TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Mail, telephone, web-based survey	85,000	1	85,000	.42 (25 minutes)	35,700

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

Since the last OMB approval of this information collection request, FDA submitted three requests to increase the total burden hours. Therefore, this request for extension of OMB approval adjusts the number of respondents by an increase of 30,000 and the total burden hours by an increase of 21,950.

Dated: April 19, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08640 Filed 4–24–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2657]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by May 25, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is ''Food and Drug Administration's Study of Assessing Physiological, Neural and Self-Reported Response to Tobacco Education Messages.'' Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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).

In the **Federal Register** of November 22, 2022 (87 FR 71335), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that was not PRA related.

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
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: April 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08684 Filed 4–24–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1357]

Authorization of Emergency Use of a Medical Device During COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for a medical device related to the Coronavirus Disease 2019 (COVID–19) public health emergency. FDA has issued the Authorization indicated in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the February 4, 2020, determination by the Secretary of Health and Human Services (HHS), as amended on March 15, 2023, that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad and that involves the virus that causes COVID–19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID–19, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is specified in this document, and can be accessed on FDA's website from the links indicated.

DATES: The Authorization is effective on the date of issuance.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50 of the U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under section 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b,

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.