

US gives full approval to Moderna's COVID-19 vaccine

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U.S. health regulators on Monday granted full approval to Moderna's COVID-19 vaccine, a shot that's already been given to tens of millions of Americans since its emergency authorization over a year ago.

The action by the Food and Drug Administration means the agency has completed the same rigorous, time-consuming review of Moderna's shot as dozens of other long-established vaccines.

The decision was bolstered by real-world evidence from the more than 200 million doses administered in the U.S. since the FDA cleared the shot in December 2020. The FDA granted full approval of Pfizer's vaccine last August.

Public health advocates initially hoped the regulatory distinction would boost public confidence in the shots. But there was no discernable bump in vaccinations after the Pfizer approval, which was heavily promoted by President Joe Biden and other federal officials. Still, regulators said Monday they hoped the extra endorsement would encourage more people to get vaccinated.

More than 211 million Americans, or 63% of the total population, are fully vaccinated. About 86 million people have gotten a booster dose. Vaccinations peaked last spring at more than 3 million per day, and now average less than 750,000 per day. The pace of vaccinations briefly spiked following news of the omicron variant in December but has since slowed again.

The FDA reviewed months of additional follow-up data submitted by Moderna to confirm the vaccine's effectiveness against COVID-19. The FDA also analyzed and kept watch for serious side effects that have proved to be very rare. The vaccine includes a warning about a rare type of heart inflammation that mostly occurs in young men following the second dose. Most cases are mild and resolve quickly.

Additionally, FDA reviewed the company's manufacturing process and facilities.

"The public can be assured that this vaccine was approved in keeping with the FDA's rigorous scientific standards," said Dr. Peter Marks, FDA's top vaccine regulator, in a statement.

With full approval, Moderna will now market the vaccine under the brand name, Spikevax. It is the first FDA-approved product for the Cambridge, Massachusetts-based company.

In the U.S., Moderna is used only by adults, for initial vaccination and as a half-dose booster. The company said last fall that FDA had delayed deciding whether to clear the shots for 12- to 17-year-olds as it examined the heart inflammation risk.

Johnson & Johnson has not yet applied for full approval of its COVID-19 vaccine.

Also Monday, Novavax Inc. formally requested FDA authorization of a different type of COVID-19 vaccine, in hopes of becoming the fourth U.S. option.

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