campus. The REOI specified minimum and additional functional, geographical, and environmental criteria that would be used to evaluate sites for suitability. In particular, candidate sites were to be from 10 to 17 acres in size and located in Cincinnati, within a certain area (Delineated Area) defined by factors such as transportation infrastructure, proximity to other research facilities, and the residence patterns of current NIOSH employees.

In response to the REOI, GSA received seven expressions of interest (*i.e.,* Solicited Sites). Following an assessment of each site based on the minimum and additional criteria, GSA found that only one site qualified for further consideration. During this screening and assessment process, GSA identified one additional site (*i.e.,* Unsolicited Site) that was added to the qualifying Solicited Site to create a larger parcel better capable of supporting the development of the proposed campus. The resulting combined site (*i.e.,* the Site) encompasses all land between Martin Luther King Drive East to the south, Harvey Avenue to the west, Ridgeway Avenue to the north, and Reading Road to the east in Cincinnati, Ohio. All other Solicited Sites were eliminated from further consideration because they did not adequately meet the selection criteria specified in the REOI or, in one case, were withdrawn from consideration by the offeror.

In accordance with NEPA, as implemented by the CEQ regulations (40 CFR parts 1500–1508), CDC is initiating the preparation of an EIS for the proposed acquisition of the Site and construction of a new consolidated CDC/NIOSH campus on the Site. Under NEPA, Federal agencies are required to evaluate the environmental effects of their proposed actions and a range of reasonable alternatives to the proposed action before making a decision. At a minimum, the EIS will evaluate the following two alternatives: the Proposed Action Alternative (acquisition of the Site and construction of a new consolidated CDC/NIOSH campus) and the No Action Alternative (continued use of the existing campuses for the foreseeable future).

Scoping Process: In accordance with NEPA, a public scoping process will be conducted to establish the range of issues to be addressed during the preparation of the EIS. Scoping is an early and open process for determining the scope of issues to be addressed and identifying issues that should be taken into account in selecting an alternative for implementation. To that end, during the scoping process, CDC will actively seek input from interested people, organizations, Federally-recognized Native American tribes, and Federal, state, and regional agencies.

The purpose of this Notice is to inform interested parties regarding CDC's plan to prepare an EIS for the proposed Site acquisition in Cincinnati, Ohio and the development of the Site into a new consolidated HHS/CDC/NIOSH campus; to provide information on the nature of the Proposed Action; and to initiate the scoping process. The public scoping meeting will be held on August 1, 2017 at the Walnut Hills High School, 3250 Victory Parkway, Cincinnati, Ohio 45207, from 6:00 p.m. to 9:00 p.m. Eastern Time. Attendees should use the Parking Lot D entrance. The public scoping meeting will be in open house format. General information on the Site and the Proposed Action will be provided and representatives of CDC and GSA will be available to answer one-on-one questions. There will be no formal presentation or question-and-answer session. Participants may arrive at any time between 6:00 p.m. and 9:00 p.m. Eastern Time. Comment forms will be provided for written comments and a stenographer will be available to transcribe oral comments. Through the NEPA scoping process, CDC will also facilitate consultation with the public as required by Section 106 of the NHPA.

Dated: July 6, 2017.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2017–14474 Filed 7–13–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–17–1140]

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

Zika virus persistence in body fluids of patients with Zika virus infection in Puerto Rico (ZIPER Study) (OMB Control Number 0920–1140, Expiration Date 10/31/2017)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is seeking a one-year OMB approval to extend the ZIPER Study information collection.

The Zika Persistence (ZIPER) study will help inform the presence and duration of ZIKV shedding in several body fluids among RT–PCR-positive ZIKV cases from Puerto Rico. It will also provide information regarding the duration of detection of anti-ZIKV IgM antibodies and the time for development of IgG antibodies among the same population. In addition, this study will determine the prevalence of anti-ZIKV IgM and IgG, and virus shedding in body fluids among household contacts of ZIKV cases.

We propose to investigate the persistence (shedding) of ZIKV in different body fluids and its relation to

immune response to provide a basis for development of non-blood-based diagnostic tools, and target and refine public health interventions to arrest ongoing spread of infection. To do so, we will conduct a prospective cohort study of individuals with reverse transcription-polymerase chain reaction (RT–PCR) positive ZIKV infection and a cross-sectional study of their household contacts. Results and analyses will be used to update relevant counseling messages and recommendations from the CDC.

The study will include baseline and follow-up questionnaires and the collection of the following specimens: blood, saliva, urine from participants of all ages, and semen/vaginal secretions from adults (ages 21 years or older) and legally emancipated minors (support themselves financially, live independent of their parents, are pregnant, or have children).

Individuals with RT–PCR positive ZIKV infection will be recruited through the Sentinel Enhanced Dengue Surveillance System (SEDSS) at Saint Luke's Episcopal Hospital in Ponce, Puerto Rico and through passive surveillance in selected municipalities in Puerto Rico. SEDSS was established in 2012 through a cooperative agreement between the hospital in Consortium with the Ponce School of Medicine and Ponce Research Institute from the Ponce Health Sciences University and the CDC (Protocol #6214).

Specimens will be tested for the presence of ZIKV RNA by RT–PCR at the CDC Dengue Branch Laboratory in San Juan, and positive specimens will be further tested for virus isolation to evaluate infectivity. Each body fluid will be collected on a weekly basis for four weeks and biweekly thereafter until two consecutive negative RT–PCR results are obtained from all specimens. Irrespective of RNA detection, body fluids will also be collected for RT–PCT at 2, 4, and 6 months to investigate intermittent shedding. Analyses of antibody response through titers of IgM and IgG will be performed at baseline and repeated at 2, 4, and 6 months.

Among symptomatic participants seven milliliters of blood will be drawn at each study visit split into a tiger top tube (5ml) and a purple top tube (2ml) for a total not to exceed 50 ml during any given 8-week period. At enrollment healthy non-pregnant adults will have 20 ml of blood collected following standard procedures. Two tiger top tubes of 8.5 ml and one 3ml purple top tubes will be collected. These procedures will be repeated at each follow-up visit.

RT–PCR-positive participants will be asked to refer up to five household members to establish the percentage of household members with detectable and potentially infectious Zika virus RNA in body fluids. Household members who are found to be ZIKV RT–PCR-positive in any body fluid will be invited to participate in the cohort study. A second study visit will be scheduled with household contact at 2 or 4 months, to detect new infections and estimate incidence. Because the original study consent forms do not include this visit, household contacts will be contacted by study staff and will be consented again using the same consent form.

Since gaining OMB approval in October 2016, the project has enrolled 295 Zika virus-infected individuals into the Zika virus Persistence study, which is 55 individuals below the target enrollment of 350 individuals.

Preliminary findings have been published in New England Journal of Medicine, where we also expect that the final report that includes the full sample size will be published.

This is a request to continue information collection with minor modifications. Modifications have been made to reflect the developing nature of the science surrounding Zika virus infection and potential outcomes associated with infection, as well as additional questions that were best answered by taking advantage of the existing study platform. Specifically, CDC proposes the addition of two components to the collection of data under this study, one of which has already begun:

1. A follow-up household visit has been added to determine how many household members of Zika virus-infected participants become infected during the 4 months following initial screening. For any household members that had no evidence of Zika virus infection at the initial visit, the same questionnaires used at the initial household visit will again be completed ~4 months later. Such information will provide additional information regarding the incidence of Zika virus infections among households with a Zika-positive household member.

2. Additionally, CDC proposes following up with men with Zika virus-positive semen specimens to better understand the effect of Zika virus infection on sperm. To do this, 8–14 semen ejaculates from 10–20 men participating in the ZIPER study will be used to determine the presence and/or detection of the Zika virus in different fractions of the semen ejaculate (*i.e.,* seminal plasma, cellular debris, including White Blood Cells and spermatozoa). CDC has received Institutional Review Board approval for this modification, but information collection has not begun.

Authorizing legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241). The total estimated annualized number of burden hours is 243. There is no cost to respondents other than the 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 hours)
Public health personnel	Shedding Questionnaire	18	30	15/60
General public	Shedding Questionnaire (Symptomatics)	55	8	10/60
	Shedding Questionnaire (Cross-Sectional Asymptomatics).	100	1	10/60
	Questionnaire for men in Semen sub-study	30	1	20/60
	Shedding Eligibility Form	160	1	2/60
	Contact Information Form	32	1	2/60

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.

[FR Doc. 2017–14790 Filed 7–13–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The guidances, when finalized, provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's Web site. The guidances identified in this notice were developed using the process described in that guidance.

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 a draft guidance announced in this notice before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 12, 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–2007–D–0369 for ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' 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 Dockets Management Staff. 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.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's Web site