



Menthol Report

Tobacco Products Scientific Advisory Committee Meeting
February 10, 2011

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Charge to the TPSAC

Produce a report and recommendations on the impact of the use of menthol in cigarettes on public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities.

Report is due March 23, 2011.



Menthol Report: What to Expect

Upcoming Meetings

- Menthol Report Subcommittee: February 11, 2011
- Full Committee: March 1-2, 2011
- Full Committee: March 17-18, 2011

Draft Chapters

- Draft chapters of the report will be discussed in open public meetings of the TPSAC as they become available.
 - FDA intends to make chapter drafts available to the public as background materials on the FDA Web site at least 2 business days before meetings where draft chapters will be discussed.
 - The availability of draft chapters as background materials is contingent on the Committee's progress. Thus, FDA cannot specify at which upcoming meetings draft chapters will be available as background materials.

Final Report

The final report will be made available to the public on FDA's Web site once it has been reviewed for redaction of any commercial confidential or trade secret information.

FDA Action

- Once the report is received, FDA will consider the report and recommendations of the Committee, as well as other scientific evidence concerning menthol cigarettes and make a determination about what action(s), if any, are warranted.
- There is no required deadline or timeline for FDA to make such a determination.
- Any sale/distribution restrictions (Section 906(d)) or product standards (Section 907) are implemented with notice-and-comment rulemaking.



Status of Information Requested by the TPSAC

Status Update

- Obtain peer review literature on the topic of menthol cigarettes: completed
- Industry presentations: completed
- Legacy database document review: completed
- Secondary data analyses from existing data sources: completed
- Review of marketing data (Nielsen and FTC data analyses): completed
- Industry document request: Completed except for topics 5, 6, & 7, which are in progress
- Model on effect of menthol on initiation and cessation: in progress

Status Update

- The February meeting is the last meeting where FDA intends to provide new information to TPSAC.
 - Except for the completion of the model on the effect of menthol cigarettes on initiation and cessation
- Analyses of industry documents submitted in response to topics 5 ,6, & 7 are not expected to be complete in time for consideration by TPSAC in preparing their report.
- Analyses will be considered by FDA when complete.



Today's Meeting

Topics for the February 10, 2011, Meeting

- Closed meeting
 - Commercial confidential/trade secret information from industry document submissions and confidential FTC data
- Open meeting
 - Information from industry document submissions on topics 1, 2, 9, & 11-12 that can be shared publicly
 - Update on the model of the impact of menthol on initiation and cessation
 - RTI NSDUH analyses in response to Committee request for additional clarification of industry data presented in January
 - Public comments
 - Discussion of Chapters 1 and 2

Industry Document Submissions

- Analyses of documents identified by the industry as responsive to topics 1, 2, 9 and 11-12 have been reviewed by RTI under a contract from FDA.
- FDA review of the RTI summaries has determined that some of the information is commercial confidential/trade secret.
 - That information was provided to TPSAC SGEs

Industry Document Submissions

- Information that was not deemed commercial confidential or trade secret will be presented at today's meeting.
 - However, the information that can be presented publicly is limited.

Questions for the Committee for the February 10, 2011, Meeting

- What comments does the TPSAC have regarding the proposed model?
- What feedback does the TPSAC have regarding draft chapters 1 and 2?



Clarifying Questions?