

FDA sets June meetings on COVID vaccines for youngest kids

April 29 2022, by Matthew Perrone

The Food and Drug Administration on Friday set tentative dates in June to publicly review COVID-19 vaccines for the youngest American children, typically the final step before authorizing the shots.

The meeting announcement follows months of frustration from families impatient for a chance to vaccinate their little children, along with complaints from politicians bemoaning the slow pace of the process.

The FDA said it plans to convene its outside panel of vaccine experts on June 8, 21 and 22 to review applications from Moderna and Pfizer for child vaccines. The dates are not final and the FDA said it will provide more details as each company completes its application.

While questions have swirled about what's taking so long, FDA Commissioner Robert Califf emphasized Friday that the agency can't evaluate the vaccines until all the data is submitted.

"There will be no delays," Califf told reporters at a health journalism conference. "We'll review the data, hold an advisory committee meeting and make a decision as quickly as possible once we get the applications."

Currently, only children ages 5 or older can be vaccinated in the U.S. with Pfizer's vaccine, leaving 18 million younger tots unprotected.

On Thursday, Moderna submitted some of its data to the FDA that it hopes will prove its two low-dose shots can protect children younger

than 6. Moderna has filed FDA applications for older kids, but the FDA hasn't ruled on them. It's not clear if that data children will be considered at the June meetings.

Pfizer is soon expected to announce if three of its even smaller-dose shots work for the littlest kids, months after the disappointing discovery that two doses weren't quite strong enough.

On Monday, a top House Democrat requested a briefing from FDA on the status of vaccines for children after media reports that the FDA was considering delaying its work on Moderna's application to jointly review it with Pfizer's at a later date.

The FDA also set a June 7 meeting to review Novavax's COVID-19 vaccine for adults. The Maryland-based company's shots are authorized in Europe and elsewhere but have been delayed by production problems.

The advisory group will also convene June 28 to discuss whether the current U.S. COVID-19 vaccines should be updated to better target coronavirus variants.

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