ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)
General population	90-day Follow-up Survey	320	1	18/60
CMEP–WILLOW grantees	90-day SDN Submission	4	12	5/60
General population	180-day Follow-up Survey	320	1	18/60
CMEP–WILLOW grantees	180-day SDN Submission	4	12	5/60

Leroy 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. 2014–13397 Filed 6–9–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–14–0895]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Community-based Organization (CBO) Monitoring and Evaluation Project (CMEP) of RESPECT (CMEP–RESPECT) (OMB No. 0920–0895, expires 8/31/2014)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC began formally partnering with CBOs in the late 1980s to expand the reach of HIV prevention efforts. CBOs were, and continue to be, recognized as important partners in HIV prevention because of their history and credibility with target populations and their access to groups that may not be easily reached. Over time, CDC's program for HIV prevention by CBOs has grown in size, scope, and complexity to respond to changes in the epidemic, including the diffusion and implementation of Effective Behavioral Interventions (EBIs) for HIV prevention.

CDC's EBIs have been shown to be effective under controlled research environments, but there is limited data on intervention implementation and client outcomes in real-world settings (as implemented by CDC-funded CBOs). The purpose of CMEP is to improve the performance of CDC-funded CBOs delivering particular individual- or group-level behavioral interventions. This is done by monitoring changes in clients' self-reported HIV transmission risk behaviors after participating in the intervention.

CDC funded four (4) CBOs to participate in CMEP-Respect for five (5) years (September 2010–August 2015). CDC funded CMEP-Respect for five (5) years (September 2010–August 2015). From April 1, 2012 through April 30, 2014 baseline surveys were conducted with an estimated 871 participants; 90–day follow up surveys were completed with 576 participants, and 180-day follow up surveys were completed with 484 participants.

CDC is requesting additional time to complete follow up surveys at 90- and 180-days for participants completing the intervention on or before 8/31/2014. Following their participation in the Respect intervention, participants will complete an 18 minute, self-administered, computer based interview at two follow-up time points (90- and 180-days following the Respect intervention) to assess their HIV-related attitudes and behavioral risks. CBOs will be expected to retain 80% of these participants at both follow-up interviews. CBO agency staff will submit data files to CDC monthly. It is estimated it will take 5 minutes to upload to the CDC's Secure Data Network (SDN).

Throughout the project, funded CBOs will be responsible for managing the daily procedures of CMEP-Respect to ensure that all required activities are performed, all deadlines are met, and quality assurance plans, policies and procedures are upheld. CBOs will be responsible for participating in all CDC-sponsored grantee meetings related to CMEP-Respect. The total estimated annual burden hours are 200.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)
General population	90-Day Follow-Up Survey	320	1	18/60
CMEP-Respect grantees	90-Day SDN Submission	4	12	5/60
General Population	180-day Follow-up Survey	320	1	18/60
CMEP-Respect grantees	180-Day SDN Submission	4	12	5/60

Leroy 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. 2014–13396 Filed 6–9–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1558]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products

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 July 10, 2014.

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 0910–0673. 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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.

Guidance for Industry and Food and Drug Administration Staff on Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products—(OMB Control Number 0910–0673)—(Extension)

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new chapter granting FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) authorizes FDA to establish the form for the submission of information related to substantial equivalence. In a level 1 guidance document issued under the Good Guidances Practices regulation (21 CFR 10.115), FDA provides recommendations intended to assist persons submitting reports under section 905(j) of the FD&C Act and explains, among other things, FDA's interpretation of the statutory sections related to substantial equivalence.

In the **Federal Register** of December 27, 2013 (78 FR 78974), FDA published a 60-day notice requesting public comment on the proposed collection of information. Six comment submissions were received, some of which included multiple comments. Two of the six comment submissions were in favor of FDA's regulation of tobacco products. Three comment submissions were considered to contain PRA-related comments and three comment submission were not considered to contain PRA-related comments. The three comment submissions not considered to contain PRA-related comments are beyond the scope of this **Federal Register** notice.

(Comment 1) One commenter supported FDA in its mission to regulate tobacco products for the benefit of public health and safety and indicated that language in the guidance be strengthened to assist in FDA reviews. The commenter also suggested that the respondents provide additional information to minimize future Freedom of Information Act requests.

(Response 1) FDA agrees that the request in this collection of information is necessary to fulfill the requirements of the FD&C Act. The type of data for a given new product may vary depending on whether the characteristics of the product are the same or different from a predicate tobacco product, and the information is needed to allow FDA to make informed decisions when reviewing a substantial equivalence application.

(Comment 2) Several commenters indicated that FDA has improperly implemented the substantial equivalence provisions of the statute (the FD&C Act, as amended by the Family Smoking Prevention and Tobacco Control Act (FSPTCA)), and maintain that FDA is asking for reports that are neither authorized nor relevant to a substantial equivalence determination.

(Response 2) FDA disagrees with the comment. The information FDA is requesting is related to new products using the substantial equivalence pathway to assist FDA in making a determination of whether a product is substantially equivalent.

(Comment 3) Several commenters asserted that FDA was not asking for enough information, while other commenters asserted that FDA was asking for too much information.

(Response 3) FDA believes that the collection of information is necessary and the burden estimates are appropriate and reflect the amount of time a respondent would need to prepare a substantial equivalence submission.

(Comment 4) One commenter noted that under FDA's interpretation, every new, including modified, product