



My View Following Saved

July 1, 2022 · 5:56 AM GMT+8
Last Updated a day ago

< COVID-19 Health >

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

By Michael Erman

2 minute read





The corporate logo of the U.S. Food and Drug Administration (FDA) is shown in Silver Spring, Maryland, November 4, 2009. REUTERS/Jason Reed

NEW YORK (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 versions of Omicron 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 lineage, as well as manufacturing data, for emergency use authorization submissions before the fall.

Advertisement · Scroll to continue

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

Reuters.com

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 sublineages.

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.

Advertisement · Scroll to continue

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."

Register now for FREE unlimited access to

Register