dissemination of UF Council recommendations, decisions, actions, and other information related to the responsibilities of the UF Council through a Project Manager

The Deputy Commissioner for Planning will serve as OC Vice-Chair. The OC Vice-Chair is responsible for the following activities:

- Lead and facilitate UF Council discussions related to development of clear and consistent measurement and accounting for user fee workload across all FDA components engaged in or supported by a given user fee program

- Lead the effort to ensure a transparent, effective, and equitable process to calculate standard costs for all FDA user fee programs

- Serve as an alternate chair for the Council in the absence of the Chairperson

A lead Directorate, Center or ORA representative will be appointed by the FDA Management Council as the Program Vice-Chair. The appointment of this representative will rotate annually. The Program Vice-Chair is responsible for:

- Lead and facilitate UF Council discussions to prepare and position the Agency for future rounds of user fee negotiations, reflecting the perspective of the programs that are ultimately responsible for meeting the associated performance commitments

- Lead and facilitate UF Council discussions to elicit program perspectives on the allocation of indirect and other costs and understanding and justifying the allocation of various costs to different agency user fee programs potentially under the scrutiny of external audiences

- Serve as an alternate chair for the Council in the absence of the Chairperson

Voting Members

- Chairperson – FDA Chief Financial Officer (CFO)
- OC Vice Chairperson – Deputy Commissioner for Planning
- Program Vice Chairperson – Lead Directorate, Center or ORA Representative
- Executive Officers or Representative from, Centers, ORA and OC:

Non-voting Members

- National Center for Toxicological Research (NCTR)
- Office of Food and Veterinary Medicine (OFVM)
- Office of Global Regulatory Operations and Policy (OGROP)
- Office of the Commissioner (OC)
- Office of Medical Products and Tobacco (OMPT)
- Office of Human Resources (OHR, advisory only)
- Office of Office of Information Management and Technology)
- Office of Facilities Engineering and Mission Support Services (OFEMS)
- Office of Special Medical Programs (OSMP)
- Office of Chief Counsel (OCC, advisory only)
- Office of Financial Management (OFM, advisory only)

Program Manager

A Project Manager will be appointed by the Chairperson and will be responsible for:

- Maintain an accurate membership list
- Prepare agendas and organizing meeting logistics
- Distribute agendas, documents, and information to UF Council members for appropriate and timely review

- Ensure the documentation of minutes of meetings, assuring actions items are clearly defined and posting documents to the FDA intranet

- Maintain records of UF Council activities

Members of the UF Council will serve as long as they are in the above-mentioned positions. The UF Council is for Principals only. A list of alternates will be provided to the Project Manager prior to each meeting.

Other participants, observers, and consultants from within the agency and from other Federal government organizations may participate at the discretion of the Chairperson.

6. PROCEDURES

UF Council meetings:

- Regular meetings will be held generally monthly, but not less than quarterly

- Proposed agenda items may be submitted by a UF Council member to the Project Officer one week in advance of a meeting

- The Chairperson will determine the agenda. It will be indicated on the agenda if the meeting is a decision meeting.

- Decisions are reached through consensus. If consensus is not applicable, formal voting will take place. A quorum will be required to move to formal voting. A quorum will consist of two-thirds (2/3) of the voting member. Motions will carry by a simple majority of votes cast.

- All Council decisions are subject to review by the FDA Management Council

- Chairpersons will provide the Office of Operations, Executive Secretariat a schedule/timeline of UFC activities semi-annually

Subcommittees

Subcommittees may be established under the following circumstances:

- The UF Council identifies a specific need, which could be best addressed by a few members with subject matter expertise.

- The UF Council establishes a new subcommittee to achieve specific objectives, and appoints a Chair for the subcommittee.

- The Chair of the subcommittee will submit a project charter and work plan for subcommittee assignment to the UF Council within 30 days for review and ratification by the Council.

- Standing sub-committees – The Council will have standing sub-committees for the following: Five-year financial plans and HQ allocations

Charter Updates

Amendments to the UF Council charter can be proposed by UF Council members at any time. Adoption of amendments to the charter will be in accordance with the decision procedure described above.

This charter will remain in effect for five years after the effective date.

7. EFFECTIVE DATE

The effective date of this guide is August 13, 2015.

8. Document History – SMG 2010.14, FDA User Fee Council

VERSION	STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
1.0	Initial	05/14/2015	N/a	OO/PEO	Walter S. Harris, FDA Chief Operating Officer