before, manufacturers who submit 510(k)s and receive marketing clearance will continue to be exempt from the Electronic Product Radiation Control reporting requirements in 21 CFR 1002.12, for diagnostic ultrasound devices, as described in the notice to industry entitled ''Exemption from Reporting under 21 CFR 1002'' dated February 24, 1986.[1]

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of October 2, 2017 (82 FR 45856). FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on information for manufacturers seeking marketing clearance of diagnostic ultrasound systems and transducers. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Marketing Clearance of Diagnostic Ultrasound Systems and Transducers'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 560 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
801	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
1002 and 1010	Reporting and Recordkeeping for Electronic Products—General Requirements.	0910–0025
814, subpart A–E	Premarket Approval of Medical Devices	0910–0231
513(f)(2) FD&C Act	De Novo Classification Process (Evaluation of Automatic Class III Designation).	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756

Dated: June 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13687 Filed 6–26–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0075]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study on Measuring Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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: Fax written comments on the collection of information by July 29, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Experimental Study on Measuring Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Experimental Study on Measuring Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke OMB Control Number 0910–NEW

[1] Available at *https://www.fda.gov/downloads/RadiationEmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/UCM509874.pdf.*

I. Background

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act) was signed into law. This law amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors. The Tobacco Control Act also gave FDA the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the FD&C Act (section 901(b) of the FD&C Act (21 U.S.C. 387a(b))).

In accordance with that authority, on May 10, 2016 (81 FR 28974), FDA issued a final rule deeming all products that meet the statutory definition of tobacco product, except accessories of newly deemed tobacco products, to be subject to FDA's tobacco product authority. The deemed products include electronic nicotine delivery systems, cigars, waterpipe (hookah), pipe tobacco, nicotine gels, dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future.

Among other requirements, section 904(e) of the FD&C Act (21 U.S.C. 387d(e)) requires FDA to establish, and periodically revise as appropriate, a list of harmful and potentially harmful constituents (HPHCs), including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand. Section 904(d)(1) of the FD&C Act further requires that this list be published in a format that is understandable and not misleading to a lay person (the Section 904(d) list).

FDA has undertaken a rigorous science-based research approach to ensure that the Section 904(d) list is not misleading to lay persons. As part of this research, FDA is seeking to conduct an experimental/quantitative study (4,500 online surveys), consisting of adult and youth (aged 13 to17) participants to evaluate the best way to convey information about HPHCs in tobacco products and tobacco smoke, by brand and by quantity in each brand and subbrand, in a format that is understandable and not misleading to a lay person. Participants will view sample formats and complete an online survey that will include questions regarding their understanding of the HPHC information presented to them. The purpose of the research is to gain insight on consumer comprehension of, and preferences regarding, HPHC presentations that will inform the Agency's efforts in connection with publishing the Section 904(d) list.

In the **Federal Register** of February 11, 2019 (84 FR 3188), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received comments from six individuals or organizations, three of which were PRA related.

(Comment) One comment recommended that FDA make the study design, sample formats, and all study measures available for public comment.

(Response) FDA notes that the study protocol, list formats, and the survey questionnaire are available for review upon request and are described in detail as part of the overall information collection request submitted to OMB for review.

(Comment) One comment suggested that FDA add a control group that does not view a sample format to our study design.

(Response) FDA considered the utility of adding a no-exposure control group to this study. However, FDA determined that this is not in line with the study aims. The aims of the study are derived from section 904(e) of the FD&C Act which requires FDA to publish a list of HPHCs in each brand and sub-brand of tobacco product, in a way that people find understandable and not misleading. Therefore, the proposed study will test different formats of HPHC lists to meet this statutory requirement. A condition in which people do not see a list of HPHCs in a tobacco product does not approximate real-life conditions.

(Comment) One comment suggested that FDA should clarify whether the HPHC sample formats will include smokeless brands since items in the draft survey are exclusive to cigarettes. The comment also noted that FDA should clarify whether smokeless tobacco and exclusive cigarette users will only view HPHC lists in their respective categories.

(Response) HPHC sample formats will not include smokeless brands because HPHC lists for cigarettes are the focus of the proposed study. All participants will view HPHC lists for cigarettes only to allow for a parsimonious and focused design that is adequately powered to detect effects.

(Comment) One comment suggested that FDA should use validated survey measures, establish the validity of other metrics prior to use, and consider using validated risk perception metrics.

(Response) FDA agrees that validated items should be used whenever possible. FDA engaged in a multistep process to select validated survey items for this study. First, FDA conducted a literature review and used available validated survey measures, including measures from past HPHC research (Ref. 1). However, for some outcomes (*e.g.,* knowledge about the tested format), validated measures do not exist because questions are specific to the stimuli. Second, FDA conducted qualitative research to inform our measures. Based on insights uncovered during this research, we created and modified survey items. Third, FDA conducted cognitive testing to refine the measures. It should be noted that there are many ways to measure these constructs, including harm perceptions. The harm perceptions items that FDA used are based on a systematic review that identified the most commonly measured tobacco-related health consequences in the literature (Ref. 2).

(Comment) One comment suggested that FDA should get end-user input into the development and refinement of the survey items. The comment suggested that survey items should be subject to cognitive testing, with individuals representing end users until the point of saturation is reached.

(Response) FDA agrees that it is important to test a survey before collecting responses. As part of the research program, FDA conducted 54 indepth interviews, ''Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products'' (OMB control number 0910–0796), as a first step to develop items. Based on the findings from that study and a literature review to uncover validated measures, FDA developed a draft survey. Next, FDA cognitively tested the draft survey and stimuli and refined each by reducing redundant content and editing any confusing items. FDA reached saturation in both qualitative studies.

(Comment) One comment suggested that including a midpoint on some of the scales (*e.g.* ''neutral'' and ''neither agree nor disagree'') may be difficult for some respondents to understand. The comment suggested that FDA incorporate a ''don't know'' response option for some items including the HPHC general knowledge questions.

(Response) The inclusion of a ''don't know'' response on the knowledge items was made in order to best match the source of those items (Refs. 1 and 3). That is, FDA included a ''don't know'' option when the source item did so. Although it is true that individuals interpret middle options like ''neutral'' in different ways, these personal interpretations should be randomly distributed across condition and thus

not affect the comparisons among the stimuli (Ref. 4).

(Comment) One comment recommended that FDA ask several of the post-test items (*e.g.*, items 33, 34, 38) during the pre-test so that we can obtain a baseline estimate of misperceptions and determine whether there was any change in respondents' incorrect beliefs following exposure to the stimulus.

(Response) The primary purpose of this study is to test formats to see if they are understandable and not misleading. This can be achieved by comparing post-test measures of understanding and misleading across conditions and does not require a pre-test. We note that participants may have baseline misperceptions that are not accounted for in this design; however, since we are collecting data from a representative sample of people, we can account for these differences during the analysis. Further, as these items are part of a validated scale if FDA selects only a few items to ask in the pre-test, this may lead to data that is not reliable or valid. As these items are part of a larger scale that has been used and tested in previous research, only selecting a few questions may alter how participants respond to these and other questions in the survey. Also, these items have not been tested to be used alone.

(Comment) One comment suggested that FDA add an attention check and measures of believability, truthfulness, or skepticism to provide additional context for the study results.

(Response) The knowledge items in the survey are inherently an attention check because the participant can use the information in the stimulus to answer questions. Adding an attention check will not provide any additional benefit. Adding additional measures about believability, truthfulness, or skepticism are outside of the scope and purpose of this study.

(Comment) One comment suggested that FDA oversample vulnerable populations including youth, minorities, and those with low levels of education in our survey. An additional comment commended FDA for including youth aged 13 to 17 in this study as it is critically important because most tobacco consumers begin using tobacco before the age of 18. Further, including youth in the sample underscores FDA's recognition that it is possible to survey youth about the comprehension of information about tobacco without violating ethical standards.

(Response) FDA agrees, we have established quotas in the recruitment to ensure that the sample is comprised of at least 20 percent of low socioeconomic participants (income of less than $25,000 year) and at least 20 percent of adults without a high school diploma or GED. These proportions are not exclusive because low education and low socioeconomic status are strongly correlated. Further, the study sample will include approximately 1,500 adolescent tobacco users and adolescents at risk for using tobacco (ages 13 to 17).

(Comment) One comment suggested that FDA collect demographic information pertaining to race/ethnicity, age, and education level.

(Response) FDA agrees, we already plan to collect this demographic information as part of the screening procedures.

(Comment) One comment suggested that FDA ask participants where they would look for information about tobacco constituents.

(Response) FDA appreciates the suggestion. As previously mentioned in our comment responses FDA conducted 54 indepth interviews where this was assessed. There is also an item on the survey that asks, ''Where would you most like to see information on chemicals in cigarettes and cigarette smoke?'' The response options are ''on cigarette packs,'' ''in stores,'' and ''online.'' Between this item and the indepth interviews FDA conducted, this will provide FDA with adequate information on where participants would look for information about tobacco constituents.

(Comment) One comment suggested that FDA add ''to the best of your knowledge'' at the beginning of questions 6 through 10.

(Response) FDA does not believe this is necessary as these questions include a ''don't know'' response option. Further, these questions were used in previous research (Ref. 1).

(Comment) There were a few comments about the ''understanding'' section of the survey. One comment suggested that FDA add nicotine, acetone, and carbon monoxide to this section. Another comment suggested that FDA expand the ''Understanding'' section to include a section on addiction. The comment suggested that the section list specific constituents and ask participants if they cause addiction. One comment suggested that FDA modify the question that asks, ''does smoking cause addiction'' and change it to ''does smoking cigarettes cause addiction.''

(Response) FDA appreciates these suggestions. FDA declines to add additional items or modify items in the ''understanding'' section as it is consistent with prior research. Further, these items were part of cognitive testing and did not cause confusion. Prior research deliberately selected two chemicals that would be familiar to respondents (ammonia and lead) and three that would be unfamiliar (1-aminonaphthalene, acrylonitrile, and isoprene) (Ref. 1). Further, even though there is not a specific question about the link between certain chemicals and addiction, FDA assesses participants' understanding of whether smoking causes addiction in items 11 to 24.

(Comment) There were two comments that asked FDA to add additional items measuring participants behavior. One comment suggested that FDA should add additional questions so that the survey could also determine how likely someone is to not only switch brands, but also whether they are likely to quit or switch to a different product. Another comment suggested that FDA add questions to the post-test to measure the behavioral impacts of these formats including cessation intentions.

(Response) Although measuring these behavioral intentions and outcomes are interesting, these questions are outside the scope of this study. The focus of this study is to assess whether displays of HPHC information are understandable and not misleading per the statutory requirement.

(Comment) FDA received two comments that supported the collection of this information. One comment urged FDA to move forward promptly with this study.

(Response) FDA appreciates this comment and intend to move forward with the study promptly. We note that data collection will occur within 2 months following OMB approval.

(Comment) One comment noted that FDA was required to publish a list of constituents in a format that is understandable and not misleading to a lay person by June 2012. However, no such list has been published. The comment also noted that it is important for FDA to ensure that information is disclosed in a way that is not misleading.

(Response) FDA agrees that the proposed study is important to help FDA fulfill its statutory requirement. FDA has undertaken an extensive program of research to ensure that we not only publish a list of constituents in a manner that is understandable and not misleading, but also avoid any unintended consequences of such a list.

(Comment) One comment noted that FDA should make it clear that characterizations of information on the list by tobacco product manufacturers in advertising or promotional material are subject to the requirements of the

provisions of section 911 of the Tobacco Control Act (21 U.S.C. 387k) regarding modified risk claims.

(Response) Thank you for this suggestion. However, this comment is outside the scope of the present study as it is about the implementation of the public displays of HPHCs and not about testing the display.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Youth Screener	1,800	1	1,800	0.05	90
Youth Survey	1,500	1	1,500	0.33	500
Total Youth Hours					590
Adult Screener	3,400	1	3,400	0.05	170
Adult Survey	3,000	1	3,000	0.33	1,000
Total Adult Hours					1,170
Total Burden Hours					1,760

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

For this study, potential participants will be recruited by a market research firm that maintains an internet panel, and information will be collected through self-administered, online screening tests and surveys of youth aged 13 to17 and adults aged 18 and older. Approximately 5,200 respondents (1,800 youth and 3,400 adults) will be requested to complete a screening test to determine eligibility for participation in the study, estimated to take approximately 3 minutes (0.05 hour) per screening test, for a total of 260 hours for screening activities. Respondents who qualify for the study will be directed to the survey. Approximately 4,500 participants (1,500 youth and 3,000 adults) will complete the survey, estimated to take 20 minutes (0.33 hour) per survey, for a total of 1,500 hours for completion of both adult and adolescent samples. The length of time to complete the screening test and survey are based on the research firm's experience that panel members answer approximately 2.5 questions per minute. This data collection will take place one time in 2019. Thus, the total estimated burden is estimated to be 1,760 hours.

II. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov*. References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff.

1. Byron, M.J., A.J. Lazard, E. Peters, et al. (2018). ''Effective Formats for Communicating Risks from Cigarette Smoke Chemicals.'' *Tobacco Regulatory Science, 4*(2), 16–29. doi:10.18001/TRS.4.2.2.

* 2. O'Brien, E.K., A. Persoskie, and J. Tam (2019). ''Multi-Item Measures of Tobacco Health Perceptions: A Review,'' *American Journal of Health Behavior, 43*(2), 266–278. doi:10.5993/AJHB.43.2.4.

3. Brewer, N.T., J.C. Morgan, S.A, Baig, et al. (2017). ''Public Understanding of Cigarette Smoke Constituents: Three US Surveys.'' *Tobacco Control, 26*(5), 592–599.

* 4. Nadler, J.T., R. Weston, and E.C. Voyles (2015). ''Stuck in the Middle: The Use and Interpretation of Mid-Points in Items on Questionnaires,'' *The Journal of General Psychology, 142*(2), 71–89.

Dated: June 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13758 Filed 6–26–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3516]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Disease Awareness and Prescription Drug Promotion on Television

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 (PRA).

DATES: Fax written comments on the collection of information by July 29, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Disease Awareness and Prescription Drug Promotion on Television.'' 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.* For copies of the questionnaire contact: Office of Prescription Drug Promotion (OPDP) Research Team, *DTCresearch@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.