

the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments.

Section 911(g) of the FD&C Act describes the demonstrations applicants must make to obtain an order from FDA under either section 911(g)(1) or (g)(2). The applicant, 22nd Century Group Inc., is seeking a renewal of an order previously issued under section 911(g)(2) of the FD&C Act.

FDA may issue an order under Section 911(g)(2) of the FD&C Act with respect to a tobacco product that does not satisfy the section 911(g)(1) standard. A person seeking an order under section 911(g)(2) of the FD&C Act must show that:

- Such an order would be appropriate to promote the public health;
- any aspect of the label, labeling, and advertising for the product that would cause the product to be an MRTP is limited to an explicit or implicit representation that the tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;

- scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards for obtaining an order under section 911(g)(1);

- the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies;

- the magnitude of overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;

- the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;

- testing of actual consumer perception shows that, as the applicant

proposes to label and market the product, consumers will not be misled into believing that the product is or has been demonstrated to be less harmful or presents or has been demonstrated to present less of a risk of disease than one or more other commercially marketed tobacco products; and

- issuance of an order with respect to the application is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

Section 911(g)(4) of the FD&C Act describes factors that FDA must take into account in evaluating whether a tobacco product benefits the health of individuals and the population as a whole.

FDA is issuing this notice to inform the public that MRTPAs for the following products submitted by 22nd Century Group Inc. have been filed and are being made available for public comment:

- MR0000296.PD1: VLN® King
- MR0000296.PD2: VLN® Menthol King

The applicant is seeking renewal of the authorization to market VLN® King and VLN® Menthol King, both combusted, filtered cigarettes, as modified risk tobacco products under section 911(g)(2) of the FD&C Act.<sup>1</sup> These products previously received such authorization on December 23, 2021, and the applicant is including information from the previous MRTPAs by cross-reference.

FDA will post the application documents, including any amendments, to its website for the MRTPAs (see section II) for public comment on a rolling basis as they are redacted in accordance with applicable laws. In this document, FDA is announcing the availability of the first batch of application documents for public comment. FDA intends to establish a closing date for the comment period that is both at least 120 days after the date this notice and at least 30 days after the final documents from the application are made available for public comment. FDA will announce the closing date at least 30 days in advance. FDA believes that this comment period is appropriate given the volume and complexity of the applications being posted.

FDA will notify the public about the availability of additional application documents and comment period closing

<sup>1</sup> The notice of availability for the VLN® MRTPAs that received a modified risk granted order appeared in the *Federal Register* on July 25, 2019 (84 FR 35869) and the docket containing notices and public comments, FDA-2019-N-0994, is accessible at: <https://www.regulations.gov/search?filter=FDA-2019-N-0994>.

date via the Agency's web page for the MRTPAs (see section II) and by other means of public communication, such as by email to individuals who have signed up to receive email alerts. To receive email alerts, visit FDA's email subscription service management website (<https://www.fda.gov/about-fda/contact-fda/get-email-updates>), provide an email address, scroll down to the "Tobacco" heading, select "Modified Risk Tobacco Product Application Updates", and click "Submit." To encourage public participation consistent with section 911(e) of the FD&C Act, FDA is making the redacted MRTPAs that are the subject of this notice available electronically (see section II).

## II. Electronic Access

Persons with access to the internet may obtain the document(s) at <https://www.fda.gov/tobacco-products/advertising-and-promotion/22nd-century-group-inc-modified-risk-tobacco-product-mrtp-applications>.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0407-30D]

### Agency Information Collection Request. 30-Day Public Comment Request

**AGENCY:** Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of Minority Health, U.S. Department of Health and Human Services, is announcing that the following summary of a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance.

**DATES:** Submit written comments (including recommendations) on the information collection request (ICR) on or before June 12, 2026.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting

“Currently under 30-day Review—Open for Public Comments” or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Submit requests to *minorityhealthinfo@hhs.gov* or (240) 453–0492. When submitting comments or requesting information, please include the document identifier OS–0990–0407–30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* OMH Think Cultural Health.

*Type of Collection:* Extension of a Currently Approved Collection.  
*OMB No.:* 0990–0407.

*Abstract:* The Office of Minority Health (OMH), Department of Health and Human Services (HHS), is requesting approval by the Office of Management and Budget (OMB) on an extension of a currently approved collection of information. The Think Cultural Health (TCH) website is an initiative of HHS OMH that provides resources and tools to promote cultural and linguistic competency in health and health care. The TCH website offers a suite of e-learning programs that afford health and health care professionals the ability to earn continuing education credits through training in cultural and linguistic competency. A 60-Day **Federal Register** Notice was published in the **Federal Register** on February 20, 2026, vol. 91, No. 34; pp. 8259.

*Need and Proposed Use of the Information:* The data will be used to enable health and health care professionals to register for courses, obtain accredited continuing education

credits, and help ensure that TCH offerings remain relevant, useful, and responsive to the needs of their target audiences. The findings from the data collection will be of interest to HHS OMH in supporting maintenance and revisions of the offerings on the TCH website.

*Likely Respondents:* Likely respondents are users of the TCH e-learning program(s) and/or e-resource(s). There are no requirements for annual, quarterly or monthly responses. A single respondent completes the registration process to access an e-learning program or e-resource on the website only once and completes a course-specific evaluation form for each e-learning program course/unit or e-resource per completion. A respondent may be invited to participate in the follow-up survey, a focus group, or a key informant interview and will not be asked to participate in more than one follow-up activity (*i.e.*, survey, focus group, or key informant interview).

**TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS**

Forms	Respondents	Number of respondents	Number of responses per respondents	Average burden per response (hours)	Total burden hours
Registration Form .....	Health and Health Care Professionals .....	118,352	1	0.05	5,918
Course/unit Evaluation Form .....	Health and Health Care Professionals .....	118,352	1	0.05	5,918
Follow-Up Survey .....	Health and Health Care Professionals .....	4,208	1	0.17	701
Focus Groups .....	Health and Health Care Professionals .....	15	1	2	30
Key Informant Interviews .....	Health and Health Care Professionals .....	13	1	1	13
<b>Total .....</b>	.....	<b>240,940</b>	.....	.....	<b>12,580</b>

**Catherine Howard,**  
*Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.*  
[FR Doc. 2026–09567 Filed 5–12–26; 8:45 am]  
**BILLING CODE 4150–29–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial

property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: Integrated Approaches in Neurodegeneration.  
*Date:* June 16–17, 2026.

*Time:* 8:00 a.m. to 8:30 p.m.  
*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.  
*Contact Person:* Bernard Rajeev Srambical Wilfred, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–6813, *bernard.srambicalwilfred@nih.gov*.

*Name of Committee:* Population Sciences and Epidemiology Integrated Review Group;

Social and Environmental Determinants of Health Study Section.

*Date:* June 16, 2026.  
*Time:* 9:00 a.m. to 6:00 p.m.  
*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.  
*Contact Person:* Gheda Khodr Temsah, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–2342, *temsahgk@csr.nih.gov*.

*Name of Committee:* Biobehavioral and Behavioral Processes Integrated Review Group; Language and Communication Study Section.

*Date:* June 16–17, 2026.  
*Time:* 9:00 a.m. to 5:00 p.m.  
*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.