

US FDA approves Moderna's next-generation COVID vaccine for adults 65 or older

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Bengaluru: The U.S. Food and Drug Administration has approved Moderna's next-generation COVID-19 vaccine for everyone aged 65 and above, the company said on Saturday, the first endorsement since the

regulator tightened requirements.

The vaccine has also been approved for people aged 12 to 64 with at least one or more underlying risk factors, Moderna said in a statement.

Moderna said it expects to have the vaccine, called mNEXSPIKE, available for the 2025-2026 respiratory virus season.

"The FDA approval of our third product, mNEXSPIKE, adds an important new tool to help protect people at high risk of severe disease from COVID-19," CEO Stephane Bancel said in the statement.

The Department of Health and Human Services, under the leadership of long-time vaccine skeptic Robert F. Kennedy Jr., is increasing regulatory scrutiny on vaccines.

The FDA said on May 20 it planned to require drugmakers to test their COVID booster shots against an inert placebo in healthy adults under 65 for approval, effectively limiting them to older adults and those at risk of developing severe illness.

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The Centers for Disease Control and Prevention, which Kennedy also oversees, said on Thursday that COVID vaccines remain an option for healthy children when parents and doctors agree that it is needed, stopping short of Kennedy's announcement days earlier that the agency would remove the shots from its immunization schedule.

The CDC announcement eases investor concern to some extent, analysts say, as it keeps the existing framework for older adults and at-risk people who generally seek out the shots.

Moderna is betting on its newer messenger RNA vaccines as it grapples with waning demand for its original COVID vaccine Spikevax and lower-than-expected uptake of its respiratory syncytial virus vaccine.

The approval for mNEXSPIKE was based on late-stage trial data, which showed the shot was not inferior in efficacy compared to Spikevax in individuals aged 12 years and older.

The shot also showed superior efficacy compared to Spikevax in adults 18 years of age and older in the study.

News Source:

https://pharma.economictimes.indiatimes.com/news/drug-approvals-and-launches/modernas-mnexspike-covid-vaccine-approved-for-seniors-65-and-older-by-fda/121530583?utm_source=whatsapp_web&utm_medium=social&utm_campaign=socialsharebuttons