

FDA STAFF MANUAL GUIDES, VOLUME III – GENERAL ADMINISTRATION

FDA OFFICIAL COUNCILS AND COMMITTEES

FDA NICOTINE STEERING COMMITTEE

Effective Date: 01/29/2018

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1. PURPOSE.

The Commissioner established the FDA Nicotine Steering Committee (herein referred to as *Committee*) to develop a strategy to address the regulation of nicotine products with the goal of reducing tobacco use. This strategy will be implemented across the Agency.

This charter describes the duties and responsibilities of the Committee, its organization and operating procedures, and the responsibilities of its members.

2. POLICY.

The Committee is a forum for developing and implementing nicotine policy and regulation. The Committee comprises senior leaders from the Center for Drug Evaluation and Research (CDER), the Center for Tobacco Products (CTP), and the Office of the Commissioner. The Committee ensures alignment of FDA's centers and facilitates consensus and development of unified FDA positions on cross-cutting issues.

The primary focus of the Committee is on the use of therapeutic nicotine for combustible tobacco product cessation.

Although the Committee does not meet with external stakeholders, it may communicate with external stakeholders, for example, to gain a better understanding of related issues or to aid in policy development.

3. RESPONSIBILITIES.

A. Responsibilities of the Committee:

1. Develop a nicotine policy strategy that seeks to reduce tobacco use and move cigarette smokers to less harmful means of nicotine delivery through the use of therapeutic nicotine for tobacco product cessation.
2. Establish working groups and/or open dockets for public comment on matters related to topics the Committee is discussing or evaluating; review the resulting recommendations and public comments.
3. Promote and coordinate internal and/or external communication of policy decisions when appropriate.

B. Responsibilities of Committee members:

1. Represent their organizational unit views on issues under consideration by the Committee.
2. Serve as point of contact for communications with their organizational unit.
3. Attend meetings in person or by teleconference. If a member cannot attend a meeting, an alternate may be designated by the Committee member. The alternate must be able to represent the organization in place of the member. If deemed appropriate by the Chairperson, email communication can be used to obtain Committee input.
4. Identify SMEs for working groups, as appropriate.

C. Responsibilities of the Committee Chairperson:

1. Directs the activities of the Committee.
2. Facilitates discussion on issues within the Committee.

D. Responsibilities of the Committee Vice-Chairperson:

1. Assists the Chairperson in performing his/her duties and responsibilities.
2. Acts as the Chairperson if he/she is unable to attend or carry out his/her duties.

3. Performs activities at the direction of the Chairperson, which may include research, problem solving, and other activities.
4. Oversees any working group activities launched by the Committee

E. Responsibilities of the Executive Secretary:

1. Maintains the Committee roster and the rosters of any working groups formed (including information such as the creation date, Committee-assigned responsibilities, and sunset of working groups).
2. Prepares documents and papers as requested by the Chairperson.
3. Distributes documents relevant to the activities of the Committee.
4. Schedules meetings and assists in preparing materials for scheduled meetings.
5. Arranges and organizes meeting logistics.
6. Notes action items generated during Committee meetings and follows up on action items.

F. Committee organization:

1. The Committee sits in the Office of Medical Products and Tobacco (OMPT) in the Office of the Commissioner.
2. The Committee Chairperson is FDA's Principal Deputy Commissioner of Food and Drugs.
3. The Committee Vice Chairperson is appointed by the Chairperson.
4. The Executive Secretary is appointed by the Chairperson.
5. The Committee is composed of:
 - a. Senior Agency leaders, as designated by the Commissioner, in coordination with the Chairperson and the Directors of CDER and CTP.
 - b. Other participants, observers, and consultants from within the Agency may participate in the activities of the Committee at the discretion of the Chairperson.

4. PROCEDURES

- A. The Committee will generally meet monthly, or as needed at the discretion of the Chairperson.
- B. Agenda items can be suggested by the members who serve as representatives on the Committee as well as by the Executive Secretary, Vice-Chairperson, and the Chairperson.
- C. SMEs from Agency staff will be invited to participate in the discussion at the Chairperson's discretion.
- D. SMEs from Agency staff will be invited to participate in working groups at the Committee's discretion.
- E. Meeting minutes with discussion topics, action items with personnel assignments and due dates, and a decision log will be maintained for each meeting.

5. COMMITTEE RECORDS.

- A. The Chairperson, Vice-Chairperson, and the Executive Secretary ensure that the activities of the Committee, including any reports, recommendations, decisions, issues, action items, or other pertinent materials attributable to the Committee are documented and communicated to senior management and relevant staff, as appropriate.
- B. The Committee will review this charter on an as-needed basis; revisions can be made as needed.

6. TERMINATION.

The Committee will terminate at the discretion of the Chairperson.

7. EFFECTIVE DATE.

The effective date of this charter is January 29, 2018.

8. Document History – SMG 2010.20. “FDA Nicotine Steering Committee”

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	01/25/2018	N/a	FDA/OMPT	Scott Gottlieb, M.D., Commissioner of Food and Drugs

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