

FDA questions strength of Johnson & Johnson's booster shot data

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In a development that could mean Johnson & Johnson might encounter

resistance over its application for authorization of a booster shot of its coronavirus vaccine, a new analysis filed by the U.S. Food and Drug Administration on Wednesday suggests the company's evidence may not be strong enough for approval.

A key test used by the company to measure [immune response](#) from a [booster shot](#) six months after the original shot was likely not sensitive enough, according to the FDA analysis. The agency also questioned whether the boost in immune response was as big as the data suggested.

"It is likely that the results seen are due to the low sensitivity of the psVNA assay used," the agency stated in its report.

Also, the agency said that it didn't have enough [time](#) before Friday's meeting on the J&J booster shot to independently review much of the raw data from a number of company [trials](#) on the booster.

About 15 million Americans have received the J&J vaccine, and now it's not clear if they'll be given the [green light](#) to get a booster shot of the same vaccine, or will have to get one using another vaccine, *The New York Times* reported.

In its application for booster shot approval, Johnson & Johnson included the results of a large-scale trial that began last November, in which they gave half their volunteers a second dose two months after the first. The other half received a placebo.

In August, the company said the U.S. portion of that trial showed an overall efficacy rate of 94%, but the FDA analysis focused on the worldwide results, in which the increase rose to 75%, the *Times* reported.

Against severe to critical COVID-19, two shots had an efficacy of 100%. But regulators warned in the analysis that there was little data

from that trial on the highly contagious Delta variant, which now causes the vast majority of infections in the United States.

The FDA did note the company trial showed a potential boost in protection from a J&J booster given two months after the first shot.

"Although not independently confirmed by FDA from datasets, summaries of the data suggest there may be a benefit in a second dose administered approximately 2 months after the primary dose," the agency said.

A Johnson & Johnson spokesperson did not immediately respond to a request for comment on the FDA analysis, the *Times* said.

The FDA has already approved a booster shot for Pfizer's [COVID-19 vaccine](#) for people who are older than 65 or have health conditions or workplace exposures that put them at risk.

Moderna has also submitted a [booster](#) shot application that will be evaluated by FDA advisers on Thursday, the *Times* reported.

More information: Visit the U.S. Food and Drug Administration for more on [COVID vaccines](#).

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