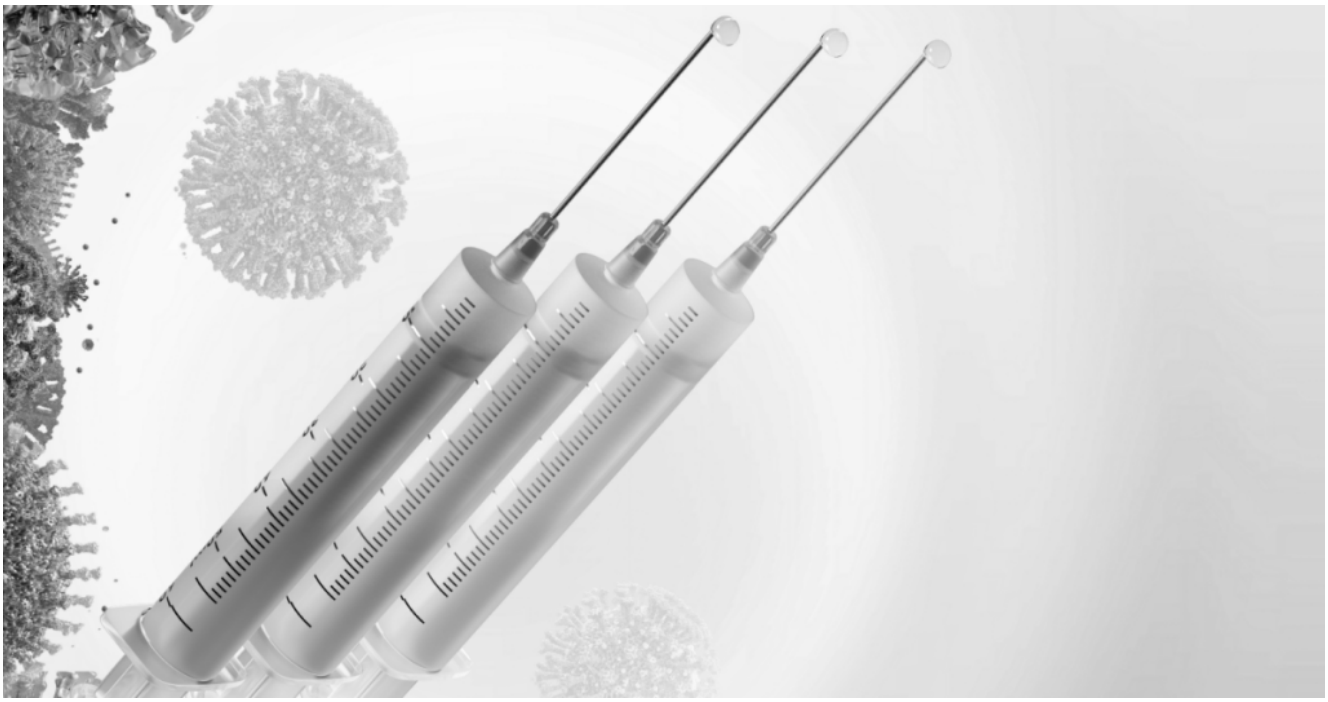
FDA Signs Off on Experimental Bivalent COVID Boosters for Infants and Toddlers Without Safety Data



The U.S. Food and Drug Administration (FDA) on Thursday authorized Pfizer and Moderna's experimental bivalent COVID-19 booster vaccines for children as young as 6 months of age, despite the fact no actual data shows the bivalent shots are safe for the country's youngest age group.

Bivalent boosters were previously authorized for everyone five years of age and older in October.

"More children now have the opportunity to update their protection against COVID-19 with a bivalent COVID-19 vaccine, and we encourage parents and caregivers of those eligible to consider doing so – especially as we head into the holidays and winter months where more time will be spent indoors," FDA Commissioner Robert Califf said in a statement.

“As this virus has changed, and immunity from previous COVID-19 vaccination wanes, the more people who keep up to date on COVID-19 vaccinations, the more benefit there will be for individuals, families and public health by helping prevent severe illnesses, hospitalizations, and deaths,” he added.

The Pfizer/BioNTech booster can now be given to kids 6 months through 4 years who have not received a booster dose after the primary series. Moderna’s bivalent shot can be given to children 6 months through 5 years of age, two months after their 2-dose primary series.

Whereas the original booster targets only the Wuhan strain no longer circulating, the modified booster targets the original strain and the BA.4/BA.5 omicron subvariants soon to be obsolete.

According to the Centers for Disease Control and Prevention, about 63% of COVID-19 cases in the U.S. are now caused by the BQ.1 or BQ.1.1 variants. BA.5 is now only responsible for 14% of cases. So how well will bivalent boosters work against BQ.1 and BQ.1.1 variants? Nobody knows.

No data on bivalent boosters in infants and toddlers

As part of its decision to authorize Moderna’s bivalent booster, the FDA analyzed data from a clinical study comparing the immune response among only 56 study participants 17 months through 5 years of age who received a single booster dose of Moderna’s monovalent COVID-19 vaccine at least six months after completion of a two-dose primary series to the immune response among 300 study participants 18 through 25 years of age who received a two-dose primary series of Moderna’s monovalent vaccine in a previous study that claimed the vaccine is effective in “preventing” COVID-19.

The immune response to Moderna's monovalent booster dose in the 17 months through 5 years age group was comparable to the immune response of the two-dose primary series in the adult participants.

According to the FDA, the safety of a single booster dose of Moderna's bivalent booster for children 6 months through 5 years of age was supported by "safety data" from a clinical trial on an experimental bivalent booster targeting an entirely different strain of omicron (BA.1) the primary booster dose clinical trial safety data involving a mere 145 participants and supposed "postmarketing safety data" on monovalent and bivalent Moderna vaccines.

The FDA's authorization of Pfizer's bivalent booster was based on previous analyses of the effectiveness of primary vaccination with the monovalent Pfizer vaccine in individuals 16 years of age and older and individuals 6 months through 4 years of age and previous analyses of immune response data in adults greater than 55 years of age who received a two-dose primary series and one Pfizer monovalent booster dose and a second booster dose with the experimental Pfizer bivalent booster targeting the original and BA.1 strains.

The safety of Pfizer's bivalent booster shot in children 6 months through 4 years of age is based on safety data from a clinical study that evaluated a different Pfizer booster (original and BA.1) in individuals 55 years and older, safety data from clinical trials which evaluated primary vaccination in individuals 6 months of age and older with the monovalent Pfizer vaccine, safety data from clinical trials that evaluated the original Pfizer booster in kids 5 years of age and older and postmarketing safety data with the monovalent and bivalent Pfizer vaccines.

According to the FDA's press release, the agency's decision was not based on safety or efficacy data on the actual bivalent COVID-19 booster authorized for infants and children.