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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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	No. of Respondents	No. 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
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: 11/21/2022 8:45 am; Publication Date: 11/22/2022]