

FDA approves Novavax COVID vaccine with new conditions

According to the approval letter, the license restricts the use of the vaccine called Nuvaxovid to individuals aged 65 and older, and those between 12 and 64 who have at least one underlying condition that increases their risk of developing severe illness from COVID.



Bengaluru: The U.S. Food and Drug Administration on Friday approved Novavax's COVID-19 vaccine, but placed additional conditions on individuals who would be able to receive the vaccine.

According to the approval letter, the license restricts the use of the vaccine called Nuvaxovid to individuals aged 65 and older, and those between 12 and 64 who have at least one underlying condition that increases their risk of developing severe illness from COVID.

The letter did not specify what qualified as an underlying condition.

The FDA also deferred submission of pediatric studies from birth to less than 12 years for the application, as pediatric studies had not been completed.

Novavax CEO John Jacobs said the approval was a "significant milestone" that solidifies a path for people to access the vaccine.

The vaccine's prospects were thrown into doubt after the FDA missed its April 1 target to approve the shot. U.S. Health and Human Services Secretary Robert F. Kennedy Jr. attributed the delay to the shot's composition in a CBS interview earlier that month.

Novavax, whose protein-based shot uses an older technology, missed out on the pandemic vaccine windfall - enjoyed by rivals Moderna and Pfizer which make messenger RNA-based vaccines - due to manufacturing issues and regulatory hurdles. (Reporting by Chandni Shah and Rajveer Singh in Bengaluru Editing by Shri Navaratnam)

News Source:

<https://pharma.economictimes.indiatimes.com/news/drug-approvals-and-launches/fda-approves-novavax-covid-vaccine-with-new-conditions/121245439>