TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
530.22(b); Submission(s) of analytical method	2	1	2	4,160	8,320

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–23740 Filed 11–20–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–13368]

Tobacco Products Scientific Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; 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 FDA on regulatory issues related to tobacco products. The meeting will be open to the public. FDA is establishing a docket for public comments related to the TPSAC meeting.

DATES: The meeting will be held on January 21, 2027, from 9 a.m. to 4:30 p.m. Eastern Time (ET).

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 also have the option to participate in person, and the advisory committee meeting 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 (AC) meetings, including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FDA is establishing a docket for public comments on this meeting. The docket number is FDA–2026–N–13368. The docket will close on January 12, 2027. Comments received on or before January 12, 2027, will be provided to the Committee. The electronic filing system will accept comments until 11:59 p.m. ET at the end of January 12, 2027. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date. In the event that the meeting is cancelled, FDA will update its website with information on the rescheduled date and will continue to evaluate any relevant information, and consider any comments submitted to the docket, as appropriate.

As required under Section 911 of the FD&C Act, FDA also is accepting public comments on the Modified Risk Tobacco Product Application: Renewal Applications for VLN® King and VLN® Menthol King, Cigarette Products Submitted by 22nd Century Group Inc. via Docket No. FDA–2019–N–0994–0230, which is separate from the docket intended for comments for TPSAC: FDA–2026–N–13368.

- For comments to be considered as part of scientific review for the MRTPA, submit comments to FDA–2019–N–0994–0230. Comments in this docket will not be referred to the Committee.
- For comments to be considered by the TPSAC as part of the January 21, 2027, TPSAC meeting discussion, submit comments to FDA–2026–N–13368 by January 12, 2027, as noted above.
- For comments to be considered as part of the scientific review for the MRTPA and the January 21, 2027, TSPAC meeting discussion, submit comments to both dockets.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–13368 for ''Tobacco Products Scientific Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m. ET, Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be

made publicly available, submit your comments only as a written/paper submission. You should submit two copies in total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

- Advisors and Consultants Staff, 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 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 the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On January 21, 2027, the Committee will convene to discuss the renewal of modified risk granted orders issued to 22nd Century Group Inc., for the following combusted cigarette products:

MR0000159: VLN® King, and

MR0000160: VLN® Menthol King.

Discussion generally will focus on whether the statutory standard for exposure modification orders under Section 911(g)(2) continues 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 on FDA's website at the time of the advisory committee meeting and after the meeting. Background material will be available at the location of the advisory committee meeting and at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Oral presentations from the public will be scheduled approximately between 1 p.m. and 2 p.m. ET. Those individuals interested in making formal oral presentations should notify Advisors and Consultants Staff, CTP (see **FOR FURTHER INFORMATION CONTACT**) and submit a brief statement of the general nature of the evidence or arguments they wish to present, along with the names, phone numbers, and email addresses of proposed participants on or before December 28, 2026. 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.

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

For press inquiries, please contact the FDA Newsroom at *www.fda.gov/news-events/fda-newsroom.*

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 Advisors and Consultants Staff, CTP (see **FOR FURTHER INFORMATION CONTACT**) at least 7 business 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.

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(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. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–23750 Filed 11–20–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Microbiome Subcommittee of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice; 29th public meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB).

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a virtual meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB).

DATES: The meeting is scheduled to be held on December 2, 2026, at 9:00 a.m. ET (times are tentative and subject to change). The confirmed time and agenda items for the meeting will be