FDA VACCINE FACTS

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#FDAVaccineFacts

The Path for a COVID-19 Vaccine from Research to Emergency Use Authorization

A vaccine manufacturer conducts laboratory research to develop a vaccine candidate.

The manufacturer compiles the results of laboratory research and testing in animals and information about the manufacturing technology and the quality of the vaccine and must submit an Investigational New Drug (IND) application to FDA before beginning human clinical trials. Such a clinical trial in humans is not permitted to proceed without the prior written authorization from FDA.

Clinical trials are conducted to generate data on safety and effectiveness of the vaccine.

A Data Safety Monitoring Board evaluates data from the Phase 3 clinical trial and advises the vaccine manufacturer regarding whether criteria for the pre-specified clinical endpoint, as discussed and agreed to in advance with FDA, has been met for their COVID-19 vaccine.

Company reviews data to determine whether the company's scientists and technical experts believe that the vaccine meets FDA's outlined expectations for safety and effectiveness.

Taking into consideration input from FDA, a company decides whether and when to submit a request for Emergency Use Authorization (EUA) to FDA.

Once submitted, career scientists and physicians in the FDA's Center for Biologics Evaluation and Research (CBER) will evaluate an EUA request taking into account the totality of scientific evidence about the vaccine that is available to FDA.[1]

FDA convenes a public meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss the data from the clinical trials.

Following the advisory committee meeting, CBER's career professional staff will consider the input of the advisory committee members and continue their evaluation to determine whether the available safety, effectiveness, and manufacturing data support authorization for use of the particular COVID-19 vaccine in the U.S.

If FDA determines that the criteria for an EUA are met, including that the known and potential benefits outweigh the known and potential risks of the vaccine and that the manufacturing information is adequate to ensure its quality and consistency, FDA may authorize the vaccine for emergency use.[2]

FDA informs the company that its EUA has been authorized.

[1] Part of FDA's evaluation of an EUA request for a COVID-19 vaccine includes evaluation of the chemistry, manufacturing, and controls information for the vaccine. Sufficient data should be submitted to ensure the quality and consistency of the vaccine product. FDA will use all available tools and information, including records reviews, site visits, and previous compliance history, to assess compliance with current good manufacturing practices.

[2] FDA has made clear in its October 2020 guidance entitled Emergency Use Authorization for Vaccines to Prevent COVID-19, that, for a COVID-19 vaccine for which there is adequate manufacturing information to ensure its quality and consistency, issuance of an EUA would require a determination by FDA that the vaccine's benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner.

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