

What is

FDA

Full 
Authorization?

COVID-19 Vaccines

What to Know

As of September 1



California Consortium
for **Urban Indian** Health

Before the FDA can approve a drug

the agency must determine whether the clinical data and other information show that the drug is

Safe

&

Effective

for its intended use

and

**can be made according
to federal quality standards.**



**California Consortium
for Urban Indian Health**

As of September 1

When the FDA approves a drug

it means the agency has determined,
based on substantial evidence the following:

that the drug is effective for its intended use

the Pfizer vaccine is designed to reduce the risk of severe COVID-19 symptoms, not prevent it altogether.

and that the benefits of the drug outweigh its risks when used according to the product's approved labeling.

So while there is some degree of risk associated with the vaccine, it is safe in the overwhelming number of cases and can still be confidently recommended.



What is an FDA-issued EUA?

An Emergency Use Authorization (EUA)

is one of several tools the FDA is using to help make certain medical products available quickly during the **COVID-19** pandemic.

In certain emergencies, the FDA can issue an EUA to provide access to medical products that may potentially be used **when there are no adequate, approved, and available options.**

Under an EUA...

and in an emergency

the FDA makes a product available to the public based on the best available evidence, without waiting for all the evidence that would be needed for FDA approval or clearance.

This is done, when the chance for the product to save lives or prevent disaster outweighs the known risk based on current evidence.

EUA: Risk versus Benefit

How they make the decision

When evaluating an EUA, the FDA...

carefully balances the potential risks and benefits of the products based on the data currently available.

