

**Jeffrey M. Zirger,**

*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**

[30Day–19–0920]

**Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled *Data Collection Through Web Based Surveys for Evaluating Act Against AIDS Social Marketing Campaign Phases Targeting Consumers* to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on June 6, 2018 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (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*. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

**Proposed Project**

Data Collection Through Web Based Surveys for Evaluating Act Against AIDS Social Marketing Campaign Phases Targeting Consumers (OMB #0920–0920, Exp. 6/30/2018)—Reinstatement with Change—National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

In response to the continued HIV epidemic in our country, CDC launched Act Against AIDS (AAA), a multifaceted communication campaign to reduce HIV incidence in the United States in 2009. CDC has released the campaign in phases, with some of the phases running concurrently. Each phase of the campaign uses mass media and direct-to-consumer channels to deliver messages. Some campaigns provide basic education and increase awareness of HIV/AIDS among the general public, whereas others emphasize HIV prevention and testing among specific subgroups or communities at greatest risk of infection. CDC will also develop new messages to address changes in prevention science and subpopulations affected by HIV. The proposed study

will assess the effectiveness of these social marketing messages aimed at increasing HIV/AIDS awareness, increasing prevention behaviors, and improving HIV testing rates among consumers.

The reinstatement with change of this ongoing study will allow for continued evaluation of the effectiveness of AAA social marketing campaign through surveys with consumers. A total of 10,750 respondents were approved for the previously renewed generic ICR (0920–0920) and since the approval date, 4,305 respondents were surveyed under the GenIC, “Development of Messages for the Act Against AIDS National Testing”. The information collected from these data collections was used to evaluate a specific AAA campaign phase. We are requesting the same amount of time to continue surveying AAA target audiences as new phases are developed.

Through the continuation of this collection, we plan to reach the remaining approved 6,445 respondents. To obtain the remaining respondents, we anticipate screening approximately 32,220 individuals. Depending on the target audience for the campaign phase, the study screener will vary. The study screener may address one or more of the following items: Race/ethnicity, sexual behavior, sexual orientation, gender identity, HIV testing history, HIV status, and injection drug use. Each survey will have a core set of items asked in all rounds, as well as a module of questions relating to specific AAA phases and activities.

Respondents will be recruited through national opt-in email lists, the internet, and external partnerships with community-based and membership organizations that work with or represent individuals from targeted populations (e.g., National Urban League, the National Medical Association). Respondents will self-administer the survey at home on personal computers. There is no cost to the respondents other than their time. The total annualized burden hours are 1,432.

**ESTIMATED ANNUALIZED BURDEN HOURS**

| Type of respondents   | Form name          | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|---|--------------------|-----------------------|------------------------------------|--|
| Individuals (male and female) aged 18 years and older ..... | Study Screener ... | 10,740                | 1                                  | 2/60                                   |
|   | Survey .....       | 2,148                 | 1                                  | 30/60                                  |

**Jeffrey M. Zirger,**

*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

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA-CE19-001; Correction

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA-CE19-001; October 30–November 2, 2018, 8:30 a.m.–5:00 p.m., EDT which was published in the **Federal Register** on August 23, 2018 Volume 83, Number 164, pages 42655–42656.

The date should read as follows: October 29, 2018, 3:00 p.m.–5:00 p.m., EDT, October 30–November 2, 2018, 8:00 a.m.–5:00 p.m., EDT.

**FOR FURTHER INFORMATION CONTACT:** Mikel L. Walters, M.A., Ph.D., Scientific Review Official, NCIPC, CDC, 4770 Buford Highway NE, Mailstop F-63, Atlanta, Georgia 30341, (404)639-0913; [mwalters@cdc.gov](mailto:mwalters@cdc.gov).

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Sherri Berger,**

*Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2018-23297 Filed 10-24-18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-1262]

#### Issuance of Priority Review Voucher; Rare Pediatric Disease Product

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that REVCovi (elapegademase-lvlr) Injection, manufactured by Leadiant Bioscience Inc., meets the criteria for a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:** Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4061, Fax: 301-796-9856, email: [althea.cuff@fda.hhs.gov](mailto:althea.cuff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that REVCovi (elapegademase-lvlr) Injection, manufactured by Leadiant Bioscience Inc., meets the criteria for a priority review voucher. REVCovi (elapegademase-lvlr) Injection is indicated for the treatment of Adenosine Deaminase-Severe Combined Immunodeficiency (ADA-SCID) in pediatric and adult patients.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about REVCovi (elapegademase-lvlr) Injection, go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: October 22, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-D-3462]

#### Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs; 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 “Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs.” The draft guidance addresses the verification systems that manufacturers, repackagers, wholesale distributors, and dispensers must have in place to comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Drug Supply Chain Security Act (DSCSA). Specifically, this draft guidance covers the statutory verification system requirements that include quarantine and investigation of a product determined to be suspect and quarantine and disposition of a product determined to be illegitimate. The draft guidance also addresses the statutory requirement for notification to the Agency of a product that has been cleared by a manufacturer, repackager, wholesale distributor, or dispenser after a suspect product investigation because it is determined that the product is not an illegitimate product.

**DATES:** Submit either electronic or written comments on the draft guidance by December 24, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time 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