DATES: The meeting will be held virtually on December 8, 2022, from 9 a.m. to 4 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Rakesh Raghuwanshi, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993, 301–796–4769, *rakesh.raghuwanshi@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 Agency'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: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The Science Board will consider research needs for the evaluation of potential adverse health effects in children associated with oral cadmium exposure. The Science Board will also hear about the Agency's cross-cutting regulatory science research activities and its recent Focus Areas of Regulatory Science report.

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. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio 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 made to the contact person on or before December 2, 2022. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 1, 2022. 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. The contact person will notify interested persons regarding their request to speak by December 2, 2022.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

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 Rakesh Raghuwanshi (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.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–25405 Filed 11–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2657]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration's Study of Assessing Physiological, Neural and Self-Reported Response to Tobacco Education Messages

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's investigation of how youth and young adults process tobacco education messaging and to identify effective tobacco prevention and education message strategies.

DATES: Either electronic or written comments on the collection of information must be submitted by January 23, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 23, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2022–N–2657 for ''Food and Drug Administration's Study of Assessing Physiological, Neural and Self-Reported Response to Tobacco Education Messages.'' 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., 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 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.'' The Agency 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 to 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 this 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: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food and Drug Administration's Study of Assessing Physiological, Neural and Self-Reported Response to Tobacco Education Messages

OMB Control Number 0910–NEW

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products; to inform the public on health-related issues; and to protect public health by reducing tobacco use and by preventing death and disease caused by tobacco use.

FDA's Center for Tobacco Products (CTP) was created to carry out the authorities granted under the Tobacco Control Act, to educate the public about the dangers of tobacco use and serve as a public health resource for tobacco and health information. Through CTP, FDA researches, develops, and distributes information about tobacco and health to the public, professionals, various branches of government, and other interested groups nationwide using a wide array of formats and media channels. FDA's ''The Real Cost'' campaign (*https://www.fda.gov/tobacco-products/public-health-education-campaigns/real-cost-campaign*) uses evidence-based paid media advertising to highlight the negative health consequences of tobacco use. To develop the appropriate messaging to inform the public, it is important for FDA to conduct research to assess youth and young adults' perceptions of tobacco use prevention messaging.

The study of ''Assessing Physiological, Neural and Self-Reported Response to Tobacco Education Messages'' is voluntary research. Information obtained through this study will primarily be used to assess the performance of ads developed to reduce tobacco initiation and use among at-risk youth and young adults as part of CTP's ''The Real Cost'' campaign. Traditionally, message testing research employs self-reported measures of perceived effectiveness (*e.g.,* an individual's perception that the ad would make one less likely to use tobacco), but research indicates that while these self-reported measures are useful, they may be imperfect proxies for real world knowledge, attitude, and behavior change. This imprecision

could lead message developers to select less than optimal messages or cost-ineffective strategies for widespread dissemination.

Physiological and neural responses to tobacco education messages offer an innovative and useful supplement to traditional self-report measures. Indicators such as heart rate variability, galvanic skin response, and facial electromyography can assess arousal and affective response to messages, while tools such as eye tracking and neuroimaging can measure attention and levels of activation in key areas in the brain associated with message processing and message acceptance. Research indicates that these techniques can be more effective than self-report measures at predicting ''real world'' tobacco education message effectiveness.

There is a need for research that implements these techniques to identify the most effective tobacco prevention and education message strategies. Additionally, there is a need to triangulate data collected through physiological and neuroimaging-based approaches with self-reported measures to better understand how self-reported measures can be implemented in order to accurately predict knowledge, attitude, and behavior change.

This study will recruit participants from the Baltimore, Maryland area to participate in an in-person study visit at Johns Hopkins University Bloomberg School of Public Health. Inclusion and exclusion criteria are based on the target populations for ''The Real Cost'' campaign. Specifically, the study will collect data from two groups: 50 youth (aged 13–17) and 50 young adults (aged 18–24 years old). Participants will be stratified by electronic nicotine delivery systems and cigarette use, so that approximately half of each sample will be: (1) at risk for initiating a tobacco product (*i.e.,* think they might try one in the near future or would try one if a friend offered it to them) or (2) tobacco experimenter (have had at least 1 but less than 100 cigarettes in their lifetime; have had at least 1 puff of an e-cigarette). Individuals who respond that they have never used tobacco products and respond ''definitely not'' to all questions assessing openness to tobacco use will be excluded from participation. Additionally, those who have established tobacco use patterns will be excluded from participation. Both groups are outside the target demographic for ''The Real Cost'' campaign.

The study will use community-based recruiting, using methods such as flyers posted at locations frequented by young adults, teenagers, and their parents (*e.g.,* local Baltimore City colleges, markets, and other relevant venues), social media, and word-of-mouth. Flyers will be posted with permission and advertise the study as assessing perceptions of tobacco education messages using monitors placed on the head, face, and fingers; special glasses; and a survey. Participants will be directed to complete an online screening survey before scheduling their study visit.

For youth participants, eligible participants will provide contact information for their parent/guardian. The study team will then contact the parent and receive parental permission and schedule a study visit. At the study visit, study personnel will confirm that 13–15-year-olds are accompanied by someone 18 or older, and then the youth will provide assent. For young adult participants, after completing the screener, eligible participants will provide their contact information. The study team will then contact the participant and schedule a study visit. At the study visit, young adult participants will provide informed consent prior to beginning study participation.

After the consenting/assenting process, participants will complete one study visit (90 minutes long) in which they will view four FDA tobacco education and prevention ads. First, participants will complete a survey and be fitted with neuroimaging and psychophysiological equipment. Second, participants will be fitted for a functional near-infrared spectroscopy (fNIRS) headband (the headband can be adjusted based on head circumference) and then have the fNIRS headband and electrodes for physiological data collection, and eye-tracking glasses placed on them. They will then complete a series of computer tasks to ensure placement of the fNIRS headband and fill out part one of the survey on demographic characteristics, tobacco use behaviors, and social influence related to tobacco use. Next, they will view tobacco education messages, and complete part two of the survey providing self-reported response data (*e.g.,* how much they liked the ad) after each message. Participants will conclude the survey by completing the third part of the survey assessing psychosocial variables. Participants will receive a small incentive as a token of appreciation in exchange for their survey participation. Additionally, for youth (ages 13–15) participants, the adult who accompanies the youth will receive a token of appreciation in exchange for costs of accompanying the youth to the study site (*e.g.,* parking, gas, and potential loss of income/childcare needed for youth to participate).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Participant subgroup	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [1]
Number to take the eligibility screener					
Youth (aged 13–17)	150	1	150	0.083 (5 minutes)	13
Young adults (aged 18–24)	150	1	150	0.083 (5 minutes)	13
Total					26
Number to obtain parental permission process (for parents of youth only) and schedule site visit					
Parents of youth participants	75	1	75	0.167 (10 minutes)	13
Young adults (aged 18–24)	50	1	50	0.083 (5 minutes)	4
Total					17

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Participant subgroup	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [1]
Number to complete consent (5 min) and main study (85 min)					
Youth (aged 13–17)	50	1	50	1.5	75
Young adults (aged 18–24)	50	1	50	1.5	75
Total					150
Total					193

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

FDA's burden estimate is based on prior experience with research that is similar to this proposed study. Applying assumptions from previous experience in conducting similar studies, approximately 150 youth and 150 young adults would take the eligibility screener, which is estimated to take 5 minutes to read and respond. An estimated 75 parents of youth participants will provide parental permission and schedule a site visit (10 minutes total); and an estimated 50 young adults will schedule a site visit (5 minutes). Finally, approximately 50 youth and 50 young adults will complete an in-person study visit that consists of the consent/assent (5 minutes) and complete the main study (85 minutes) to yield the desired sample size of 100 total. The total estimated burden for the data collection is 193 hours. Table 1 details these estimates.

Dated: November 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–25406 Filed 11–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Advisory Committee on Infant and Maternal Mortality

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates for consideration for appointment as members of the Advisory Committee on Infant and Maternal Mortality (ACIMM or Committee). ACIMM advises the Secretary of HHS (Secretary) on department activities, partnerships, policies, and programs directed at reducing infant mortality, maternal mortality and severe maternal morbidity, and improving the health status of infants and women before, during, and after pregnancy. HRSA is seeking nominations of qualified candidates to fill open positions on the ACIMM.

DATES: Written nominations for membership on the ACIMM must be received on or before January 23, 2023.

ADDRESSES: Nomination packages must be submitted electronically as email attachments to Vanessa Lee, MPH, the ACIMM's Designated Federal Official, at: *SACIM@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Vanessa Lee, MPH, Designated Federal Official, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18N84, Rockville, Maryland 20857; 301–443–0543; or *SACIM@hrsa.gov.* A copy of the ACIMM charter and list of the current membership may be obtained by accessing the ACIMM website at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

SUPPLEMENTARY INFORMATION: The ACIMM was established in 1991 and advises the Secretary on department activities, partnerships, policies, and programs directed at reducing infant mortality, maternal mortality and severe maternal morbidity, and improving the health status of infants and women before, during, and after pregnancy. The Committee provides advice on how to coordinate federal, state, local, tribal, and territorial governmental efforts designed to improve infant mortality, related adverse birth outcomes, and maternal health, as well as influence similar efforts in the private and voluntary sectors. The Committee provides guidance and recommendations on the policies, programs, and resources required to address the disparities and inequities in infant mortality, related adverse birth outcomes and maternal health outcomes, including maternal mortality and severe maternal morbidity. With its focus on underlying causes of the disparities and inequities seen in birth outcomes for women and infants, the Committee advises the Secretary on the health, social, economic, and environmental factors contributing to the inequities and proposes structural, policy, and/or systems level changes. The ACIMM shall meet approximately four times per year, or at the discretion of the Designated Federal Officer in consultation with the Chair.

Nominations: HRSA is requesting nominations for voting members to serve as Special Government Employees (SGEs) on the ACIMM to fill open positions. The Secretary appoints ACIMM members with the expertise needed to fulfill the duties of the Advisory Committee. Information about SGE membership on the ACIMM is set forth in the ACIMM charter. Nominees sought are medical, technical, or scientific professionals with special expertise in the field of maternal and child health, in particular infant and/or maternal mortality and related health disparities; members of the public having special expertise about or concern with infant and/or maternal mortality; and/or representatives from such public health constituencies, consumers, and medical professional societies. Interested applicants may self-nominate or be nominated by another individual or organization.

ACIMM consists of up to 21 members appointed by the Secretary for a term of up to 4 years. Individuals selected for appointment to the Committee will be invited to serve for up to 4 years. Members appointed as SGEs receive a stipend and reimbursement for per diem and travel expenses incurred for attending ACIMM meetings and/or conducting other business on behalf of the ACIMM, as authorized by 5 U.S.C. 5703 for persons employed intermittently in government service.