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CDC, FDA say booster doses not needed as Pfizer eyes authorization

Pfizer and BioNTech announced positive initial findings from an ongoing trial assessing a booster dose of their COVID-19 vaccine and said they plan to submit the data soon to the FDA.

But federal health officials said a booster program for COVID-19 vaccines is not yet necessary, and that fully vaccinated people are protected against serious illness from all SARS-CoV-2 viruses, including variants.



Pfizer and BioNTech are moving forward with a COVID-19 vaccine booster program.

Source: Adobe Stock.

"Americans who have been fully vaccinated do not need booster shot at this time," the CDC and FDA said in a joint statement, adding that federal health agencies "are engaged in a science-based, rigorous process to consider whether or when a booster may be necessary."

"We continue to review any new data as [they become] available and will keep the public informed," the CDC and FDA said. "We are prepared for booster doses if and when the science demonstrates that they are needed."

In addition to moving forward on a booster program, Pfizer and BioNTech said they are developing an updated COVID-19 vaccine that specifically targets the [highly transmissible delta variant](#), which the CDC said this week has become the [most dominant SARS-CoV-2 virus](#) in the United States. Clinical studies of the updated shot are expected to begin in August.

Data on the efficacy of a booster shot has not undergone peer review, but Pfizer and BioNTech said they would soon release "more definitive data soon" and publish it in a peer-reviewed journal. According to a news release issued by the companies, a [booster dose](#) of the original vaccine given 6 months after the second dose demonstrated "a consistent tolerability profile while eliciting high neutralization titers against the wild type and the Beta variant" — 5 to 10 times higher than after the initial two doses.

The CDC and FDA said the U.S. “is fortunate to have highly effective vaccines that are widely available for those aged 12 and up”

“People who are fully vaccinated are protected from severe disease and death, including from the variants currently circulating in the country such as delta,” they wrote. “People who are not vaccinated remain at risk. Virtually all COVID-19 hospitalizations and deaths are among those who are unvaccinated. We encourage Americans who have not yet been vaccinated to get vaccinated as soon as possible to protect themselves and their community.”

References:

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<https://investors.biontech.de/news-releases/news-release-details/pfizer-and-biontech-provide-update-booster-program-light-delta>. Accessed on July 9, 2021.

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HHS. Joint CDC and FDA statement on vaccine boosters.

<https://www.hhs.gov/about/news/2021/07/08/joint-cdc-and-fda-statement-vaccine-boosters.html>.

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