

identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 822 have been approved under OMB control number 0910–0449; the collection of information in 21 CFR part 860, subpart C have been approved under OMB control number 0910–0138; and the collections of information in the guidance document regarding requests for feedback on medical device submission have been approved under OMB control number 0910–0756.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: April 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–08363 Filed 4–10–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2294]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Food and Drug Administration's 'Fresh Empire' Multicultural Youth Tobacco Prevention Campaign

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.

DATES: Fax written comments on the collection of information by May 13, 2015.

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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–NEW and title “Evaluation of the Food and Drug Administration's ‘Fresh Empire’ Multicultural Youth Tobacco Prevention Campaign.” Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Evaluation of the Food and Drug Administration's 'Fresh Empire' Multicultural Youth Tobacco Prevention Campaign (OMB Control Number 0910–NEW)

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco

products to protect public health and to reduce tobacco use by minors. Section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) supports the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA is currently developing and implementing a youth-targeted public education campaign (‘Fresh Empire’) to help prevent tobacco use among multicultural youth and thereby reduce the public health burden of tobacco. The campaign will feature events, advertisements on television and radio and in print, digital communications including social media, and other forms of media.

In support of the provisions of the Tobacco Control Act that require FDA to protect the public health and to reduce tobacco use by minors, FDA requests OMB approval to collect information needed to evaluate FDA's ‘Fresh Empire’ multicultural youth tobacco prevention campaign. Comprehensive evaluation of FDA's public education campaigns is needed to ensure campaign messages are effectively received, understood, and accepted by those for whom they are intended. Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions.

FDA plans to evaluate the effectiveness of its multicultural youth tobacco prevention campaign through an outcome evaluation study that will be designed to follow the multiple, discrete waves of media advertising planned for the campaign.

The outcome evaluation study consists of a pre-test survey of multicultural youth aged 12 to 17 before campaign launch. The pre-test survey will be followed by ongoing cross-sectional surveys of the target audience of youth beginning approximately 3 months following campaign launch. Information will be collected about youth awareness of and exposure to campaign events and advertisements and about tobacco-related knowledge, attitudes, beliefs, intentions, and use. Information will also be collected on demographic variables including age, sex, race/ethnicity, grade level, and primary language.

All information will be collected through in-person and Web-based questionnaires. Youth respondents will be recruited from two sources: (1) A sample drawn from 30 U.S. media markets gathered using an address-based postal mail sampling of U.S. households for the outcome evaluation studies and (2) targeted social media

(e.g., Facebook). Participation in the study is voluntary.

The information collected is necessary to inform FDA's efforts and measure the effectiveness and public health impact of the campaign. Data will be used to estimate awareness of and exposure to the campaign among youth in target markets where the campaign is active. Data will also be used to examine statistical associations between exposure to the campaign and subsequent changes in specific outcomes of interest, which will include knowledge, attitudes, and beliefs, related to tobacco use.

FDA's burden estimate is based on prior experience with in-person and Internet panel studies similar to the Agency's plan presented in this document. Since the 60-day notice published, FDA has revised the estimated burden. The original burden estimate accounted for evaluation of more than one FDA multicultural campaign. The current burden estimate accounts for the evaluation of one campaign, FDA's 'Fresh Empire' Youth Tobacco Prevention Campaign.

A mail-based screener will be one of the methods used to identify eligible youth. Parents or guardians will be

asked to provide consent and their contact information on this form. For the pre-launch survey, the 5-minute screener will be completed by 13,816 households for a total of 1,151 burden hours for youth and an additional 230 hours for the parents or guardians. For the pre-test survey, 2,100 youth will complete a questionnaire with an estimated burden of 30 minutes per respondent, for an annualized total of 1,050 hours. For the post-test screening survey, the estimated burden is 3,453 hours for youth and 691 hours for adults. For the post-test surveys, the estimated burden is 45 minutes per respondent, for a total of 4,725 burden hours.

We will also recruit youth through social media (e.g., Facebook, Twitter) as a secondary strategy to recruit youth 13 to 17. An online version of the screener described above will be used to identify eligible youth (included in Attachment 3). Eligible youth will be asked to provide their parents' or guardians' contact information. The screener will take 5 minutes and will be completed by 2,500 youth for the pre-test survey for a total of 208 burden hours. Of these, 500 will be eligible and complete the pre-test survey for a total of 250 burden

hours. For the post-test survey, 10,500 youth will complete the 5-minute screener, for 875 burden hours. Of these, 2,100 will be eligible and complete the post-test survey online (up to 45 minutes), for a total of 1,575 burden hours.

The target number of completed campaign questionnaires for all respondents is 134,528, and the annualized response burden is estimated at 14,208 hours.

In the **Federal Register** of January 5, 2015 (80 FR 230), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received, however, only one was PRA related.

Comment: One comment stated that the media tracking survey and the outcome evaluation study proposed by FDA are critical to FDA's efforts to develop and implement an effective multicultural youth tobacco prevention campaign.

Response: FDA agrees that this collection of information is necessary to the Agency's efforts to promote and improve public health.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Type of respondent	Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Youth aged 12 to 17 in the United States.	Screener and Consent Process—Pre-test outcome survey.	13,816	1	13,816	0.0833 (5 min.)	1,151
Adults 18 and older in the United States.	Screener and Consent Process—Pre-test outcome survey.	13,816	1	13,816	0.0166 (1 min.)	230
Youth aged 12 to 17 in the United States.	Screener and Consent Process—post-test outcome survey.	41,448	1	41,448	0.0833 (5 min.)	3,453
Adults 18 and older in the United States.	Screener and Consent Process—post-test outcome survey.	41,448	1	41,448	0.01666 (1 min.)	691
Multicultural Youth aged 12–17 in select media markets.	Pre-test outcome evaluation survey.	2,100	1	2,100	0.5 (30 min.)	1,050
Multicultural youth aged 13–17 in the select media markets recruiting through social media.	Post-test evaluation survey	6,300	1	6,300	0.75 (45 min.)	4,725
	Pre-test online screener	2,500	1	2,500	0.0833 (5 min.)	208
	Pre-test online survey	500	1	500	0.5 (30 min.)	250
	Post-test online screener	10,500	1	10,500	0.0833 (5 min.)	875
	Post-test online survey	2,100	1	2,100	0.75 (45 min.)	1,575
Total		134,528				14,208

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

Dated: April 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-08466 Filed 4-10-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS-OS-0990-0391-30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for reinstatement of a previously-approved information collection assigned OMB control number 0990-0391, which expired on March 31, 2015. Comments submitted during the first public review of this ICR will be provided to OMB.

OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before May 13, 2015.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.Collection.Clearance@hhs.gov* or (202) 690-6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS-OS-0990-0391-30D for reference.

Information Collection Request Title: The Hospital Preparedness Program

OMB No.: 0990-0391.

Abstract: The Science Healthcare Preparedness Evaluation and Research (SHAPER), part of the Department of Health and Human Services (HHS), Assistant Secretary for Preparedness and Response (ASPR), Office of Emergency Management (OEM), Division of National Healthcare Preparedness Programs (NHPP), in conjunction with the Hospital Preparedness Program (HPP) is seeking a reinstatement with change on a currently approved clearance by the Office of Management of Budget (OMB) for a Generic Data Collection Form to

serve as the cornerstone of its effort to assess awardee program under the HPP Cooperative Agreement (CA) Program. Program data are gathered from awardees as part of their Ad-hoc and End-of-Year Progress Reports and other similar information collections (ICs) which have the same general purpose, account for awardee spending and program on all activities conducted in pursuit of achieving the HPP Grant goals.

This data collection effort is crucial to HPP's decision-making process regarding the continued existence, design and funding levels of this program. Results from these data analyses enable HPP to monitor healthcare emergency preparedness and progress towards national preparedness goals. HPP supports priorities outlined by the National Preparedness Goal (the Goal) established by the Department of Homeland Security (DHS) in 2005. The Goal guides entities at all levels of government in the development and maintenance of capabilities to prevent, protect against, respond to and recover from major events. Additionally, the Goal will assist entities at all levels of government in the development and maintenance of the capabilities to identify, prioritize and protect critical infrastructure.

Likely Respondents: Hospital Preparedness Program Awardees.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Data collection activity	Number of respondents	Number of responses	Response time (hours)	Total annual burden hours (for all awardees)	3-Year total (for all awardees)
Generic and Future Program Data Information Collection(s)	62	1	58	3,596	
Total				3,596	10,788

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2015-08298 Filed 4-10-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on

proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the

quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Primary and Behavioral Health Care Integration Program (OMB No. 0930-0340)—Revision

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services, (CMHS) is requesting a revision from the Office of Management and Budget (OMB) for data collection activities associated with their Primary and Behavioral Health Care Integration