FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Announces Advisory Committee Meeting to Discuss COVID-19 Vaccine Candidate

For Immediate Release:

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The U.S. Food and Drug Administration has scheduled a meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) on Dec. 10 to discuss the request for emergency use authorization (EUA) of a COVID-19 vaccine from Pfizer, Inc. in partnership with BioNTech Manufacturing GmbH.

"The FDA recognizes that transparency and dialogue are critical for the public to have confidence in COVID-19 vaccines. I want to assure the American people that the FDA's process and evaluation of the data for a potential COVID-19 vaccine will be as open and transparent as possible," said FDA Commissioner Stephen M. Hahn, M.D. "The FDA has been preparing for the review of EUAs for COVID-19 vaccines for several months and stands ready to do so as soon as an EUA request is submitted. While we cannot predict how long the FDA's review will take, the FDA will review the request as expeditiously as possible, while still doing so in a thorough and science-based manner, so that we can help make available a vaccine that the American people deserve as soon as possible. A discussion about the safety and effectiveness of Pfizer and BioNTech's vaccine with this committee, made up of outside scientific and public health experts from around the country, will help ensure clear public understanding of the scientific data and information that the FDA will evaluate in order to make a decision about whether to authorize a vaccine for emergency use for the prevention of COVID-19."

The FDA intends to make background materials available to the public, including the meeting agenda and committee roster, no later than two business days prior to the meeting. In general, advisory committees include a chair, members with scientific and public health expertise, and a consumer, industry, and sometimes a patient representative. Additional experts with specific expertise may be added for individual meetings as needed.

Although the VRBPAC members provide advice to the agency, which may include advice on the safety and effectiveness data submitted in the EUA request, final decisions on whether to authorize the vaccine for emergency use are made by the FDA. In terms of timing of the VRBPAC meeting following the submission of the EUA request, this amount of time will allow

the FDA to thoroughly evaluate the data and information submitted in the EUA request before the meeting and to be prepared for a robust public discussion with the advisory committee members.

The week of Nov. 23, the FDA intends to issue a Federal Register notice with details of the meeting, which will include information about a public docket for comments. At that time, public comments can be submitted. These comments will be reviewed by the FDA.

The FDA intends to livestream the VRBPAC meeting on the agency's YouTube, Facebook and Twitter channels; the meeting will also be webcast from the FDA website.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- COVID-19 Vaccines (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines)
- Emergency Use Authorization for Vaccines Explained (/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained)
- Emergency Use Authorization for Vaccines to Prevent COVID-19; Guidance for Industry (/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19)

- Development and Licensure of Vaccines to Prevent COVID-19; Guidance for Industry (/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19)
- Vaccines and Related Biological Products Advisory Committee October 22, 2020 Meeting Announcement (/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-22-2020-meeting-announcement)

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