4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-2030]

Tobacco Products Scientific Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Tobacco Products Scientific Advisory Committee (TPSAC, the Committee). The general function of the Committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on October 7, 2025, from 9:00 a.m. to 4:30 p.m. Eastern Time.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. The public will have the option to participate, and the advisory committee meeting and meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

For those unable to attend in person, the meeting will also be webcast and will be available at the following links:

Live Link: https://youtube.com/live/MNXGH9aki4I?feature=share

Caption Link: http://upload.youtube.com/closedcaption?cid=jfzr-97fr-a9ax-sxcz-c31k

FOR FURTHER INFORMATION CONTACT: Rachel Jang, PharmD, DFO, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002, 1-877-287-1373, TPSAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the *Federal Register* about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at https://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On October 7, 2025, the Center for Tobacco Product's TPSAC will convene for one open session, during which the Committee will discuss the renewal of modified risk granted orders issued to Philip Morris Products S.A. for the following products:

- MR0000059: Marlboro Amber HeatSticks
- MR0000060: Marlboro Green Menthol HeatSticks
- MR0000061: Marlboro Blue Menthol HeatSticks
- MR0000133: IQOS 2.4 System Holder and Charger
- MR0000192: IQOS 3.0 System Holder and Charger

Discussion will focus on whether the statutory standards continue to be met.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting and be posted on the FDA's website after the meeting. Background

material and the link to the online teleconference and/or video conference meeting will be available at https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Written submissions may be submitted to the contact person on or before September 25, 2025. Oral presentations from the public will be scheduled between 1:00 p.m. and 2:00 p.m. ET on October 7, 2025. Those individuals interested in making formal oral presentations should notify the contact person (see FOR FURTHER INFORMATION CONTACT) and submit a brief statement describing the general nature of the evidence or arguments they wish to present, the names and email addresses of proposed participants, and whether they would like to present online or in-person, on or before September 11, 2025. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in-person. The contact person will notify interested persons regarding their request to speak by September 15, 2025.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due

to a disability, please contact Rachel Jang, PharmD, DFO (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

For press inquiries, please contact the HHS Press Room at www.hhs.gov/press-room/index.html or 202-690-6343.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. § 1001 et seq.). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see location). This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. No participant will be prejudiced by this waiver, and that the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: July 25, 2025.

Grace R. Graham

Deputy Commissioner for Policy, Legislation, and International Affairs.

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