

# Pfizer asks FDA to approve omicron-specific booster shot

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The BA.5 subvariant accounts for nearly 90 percent of new U.S. COVID-19 cases, [according to](#) the U.S. Centers for Disease Control and Prevention.

The FDA plans to review the data in September. If authorized, the vaccine can be distributed immediately, *NBC News* reported. Harvard epidemiologist Bill Hanage, Ph.D., told the news outlet that the turnaround time for this new vaccine was "remarkably quick." It usually takes years for vaccines to be developed and distributed, and the latest omicron subvariants only began spreading in the United States widely in early June.

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Pfizer Inc. said Monday that it has asked the U.S. Food and Drug Administration to approve the emergency use of an updated booster shot that targets several versions of the omicron variant.

Animal studies show that the new mRNA vaccine produces an [immune response](#) against both the BA.4 and BA.5 subvariants, with [clinical trials](#) set to begin this month, the company said in a [news release](#) announcing the application.

"The agility of the mRNA platform, together with extensive clinical experience with the Pfizer-BioNTech COVID-19 Vaccine, has allowed us to develop, test, and manufacture updated, high-quality vaccines that align to circulating [strains](#) with unprecedented speed," Pfizer Chairman and CEO Albert Bourla said in the news release. "Having rapidly scaled up production, we are positioned to immediately begin distribution of the bivalent omicron BA.4/BA.5 boosters, if authorized, to help protect individuals and families as we prepare for potential fall and winter surges."

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