



Moderna asks FDA to authorize COVID vaccine for children under 6 years

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Update 4/29/22: The FDA [tentatively scheduled meetings](#) in June to review several COVID-19 vaccine applications. For the latest news on COVID-19, visit <http://bit.ly/AAPNewsCOVID19>.

Moderna is requesting emergency use authorization (EUA) for its COVID-19 vaccine for children under 6 years and the AAP is urging a thorough, transparent review process to begin as soon as possible.

“For families with young children, the anxiety and frustration of the pandemic is ongoing, as they still lack the protection of a COVID-19 vaccine,” AAP President Moira A. Szilagyi, M.D., Ph.D., FAAP, [said in a statement](#). “We urge the FDA (Food and Drug Administration) and CDC (Centers for Disease Control and Prevention) to move with all possible speed to review the data on the Moderna vaccine, and if it is safe and effective, to authorize it as soon as possible for this age group. Our youngest children deserve to have the same protection from a vaccine as every other group in our society.”

The manufacturer has filed a request with the FDA for a primary series of two 25-microgram (μg) doses. Clinical trial data from 6,700 children found vaccine efficacy of 51% in preventing infection for those ages 6 months through 1 year and 37% for children ages 2 through 5 years, based on cases confirmed by polymerase chain reaction test, according to summary data from a [company press release](#). Both age groups had similar immunogenicity to adults 18 to 25 years, meeting the noninferiority criteria.

Most adverse events were mild or moderate. About 17% of children 6 months through 1 year and about 15% of those 2 through 5 years experienced a fever greater than 38 degrees Celsius (100.4 degrees Fahrenheit).

About 0.2% of each group experienced a fever greater than 40 degrees Celsius (104 degrees Fahrenheit). There were no cases of myocarditis or pericarditis and no deaths.

The FDA's Vaccines and Related Biological Products Advisory Committee is expected to review Moderna's EUA request, but a meeting date has not been announced.

Moderna's COVID-19 vaccine has not been approved for people younger than 18 years. Pfizer-BioNTech vaccine is the only one authorized in the U.S. for adolescents and children as young as 5 years.

Pfizer and BioNTech also are expected to release data this spring on a COVID-19 vaccine for young children. The companies have been studying a three-dose series in children under 5 years after finding a two-dose series with a 3- μ g dosage did not meet noninferiority criteria for those ages 2-4 years.

Earlier this week, the CDC [released data](#) showing about 75% of children and adolescents have evidence of a previous SARS-CoV-2 infection. [Another recent study](#) showed about 87% of children ages 5-11 years hospitalized with COVID-19 this winter were unvaccinated.

Vaccine uptake in children has been slow. Just 28% of children ages 5-11 years are fully vaccinated, [according to CDC data](#).

Resources

- [AAP COVID vaccination resources](#)
- [CDC clinical considerations for administering COVID-19 vaccines](#)
- [Information from HealthyChildren.org on preparing children for a COVID-19 vaccine](#)