FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Expands Eligibility for COVID-19 Vaccine Boosters

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Today, the U.S. Food and Drug Administration amended the emergency use authorizations (EUA) for both the Moderna and Pfizer-BioNTech COVID-19 vaccines authorizing use of a single booster dose for all individuals 18 years of age and older after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine. The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (https://www.cdc.gov/vaccines/acip/index.html) will meet later today to discuss further clinical recommendations.

"Throughout the course of the COVID-19 pandemic, the FDA has worked to make timely public health decisions as the pandemic evolves. COVID-19 vaccines have proven to be the best and highly effective defense against COVID-19. Authorizing the use of a single booster dose of either the Moderna or Pfizer-BioNTech COVID-19 vaccine for individuals 18 years of age and older helps to provide continued protection against COVID-19, including the serious consequences that can occur, such as hospitalization and death," said Acting FDA Commissioner Janet Woodcock, M.D.

Prior to today's authorizations, a single booster dose of the Moderna and Pfizer-BioNTech COVID-19 vaccines was authorized for administration to individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19 and individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2. Today's action expands the use of booster doses of both vaccines to include all individuals 18 years of age and older at least six months after completion of the primary vaccination series of the Moderna COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine or at least two months after completion of primary vaccination with the Janssen COVID-19 Vaccine.

"The FDA has determined that the currently available data support expanding the eligibility of a single booster dose of the Moderna and Pfizer-BioNTech COVID-19 vaccines to individuals 18 years of age and older," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research. "Streamlining

the eligibility criteria and making booster doses available to all individuals 18 years of age and older will also help to eliminate confusion about who may receive a booster dose and ensure booster doses are available to all who may need one."

Data Supporting Effectiveness

The EUA for a single booster dose for individuals 18 years of age and older for the Moderna (administered as half of the dose of a primary series dose) and Pfizer-BioNTech COVID-19 vaccines is based on the FDA's analysis of immune response data that supported use in the previously authorized populations for boosters.

For the Moderna COVID-19 Vaccine booster dose, the FDA analyzed the immune response data from 149 participants 18 years of age and older from the original clinical studies who received a booster dose at least six months after their second dose and compared it to the immune responses of 1,055 study participants after completing their two-dose series. The antibody response against the SARS-CoV-2 virus 29 days after a booster dose of the vaccine demonstrated a booster response.

For the Pfizer-BioNTech COVID-19 Vaccine booster dose, the FDA analyzed the immune response data from approximately 200 participants 18 through 55 years of age who received a single booster dose about six months after their second dose. The antibody response against the SARS-CoV-2 virus one month after a booster dose of the vaccine when compared to the response one month after the two-dose primary series in the same individuals demonstrated a booster response.

FDA Evaluation of Benefits and Risks

Since Moderna and Pfizer-BioNTech initially submitted safety and effectiveness data on a single booster dose following primary vaccination to the FDA, additional real-world data have become available on the recently increasing number of cases of COVID-19 in the U.S. and on the risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the outer lining of the heart) following vaccination with these vaccines. These additional data enabled the FDA to reassess the benefits and risks of the use of these vaccines in the general adult population. The FDA has determined that the benefits of a single booster dose of either the Moderna or Pfizer-BioNTech COVID-19 vaccines outweigh the risks of myocarditis and pericarditis in individuals age 18 years of age and older when used following completion of primary vaccination to provide continued protection against COVID-19 and the associated serious consequences that can occur including hospitalization and death.

Both Pfizer and Moderna are conducting post-authorization/post-marketing studies to assess known serious risks of myocarditis and pericarditis. In addition, the FDA and the CDC have several systems in place to continually monitor COVID-19 vaccine safety and allow for the rapid detection and investigation of potential safety concerns.

The fact sheets for both vaccines for recipients and caregivers and for healthcare providers contain information about the potential side effects, including the risk of myocarditis and pericarditis. The most commonly reported side effects by individuals who received a booster dose of the vaccines were pain, redness and swelling at the injection site, as well as fatigue, headache, muscle or joint pain and chills. Of note, swollen lymph nodes in the underarm were observed more frequently following the booster dose than after the primary two-dose series.

The FDA did not hold a meeting of the Vaccines and Related Biological Products Advisory Committee on these actions as the agency previously convened the committee for extensive discussions regarding the use of booster doses of COVID-19 vaccines and, after review of both Pfizer's and Moderna's EUA requests, the FDA concluded that the requests do not raise questions that would benefit from additional discussion by committee members.

The amendments to the EUAs were granted to ModernaTX Inc. and Pfizer Inc.

Related Information

- Moderna COVID-19 Vaccine (https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine)
- Pfizer-BioNTech COVID-19 Vaccine (https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine)
- COVID-19 Vaccines (https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines)
- Emergency Use Authorization for Vaccines Explained (https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained)
- News Release: FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations (https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations)
- News Release: Coronavirus (COVID-19) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID-19 Vaccines (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines)

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