

Second Booster Dose of Two COVID-19 Vaccines

On March 29, 2022, the U.S. Food and Drug Administration (FDA) authorized a second booster dose of either the Pfizer-BioNTech or Moderna COVID-19 vaccines for older people and certain immunocompromised individuals. The FDA previously authorized a single booster dose for certain immunocompromised individuals following completion of a three-dose primary vaccination series. This action will now make a second booster dose (or dose #5) of these vaccines available to other populations at higher risk for severe disease, hospitalization and death.

The FDA amended the emergency use authorizations as follows:

- A second booster dose of the Pfizer-BioNTech COVID-19 Vaccine or Moderna COVID-19 Vaccine may be administered to individuals 50 years of age and older at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.
- A second booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered to individuals 12 years of age and older with certain kinds of immunocompromise at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine. These are people who have undergone solid organ transplantation, or who are living with conditions that are considered to have an equivalent level of immunocompromise.
- A second booster dose of the Moderna COVID-19 Vaccine may be administered at least 4 months after the first booster dose of any authorized or approved COVID-19 vaccine to individuals 18 years of age and older with the same certain kinds of immunocompromise.

Following the FDA's regulatory action, the CDC updated its recommendations to allow certain immunocompromised individuals and people over the age of 50 who received an initial booster dose at least 4 months ago to be eligible for another mRNA booster to increase their protection against severe disease from COVID-19.

Separately and in addition, based on newly published data, adults who received a primary vaccine and booster dose of Johnson & Johnson's Janssen COVID-19 vaccine at least 4 months ago may now receive a second booster dose using an mRNA COVID-19 vaccine.

Information to Support Authorization of a Second COVID-19 Booster Dose:

A summary of safety surveillance data provided to the FDA by the Ministry of Health of Israel on the administration of approximately 700,000 fourth (second booster) doses of the Pfizer-BioNTech COVID-19 Vaccine given at least 4 months after the third dose in adults 18 years of age and older (approximately 600,000 of whom were 60 years of age and older) revealed no new safety concerns.

The safety of Moderna COVID-19 Vaccine, when administered as a second booster dose, is informed by experience with the Pfizer-BioNTech COVID-19 Vaccine and safety information reported from an independently conducted study in which the Moderna COVID-19 Vaccine was administered as a second booster dose to 120 participants 18 years of age and older who had received a two-dose primary series and a first booster dose of Pfizer-BioNTech COVID-19 Vaccine at least 4 months prior. No new safety concerns were reported during up to three weeks of follow up after the second booster dose.

Immunogenicity data from an ongoing, open-label, non-randomized clinical study in healthcare workers at a single health center in Israel were reported in a publication provided to the FDA. In this study, individuals 18 years of age and older who had received primary vaccination and a first booster dose with Pfizer-BioNTech COVID-19 Vaccine were administered a second booster dose of Pfizer-BioNTech COVID-19 Vaccine (154 individuals) or Moderna COVID-19 Vaccine (120 individuals) at least four months after the first booster dose. Among these individuals, increases in neutralizing antibody levels against SARS-CoV-2 virus, including delta and omicron variants were reported two weeks after the second booster as compared to 5 months after the first booster dose.

If you have any questions regarding second booster, please, talk to your Provider. To locate a COVID-19 vaccination clinic near you, go to www.vaccines.gov.