

FDA clears Moderna, Pfizer COVID-19 boosters for all US adults

Boosters can be used in all individuals ages 18 and older who have completed a primary vaccination

The Food and Drug Administration on Friday approved requests by COVID-19 vaccine makers Moderna and Pfizer to expand the administration of their booster shots to all U.S. adults.

In a release announcing the news, biotechnology company Moderna said the FDA extended the emergency use authorization of a booster dose of the Moderna COVID-19 vaccine at the 50 µg dose level to all adults aged 18 and older.

The booster can be used in all individuals 18 years and older who have completed a primary vaccination with any other authorized or approved COVID-19 vaccine.

“This emergency use authorization comes at a critical time as we enter the winter months and face increasing COVID-19 case counts and hospitalizations across the country,” Moderna CEO Stéphane Bancel said in a statement. “We thank the FDA for their review, and are confident in the robust clinical evidence that a 50 µg booster dose of mRNA-1273 induces a strong immune response against COVID-19.”

Pfizer, which partnered with BioNTech on the vaccine, said its booster dose is to be administered at least six months after completion of the primary series and is the same dosage strength as the doses in the primary series.

“With boosters, more adults will now have the opportunity to help preserve a high-level of protection against this disease,” Pfizer CEO Albert Bourla said in a statement. “We are grateful to the FDA for their rigorous review, and the action taken today that we hope will help accelerate our path out of this pandemic.”

“Today’s FDA decision is supported by clinical data showing robust immune responses following a booster dose of our vaccine, exceeding what has been seen even after the completion of the highly-effective two-dose primary schedule,”

BioNTech CEO Ugur Sahin said. "These data suggest a booster dose of our vaccine has the potential to maintain a high-level of protection against tested variants, including Delta."

Later Friday, the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) will meet to discuss a potential recommendation for the rollout of COVID-19 boosters to the U.S.

CDC data shows that more than 32 million Americans have already received a booster dose.

Source:

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