FDA will not require clinical trial data to authorize redesigned COVID boosters -official

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NEW YORK, June 30 (Reuters) - The U.S. Food and Drug Administration will not require companies to submit clinical trial data on COVID-19 vaccines modified to protect against the BA.4 and BA.5 Omicron subvariants in order to authorize those shots, a top FDA official said on Thursday.

Dr. Peter Marks, head of the agency's Center for Biologics Evaluation and Research, told Reuters the agency will rely on data from clinical trials vaccine makers have run on shots designed to combat the BA.1 Omicron variant, as well as manufacturing data, for emergency use authorization submissions before the fall.

Preclinical data from animal studies and safety data could also be available, he said.

The FDA on Thursday recommended COVID-19 vaccine manufacturers change the design of their booster shots beginning this fall to include components tailored to combat the currently dominant Omicron BA.4 and BA.5 subvariants of the coronavirus. read more

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.

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

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