

# Pfizer sends first data to FDA on COVID vaccines for younger kids

September 28 2021

---



(HealthDay)—Pfizer Inc. announced Tuesday that it has submitted initial

data to federal regulators on the efficacy of its COVID-19 vaccine among younger children.

The company is also expected to submit the same data on kids aged 5 to 11 to the European Medicines Agency and other regulatory authorities in the next few weeks, *CNN* reported.

Last week, Pfizer released trial data that showed that the vaccine was safe and effective for [children](#) aged 5 to 11. That trial included nearly 2,300 participants who were given two doses of the vaccine 21 days apart.

The U.S. Food and Drug Administration has said that it could authorize a vaccine for [younger children](#) in a matter of weeks after the agency receives trial data. The FDA is expected to vet the vaccine through its panel of expert advisors before authorizing it, *CNN* noted.

If the FDA approves the vaccine for [young kids](#), an [advisory panel](#) to the U.S. Centers for Disease Control and Prevention will then consider whether to recommend its use.

Nearly 28 million children aged 5 to 11 would be eligible for the vaccine in the United States, far more than the 17 million children aged 12 to 15 who became eligible for the vaccine in May, *The New York Times* reported. Only 42% of U.S. kids aged 12 to 15 have been fully vaccinated.

The same may hold true for the younger age group: A survey published last month by the Kaiser Family Foundation found that 26% of parents of children aged 5 to 11 would vaccinate their children immediately after they are eligible, while 40% said they would "wait and see" how the [vaccine](#) worked and 25% said they would not have their child vaccinated at all, the *Times* reported.

Dr. Anthony Fauci, director of the U.S. National Institute of Allergy and Infectious Diseases, told *CNN* that, hopefully, vaccines can go into kids' arms by Halloween.

"The FDA takes very seriously the importance of getting vaccines shown to be safe and effective in children, to getting it into the arms of children, in this case, children from 11 down to 5," Fauci said on *MSNBC's* "Morning Joe" show on Tuesday. "The FDA, you never want to get ahead of their judgment, but I would imagine in the next few weeks, they will examine that data and hopefully they'll give the OK so that we could start vaccinating children, hopefully before the end of October."

Data on the [immune response](#) and safety for children ages 2 to 5, and 6 months to 2 years are expected "as soon as the fourth quarter of this year," Pfizer said, *CNN* reported.

**More information:** Visit the U.S. Centers for Disease Control and Prevention for more on [COVID vaccines](#).

Copyright © 2021 [HealthDay](#). All rights reserved.

Citation: Pfizer sends first data to FDA on COVID vaccines for younger kids (2021, September 28) retrieved 19 November 2023 from <https://medicalxpress.com/news/2021-09-pfizer-fda-covid-vaccines-younger.html>

<p>This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.</p>
--