SMG 2010.16

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FDA OFFICIAL COUNCILS AND COMMITTEES

FDA COMPLIANCE POLICY COUNCIL

Effective Date: January 19, 2016

1. PURPOSE

This charter describes the duties and responsibilities of the Compliance Policy Council (CPC), its membership, and its operating procedures. The CPC was formed to develop recommendations for establishing important Agency wide compliance policy and ensuring consistency in application of compliance policy across all program areas.

2. BACKGROUND

The CPC has been in existence since 1978 as a means of assisting the Commissioner and Associate Commissioner for Regulatory Affairs in assuring that the various program offices of the FDA act as a single Agency in the administration of the Food, Drug, and Cosmetic act and other acts and the regulation of the industries and products which fall under its jurisdiction. This council, composed of the senior compliance officers of the Agency, continues to be the Agency's primary deliberative body for compliance policy matters.

3. SCOPE

The Council is charged with assuring the consistency of compliance actions and strengthening the daily implementation of compliance policy through its deliberations of high-level, Agency-wide compliance policy matters. This includes:

- Identifying and resolving, whenever possible, conflicting policy;
- Identifying, revising, or eliminating outdated policy as appropriate; and

- Determining the need for new policy.

Participation in activities of the council is restricted to the principals listed in the Membership section of this charter or their alternate. Alternates may represent their office and must be prepared to represent their unit completely in discussions and decisions.

4. MEMBERSHIP

This council is composed of the senior compliance officers of the Agency, both in the Centers, ORA, and OGC. Other participants, observers, and subject matter experts may be invited to attend and participate as decided by the Council or a principal.

Assistant Commissioner for Compliance Policy (ACCP) - Chairperson
Director, Office of Enforcement and Import Operations, ORA
Director, Office of Compliance and Biologics Quality, CBER
Director, Office of Compliance, CDER
Director, Office of Compliance and Surveillance, CDRH
Director, Office of Compliance, CFSAN
Director, Office of Compliance and Enforcement, CTP
Director, Office of Surveillance and Compliance, CVM
Litigation Deputy, Office of Chief Council

5. RESPONSIBILITIES

A. Chairperson

1. Establish areas of priority for Council consideration.

2. Gather details/additional information to support Council activities, meetings, initiatives.

3. Manage logistics, including arranging and organizing the meeting, distributing documents to Council members, maintaining records of Council activities and actions/decisions, and preparing meeting minutes.

4. Where appropriate, the ACCP will forward the Council's recommendation to the appropriate individual for a final determination.

B. Members

1. Make every effort to attend the Council meetings in person. In the event of a scheduling conflict, the principal will designate an alternate.

2. Identify compliance policy issues for Council consideration.

3. Engage in Council activities, including identification of working group participants.

6. PROCEDURES

Council Meetings

- The council will meet regularly every two months, or more frequently as required. Recurring meetings will be scheduled in advance. Additional meetings will be called by the council chair, either independently or at the request of council members.

- Agenda items may be submitted by any Council member to the Chairperson. Items should be submitted at least one week in advance of the meeting. All supporting documents should also be submitted for distribution to the Council.

- Meeting minutes will be prepared and distributed to all Council members. Minutes will include attendees, issues presented, decisions made, and any outstanding action items.

Working Groups

- The council is authorized to form working groups to handle specific assignments.

- The council will approve work plans and timetables for working groups and will monitor their progress.

- Recommendations of the working groups will be evaluated by the council.

Decision Making

- Policy recommendations will be summarized by the Council and referred to the appropriate principals for final determination.

- The implementation of new policy or changes in policy will be monitored by the council.

7. EFFECTIVE DATE

The effective date of this guide is January 19, 2016.

8. Document History - SMG 2010.16, FDA Compliance Policy Council

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	01/06/2016	N/a	ORA/OPRM	Katherine N. Bent, Assistant Commissioner for Compliance Policy