

have been updated, with questions added, removed, and reorganized to decrease response burden and maximize usability. The final VAERS 2.0 Form can be found at <http://www.regulations.gov> and www.vaers.hhs.gov.

During the development of the VAERS 2.0 Form, CDC and FDA sought input from key stakeholders in the Federal government, State Health Officials involved in vaccine safety and vaccine programs, and other public health partners. In addition, the VAERS 2.0 Form was presented to three Federal advisory committees, the Advisory Commission on Childhood Vaccines (September 5, 2014), the National Vaccine Advisory Committee (September 9, 2014), and the Advisory Committee on Immunization Practices (October, 2014). Finally, the final VAERS form was tested with potential users (e.g., physicians, nurses, pharmacists, patients, and parents).

On November 24, 2014 HHS/CDC published a notice in the **Federal Register** (79 FR 69853) announcing the opening of a docket to obtain public comment on the draft VAERS 2.0 Form. HHS/CDC received 19 comments on the draft VAERS 2.0 Form from members of the general public and professional and advocacy organizations. All comments were carefully reviewed and considered in the preparation of the final VAERS form.

Dated: July 31, 2017.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-17-17WE]

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

Knowledge, Attitudes, and Practices related to a Domestic Readiness Initiative on Zika Virus Disease—New—Office of the Associate Director for Communication, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Since late 2015, Zika has rapidly spread through Puerto Rico. As of November 2016, there have been 35,136 confirmed cases of Zika in Puerto Rico, with 2,797 cases among pregnant women and 67 cases of Guillain-Barré caused by Zika. In the continental United States, there have been 4,432 travel-associated cases of Zika and 185 locally-acquired Zika cases in Florida and Texas. Due to the urgent nature of this public health emergency, CDC is implementing a Zika prevention communication and education initiative.

The purpose of this survey is to assess a domestic U.S. and Puerto Rico-based communication and education initiative aimed at encouraging at-risk populations to protect themselves and their families from Zika virus infection. CDC will assess the following communication and education

objectives: (1) Determine the reach and saturation of the initiative's messages in Puerto Rico and the domestic U.S.; (2) measure the extent to which messages were communicated clearly across multiple channels to advance knowledge and counter misinformation; and (3) monitor individual and community-level awareness, attitudes and likelihood to follow recommended behavior. This data collection includes 2,400 surveys conducted in four geographic locations following peak campaign activity to assess key outcomes of the initiative. The information will be used to make recommendations for improving communication and education regarding the prevention and spread of the Zika virus. Information may also be used to develop presentations, reports, and manuscripts to document the communication effort and lessons learned in order to inform future similar communication efforts.

The goal of this project is to determine knowledge, attitudes, and practices related to a Domestic Readiness Initiative on Zika Virus Disease being launched in the United States (U.S.) mainland and Puerto Rico.

CDC will seek to gain OMB approval of this new information collection request to conduct a final survey (wave 3) to evaluate the CDC Domestic Readiness Initiative for Zika Virus. The Zika Readiness Initiative campaign has been implemented in two phases with peak campaign activity coinciding with the height of mosquito season during the summer months of 2016 (phase 1) and 2017 (phase 2). OMB granted CDC an emergency review approval in 2016 (OMB Control Number 0920-1136, expiration 3/31/2017) to conduct the first two waves of data collection which captured the effectiveness of the first phase of the campaign. The third wave of data collection will allow CDC to capture the effectiveness of the second phase of the campaign being implemented through late summer/early fall 2017.

While the campaign objectives and the call to action remain the same across both phases, campaign materials have been modified between phases based the first two waves of data collection to better address misinformation about Zika and promote a sense of urgency to adopt preventive actions. The third and final wave of data collection is vital to CDC's continued understanding of how the campaign information is received by target audiences and what actions are being taken to prevent Zika virus transmission. Findings will be used to improve planning, implementation, refinements and demonstrate outcomes

of a Zika Domestic Readiness Initiative communication and education effort.

The total estimated annualized burden hours are 560. There are no costs to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
U.S. Domestic Adults	Zika Readiness Initiative Questionnaire	1,800	1	14/60
Puerto Rico Adults	Zika Readiness Initiative Questionnaire	600	1	14/60

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-2017-D-2163]

Child-Resistant Packaging Statements in Drug Product Labeling; Draft 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 draft guidance for industry entitled “Child-Resistant Packaging Statements in Drug Product Labeling.” This guidance is intended to assist applicants, manufacturers, packagers, and distributors who choose to include child-resistant packaging (CRP) statements in prescription and over-the-counter human drug product labeling. The guidance discusses what information should be included to support CRP statements and to help ensure that such labeling is clear, useful, informative, and, to the extent possible, consistent in content and format.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 2, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2017-D-2163 for “Child-Resistant Packaging Statements in Drug Product Labeling.” Received comments will be placed in the docket and, except for those submitted as “Confidential

Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.