Proposed Project

Aggregate Reports for Tuberculosis Program Evaluation (0920–0457—Exp. 9–30–2016)—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 requests the extension of the Aggregate Reports for Tuberculosis Program Evaluation, previously approved under OMB No. 0920–0457 for 3-years. There are no revisions to the report forms, data definitions, or reporting instructions.

To ensure the elimination of tuberculosis in the United States, CDC monitors indicators for key program activities, such as finding tuberculosis infections in recent contacts of cases and in other persons likely to be infected and providing therapy for latent tuberculosis infection. In 2000, CDC implemented two program evaluation reports for annual submission: Aggregate report of follow-up for contacts of tuberculosis, and Aggregate report of screening and preventive therapy for tuberculosis infection (OMB No. 0920–0457). The respondents for these reports are the 68 state and local tuberculosis control programs receiving federal cooperative agreement funding through the CDC Division of Tuberculosis Elimination (DTBE). These reports emphasize treatment outcomes, high-priority target populations vulnerable to tuberculosis, and programmed electronic report entry, which transitioned to the National Tuberculosis Indicators Project (NTIP), a secure web-based system for program evaluation data, in 2010. No other federal agency collects this type of national tuberculosis data, and the Aggregate report of follow-up for contacts of tuberculosis, and Aggregate report of screening and preventive therapy for tuberculosis infection are the only data source about latent tuberculosis infection for monitoring national progress toward tuberculosis elimination with these activities. CDC provides ongoing assistance in the preparation and utilization of these reports at the local and state levels of public health jurisdiction. CDC also provides respondents with technical support for the NTIP software (Electronic—100%, Use of Electronic Signatures—No). There is no cost to respondents.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Data clerks and Program Managers, electronic.	Follow-up and Treatment of Contacts to Tuberculosis Cases Form (Att 3a).	100	1	30/60	50
Program Managers, manual	Follow-up and Treatment of Contacts to Tuberculosis Cases Form (Att 3a).	18	1	30/60	9
Data clerks, (manual)	Follow-up and Treatment of Contacts to Tuberculosis Cases Form (Att 3a).	18	1	3	54
Data clerks and Program Managers, electronic.	Targeted Testing and Treatment for Latent Tuberculosis Infection (Att 3b).	100	1	30/60	50
Program Managers, (manual)	Targeted Testing and Treatment for Latent Tuberculosis Infection (Att 3b).	18	1	30/60	9
Data clerks, (manual)	Targeted Testing and Treatment for Latent Tuberculosis Infection (Att 3b).	18	1	3	54
Total					226

Jeffrey M. Zirger,

Health Scientist, Acting 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–16–16ATI; Docket No. CDC–2016–0057]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on Development of CDC's Act Against AIDS Social Marketing Campaigns Targeting Consumers. CDC is requesting approval for revision to the previously approved project to continue testing HIV/AIDS prevention and treatment messages to be included in social marketing campaigns targeting consumers.

DATES: Written comments must be received on or before August 30, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0057 by any of the following methods:

- *Federal eRulemaking Portal: Regulation.gov.* Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is 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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Development of CDC's Act Against AIDS Social Marketing Campaigns Targeting Consumers—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC)

Background and Brief Description

In an effort to refocus attention on domestic HIV and AIDS, CDC launched the Act Against AIDS (AAA) initiative in 2009 with the White House and the U.S. Department of Health and Human Services. AAA is a multifaceted national communication initiative that supports reduction of HIV incidence in the U.S. through multiple, concurrent communication and education campaigns for a variety of audiences including, the general public, populations most affected by HIV and health care providers. The campaigns target consumers 18–64 years old and include the following audiences: (1) Men who have sex with men (MSM) of all races; (2) Blacks/African Americans; (3) Hispanics/Latinos; (4) Transgender individuals; (5) HIV-positive individuals; and (6) national audience of all races. All campaigns support the comprehensive HIV prevention efforts of CDC and the National HIV/AIDS Strategy (NHAS).

The goal of this study is to qualitatively test messages and materials that will be used in specific HIV social marketing campaigns under the AAA initiative that target consumers in order to increase HIV testing rates, increase HIV awareness and knowledge, challenge commonly held misperceptions about HIV, and promote HIV prevention and risk reduction. The intended use of the resulting data is for CDC to revise and/or develop timely, relevant, clear, and engaging materials for these social marketing campaigns.

Qualitative methods will be used to collect the data include focus groups, intercept interviews, and in-depth interviews. Qualitative methods provide flexible in-depth exploration of the participants' perceptions and experience; and the interviews yield descriptions in the participants' own words. Qualitative methods also allow the interviewer flexibility to pursue relevant and important issues as they arise during the discussion.

The participants will also participate in a brief 15-minute brief survey. Data collected by the brief survey will provide a source of quantitative data supplementing the qualitative data collected during the interviews. The brief survey will be administered to participants before the individual in-depth interview and focus group. The survey will collect basic background information about the participants' knowledge, attitudes and beliefs about HIV, HIV testing behaviors, risk behaviors and demographics to enable us to more fully describe the participants.

There is no cost to participants other than their time. The total estimated annualized burden hours are 2,063.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Individuals (males and females) aged 18–64.	Study screener	2338	1	2/60	78
	Exploratory—HIV Testing In-depth Interview Guide.	74	1	1	74
	Exploratory—HIV Prevention In-depth Interview Guide.	74	1	1	74
	Exploratory—HIV Communication and Awareness In-depth Interview Guide.	74	1	1	74
	Exploratory—HIV Prevention with Positives In-depth Interview Guide.	74	1	1	74
	Consumer Message Testing In-depth Interview Guide.	68	1	1	68

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
	Consumer Concept Testing In-depth Interview Guide.	68	1	1	68
	Consumer Materials Testing In-depth Interview Guide.	68	1	1	68
	Exploratory—HIV Testing Focus Group Interview Guide.	74	1	2	148
	Exploratory—HIV Prevention Focus Group Interview Guide.	74	1	2	148
	Exploratory—HIV Communication and Awareness Focus Group Interview Guide.	74	1	2	148
	Exploratory—HIV Prevention with Positives Focus Group Interview Guide.	74	1	2	148
	Consumer Concept Testing Focus Group Interview Guide.	68	1	2	136
	Consumer Message Testing Focus Group Interview Guide.	68	1	2	136
	Consumer Materials Testing Focus Group Interview Guide.	68	1	2	136
	HIV Testing Survey	250	1	15/60	63
	HIV Prevention Survey	250	1	15/60	63
	HIV Communication and Awareness Survey	250	1	15/60	63
	HIV Prevention with Positives Survey	250	1	15/60	63
	Intercept Interview Guide	700	1	20/60	233
Total					2,063

Jeffrey M. Zirger,

Health Scientist, Acting 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0500]

Early Clinical Trials With Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled ''Early Clinical Trials With Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Guidance for Industry.'' The guidance document provides investigational new drug application (IND) sponsors with recommendations regarding IND submissions for early clinical trials with live biotherapeutic products (LBPs) in the United States. The guidance announced in this notice updates the guidance of the same title dated February 2012 (February 2012 guidance) by addressing when the label on the commercially available products(s) would be considered adequate to satisfy the purpose of the chemistry, manufacturing, and control (CMC) information requirements.

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

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2010–D–0500 for ''Early Clinical Trials With Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the