

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–17–17IX; Docket No. CDC–2016–0124]

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 a proposed information collection project entitled “Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika Infections.” This project consists of telephone interviews with pregnant WIC participants in Puerto Rico.

DATES: Written comments must be received on or before February 28, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0124 by any of the following methods:

- *Federal eRulemaking Portal:* Regulations.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

Assessment of Interventions Intended to Protect Pregnant Women in Puerto Rico from Zika Infections—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID),

Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC proposes to continue the information collection initially cleared by OMB as an emergency ICR in June, 2016 (OMB Control No. 0920–1118). The expiration date for 0920–1118 is December 31, 2016. However, CDC intends to continue information collection for an additional nine months and is seeking OMB clearance to do so.

In December 2015, the Commonwealth of Puerto Rico, a United States territory, reported its first confirmed locally transmitted Zika virus case.

Starting in March 2016, The Centers for Disease Control and Prevention’s (CDC) National Center for Emerging and Zoonotic Infections Diseases (NCEZID) initiated several interventions targeting pregnant women. The ultimate goal of these interventions is/was to protect pregnant women from Zika virus and encourage Zika prevention behaviors among pregnant women. The interventions include the following:

1. Zika Education Sessions (at WIC clinics);
2. Zika Prevention Kits;
3. Communication activities; and
4. Vector control services in the community.

This ICR is for data collection over the next nine months related to Zika prevention efforts that have been and will be implemented in Puerto Rico. Specifically, CDC needs this assessment to ensure that Zika prevention activities effectively educate, equip, and encourage women to participate in as many Zika prevention behaviors as possible. On-going evaluation is an important part of this program because it can reveal novel ways that women protect themselves from Zika, how effective the distribution of the Zika Prevention Kit has been in Puerto Rico, perceived severity and susceptibility to Zika, pregnant women’s self-efficacy in protecting themselves from Zika after the interventions have been implemented, as well as the extent to which target populations are using contents of the Zika Prevention Kit.

Interviews with pregnant women in Puerto Rico can help articulate motivations for and against engaging in Zika prevention behaviors that are critical for preventing Zika-associated birth defects and morbidities. Implementing changes based on results from this assessment is expected to facilitate program improvement and ensure the most efficient allocation of resources for this public health emergency. The goal of this project is to

find out if interventions are reaching pregnant women and having the intended effects along with getting feedback from pregnant women about the Zika prevention activities that have been implemented (e.g., Zika education sessions and prevention kits, vector control activities, and communication activities).

Findings will be used to improve the delivery of interventions and to inform decisions about future Zika prevention activities for pregnant women in Puerto Rico. The plan is to conduct up to 500 telephone interviews every two months over a 9-month period, (a total of four rounds), analyze the data, and generate a report for leaders of the response to offer insights on the delivery of interventions to pregnant women. The information will be used to make recommendations for improving interventions. Information may also be used to develop presentations, reports, and manuscripts to document the program and lessons learned in order to inform future programs of this sort.

The purpose of this assessment is also to assess core components of CDC's Zika response in communicating prevention behaviors, risk messages to the public

about vector control activities, and the Zika Prevention kit.

The following factors will be assessed:

- Knowledge about Zika virus and related prevention behaviors
- Self-efficacy in engaging in Zika prevention behaviors
- Engagement in Zika prevention behaviors (e.g., protective clothing use, condom use, and bed net use)
- Knowledge about, attitudes about, and use of the Zika Prevention Kit materials
- Knowledge about, attitudes about, and use of environmental vector control activities
- Risk perceptions of Zika
- Exposures to communications along with other factors that may be important considerations in their taking action or not (e.g., does their house have screens, etc.)

CDC will conduct telephone interviews with a mix of closed-ended and open-ended questions with pregnant women. We estimate 2,000 pregnant women will participate in the project over a nine month period.

Another component of this project is to conduct qualitative inquiry to explore emerging issues related to vector control, sexual transmission,

contraception, mental health/emotional support, service/support needs of families with babies affected by Zika, or vaccine communications (if applicable). While pregnant women will be the main focus of most inquiry, other audiences could include community leaders, community members, and health care providers. The goal is to identify specific unmet needs, which can then be shared with the Department of Health and other human service agencies. The plan is to hold up to 7 focus groups (with up to 10 persons each), or up to 20 in-depth individual interviews or up to 75 brief intercept interviews. A maximum of 75 individuals would participate in this part.

Results of this project will have limited generalizability. However, results of this evaluation should provide information that can be used to enhance and revise the existing program as well as offer lessons learned to inform infectious disease control programs that use education materials.

Authorizing legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241). There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Pregnant WIC participant	Initial Telephone Interview.	2,000	1	20/60	667
WIC participants, other families affected by Zika	Focus group	70	1	120/60	140
WIC participants, other families	In-depth Interviews	20	1	60/60	20
General population in Zika affected neighborhood.	Brief intercept interview	75	1	10/60	13
Total	840

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1155]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our food labeling regulations and on Form FDA 3570, Model Small Business Nutrition Labeling Exemption Notice, which small businesses may use to claim the small business exemption from nutrition labeling.

DATES: Submit either electronic or written comments on the collection of information by February 28, 2017.