

Board of Governors of the Federal Reserve System, July 6, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015-16793 Filed 7-8-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Agency Information Collection Activities; Proposed Collection; Comment Request; Annual Reporting Requirements for the Older American Act Title VI Grant Program

AGENCY: Administration on Aging, HHS.

ACTION: Notice.

SUMMARY: The Administration on Aging (AoA) is announcing that the proposed collection of information listed below 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 or electronic comments on the collection of information by August 10, 2015.

ADDRESSES: Submit electronic comments on the collection of information by fax to (202) 395-5806 or by email to OIRA_submission@omb.eop.gov, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Cecelia Aldridge at (202) 357-3422 or Cynthia.LaCounte@aoa.hhs.gov.

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

AoA estimates the burden of this collection of information as follows: Annual submission of the Program Performance Reports are due 90 days after the end of the budget period and final project period. The current form and instructions are posted on the AoA Web site at http://www.aoa.gov/AoARoot/Grants/Reporting_Requirements\insex.aspx.

Respondents: Federally Recognized Tribes, Tribal and Native Hawaiian Organizations receiving grants under Title VI, Part A, Grants for Native Americans; Title VI, Part B, Native Hawaiian Program and Title VI, Part C, Native American Caregiver Support Program. *Estimated Number of*

Responses: 266. *Total Estimated Burden Hours:* 731.5.

Dated: July 2, 2015.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2015-16755 Filed 7-8-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-15MZ]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Project Title—Digital Media and Tobacco Outcomes Survey—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) requests a one-year OMB approval to conduct a web-based survey of smokers in the United States. This survey will be fielded for purposes of providing CDC with new, timely, and relevant information regarding the efficacy of the digital advertising component of the 2015 National Tobacco Prevention and Control Public Education Campaign (The Campaign). Specifically, CDC will evaluate associations between confirmed exposures to The Campaign's digital and social media advertising and self-reported knowledge, attitudes, beliefs about tobacco use, and smoking-related information-seeking behavior.

This information collection will consist of an online survey of

demographically similar comparison groups of Internet users who were exposed or not exposed to campaign advertising through digital and social media during the planned March–July 2015 campaign. Information will be collected about smokers' exposure to campaign digital advertisements and self-reported knowledge, attitudes, and beliefs related to smoking, and smoking-related information seeking. The survey will also measure behaviors related to smoking cessation and intentions to quit smoking. These data will be used to examine the statistical relationships between exposure to the digital campaign and changes in outcome variables of interest. This information collection fills current gaps in CDC's available data for evaluating the digital advertising components of The Campaign which, to date, have been limited to measures of ad reach and do not address digital campaign impacts on smoking-related knowledge, attitudes, and beliefs, intentions, and behaviors related to smoking cessation.

Data will be collected using the comScore Internet panel, a market research company that unobtrusively collects web behavior data on 1+ million U.S. Internet users to measure patterns in consumer behaviors online. As part of their participation, comScore panelists have previously agreed to download software on their computers that enables comScore to passively track their web behavior, including Web sites visited, searches they conduct, purchases they make, and ads that are delivered on sites visited, regardless of whether the ads are clicked or not. These data are then aggregated and weighted to provide estimates of consumer behaviors online. The panel is a convenience sample with panelists largely recruited via nonprobability-based sampling methods (e.g., online ads, partner Web sites). However, a subsample is recruited via random-digit-dialing to calibrate post-stratification weights that comScore uses to generate weighted demographic distributions that are similar to the U.S. Internet population. While our proposed analyses will also utilize such weights, all results will be interpreted in light of the sample source and direct claims of national representation will not be made.

Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 4,134.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
General Population of Internet Users Eligible participants, ages 18 and older in the U.S.	Screening and Consent Questionnaire	50,000	1	2/60
	Digital Media and Tobacco Outcomes Questionnaire (Wave 1).	5,000	1	20/60
	Digital Media and Tobacco Outcomes Questionnaire (Wave 2).	2,400	1	20/60
				Total

Leroy A. Richardson,

*Chief, Information Collection Review Office,
Office of Scientific Integrity, Office of the
Associate Director for Science, Office of the
Director, Centers for Disease Control and
Prevention.*

[FR Doc. 2015-16772 Filed 7-8-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0313]

Meetings With the Office of Orphan Products Development; Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry, researchers, patient groups, and FDA staff entitled “Meetings with the Office of Orphan Products Development.” This guidance provides recommendations to industry, researchers, patient groups, and other stakeholders (collectively referred to as “stakeholders”) interested in requesting a meeting with FDA’s Office of Orphan Products Development (OOPD) on issues related to orphan drug designation requests, humanitarian use device (HUD) designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related topics of concern. This guidance document is intended to assist these groups with requesting, preparing, scheduling, conducting, and documenting meetings with OOPD. This guidance finalizes the draft guidance of the same title dated April 2014.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Orphan Products Development (OOPD), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5295, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling OOPD at 301-796-8660. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: James D. Bona, Office of Orphan Products Development (OOPD), Food and Drug Administration, Bldg. 32, Rm. 5204, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8673, email: james.bona@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry, researchers, patient groups, and FDA staff entitled “Meetings with the Office of Orphan Products Development.” Each year, OOPD staff participates in meetings with stakeholders who seek guidance or clarification relating to orphan drug or HUD designation requests, OOPD grant programs, or other rare disease issues. These meetings can be “informal” or “formal” and help build a common understanding on FDA’s thoughts on orphan products, which may include drugs, biological products, devices, or medical foods for a rare disease or condition. These meetings may represent critical points in the orphan product development process and may even have an impact on the eventual

availability of products for patients with rare diseases and conditions. It is important that these meetings be scheduled within a reasonable time, conducted effectively, and documented where appropriate. This guidance is intended to provide consistent procedures to promote well-managed meetings between OOPD and stakeholders.

Topics addressed in this guidance include: (1) Clarification of what constitutes an “informal” or “formal” meeting, (2) program areas within OOPD that may be affected by this draft guidance, (3) procedures for requesting and scheduling meetings with OOPD, (4) description of what constitutes a meeting package, and (5) procedures for the conduct and documentation of meetings with OOPD.

In the **Federal Register** of April 9, 2014 (79 FR 19623), FDA issued, for public comment, “Draft Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings with the Office of Orphan Products Development.” The Agency issued this draft guidance to assist stakeholders with requesting, preparing, scheduling, conducting, and documenting meetings with OOPD. In particular, the draft guidance provided clarification on what constitutes an “informal” or “formal” meeting, program areas within OOPD that may be affected by the guidance, procedures for requesting and scheduling meetings with OOPD, description of what constitutes a meeting package, and procedures for the conduct and documentation of meetings.

We received several comments on the draft guidance. Most comments appreciated the clarification and explanation provided by the draft guidance. Some comments made recommendations to improve clarity.

FDA is issuing the draft guidance in final form with minor revisions to improve clarity. This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the