

## FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

### Sunshine Act Meetings; Federal Retirement Thrift Investment Board Member Meeting

**TIME AND DATE:** 4:00 p.m. (telephonic), March 28, 2018.

**STATUS:** Closed session.

**MATTERS TO BE CONSIDERED:** Information covered under 5 U.S.C. 552b (c)(9)(B).

**CONTACT PERSON FOR MORE INFORMATION:** Kimberly Weaver, Director, Office of External Affairs, (202) 942-1640.

Dated: March 27, 2018.

**Dharmesh Vashee,**

*Deputy General Counsel, Federal Retirement Thrift Investment Board.*

[FR Doc. 2018-06427 Filed 3-27-18; 11:15 am]

**BILLING CODE 6760-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Government-Owned Inventions; Availability for Licensing and Collaboration; Notification of Q&A Webinar

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The invention named in this notice is owned by agencies of the United States Government and is available for licensing in accordance with the U.S. Federal Technology Transfer Act of 1986. Related data for 510(k) submission is available as part of the licensing package. The technology and related data are being licensed to achieve expeditious commercialization of federally funded research and development. A U.S. Provisional patent application has been filed to extend market coverage. CDC also seeks collaboration partners with interest in adapting the test for different equipment, point-of-care, or more rapid processing.

**DATES:** Individuals interested in this technology opportunity are invited to participate in a live question and answer webinar on April 27, 2018 at 10 a.m. Eastern Daylight Time.

**ADDRESSES:** Licensing, related data for 510(k) submission, and other information pertaining to the technology listed below, may be obtained by writing to Technology Transfer Office, Centers for Disease Control and

Prevention, 1600 Clifton Road NE, Mailstop D-42, Atlanta, GA 30329; Telephone (404)639-1330; or email [tto@cdc.gov](mailto:tto@cdc.gov).

#### SUPPLEMENTARY INFORMATION:

##### Description of Technology

CDC Triplex Real-time RT-PCR (Reverse Transcription Polymerase Chain Reaction) Assay for Detection of Zika, Dengue, & Chikungunya Virus Infections CDC ref. no.: I-009-17 NIH ref. no.: E-081-2017 (See <https://www.ott.nih.gov/technology/e-081-2017>.)

CDC has developed the Triplex real-time RT-PCR test to detect evidence of Zika, dengue and chikungunya virus infections, all of which are spread by mosquito bites from the same *Aedes* species and cause epidemics in more than 100 countries. The real-time RT-PCR assay is for qualitative detection and differentiation of RNA (ribonucleic acid) from dengue, chikungunya, and Zika viruses in serum, whole blood, and cerebral spinal fluid, and for the qualitative detection of Zika virus RNA in urine and amniotic fluid. This assay protocol is designed to facilitate simultaneous testing for the three viruses using a single sample in the same plate well (multiplex). A singleplex reaction (measuring one analyte at a time) is also an option for chikungunya, and dengue testing if one primer/probe set per well is preferred. The test can be run in different modalities and equipment available in most laboratories. The test has been designed to minimize the likelihood of false positive results. Cross-reactivity for any of the components is not expected. The Food & Drug Administration (FDA) issued emergency use authorization (EUA) for the Triplex assay on March 17, 2016. Additional information can be found at: <http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM491592.pdf>.

Currently, there are no vaccines or therapeutics commercially available for Zika, dengue, or chikungunya virus infections.

Competitive advantages:

- Currently, there is no multiplex assay on the market that can detect Zika, chikungunya and the four dengue subtypes in one test; this test will also help assess disease severity in dengue secondary infections
- There is no FDA-approved chikungunya PCR test on the market and current Zika and dengue tests must be run separately
- This was the first molecular test for Zika to receive FDA's EUA

#### Question and Answer Webinar

Individuals interested in this technology opportunity are invited to participate in a live question and answer webinar on April 27, 2018 at 10 a.m. Eastern Daylight Time. Individuals must pre-register for the session by sending an email to [tto@cdc.gov](mailto:tto@cdc.gov) by Thursday, April 26, at 1 p.m. EDT.

After requesting the registration, participants will receive a confirmation of their registration along with access information to enter prior to the webinar. Persons interested in this technology are strongly encouraged to register for and participate in the webinar.

A signed Confidential Disclosure Agreement (available under Forms at [www.cdc.gov/tto](http://www.cdc.gov/tto)) will be required to receive copies of unpublished patent applications and other information.

Inventors: Jorge Munoz-Jordan, Robert Lanciotti, and Gilberto Santiago.

U.S. PCT (Patent Cooperation Treaty) Application No. PCT/US2017/023021: Filed March 17, 2017.

(CDC Ref. #: I-009-17; NIH Ref. #E-081-2017—See <https://www.ott.nih.gov/technology/e-081-2017>.)

Dated: March 26, 2018.

**Sandra Cashman,**

*Executive Secretary, Centers for Disease Control and Prevention.*

[FR Doc. 2018-06306 Filed 3-28-18; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10148]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our

burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by May 29, 2018.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786-4669.

#### SUPPLEMENTARY INFORMATION:

##### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

#### *CMS-10148 HIPAA Administrative Simplification (Non-Privacy/Security) Complaint Form*

Under the 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. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

#### Information Collection

1. *Type of Information Collection Request:* Revision of the currently approved collection.; *Title of Information Collection:* HIPAA Administrative Simplification (Non-Privacy/Security) Complaint Form; *Use:* The authority for administering and enforcing compliance with the non-privacy/security Health Insurance Portability and Accountability Act (HIPAA) rules has been delegated to the Centers for Medicare & Medicaid Services (CMS). At present, CMS' compliance and enforcement activities are primarily complaint-based. Although our enforcement efforts are focused on investigating complaints, they may also include conducting compliance reviews to determine if a covered entity is in compliance. Potential violations can come through a complaint form or a compliance review.

This standard form collects identifying and contact information of the complainant, as well as, the identifying and contact information of the filed against entity (FAE). This information enables CMS to respond to the complainant and gather more information if necessary, and to contact the FAE to discuss the complaint and CMS' findings.

In addition to the identifying and contact information, the standard form collects a summary which outlines the nature of the complaint. This summary is used to determine the validity of the complaint, and to categorize the complaint as related to transactions, standards, code sets, unique identifiers, and/or operating rules. This ensures the

appropriate direction of the complaint process and enables CMS to produce accurate reports regarding complaint activity.

The revision form associated with this submission adds an option for filing complaints under Unique Identifier and Operating Rules. It also requests an email address for filed against entities, if available. *Form Number:* CMS-10148 (OMB Control number: 0938-0948); *Frequency:* Occasionally; *Affected Public:* Individuals; *Number of Respondents:* 125; *Total Annual Responses:* 125; *Total Annual Hours:* 125. (For policy questions regarding this collections contact Kevin Steward at 410-786-6149.)

Dated: March 26, 2018.

**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2018-06312 Filed 3-28-18; 8:45 am]

**BILLING CODE 4120-01-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2007-D-0369]

#### Product-Specific Guidance for Doxycycline Hyclate; Revised 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 revised draft guidance for industry on generic doxycycline hyclate oral delayed-release tablets, entitled "Product-Specific Guidance for Doxycycline Hyclate." The revised draft guidance, when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for doxycycline hyclate oral delayed-release tablets.

**DATES:** Submit either electronic or written comments on the draft guidance by May 29, 2018 to ensure that the Agency considers your comments on the 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: