

# US urges Pfizer to apply for under-5 COVID shots

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Nurse Lydia Holly prepares a child's COVID-19 vaccine dose, on Nov. 3, 2021, at Children's National Hospital in Washington. U.S. regulators are urging drugmaker Pfizer to apply for emergency authorization for a two-dose regimen of its COVID-19 vaccine for children ages 5 and under while awaiting data on a three-dose course, aiming to clear the way for the shots as soon as late February. Credit: AP Photo/Carolyn Kaster, File

U.S. regulators are urging drugmaker Pfizer to apply for emergency authorization for a two-dose regimen of its COVID-19 vaccine for children six months to 5 years old while awaiting data on a three-dose course, aiming to clear the way for the shots as soon as late February, a person familiar with the matter told The Associated Press Monday.

The company's application was expected to be submitted as soon as Tuesday.

Early Pfizer data has shown the vaccine—which is administered to younger kids at one-tenth the strength of the adult shot—is safe and produces an immune response. But last year Pfizer announced the two-dose shot proved to be less effective at preventing COVID-19 in kids ages 2-5, and regulators encouraged the company to add a [third dose](#) to the study on the belief that another dose would boost the vaccine's effectiveness much like booster doses do in adults.

Now, the Food and Drug Administration is pushing the company to submit its application based on the two-dose data for potential approval in February, and then to return for additional authorization once it has the data from the third dose study, which is expected in March, the person familiar with the matter said. The two-step authorization process could mean that [young children](#) could be vaccinated more than a month earlier than previous estimates, assuming the FDA and the Centers for Disease Control and Prevention greenlight the shots.

The person spoke on the condition of anonymity to discuss sensitive regulatory issues. The person said the decreased effectiveness of the two-dose [vaccine](#) was not unexpected given the emergence of the highly transmissible omicron variant of COVID-19. Allowing young kids to be vaccinated with a two-dose shot earlier would ultimately accelerate when they could get the expected stronger protection from a third dose.

Speeding the authorization of pediatric vaccines against COVID-19 has been a priority for more than a year of the Biden administration, which believes them critical to reopening and keeping open schools and day care centers—and for freeing up parents occupied by childcare responsibilities to return to the workforce.

Pfizer's primary series is administered three weeks apart. The third dose for [young kids](#) is being studied for administration at least two months after the second dose.

News of the earlier regulatory review was first reported by The Washington Post.

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