FDA Authorizes Modified COVID Boosters Without Human Clinical Trials

The Food and Drug Administration (FDA) on Wednesday authorized modified COVID-19 booster shots without requiring any human clinical trials to be completed to determine the safety or efficacy of the experimental shots.

"We have worked closely with the vaccine manufacturers to ensure the development of these updated boosters was done safely and efficiently. The FDA has extensive experience with strain changes for annual influenza vaccines. We are confident in the evidence supporting these authorizations," said Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research.

"The public can be assured that a great deal of care has been taken by the FDA to ensure that these bivalent COVID-19 vaccines meet our rigorous safety, effectiveness and manufacturing quality standards for emergency use authorization."

Pfizer's new booster is authorized for people aged 12 and older, while Moderna's is authorized for adults 18 and older. Older versions of the COVID-19 vaccines will still be given as the primary series, but will not be given as booster doses, according to the FDA.

The Centers for Disease Control and Prevention (CDC) still has to "sign off" on the boosters before people can receive them, but this is a mere formality.

The CDC's vaccine advisory committee will meet Thursday and Friday to review the data and issue its recommendations for healthcare providers.

The new boosters target both the original Wuhan strain that emerged more than 2 years ago and is no longer circulating in the U.S and omicron BA.4 and BA.5 subvariants, which are now the dominant variants in the U.S. – but will no longer be dominant in the near future.

Because the Biden administration bypassed the regulatory process to push for a fall booster campaign to begin in September, Pfizer/BioNTech and Moderna "didn't have time" to conduct proper safety studies of the reformulated boosters in people. Instead, they relied on tests in mice.

The only human trial data the FDA considered was in regard to the original Omicron BA.1 strain, according to a tweet from FDA commissioner Dr. Robert Califf.

The lack of data on humans means officials won't know whether the new shots "work" or are "safe" until after thousands and potentially millions of people have received the booster.

But don't worry, "There's no reason to think they'll be unsafe," said Dr. Celine Gounder, an infectious disease specialist at NYU Langone Health.

The FDA claims its decision to consider COVID boosters without

human data is in line with how it evaluates the influenza vaccine each year.

Clinical studies in humans aren't required for the approval of seasonal influenza vaccines, even when they're reformulated for strain changes, said Dr. Jesse Goodman, former FDA vaccine chief.

Dr. Paul Offit, a member of the FDA's vaccine advisory panel said it's not fair to compare COVID-19 vaccines to the flu vaccine.

The FDA's policy on influenza shots is based on decades of experiences with strain changes whereas the flu vaccines behaved generally in the same way. The mRNA COVID-19 vaccines were not authorized until December 2020.

The agency is making "huge assumptions" in its consideration of the new COVID-19 boosters, Offit said, adding it's likely the new shots may not be any more effective than the existing vaccines.

According to the latest data from the Vaccine Adverse Event Reporting System (VAERS), between Dec. 14, 2020, and Aug. 19 there were 1,390,597 adverse events, including 30,479 deaths reported following COVID-19 vaccines.

Historically, VAERS has been shown to report only 1% of actual vaccine adverse events.

Thus far, both the FDA and CDC have completely ignored the alarming safety signals in VAERS in favor of fast-tracking experimental vaccines that now, aren't even being subjected to human clinical trials.