Covid-19 vaccine authorization for younger children delayed as FDA seeks more data

(CNN) — Parents will have to keep waiting to find out when their youngest children can get a Covid-19 vaccine.

Pfizer and BioNTech filed a request with the US Food and Drug Administration in the first week of February for an emergency use authorization of their vaccine in children 6 months to 5 years old. The FDA's Vaccines and Related Biological Products Advisory Committee was scheduled to meet February 15 to go over data from vaccine trials and make a recommendation and whether a two-dose vaccine regimen should be authorized.

But the FDA announced Friday that it had postponed the meeting because "new data have recently emerged."

The data supported the safety of the vaccines but showed disappointing effectiveness, the Washington Post reported Friday.

The agency needs to see data from an ongoing trial of a third vaccine dose in these younger children in order to move forward with emergency use authorization, Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, said during a news briefing.

Pfizer and BioNTech said Friday that they expect to have data on three doses available in early April.

Information came in "so rapidly" during the Omicron wave "that at this time, it makes sense for us to wait until we have the data from the evaluation of a third dose before taking action," Marks said.

"The data that we saw made us realize that we needed to see data from a third dose as in the ongoing trial in order to make the determination that we could proceed with doing an authorization."

The delay is a sharp change of pace.

There are about 18 million children ages 6 months through 4 years in the United States who would be eligible for the vaccine. Jeff Zients, the White House's coronavirus response coordinator, said Wednesday that planning was well underway to roll out vaccines, needles and syringes as soon as the FDA made an authorization decision. A US Centers for Disease Control and Prevention planning document posted online had said deliveries could begin

as soon as February 21.

Winding path to authorization

In December, Pfizer said that the vaccine appeared to protect the youngest children -- infants and toddlers up to 2 -- at the same levels seen in teens and young adults, slashing symptoms in 90% of kids who got the shot. However, the 3-microgram dose did not produce the same immune response in 2- to 5-year-olds.

The dose for infants and young children is about one-third of the dose given to children age 5 to 11 and a tenth the size of the dose given to people 12 and older.

At the time, the company decided to expand its trial to include a third dose, rather than the two doses older children and adults receive in a primary vaccine series.

But high rates of infection and illness among children from the Omicron variant have allowed the company to quickly accumulate trial data. At the start of February, while it continued to investigate a third dose, the company said it had decided to submit for authorization of the two-dose vaccine "with pediatric Covid-19 cases surpassing 10 million and at the request of the FDA."
In a news release Friday, Pfizer said it continues to share data from its child vaccine trial with the FDA.

"Given that the study is advancing at a rapid pace, the companies will wait for the three-dose data as Pfizer and BioNTech continue to believe it may provide a higher level of protection in this age group," Pfizer's news release

said. "This is also supported by recent observations of three dose booster data in several other age groups that seems to meaningfully augment neutralizing antibody levels and real world vaccine protection for omicron compared to the two-dose regimen."

Pfizer said the study's independent data monitoring committee supports the continuation of the trial. It believes that the data collected indicates that the vaccine is well-tolerated and supports a potential three-dose regimen.

After the FDA postponed the meeting of its vaccine advisers, Marks said it's important for the agency to stay nimble in the face of a quickly pandemic.

"What we're dealing with is taking the approach that we very much should take as a public health agency, which is to constantly take in the data that come to us and adjust to that," Marks said. "So what we're doing now is adjusting to this, and yes, some of this was late-breaking, but that's what our job is, it's to adjust to it."

Dr. Paul Offit, director of the Vaccine Education Center at Children's Hospital of Philadelphia and a member of the FDA vaccine committee, said he is glad things played out this way.

If the committee had met on Tuesday and voted no, "that would have sent the message to the general public that something's wrong with this vaccine. And then [if] we come back a few months later and vote yes, people may still be suspicious or less likely to take the vaccine up," he said.

"My word to parents who have young children is that this is not a 'no'; it's a 'not yet,' " he added.

Dr. William Schaffner, professor in the Division of Infectious Diseases at Vanderbilt University Medical Center, said that with cases and hospitalizations going down across the country, there is a little more breathing room to look at the data and determine the right vaccine schedule up-front.

"Let's take a step back and take a deep breath. When we recommend 'should we do vaccines for all children aged 6 months to 4 years of age,' we want to be able to communicate to the parents exactly what they can expect regarding effectiveness and safety," said Schaffner, a vaccine advisers to the CDC. "If that takes us a few more days to secure those data, analyze them, think about them and then present them, let's take a few more days, because we want to be able to do this in the best possible way we can."

FDA says it will move as fast as it can

The Covid-19 case load among children has been "extremely high" during the Omicron surge, the American Academy of Pediatrics says. There have been over 7 million child cases reported since September, and more than half of them have come this year.

Children have a lower risk of serious outcomes from a Covid-19 infection compared with elderly or immunocompromised adults. But about 1% of children who catch Covid-19 will be hospitalized. Infections can also lead to long-term consequences in children as they do in adults, increasing the risk for diabetes, autoimmune disease and a delayed reaction to infection called multisystem inflammatory syndrome, which requires hospital care.

Dr. Helen Talbot, an associate professor of medicine in the Division of Infectious Diseases at Vanderbilt, called the decision to delay the meeting "heart-wrenching."

"I think as a scientist, they're going to have more data sooner than they thought and that we'll get to see and analyze and really get to delve into the data that's coming," said Talbot, who is a vaccine adviser to the CDC. "But I can imagine parents with kids less than 5 years of age are just so frustrated, and they're just so ready to have their kids vaccinated."

Marks said he understands that parents are eager to get protection for their young children, and the agency is "absolutely committed to moving as rapidly as we can once we have a submission."

"We take our responsibility for reviewing these vaccines very seriously because we're parents as well, and in looking over the data, I think parents can feel reassured that we have set a standard by which we feel that if something does not meet that standard, we can't proceed forward."

While the additional data are gathered, that means "parents will have to rely on what they've come to do well, which is they're using masking procedures, and they're making sure that they're vaccinated and taking those types of precautions with their youngest children," Marks said. "We will do our part, obviously, to move as fast as we can when we have the data, but for now, we'll have to ask parents to help to continue to do what they've been doing."

CNN's Carma Hassan contributed to this report.