Pfizer Requests Emergency Use Authorization for COVID Vaccine Booster in Children 5 to 11



Pfizer and BioNTech on Tuesday asked the U.S. Food and Drug Administration (FDA) to authorize the first COVID booster shot for children aged 5 to 11.

In a <u>press release</u>, Pfizer cited data from its Phase 2/3 trial and claimed a third dose produced a "strong immune response" in the younger age group when administered six months after the second dose.

The application was <u>based on data</u> from a small study involving only 140 children 5 through 11 years old who received a booster dose six months after the second dose of Pfizer-BioNTech's COVID vaccine as part of the primary series.

Pfizer said 30 children who participated in the study revealed a 36-fold increase in virus-fighting antibodies

- levels high enough to fight the Omicron variant - although antibody titers are not necessarily predictive of the transmission or severity of disease.

Pfizer <u>claimed</u> a third dose did not demonstrate any new safety concerns in the trial.

The booster shot is a 10-microgram dose, the same dosage as the primary vaccination series for the age group.

According to the <u>Centers for Disease Control and Prevention</u> (CDC), as of April, 72% of parents had chosen not to have their 5 to 11-year-olds vaccinated against COVID.

It is unknown whether the FDA will consult its vaccine advisory panel in making a recommendation for the younger age group, as it bypassed the panel to authorize shots for kids 12 to 15 in January and a fourth shot for people over 50 last month.

Members of the FDA panel as well as the CDC's advisory committee <u>have criticized the agencies</u> for continually moving forward with expanded booster eligibility without consulting them. Several experts on the CDC advisory panel, <u>in a public meeting last week</u>, said trying to stop infections with the current vaccines is an impossible goal.

Pfizer is also seeking FDA authorization for a three-shot vaccine regimen for children under age 5 — the only age group left in the U.S. that is not eligible for vaccination. CEO Albert Bourla <u>last week</u> said he expects the vaccine for the youngest age group to receive authorization in June.