DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0132]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration's Study of How Consumers Use Flavors To Make Inferences About Electronic Nicotine Delivery System Product Qualities and Intentions To Use (Phase 2)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) 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 March 21, 2022.

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 How Consumers Use Flavors to Make Inferences About Electronic Nicotine Delivery System Product Qualities and Intentions to Use (Phase 2).'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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 How Consumers Use Flavors to Make Inferences About Electronic Nicotine Delivery System (ENDS) Product Qualities and Intentions to Use (Phase 2)

OMB Control Number 0910—NEW

ENDS, also called electronic cigarettes, e-cigarettes, and vaporizers, are deemed tobacco products and fall under FDA's regulatory scope. FDA has the authority under the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31, H.R. 1256) to regulate and restrict the marketing of tobacco products. However, given the recency of ENDS products to the market, limited research exists to inform the regulation of certain aspects of their marketing. Research to understand ''marketing influences on youth experimentation, initiation, use and cessation of tobacco products'' is a regulatory priority for the FDA Center for Tobacco Products (CTP).[1]

Flavors are a unique and important aspect of ENDS. ENDS use a liquid (''e-liquid'' or ''e-juice'') that can span a diverse range of flavors, from tobacco flavor, menthol, mint, fruit flavors, non-fruit sweet flavors (*e.g.,* crème brulee, gummi bears), spices (*e.g.,* cinnamon, vanilla), alcohol (*e.g.,* strawberry daiquiri, bourbon, Irish cream), and ''concept flavors.'' Flavors are a regulatory area of interest, and FDA has issued an advance notice of proposed rulemaking (Docket No. FDA–2017–N–6565) ''to obtain information related to the role that flavors play in tobacco products,'' with a specific interest in how flavors may spur youth product initiation.

This study of ''How Consumers Make Inferences About ENDS'' is voluntary research. The primary goal of the study is to understand whether flavor-related imagery, descriptors, and flavor name modifiers affect product appeal, curiosity about the product, interest in using the product, and product perceptions among youth and young adults. The project will examine three features identified in the research team's prior work: The use of flavor-related imagery, the use of flavor descriptors (*e.g.,* ''cool,'' ''fresh''), and the use of flavor name modifiers (*e.g.,* Cherry Crush).

The study will collect data from two groups of consumers: 2,500 youth (aged 13 to 17 years old) and 2,500 young adults (aged 18 to 24 years old). The sample will be stratified by ENDS and cigarette use, so that 625 participants in each age group will be (a) noncigarette and non-ENDS users (N=625), (b) cigarette users only (N=625), (c) ENDS users only (N=625), and (d) dual ENDS and cigarette users (N=625). Participants will participate in a repeated measure experiment in which they will be asked to view five ads and report their liking of the ad, curiosity about using the product (an important precursor to use), and interest in using the product. Participants will also report additional perceptions of product qualities. This study is not meant to inform or guide other public health agencies' policies and messaging regarding the role of flavors in ENDS. This study will contribute to scientific knowledge regarding the use of flavors in ENDS marketing. Thus, other agencies may learn about the findings from our study through manuscripts published in peer-reviewed journals, for example, but this study is not intended to specifically influence their policies and messaging.

Study Overview: In this study, youth noncigarette and non-ENDS users, current cigarette smokers, ENDS only users, and dual users of ENDS and cigarettes, as well as young adult noncigarette and non-ENDS users, current cigarette smokers, ENDS only users, and dual users of ENDS and cigarettes will be recruited from two existing internet online panels and screened for inclusion into the study. Youth will also be recruited through their parent panelists (parents who are members of the existing online panel) and screened for inclusion into the study.

All recruited participants must complete a double opt-in procedure, and parents of youth panelists must consent for their child to be on the online panel. For this study, youth will provide assent and young adults will provide consent to participate in the surveys. Per institutional review board approval, parental consent was waived given that this study is minimal risk, documentation of parental consent would create an identifier, and verification of parental consent is difficult and could potentially bias the sample towards participants who have parents readily available and able to consent. The survey platform can detect and prevent duplicate responses by scanning for duplicate cookies and internet protocol (IP) addresses.

Participants who meet the inclusion criteria will be randomized to view five ads across five conditions to report their liking of the ad, curiosity about using the product (an important precursor to use), and interest in using the product. The order of ad presentation will be randomized. These procedures will minimize order effects as well as the likelihood of a demand characteristic in which a participant guesses the purpose of the experiment and intentionally or unintentionally alters their response. Participants will receive a small

[1] *https://www.fda.gov/tobacco-products/research/research-priorities.*

incentive as a token of appreciation in exchange for their survey participation.

Study outcomes include comparisons to assess the extent to which presence or absence of a flavor-representing image, name modifier, or descriptor will be associated with increased or decreased (a) product appeal, (b) curiosity about the product, (c) interest in using the product, and (d) increased positive product perceptions compared to a control condition ad (without or with flavor features).

In the **Federal Register** of March 3, 2021 (86 FR 12468), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received nine comments, four of which were PRA-related.

(Comment 1) One commenter supports FDA's proposed collection of information and stated that research on the advertising of flavored e-cigarettes and its impact on the perceptions of nonusers, e-cigarette users, cigarette smokers, and dual users is important. The commenter also noted that the proposed study length is acceptable and comprises typical burden for respondents in this type of research.

(Response) FDA agrees with this comment and believes the study will contribute to our understanding of how consumers interpret flavor features on product labeling to make inferences about ENDS product qualities and intentions to use. We also believe the study's burden estimate aligns with previous research studies of this kind.

(Comment 2) One commenter stated that FDA should research the role of flavored noncombustible tobacco products in converting adult smokers from cigarettes.

(Response) This study focuses on the appeal of the selected advertising tactics on youth and young adults. Expanding the sample to include older adults (or all adults) is beyond the scope of the study.

(Comment 3) FDA received a comment suggesting the Agency consider separating underage individuals from those who are of legal age to purchase tobacco products.

(Response) The aim of this study centers around appeal of the selected advertising tactics on youth and young adults. The selection of the advertising tactics to be studied was grounded in research conducted when the Federal legal age to purchase tobacco was 18 years of age. Thus, we intend to sample youth aged 13–17 and young adults aged 18–24. However, as resources allow, we will plan to conduct supplementary analyses to account for the new Federal legal age (*e.g.,* under 21 years vs. 21+ years).

(Comment 4) FDA received a comment suggesting the Agency expand the sample to include tobacco users aged 25 and older.

(Response) This study focuses on appeal of the selected advertising tactics on youth and young adults. Expanding the sample to include older adults is beyond the scope of the study.

(Comment 5) FDA received a comment suggesting the Agency include a range of flavor name modifiers.

(Response) The flavor name modifiers used in the study were selected based on careful review of prior research analyzing the tactics that ENDS companies use to advertise flavor. Our assessment is that the selected name modifiers are consistent with that research.

(Comment 6) One commenter stated that using generalized data to support premarket determinations for specific products on specific applications is scientifically inappropriate. The commenter stated that the public should have the opportunity to provide comment on any proposed regulations. Additionally, the commenter stated any proposed de facto category-wide restriction on the manufacture, marketing, and distribution of tobacco products should undergo the appropriate notice and comment rulemaking procedures.

(Response) The primary goal of the study is to understand whether flavor-related imagery, descriptors, and flavor name modifiers affect product appeal, curiosity about the product, interest in using the product, and product perceptions among youth and young adults. This study will not produce product-specific data; thus, it would not form the sole basis for any premarket determinations, but the results could be taken into consideration more broadly as part of premarket review. Additionally, this study might inform FDA's thinking regarding possible rulemaking but it will not provide sole support for any rulemaking. FDA's consideration of any future rulemaking would follow the appropriate notice and comment rulemaking procedures, which would include an explanation of the scientific basis for the proposed rule. The scientific basis would consider all relevant science, not just the results of this one study. Lastly, this study does not indicate FDA's intent to propose such a rule. The intent is to advance scientific knowledge broadly regarding the use of flavors in ENDS marketing.

(Comment 7) FDA received a comment expressing concern about exposing youth to ENDS advertisements.

(Response) Our study protocol includes measures to minimize risk of youth exposure to ENDS advertisements. Before participating in the study, participants are informed that they will be shown five ENDS advertisements. All participants are free to stop participation at any time and for any reason. At the end of the survey, participants will view a ''debrief'' screen containing information about the risks of ENDS and references to FDA and others' ENDS education and prevention campaigns.

The Johns Hopkins Bloomberg School of Public Health's Institutional Review Board reviewed and approved this study. We amended our recruitment process to further address this concern. We will also recruit youth aged 13–17 through their parent panelists (parents who are members of an existing online panel). Recruitment emails will be sent to parent panelists inviting them to have their child aged 13–17 participate in the study. Parents who are interested in having their child participate can have their child click the survey link in the recruitment email. This means that youth will be recruited to participate through two ways. First, we will recruit current youth panel members. Second, we will recruit youth through their parent panelists (parents who are members of the existing online panel).

(Comment 8) FDA received a comment expressing that the study does not provide data that would inform ''conclusions regarding the role of flavors in youth attractiveness'' and that the study does not distinguish between characterizing and noncharacterizing flavors.

(Response) The objective of this study is to examine the effect of flavor advertising tactics on consumer product perceptions and intentions to use, not the effect of actual flavors and flavor use. Therefore, this comment is out of scope for the proposed study.

(Comment 9) FDA received a comment inquiring about whether ''the survey will representatively sample/oversample for certain subpopulations—with a particular lens on race/ethnicity and other priority populations.''

(Response) The current sample was designed with a primary focus of sampling adequate numbers of youth and young adults across a variety of cigarette and ENDS use statuses (noncigarette and non-ENDS users; cigarette users only; ENDS users only; dual ENDS and cigarette users), and we are not able to do additional oversampling given that some of these groups are of low frequency in the

general population. However, we will be able to identify how our sample compares to national data, and our data will be weighted to be proportionally reflective of the U.S. population by race/ethnicity.

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
No. to read the survey invitation					
Youth (aged 13–17)	125,000	1	125,000	0.016 (1 minute)	2,084
Young adults (aged 18–24)	125,000	1	125,000	0.016 (1 minute)	2,084
Total	250,000				4,168
No. to complete the consent and screener					
Youth (aged 13–17)	3,750	1	3,750	0.116 (7 minutes)	438
Young adults (aged 18–24)	3,750	1	3,750	0.116 (7 minutes)	438
Total	7,500				876
No. to complete main study					
Youth (aged 13–17)	2,500	1	2,500	0.333 (20 minutes)	834
Young adults (aged 18–24)	2,500	1	2,500	0.333 (20 minutes)	834
Total	5,000				1,668
Total					6,712

[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 (OMB control number 0910–0848). Applying assumptions from previous experience in conducting similar studies, approximately 250,000 respondents from an internet panel will be recruited via an email invitation, which is estimated to take 1 minute to read and respond. An estimated 7,500 (3,750 youth and 3,750 young adults) respondents will provide assent and consent and be screened to yield the desired sample size of 5,000 total (2,500 youth and 2,500 young adults) participants. The consent/screening process is estimated to take an average of 7 minutes per respondent. Participants that qualify for the study will be automatically directed to begin the online survey, which is estimated to take an average of 20 minutes per respondent.

The total estimated burden for the data collection is 6,712 hours.

Dated: February 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

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

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: *https://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or