

Emergency Use Authorization

About Emergency Use Authorizations (EUAs)

The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against CBRN threats by facilitating the availability and use of MCMs needed during public health emergencies.

Under section 564 of the Federal Food, Drug and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved and available alternatives.

Section 564 of the FD&C Act was amended by the Project Bioshield Act of 2004 and was further amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), the 21st Century Cures Act of 2016, and Public Law 115-92 of 2017.

Emergency Use Authorization for Vaccines to Prevent COVID-19

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide sponsors of requests for Emergency Use Authorization (EUA) for COVID-19 vaccines with recommendations regarding the data and information needed to support the issuance of an EUA under section 564 of the FD&C Act (21 U.S.C.360bbb-3) for an investigational vaccine to prevent COVID-19 for the duration of the COVID-19 public health emergency.

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19>

December 2, 2020

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This policy and procedure is not intended to replace the informed judgment of individual physicians, nurses or other clinicians nor is it intended as a statement of prevailing community standards or minimum standards of practice. It is a suggested method and technique for achieving optimal health care, not a minimum standard below which residents necessarily would be placed at risk.