

or Joanne Lipkin at least 7 days in advance of the meeting.

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

Dated: May 10, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-10414 Filed 5-15-18; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0987]

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications**

**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 June 15, 2018.

**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](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0796. 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](mailto: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.

#### **Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications**

*OMB Control Number 0910-0796—Extension*

Under section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)), FDA is authorized to conduct educational and public information programs.

In conducting studies relating to the regulation and communications related to tobacco products, FDA will need to employ formative qualitative research including focus groups, usability testing, and/or in-depth interviews (IDIs) to assess knowledge and perceptions about tobacco-related topics with specific target audiences. The information collected will serve three major purposes. First, formative research will provide critical knowledge about target audiences. FDA must understand people's knowledge and perceptions about tobacco-related topics before developing survey/research questions as well as stimuli for experimental studies. Second, by collecting communications usability information, FDA will be able to serve and respond to the ever-changing demands of consumers of tobacco products. Additionally, we will be able to determine the best way to present messages. Third, initial testing will allow FDA to assess consumer understanding of survey/research questions and study stimuli. Focus groups and/or IDIs with a sample of the target audience will allow FDA to refine the survey/research questions and study stimuli while they are still in the developmental stage. FDA will collect, analyze, and interpret information gathered through this generic clearance in order to: (1) Better understand

characteristics of the target audience—its perceptions, knowledge, attitudes, beliefs, and behaviors—and use these in the development of appropriate survey/research questions, study stimuli, or communications; (2) more efficiently and effectively design survey/research questions and study stimuli; and (3) more efficiently and effectively design experimental studies.

FDA is requesting approval of this new generic clearance for collecting information through the use of qualitative methods (*i.e.*, individual interviews, small group discussions, and focus groups) for studies involving all tobacco products regulated by FDA. This information will be used as a first step to explore concepts of interest and assist in the development of quantitative study proposals, complementing other important research efforts at FDA. This information may also be used to help identify and develop communication messages, which may be used in education campaigns. Focus groups play an important role in gathering information because they allow for an in-depth understanding of individual attitudes, beliefs, motivations, and feelings. Focus group research serves the narrowly defined need for direct and informal public opinion on a specific topic. In the **Federal Register** of November 17, 2017 (82 FR 54351), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment by a private citizen that was PRA-related.

(Comment) The commenter stated that FDA should use the data we have collected in the past instead of collecting new information. The comment does not go in detail or provide any alternatives.

(Response) This collection is a valuable tool for conducting research. The studies FDA has conducted through this collection of information have been essential in helping FDA meet its mission as a science-based regulatory agency and implementing the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31). Future submissions submitted under this generic clearance will continue to assist FDA in its mission to protect and promote public health.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Type of interview	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
In-Person Individual IDIs .....	1,092	1	1,092	1 .....	1,092
IDI Screener .....	1,800	1	1,800	.083 (5 minutes) .....	149
Focus Group Interviews .....	4,701	1	4,701	1.5 .....	7,052
Focus Group Screener .....	3,996	1	3,996	.25 (15 minutes) .....	999
Usability Testing .....	2,322	1	2,322	.5 (30 minutes) .....	1,161
Usability Testing Screener .....	2,028	1	2,028	.083 (5 minutes) .....	168
<b>Total</b> .....					<b>10,621</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of respondents to be included in each new pretest may vary, depending on the nature of the material or message being tested and the target audience. Table 1 provides examples of the types of studies that may be administered and estimated burden levels during a 3-year period. Time to read, view, or listen to the message being tested is built into the “Hours per Response” figures.

FDA has updated the estimated burden that was published in the 60-day notice. The estimated burden for this collection has increased by 4,437 hours from 6,184 to 10,621. FDA attributes this increase to adding usability testing, and increasing the overall number of studies planned the next 3 years.

Dated: May 10, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–10457 Filed 5–15–18; 8:45 am]

**BILLING CODE 4164-01-**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: OS-0990—New]

**Agency Information Collection Request. 30-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before June 15, 2018.

**ADDRESSES:** Submit your comments to *OIRA\_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting

comments or requesting information, please include the document identifier 0990—New—30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Trafficking Victim Assistance Program Social Network Analysis—Network Survey.

*Type of Collection:* New.

*OMB No. 0990-NEW*—Office of the Assistant Secretary for Planning and Evaluation—Administration for Children and Families’ Trafficking Victim Assistance Program.

**Abstract**

The Office of the Assistant Secretary for Planning and Evaluation (ASPE), in partnership with the Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is requesting Office of Management and Budget (OMB) approval for a new information collection request titled, “Trafficking Victim Assistance Program (TVAP) Social Network Analysis—Network Survey.” Under the guidance of ASPE and ACF, a contractor is carrying out this assessment. The data collected and analyzed under this submission will help HHS better understand the type and extent of the relationship between the TVAP grantees, TVAP subrecipients, and other service providers operating in TVAP subrecipient areas. It will also help illuminate each grantee’s and

subrecipient’s types and number of services provided, estimated costs of services, service coordination between grantees or subrecipients and other services providers, and type and strength of relationships between grantees and subrecipients. This information will enable HHS to understand the structure of the grantee/subrecipient network and inform recommendations for more efficient network management and distribution of support.

TVAP, as authorized by the Trafficking Victims Protection Act of 2000, provides comprehensive case management services to foreign-born victims of human trafficking residing in the United States. Since its inception, TVAP funding and infrastructure have remained relatively unchanged. Services are paid on a per capita basis, and funds are managed through three primary grantees that enter into cooperative agreements with service providers (subrecipients). Given the changing landscape and the greater understanding of the nature and extent of trafficking, HHS is undertaking a program assessment to understand whether any efficiencies can be gained in the program administration and structure. To supplement an earlier fiscal year 2018 assessment to solicit qualitative feedback from a range of program stakeholders, the information collected for this program survey aims to help HHS determine if efficiencies can be gained through improved coordination among TVAP grantees, TVAP subrecipients, and other service providers.

Data will be collected through an electronic survey of fiscal year 2016 TVAP grantees and subrecipients. Key staff at grantee sites and subrecipient organizations will complete a self-administered online survey that will include questions about each respondent’s services provided, estimated costs of services, service coordination between grantees or subrecipients, and type and strength of