

What Is Emergency Use Authorization?

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The [Federal Drug Administration](#) uses “Emergency Use Authorization (EUA)” to “help strengthen the nation’s public health protections against chemical, biological, radiological, and nuclear (CBRN) threats including infectious diseases.” The FDA uses [medical countermeasures](#) (MCMs) when public health emergencies require more aggressive procedures to protect the public from harm – such as during the COVID-19 pandemic.

COVID-19 Vaccination Requirements and Laws

The US Centers for Disease Control and Prevention has clinical care guidelines for the three vaccines that have been approved – the two mRNA vaccines and the Jansen vaccine.

How does the EUA authority process work?

According to the FDA,

“A determination under section 319 of the Public Health Service Act that a public health emergency exists does not enable FDA to issue Emergency Use Authorizations. A separate determination and declaration are needed under section 564 of the Federal Food, Drug, and Cosmetic Act to enable FDA to issue Emergency Use Authorizations, provided other statutory criteria are met.”

The FDA cannot issue an EUA under section 564 of the FD&C Act unless one of the four following determinations occurs

- *“The Department of Defense (DoD) Secretary issues a determination of military emergency or significant potential for military emergency.*
- *The Department of Homeland Security (DHS) Secretary issues a determination of domestic emergency or significant potential for domestic emergency.*
- *The Department of Health and Human Services (HHS) Secretary issues a determination of a public health emergency or significant potential for a public health emergency.*
- *The DHS Secretary issues a material threat determination.”*

If the above criteria are met, the HHS Secretary can issue a declaration that circumstances exist to justify issuing the EUA. The FDA Commissioner or delegate can, in consultation with the HHS Assistant Secretary for Preparedness and Response

(ASPR), the CDC, and the NIH, then issue the EUA, if other statutory conditions are met.

What is the difference between emergency use authorization and full FDA approval?

According to Yale Medicine, an emergency use authorization (EUA) is a useful tool during a public health emergency that the FDA can use to expedite the availability of drugs, vaccines, and other medical products. An EUA can only be granted during the time the public health emergency exists:

- “When no adequate, approved, available alternatives exist,” and
- “When the known and potential benefits outweigh the potential risks.”

Generally, the FDA has the duty to ensure that the medical products FDA grants “full approval” to comply with “rigorous safety and efficacy standards.” Normally, this process can take years. There are still strict compliance standards for EUA approvals – but the timeline for approval is generally much shorter.

Since the COVID-19 pandemic was officially recognized in 2020, the FDA has granted many different COVID-19 EUAs including:

- Two vaccines (Pfizer-BioNTech, for ages 16 and up, and Moderna, for 18 and up)
- One treatment (Gilead Science’s remdesivir).

The history of EUAs

The authority of the FDA to grant EUAs dates back to 2004 when EUAs were used for “threats of bioterrorist attacks, including anthrax.” Since 2004, other EUAs have been granted for:

- H1N1 (swine flu)
- Ebola
- Avian flu
- Middle Eastern Respiratory Syndrome (MERS)
- Other public health threats.

The FDA has the authority to revise or revoke an EUA during a public health emergency as the FDA evaluates current needs and data.

“For example, the FDA issued an EUA for hydroxychloroquine during the first phase of the COVID-19 pandemic. Later, when it became clear that the treatment posed a risk but did not offer significant benefit, the FDA retracted the EUA.”

Key differences between an EUA and a full approval

The two main differences between an FDA EUA and an FDA “full approval” are:

- An EUA (such as for a COVID-19 vaccine) requires that “at least half of the clinical trial participants be followed for at least two months after vaccination.” The time limit for a full FDA approval is at least six months.
- Full approval of a medical product “requires more data about the vaccine maker’s processes and facilities, including inspections of manufacturing plants.”

How does the normal full FDA approval process work?

The FDA full approval process differs depending on the type of product. Vaccines, drugs, and other treatments and therapies are evaluated differently than medical devices and other medical products.

The full approval process

For vaccines and therapeutics (drugs, treatments, and therapies) the companies seeking full approval file a “biologics license application” (a BLA). For a vaccine BLA, the applicant must comply with the following steps:

- **Research and discovery stage.** In this phase, scientists test their vaccines in laboratory settings – usually testing animals.
- **Pre-clinical stage.** Here, researchers conduct additional tests on animals to test how well the vaccine works and whether humans can safely benefit from the vaccine.
- **Clinical development stage.** Before testing humans, the companies seeking FDA approval compile the results of their prior test and the applicable manufacturing technology. Manufacturers submit this information to the FDA which determines whether to approve the clinical trials which consist of four phases.
 - *Phase I.* In this phase, about 20-100 volunteers receive the trial vaccine.
 - *Phase II.* If Phase I is successful, several hundred people will receive the vaccine- based on “*varying health statuses and from different demographic groups.*”
 - *Phase III.* In this phase, thousands of people receive the vaccine. The company tests these people for efficacy (the percentage reduction of disease in people who received the trial vaccine versus those who received a placebo), safety, and immune response.
 - *Phase IV.* This phase includes “monitoring trials.”
- **Assessment of the manufacturing stage.** During the clinical trials, FDA reviews the manufacturing process by visiting the company’s facility to ensure the process meets FDA regulations.
- **Seeking approval stage.** On completion of the clinical trials and acceptance of the manufacturing process, the company submits its BLA – with all the necessary documentation confirming the steps above.
- **Full approval granted stage.** *“If the vaccine is approved (or licensed, as it is also known), the company can market it for use in the population for which it was approved.”*

FDA may seek input from its Vaccines and Related Biological Products Advisory Committee (VRBPAC)—a group of outside, independent experts from scientific and public health fields.

After FDA’s full approval, the FDA continues to monitor the safety and production of the vaccine – which includes inspection of the facilities. FDA may also require the Phase IV trials listed above to monitor the vaccine’s effectiveness and to identify “*uncommon adverse events and long-term complications.*” The Vaccine Adverse Event Reporting System (VAERS) may also participate in reviewing any reports of possible health problems after vaccination.

Stem Cell Therapies and Clinical Trials

Developers and manufacturers of stem cell therapies need to understand how to conduct clinical trials in order to process FDA investigational new drug (IND) applications.

Red Flags that Leads to FDA Warning Letters

The FDA issues warning letters for numerous products including dietary supplements. FDA violations include findings that the supplement is a new drug, product adulteration, misbranding, and [...]

The EUA approval process?

Many of the steps to obtain an EUA approval are similar to obtaining a full FDA approval. Applicants must conduct laboratory research and animal testing, and submit an application. The Phase I, II, and III clinical trial runs examine the same safety and efficacy issues. The FDA conducts an assessment of manufacturing practices.

A few of the differences are the following:

- **Safety boards.**

- *“An independent data safety monitoring board (DSMB) evaluates data from the Phase III trials and tells the manufacturer whether or not they have met criteria for a clinical endpoint (showing how well a vaccine prevents COVID-19, for example) that had been pre-established by the FDA.”* The manufacturer makes the decision *“whether and when to submit an EUA request.”* Unlike a VRBPAC, the vaccine manufacturer establishes safety boards:
 - *“As part of a trial and have access to unblinded trial data that they review while the trial is ongoing to see if there are any safety or efficacy signals that warrant action being taken before the trial is scheduled to conclude.”* For the EUA COVID vaccines, a DSMB determined that *“the vaccines were highly effective and prompted submission to the FDA —where VRBPAC then met and reviewed the formal submission.”*
- **FDA review. When the manufacturer submits an EUA,** scientists and physicians from the FDA's Center for Biologics Evaluation and Research (CBER) evaluate the application. The formally oversees the review of vaccines for both the EUA and BLA applications.
- **Public meeting.** *“The FDA convenes a public meeting of its VRBPAC to go over the data from the clinical trials.”* Public meetings are generally used for both EUA and BLA applications. *“Although the FDA is not required to consult their advisory committees, FDA typically do for major decisions, such as authorization of COVID-19 vaccines.”*
- **EUA decision.** The next step is for the CBER to review the input from the public meeting and continue their evaluation. If the EUA criteria are met, the FDA can approve the EUA – approving the vaccine for emergency use.
- **Continued monitoring.** The FDA expects that manufacturers will monitor their vaccines for *“safety, including deaths, hospitalizations, and other serious adverse events among those who receive the vaccine under an EUA.”* The FDA also expects that the manufacturers of the EUA vaccines will continue their clinical trials and pursue full FDA approval of their vaccine.

How long do full approval and EUA approvals of medical products take?

According to Yale Medicine, the median clinical development period (meaning from a Phase I trial to approval) for 21 approved vaccines over the past 10 years was just over 8 years, including a median FDA review period of about a year.

The COVID-19 vaccine from Pfizer-BioNTech (the first to receive an EUA), was under clinical development for six months before Pfizer submitted its EUA. The FDA granted the EUA less than one month later – and full approval eight months later.

The Yale Medicine report is dated March 7, 2022, and does not reflect any updates.

Additional FDA guidance

For more information on the EUA approval process, please review the following:

- [Public Readiness and Emergency Preparedness \(PREP\) Act](#)
- [Emergency Use Authorization of Medical Products and Related Authorities](#)
- [FDA questions and answer document](#), dated January 2014, about EUA authority
- [What happens to EUAs when a public health emergency ends](#)
- [Pfizer-BioNTech COVID-19 Vaccine](#)

- Emergency Use Authorizations for Drugs and Non-Vaccine Biological Products

Emergency Use Authorization helps to ensure that America has the drugs, vaccines, and other medical products the country needs during chemical, biological, radiological, and nuclear threats. While there are similarities to the FDA full approval process, the timeline for approval is generally much shorter and there are key differences in the formal approval process. Healthcare providers should understand when EAU applies to the vaccines and other medical products they prescribe – and when full approval is necessary. Generally, when the emergency ends, the EAU ends unless the drug, vaccine, or medical product receives full approval.