



DATE: July 3, 2024

TO: Office of Management

Through: NCEH/ATSDR Office of Director, Office of Science

FROM: Arthur Chang MD. MS, Chief Medical Officer,
Division of Environmental Health Science and Practice

Acting on behalf of Erik Svendsen, Director,
Division of Environmental Health Science and Practice

SUBJECT: Outbreak investigation related to Diamond Shruumz™ brand chocolate bars, cones, and gummies / Request for Approval Under the Generic Clearance for Emergency Epidemic Investigation Data Collections (GenIC)

ACTION REQUESTED

CDC is requesting approval of GenIC “*Investigation of multistate outbreak of severe illness related to consumption of Diamond Shruumz™ Brand products, United States, 2024*” under the Generic, Emergency Epidemic Investigation, OMB control No. 0920-1011, expiration date 12/31/2025.

We are requesting a 72-HOUR approval period from the initial submission; approval is requested by July 5th

JUSTIFICATION

In accordance with requirements under 5 *CFR 1320.13*:

The collection of the information requested is needed more urgently than normal clearance procedures would provide, and the information collected is essential to the mission of the agency to protect public health.

CDC cannot reasonably comply with the normal clearance procedures under this part because additional public harm is reasonably likely to result if normal clearance procedures are followed. As of July 1, 2024, 48 cases had been reported from 24 states. Twenty-seven of the cases have required hospitalizations, and there is one (1) potentially associated death under investigation. Over 60% of cases have occurred in the last two weeks, demonstrating that the outbreak is ongoing, and any delay could result in additional harm to the public.

While the product has been recalled, there may still be product in circulation in addition to that previously purchased and not consumed. The cause of the illness is currently unknown, and CDC has been requested to coordinate a national public health investigation. Expedited clearance of

data collection tools are imperative to share with state public health agencies to understand the magnitude and scope of the incident, identify the cause(s) of the illnesses, and to inform further actions to protect the public's health and potentially prevent additional serious illnesses or deaths.

The agency has taken all practicable steps to consult with interested agencies and members of the public to minimize the burden of the collection of information. The 0920-1011 Generic ICR mechanism has gone through both the 60- and 30-day public comments periods. Further, CDC and FDA have held multiple calls amongst affected states to understand questions and needs as well as consulted with national public health partners. Several state health departments and poison centers have contacted CDC to request federal assistance with this emergency. There is a specific request to provide standardized procedures for investigating cases to understand the magnitude and scope of the incident and identify the cause.

BACKGROUND

On June 3, 2024, the Arizona Department of Health Services notified CDC of four patients with severe illness (including seizures, central nervous system depression and other symptoms) following consumption of Diamond Shroomz™ chocolate bars. Subsequently, several additional cases have been identified through reporting to poison centers. On June 7, 2024, FDA issued an adverse event investigation notice, advising people not to eat, sell, or serve Diamond Shroomz™ Brand Microdosing Chocolate Bars. On June 12, 2024, a Health Advisory was distributed via the CDC Health Alert Network to alert clinicians about the illnesses. On June 27, 2024, Prophet Premium Blends, LLC of Santa Ana, CA, initiated a recall of all flavors of Diamond Shroomz-brand Chocolate Bars, Cones, and Gummies.

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