

FDA Staff Manual Guides, Volume III - General Administration

FDA Official Councils and Committees

FDA Combination Products Policy Council

Effective Date: 09/17/2020

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1. Purpose.

As a part of the Food and Drug Administration's (FDA) modernization of the regulation of combination products, the FDA establishes a policy council on combination products, cross-labeled products, and medical product classification (herein referred to as "Council"). This charter describes the duties and responsibilities of the Council, the organization of its membership, and its operating procedures.

2. Policy.

The Council will prospectively identify regulatory and scientific issues to address and function as a forum for developing guiding principles related to combination products, cross-labeled products, and medical product classification. The Council will also resolve disagreements among centers, the Office of Combination Products (OCP), and/or sponsors on activities and policies related to medical product classification and the clearance/approval of combination products and cross-labeled products. Of note, the Council is a resource to the FDA in general, on matters relevant to this subject. The Council does not meet directly with sponsors.

The Council will ensure alignment of centers per new Intercenter Consult Agreements (provide link once available) which will include procedures regarding alignment of certain activities, (e.g., internal meetings and consult timelines).

The Council will serve as the guiding body to facilitate development of a unified FDA position and resolve disagreements on cross-cutting matters arising from combination products, cross-labeled products, and medical product classification

issues that affect more than one medical product center, including those related to designation requests.

The Council will promote and coordinate communication both internally and externally on the policy decisions made by the Council.

3. Responsibilities.

A. The Council is responsible for:

1. Reporting directly to the FDA Principal Deputy Commissioner who will serve as the Council Chairperson. If the position for FDA Principal Deputy Commissioner is vacant, the FDA Commissioner will appoint a Chairperson;
2. Addressing complex issues relating to combination products, cross- labeled products, and medical product classification;
3. Resolving disagreements among centers, OCP and/or sponsors. The Council will not meet directly with sponsors. If appropriate, a sponsor request for Council input may come through a Center or OCP;
4. Promoting and coordinating internal and/or external communication of policy decisions when appropriate.

B. Responsibilities of Council members:

1. Representing their organizational unit's views on issues under consideration by the Council;
2. Serving as the focal point of contact for communicating with their organizational unit, including their senior managers about the deliberations of the Council and obtaining their input;
3. Attending meetings in person or by teleconference. If a member cannot attend a meeting, an alternate may be designated by the Council member. The alternate must be able to represent the organization and vote in place of the member. If deemed appropriate by the Chairperson, email communication may be used to obtain Council input.
4. Creating for Council review quarterly reports on combination products and cross-labeled products as well as decisions on medical product classifications, including information on: 1) clearances/approvals; 2) Request for Designations; 3) 10.75 appeals; and 4) 513(g)s. Information should include product names, labels, and the Center/Office decision.

C. Responsibilities of the Council Chairperson:

1. Directing the activities of the Council;
2. Facilitating discussions on issues within the Council;
3. Reviewing proposed issues and determining when issues are appropriate for Council review and discussion. If the proposal is not selected for Council review by the date specified, the Chairperson (through the Executive Secretary) will provide an explanation of this decision. Reconsideration by the Council of such decisions can be requested.

D. Responsibilities of the Executive Secretary:

1. Serving as the focal point for the working groups;
2. Maintaining the roster for the Council and any working groups formed;
3. Preparing documents and papers as requested by the Chairperson;
4. Distributing documents relevant to the activities of the Council;
5. Scheduling any pre-meetings as necessary and assisting in preparing materials for scheduled meetings;
6. Arranging and organizing meeting logistics;
7. Noting action items generated during the meetings of the Council and following-up on action items;
8. Maintaining a repository that includes the quarterly reports, summaries of meeting discussions, a log and status of issues discussed and actions assigned, and copies of Council decisions and actions that can be accessible to all staff across centers.

E. The Council is organized as follows:

- The Council will be chaired by the Principal Deputy Commissioner or Commissioner Designee. The Council is comprised of two representatives from the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health. The two representatives will include the Center Director and a named center representative to serve a two-year term. The Council will also be comprised of one representative from OCP and one from the Office of Clinical Policy and Programs (Office Director or designee). The Council is supported by an Executive Secretary.

- Other participants, observers, and consultants from within the FDA (e.g., Office of the Chief Counsel and Office of Legislation) and from other Federal government organizations may participate, when appropriate, in the activities of the Council at the discretion of the Chairperson. The Council will follow applicable policies and procedures if information is to be shared outside FDA.
- The Council may establish working groups or open dockets for public comments if needed.

F. Responsibility of the Individual/Office/Center Seeking Council Evaluation:

1. A proposal for a Council meeting may be submitted by any individual involved with the regulation and review of combination products and cross-labeled products as well as medical product classification.
2. The requesting individual should submit a meeting request form (provide link) to the Executive Secretary for consideration by the Chairperson. This request form includes the following information: the issue to be resolved, the trigger that raised the issue, the date by which a response is needed, and concurrence of his/her Center or Office Director.
3. Issues appropriate for Council deliberation include when there is no precedent for a regulatory decision, when there are disagreements among Centers, OCP, and/or sponsors, and when one center/office would like to change an existing practice or identifies a novel policy question.
4. If the proposal is accepted, the requesting individual should provide a meeting background document (provide link) to the executive secretary for review at least two weeks before the Council meeting. The background document should provide all the necessary information to understand the issues to be discussed.

4. Procedures.

- A request for Council deliberation will not delay review deadlines and a Council decision does not replace the existing formal appeals process for sponsors. However, all 10.75 appeals that raise cross-cutting issues involving combination products, cross-labeled products, and medical product classification should be brought to the Council for discussion prior to issuance of a decision.
- Formal disputes that relate to internal differences of opinion regarding scientific or regulatory issues will follow the policies and procedures as described in the 2014 SMG 9010.2: Cross-Center Dispute Resolution at the FDA.

- Experts from Agency staff will be sought and invited to participate in the discussion at the Chairperson’s discretion. Suggested attendees may be provided in the meeting background document.
- The individual/office/center seeking Council evaluation will provide a brief (e.g., 10-minute) overview of the issues at the beginning of the meeting.
- Decisions will be established by a formal vote after deliberation among all parties attending the Council meeting. Each center and OCP will be entitled to one vote each (four votes total). If the vote is tied, the Chairperson has decisional authority. The Chairperson may present a case to the FDA Commissioner for a final decision.

5. Records of Council.

- A. The Chairperson and the executive secretary will assure that the activities of the Council, including quarterly reports, recommendations, decisions, issues, action items, and other pertinent materials attributable to the Council, are documented and communicated to senior management and relevant staff, as appropriate.
- B. The Council will review this charter at least annually based on experience gained by the Council and revise it as needed.

6. Effective Date.

The effective date of this charter is September 17, 2020.

7. Document History – SMG 2010.17, “FDA Combination Products Policy Council”

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	10/02/2016	N/a	CDER/OMIO	Robert M. Califf, M.D., Commissioner of Food and Drugs
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Revision	09/14/2020	N/a	OO/OB/DBFPA/ PAT	Stephen M. Hahn, M.D., Commissioner of Food and Drugs

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