DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

April 24, 2018

Dominic Mancini
Deputy Director
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC

Subject: Request for Emergency Review and Clearance

Dear Mr. Mancini:

Pursuant to Office of Management and Budget (OMB) procedures established at 5 CFR Part 1320, *Controlling Paperwork Burdens on the Public*, I request that the proposed information collection project, "Undetermined cause of Serratia marcescens infections — Multiple States, 2018" be processed in accordance with section 1320.13, Emergency Processing.

I have determined that this information must be collected prior to the expiration of time periods established under Part 1320, and that this information is essential to the CDC's support for healthcare facilities and health departments responding to outbreaks of healthcare-associated infections. Based on information reported from healthcare facilities and in published literature, CDC has determined that *Serratia marcescens* infections in these patients (primarily bloodstream infections) are related to one or more healthcare products available in U.S. hospitals and other healthcare settings; however, limited data are available to determine which products and lot numbers are implicated. The products identified in initial investigations are medically necessary and hold a large market share, leading to concerns about incorrect naming of a causative product without sufficient evidence. As of April 23, 2018, CDC has received reports of 26 patients across 8 states that are possibly linked to this outbreak, with additional laboratory testing pending for some of these patients. We are requesting approval of a public health investigation to collect data on healthcare exposures for patients with *Serratia marcencens* infections to investigate the relationship between *Serratia marcescens* infections and healthcare product exposures. This investigation is designed to answer urgent questions about possibly contaminated products that may lead to removal of one or more products from healthcare settings and the use of alternative products.

CDC cannot reasonably comply with the normal clearance process because our investigation suggests contaminated medical products are already present in healthcare facilities and must be removed quickly to prevent further harm to patients. It is critical that collection of patient data from multiple states begin rapidly to ensure that CDC and FDA are able to promptly respond to findings of contaminated products.

Because the collection of patient data is projected to begin on May 1, 2018, accelerated OMB review is requested. Therefore, CDC requests a 90-day emergency clearance to launch collection of patient data. No patients will be contacted directly and no personal identifiable information will be collected by CDC.

Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by close of business April 30, 2018.

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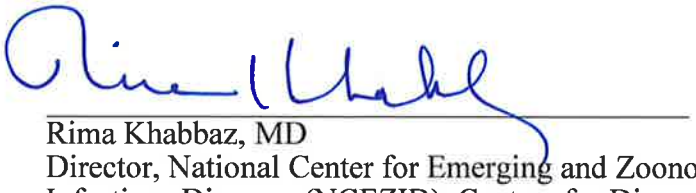
Respectfully,



Rima Khabbaz, MD
Director, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC)