US drug regulator postpones meeting on infant Covid vaccines

Description

USA: The US Food and Drug Administration on Friday announced it would hold a set of meetings on Covid vaccines in June that would include deciding whether to authorize them for the youngest children.

Children five and under are the only group not yet eligible in the United States and most countries, a source of concern for many parents as infections are once more rising due to Omicron's subvariants.

The FDA — considered the gold standard regulatory agency globally — said in a statement it was calling panels of experts to discuss and likely vote on the Pfizer and Moderna vaccines on June 8, 21 and 22.

It was not clear on which dates the agency would consider Pfizer's application to authorize their vaccine in children six months through four years and Moderna's application to authorize their vaccine in children six months through five years.

Moderna is currently only approved for adults aged 18 and up and is also seeking authorization for ages six and up — so one of the dates is reserved for this.

Of the two vaccines, Moderna appears slightly ahead, based on data announced so far.

Its two-dose regimen of 25 micrograms given to babies, toddlers and preschoolers generated similar levels of antibodies as two doses of 100 micrograms given to young people aged 18-25, indicating there would be similar levels of protection.

This was hailed as positive news by experts, who said it would help prevent severe disease, hospitalization, long-term consequences and death.

Pfizer's vaccine, dosed at three micrograms, did not meet its targets when given as two doses. The FDA subsequently asked for data on how it performed with three doses.

Even when they are unvaccinated, children under five are at very low risk for severe disease. There have been only 476 deaths in the United States this age group since the start of the pandemic, according to official data.

Among all US children, there have also been almost 8,000 cases of MIS-C, a post-viral inflammatory condition, that caused 66 deaths.

Separately, FDA panels will consider an application by Novavax for authorization in adults aged 18 and up for its protein subunit Covid vaccine.

On June 28, experts will consider whether the vaccines should be updated for new strains, and if so, which strains should be selected for this fall.

Category

1. Health-Wellness-Healing-Nutrition & Fitness
2. Main
3. Politics-Geopolitics-Gov.-Events
4. Science-Tech-AI-Medical & Gen. Research

Date Created
05/02/2022