

U.S. FDA to use existing Omicron booster data to review shots targeting new subvariants -official

[Michael Erman](#) July 1, 2022 1:16 AM GMT+2 Last Updated 5 days ago

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NEW YORK, June 30 (Reuters) - U.S. health regulators will not require companies to submit new clinical trial data on COVID-19 vaccines that target the now dominant BA.4 and BA.5 Omicron subvariants to authorize those shots, but will instead rely on studies showing the efficacy of targeting the earlier BA.1 subvariant, a top official said on Thursday.

Dr. Peter Marks, a senior official overseeing vaccines at the U.S. Food and Drug Administration, told Reuters the agency would also consider manufacturing data specific to a BA.4 and BA.5 vaccine, and that preclinical data from animal studies and safety data for those shots could also be available.

The FDA on Thursday recommended COVID-19 vaccine manufacturers Pfizer Inc ([PFE.N](#))/BioNTech SE and Moderna Inc ([MRNA.O](#)) change the design of their booster shots beginning this fall to include components tailored to combat BA.4 and BA.5. It plans to review them for emergency use authorization. [read more](#)

"It's very similar to what we do with influenza strain changes where there will be a couple of amino acids difference, but we don't expect any difference in the safety that we're going to see," Marks said.

He said he expects the immune response to the BA.4/5 booster shot to be similar to that seen with BA.1.

"We're very comfortable doing this, because it will help us get ahead of

things," Marks said.

The FDA has directed manufacturers to launch human clinical trials to study the BA.4/5 vaccines, but said that data will be used to gauge the continued effectiveness of the boosters against new variants that may arise.

Marks said he believes regulators from other countries are seriously considering using BA.1-based vaccines, which some drugmakers have already been producing and may be available sooner.

"I will tell you that globally - just so you understand - different regulators feel different levels of comfort with this," Marks said.

He said the United States should run a wider vaccination campaign this fall than the one in the spring, when the focus was on older and other high-risk people.

"I actually think that this fall we have to go all out on our booster campaign," Marks said.

"It's going to be really critical as we move into this fall where we've seen this evolution into BA4/5, where we could see further evolution, to try to get as many people boosted as we can."

Reporting by Michael Erman Editing by Bill Berkrot and Rosalba O'Brien

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