

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–16–16AVM; Docket No. CDC–2016–0065]

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; Withdrawal.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the withdrawal of the notice published under the same title on July 26, 2016 for public comment.

DATES: Effective August 9, 2016.

FOR FURTHER INFORMATION CONTACT: 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: On July 26, 2016 CDC published a notice in the *Federal Register* titled “Proposed Data Collection Submitted for Public Comment and Recommendations” (81 FR 48799). This notice with *Federal Register* Document 2016–17601 and Docket number CDC–2016–0065, was published prematurely and inadvertently. The notice is being withdrawn immediately for public comment. A new notice will be published at a later date for public comment.

Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Health Scientist, 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

[30Day–16–16AFR]

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

Emergency Operations Center (EOC) Clinical Inquiries Database—New—Office of Public Health Preparedness and Response (OPHPR), Centers for Disease Control and Prevention (CDC)

Background and Brief Description

In May 2015, the Pan American Health Organization (PAHO) issued an alert regarding the first confirmed Zika virus infections in Brazil. Since then, CDC has been responding to increased reports of Zika and has assisted in investigations with PAHO and the Brazil Ministry of Health. The first regional travel notices for Zika in South America and Mexico were posted in December 2015. In December 2015, the Commonwealth of Puerto Rico, a United

States territory, reported its first confirmed locally transmitted Zika virus case. Cases of local transmission have recently been confirmed in two other U.S. territories, the United States Virgin Islands and American Samoa. As of April 6, 2016, U.S. territories had reported 351 locally acquired Zika cases and 3 travel-associated Zika cases to CDC. Of the 354 cases reported, 37 were in pregnant women. Zika has not been spread by mosquitoes in the continental United States. However, lab tests have confirmed Zika virus in travelers returning to the United States. These travelers have gotten the virus from mosquito bites and a few non-travelers got Zika through sex. With the recent outbreaks in the Americas, the number of Zika cases among travelers visiting or returning to the United States is increasing. CDC monitors and reports to the public cases of Zika, which will help improve our understanding of how and where Zika is spreading.

Zika virus is spread to people primarily through the bite of an infected *Aedes* species mosquito (*A. aegypti* and *A. albopictus*). Mosquitoes that spread Zika virus are aggressive daytime biters, but they can also bite at night. A pregnant woman can pass Zika virus to her fetus during pregnancy. CDC is studying how Zika affects pregnancies. Zika is linked to microcephaly, a severe birth defect that is a sign of incomplete brain development. Microcephaly is a condition where a baby's head is much smaller than expected. During pregnancy, a baby's head grows because the baby's brain grows. Microcephaly can occur because a baby's brain has not developed properly during pregnancy or has stopped growing after birth.

In February and March 2016, CDC used OMB emergency clearance procedures to initiate and expedite multiple urgently needed information collections in American Samoa, Puerto Rico, Brazil, and domestically within state, tribal, local, and territorial (STLT) jurisdictions. These procedures have allowed the agency to target and refine public health interventions to arrest ongoing spread of infection.

With this notice, the CDC is announcing its intention to seek OMB clearance to continue a Zika-related information collections a call center in CDC's Emergency Operations Center (EOC) to respond to inquiries on clinical care of persons potentially of interest for Zika virus infection beyond its current emergency expiration date [OMB Control No. 0920–1101, expiration date 8/31/16]. Respondents to this information collection include the general public, clinicians, and employees at STLT health departments.

The purpose of this information collection is to document and track clinical inquiries made to the CDC EOC call center and to systematically collect standardized clinical/demographic/epidemiological information about suspected cases. The emergency clearance for this information collection dealt specifically with Zika-related

clinical inquiries. However, the new ICR will cover this project for any EOC activation. Regardless of the disease or hazard being responded to, the EOC operates this call center to answer and respond to clinical inquiries. This information collection is a necessary part of operating this call center and responding to emergency situations.

These information collections will align with their legislative authority, Section 301 of the Public Health Service Act (42 U.S.C. 241). There are no total costs to the respondents other than their time. The total annualized burden requested is 305 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
State and Local Health Departments	Clinical Inquiries Database	420	1	15/60
Clinicians and Other Providers	Clinical Inquiries Database	800	1	15/60

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-2016-N-2147]

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting, Establishment of a Public Docket, Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice, establishment of a public docket, request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on September 20 and 21, 2016, from 8 a.m. to 6 p.m.

ADDRESSES: Hilton Washington, DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900. Answers to commonly asked questions including information regarding special accommodations due

to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

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-2016-N-2147 for "General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." 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 Division of Dockets Management 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 <http://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