EMERGENCY USE AUTHORIZATION (EUA)
A Roadmap

U.S. Executive Branch (President) ← Organization (Who's In Charge)

Department of Health & Human Services (HHS) Secretary

Operating Divisions | Staff Divisions

Food and Drug Administration (FDA) Commissioner

Center for Biologics Evaluation & Research (CBER) Director

Centers for Disease Control & Prevention (CDC) Director

National Institutes of Health (NIH) Director

Sends One Representative to VRBPAC

The People

Many, many experts are involved in the EUA process. There is space for anyone with data or opinions to present their thoughts for consideration.

Vaccines and Related Biological Products Advisory Committee (VRBPAC)

- 15 voting members selected by FDA commissioner
  - Screened for conflicts of interest
  - Serve 4-year terms
- Experts in immunology, virology, infectious disease, etc.
- 1 rep each: HHS, CDC, NIH, industry, consumer
- Meetings at least quarterly, more if needed
  - 8 hours long, sometimes multiple days
  - Open to the public
  - Recorded and available
  - Anyone can present information/views orally/written

The Process*

1. Agent (like SARS-CoV-2) identified as a public health threat
2. HHS Secretary declares public health emergency
3. HHS Secretary issues declaration justifying EUA
4. Company with vaccine or therapeutic candidate submits EUA request to FDA
5. CBER evaluates all available scientific evidence and manufacturing data
6. FDA may convene meeting of VRBPAC** to discuss clinical trial data & scientific evidence
7. CBER considers VRBPAC input
8. If criteria are met, FDA Commissioner authorizes product for emergency use
9. EUA re-evaluated periodically

Must be followed (by law**) and has many checkpoints built in to ensure scientific evidence is being considered by experts

EUA terminated when:
1. Public health emergency ceases
2. Product's approval status changes (e.g. product is fully approved)

* Note: These steps represent the process and the people involved specifically in vaccines authorization. Because biological products, like vaccines, are more complicated than chemical drugs, there are many additional safety and manufacturing controls. For information on committees and processes for drugs and non-biological products refer to fda.gov.

** Federal Food, Drug, and Cosmetic Act - United States Code, Title 21

www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas

IIC

Get Immunized, Idaho

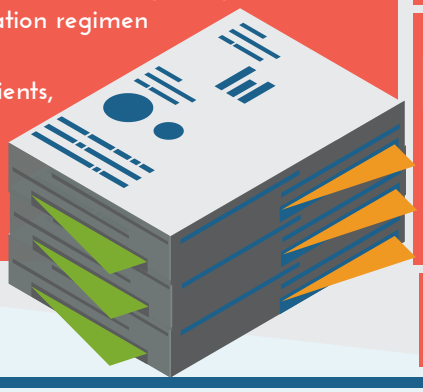
EUA ROADMAP CONTINUED

The Request

An EUA Request Must Contain:

Scientific Evidence:
All Available Clinical Trial Data on Safety/Effectiveness

Phase I and Phase II: Complete data sets
Phase III: Everything available, but MUST include:
- At least 2 months of data on at least 1/2 of participants who completed the full vaccination regimen
- At least 1 month of data from over 3,000 vaccine recipients, representing a high proportion of trial participants, who completed the full vaccination regimen



Risk/benefit analysis of both the product and the agent (SARS-CoV-2)

Descriptions of:
- Unmet need the product will address
- Current FDA approval status
- Current domestic/foreign use of product
- Availability of approved alternatives

Manufacturing Data
- Chemistry, manufacturing, controls
- List of sites product is manufactured + their current Good Manufacturing Practice status
- Quantity of finished product available
- Surge capabilities of manufacturing sites

Fact Sheet for Health Care Professionals & *Fact Sheet for Recipients*

The Rules

Criteria for Approval

1. Agent (SARS-CoV-2) is capable of causing a serious or life-threatening disease/condition
2. Product may be effective to prevent, diagnose, or treat those diseases/conditions
3. Known and potential benefits outweigh the known and potential risks of the product
4. No adequate, approved, available alternatives exist (includes having insufficient supplies)

Conditions for EUA

1. Provide *Fact Sheet for Health Care Professionals* & *Fact Sheet for Recipients* - posted on FDA website**
2. Monitor and report Adverse Events: MedWatch, Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink (VSD), the Biologics Effectiveness and Safety (BEST) Initiative etc.
3. Allow FDA access to manufacturing records

Current EUAs*

Vaccines**

Pfizer-BioNTech Vaccine/Comirnaty (mRNA vaccine)
- Licensed (fully approved) for ≥ 16 years old
- EUA for:
  - ≥ 5 years old
  - Booster for ≥ 5 years old in some cases*
  - Booster for fully vaccinated + ≥ 12 years old***

Moderna Vaccine (mRNA vaccine)
- Licensed (fully approved) for ≥ 18 years old
- EUA for booster for ≥ 18 years old***

Janssen (Johnson & Johnson)Vaccine (adenoviral vector vaccine)
- ≥ 18 years old
- Booster for ≥ 18 years old***

Drugs & Non-Biological Products

4 Treatments Targeting Viral Life Cycles
2 for mild-moderate disease in high-risk patients
2 for hospitalized patients

6 Monoclonal Antibodies/Convalescent Serum
3 for mild-moderate disease in high-risk patients
1 for hospitalized patients on steroids/oxygen
2 for immunocompromised patients

4 Alternative Products Needed (Due to Shortages) For Patients in Critical Care/ICU
2 Sedatives - for patients on mechanical ventilation
2 Dialysis Replacement Solutions - for kidney failures

* Most approvals have many caveats for use! Refer to full EUA information and fact sheets at fda.gov for complete information.
** Direct links for each vaccine with EUA are provided above. Content current as of 31Jan2022
*** All 3 vaccines with EUA are approved as a booster for fully vaccinated and ≥ 18 years old with different primary course (e.g. Moderna can be used to boost someone who got Pfizer)
www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas

IIC
Get Immunized, Idaho