DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0005]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.
FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), 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.
Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications (OMB Control Number 0910-NEW)

Under 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 and/or in-depth interviews (IDIs) to assess knowledge and perceptions about tobacco-related topics with specific target audiences. The information collected will serve two major purposes. First, formative research will provide critical knowledge about target audiences. FDA must first understand people's knowledge and perceptions about tobacco related topics prior to developing survey/research questions as well as stimuli for experimental studies. Second, 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 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 in the Agency. 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 individuals' attitudes, beliefs, motivations, and feelings. Focus group research serves the narrowly defined need for direct and informal public opinion on a specific topic.

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

Table 1.--Estimated Annual Reporting Burden

<table>
<thead>
<tr>
<th>Activity</th>
<th>No. of Respondents</th>
<th>No. of Responses per Respondent</th>
<th>Total Annual Responses</th>
<th>Hours Per Response</th>
<th>Total Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Person Individual In-Depth Interviews</td>
<td>350</td>
<td>1</td>
<td>350</td>
<td>1</td>
<td>350</td>
</tr>
<tr>
<td>General Public Focus Group Interviews</td>
<td>18,850</td>
<td>1</td>
<td>18,850</td>
<td>1.5</td>
<td>28,275</td>
</tr>
<tr>
<td>Telephone Screening Interviews</td>
<td>4,800</td>
<td>1</td>
<td>4,800</td>
<td>.08 (5 minutes)</td>
<td>384</td>
</tr>
<tr>
<td>Telephone Individual In-Depth Interviews</td>
<td>50</td>
<td>1</td>
<td>50</td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>Total</td>
<td>24,050</td>
<td></td>
<td></td>
<td></td>
<td>29,059</td>
</tr>
</tbody>
</table>

1 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 the 3-year period. Time to read, view, or listen to the message being tested is built into the "Hours Per Response" figures.

Dated: July 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy