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 press release, 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 based on data 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 claimed 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 Centers for Disease Control and Prevention (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 have criticized the agencies for continually moving forward with expanded booster eligibility without consulting them. Several experts on the CDC advisory panel, in a public meeting last week, 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 last week said he expects the vaccine for the youngest age group to receive authorization in June.