

# Advisory Commission on Childhood Vaccines (ACCV)

## Food and Drug Administration Update

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# Emergency Use Authorization for Vaccines

- An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic.
- Under an EUA, the FDA may allow the use of unapproved medical products to prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives.
  - Taking into consideration input from the FDA, manufacturers decide whether and when to submit an EUA request to FDA.
- Once submitted, FDA will evaluate an EUA request and determine whether the relevant statutory criteria are met, and review the scientific evidence about the vaccine that is available to FDA.

# Requirements for the EUA

- FDA evaluated nonclinical, clinical, and manufacturing data submitted by a vaccine manufacturer.
- For an EUA to be issued for a vaccine:
  - Adequate **manufacturing** information ensures quality and consistency
  - Vaccine benefits outweigh its risk based on data from at least one well-designed Phase 3 clinical study that in a compelling manner demonstrates:
    - **Safety**
    - **Efficacy**

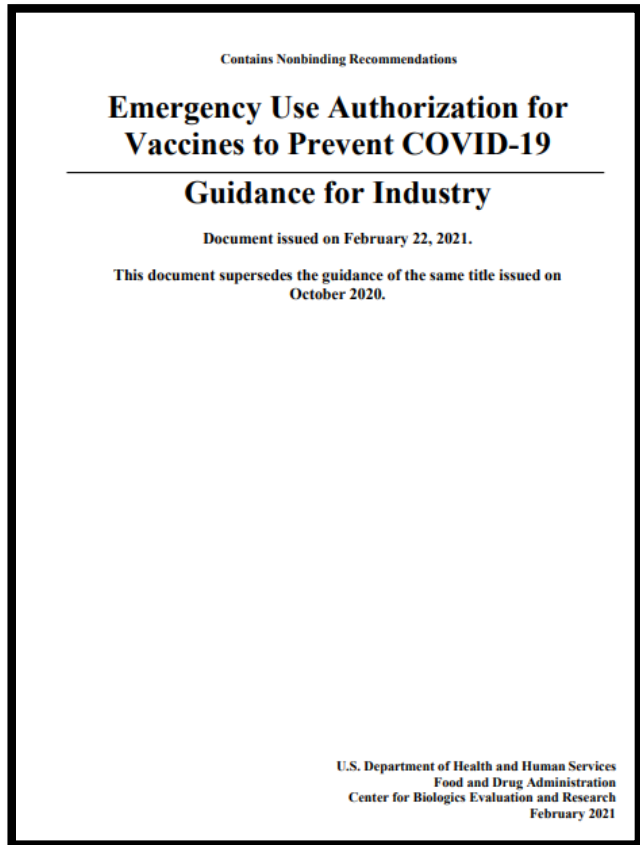
# Continued monitoring of COVID-19 Vaccines Authorized by FDA

- **USG Systems:**
  - Vaccine Adverse Event Reporting System (VAERS)
  - Vaccine Safety Datalink (VSD),
  - Biologics Effectiveness and Safety (BEST) Initiative
  - Medicare Claims Data

# EUA of COVID-19 Vaccines

- On December 11, 2020, the FDA issued the first emergency use authorization (EUA) for Pfizer’s COVID-19 Vaccine.
  - **Individuals 16 years of age and older**
  - **mRNA Vaccine**
- On December 18, 2020, the FDA issued an EUA for Moderna’s COVID-19 Vaccine.
  - **Individuals 18 years of age and older**
  - **mRNA Vaccine**
- On February 27, 2020, the FDA issued an EUA for Janssen’s COVID-19 Vaccine.
  - **Individuals 18 years and older**
  - **Adenovirus Vector Vaccine**

# Updated Guidance to Address Variants



- On February 22, 2021, the FDA updated its October 2020 guidance, Emergency Use Authorization for Vaccines to Prevent COVID-19
  - The updated guidance provides recommendations to vaccine developers, including those who have already received emergency use authorization (EUA) for their COVID-19 vaccines and are seeking to **amend their EUA to address new variants.**
    - The guidance recommends that a determination of effectiveness be supported by data from clinical immunogenicity bridging studies comparing the immune response to the modified vaccine to that induced by the original vaccine for which efficacy data are available
    - Manufacturers are encouraged to study the modified vaccine in both naïve (non-vaccinated) individuals and in individuals previously vaccinated with the authorized vaccine.
    - Additionally, the guidance outlines the FDA's recommendations for assessments of safety to support an EUA for a modified vaccine.

# Vaxchora

- On December 23, 2020, the FDA approved a supplement to the Biologics License Application (BLA) for Cholera Vaccine, Live, Oral (Vaxchora), to expand the usage to include children 2 to < 18.
- Vaxchora was first approved in the U.S. on June 10, 2016 for active immunization against disease caused by *Vibrio cholerae* serogroup O1 in adults 18 through 64 years of age traveling to cholera-affected areas.

## FDA Websites

- **Vaccine Development 101**
  - <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101>
- **Emergency Use Authorization for Vaccines Explained**
  - <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>





# Thank you!

