

US FDA reverses course, will review Moderna's flu vaccine application

In an unusually public display of corporate and regulatory wrangling, Moderna last week disclosed the contents of the FDA's refusal to review letter, and said the agency had approved the flu vaccine trial's design as adequate when the study was initiated 18 months earlier.



Bengaluru: Moderna said on Wednesday the U.S. Food and Drug Administration changed course and will review its new flu vaccine, a week after rejecting the original submission and fueling drugmaker and

investor concerns over policy changes at the agency under the administration of President Donald Trump.

Shares of the vaccine maker rose nearly 6% on Wednesday after falling as much as 12% just after the FDA refusal became public. The FDA is now expected to make a decision on the vaccine by August 5.

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FDA Commissioner Dr. Marty Makary defended the move on television and senior FDA officials held a press briefing in which they said the company was putting patients at risk by not giving a higher-strength vaccine to older participants in the control arm of its trial.

Moderna said it met with the FDA on Tuesday to discuss the vaccine and afterward, the U.S. regulator accepted a revised application seeking full approval of the shot for adults ages 50 to 64, and accelerated approval for those aged 65 and above, which would require a post-marketing confirmatory study to gain regular approval.

A spokesman for the U.S. Department of Health and Human Services, which includes the FDA, said "discussions with the company led to a revised regulatory approach and an amended application, which FDA accepted."

Moderna said it agreed to conduct the additional study in older adults once the vaccine is approved.

Under the leadership of Health Secretary and longtime anti-vaccine activist Robert F. Kennedy Jr., the FDA and Centers for Disease Control and Prevention have shifted their approach to vaccine oversight, and upended longtime childhood vaccine schedules.

LEVERAGING PUBLIC PRESSURE

The FDA's initial refusal and quick reversal amplified concerns about shifting U.S. vaccine policy under the Trump administration, which has contributed to falling vaccination rates and reshaped the regulatory landscape for new shots.

Leerink Partners analyst Mani Faroohar called the dispute's public airing uncommon and said the agency's quick reversal could mean Moderna has the tools going forward to "effectively leverage public pressure" against mRNA skeptics at the FDA.

Kennedy, a prominent critic of mRNA technology, which underpins Moderna's and most other COVID-19 vaccines, also oversaw the cancellation of a \$600 million government contract to develop mRNA vaccines for bird flu and other high-risk strains.

Makary and Vinay Prasad, head of the FDA's biologics and vaccines department, have both criticized COVID vaccines and policies. The FDA has narrowed approvals for mostly mRNA-based COVID vaccines and is reviewing deaths that it says may be linked to those shots.

Citi analyst Geoff Meacham said the FDA's about-face on Moderna's application "potentially brings back a revenue stream which had been in limbo."

SENSIBLE APPROACH FOR APPROVAL

Dr. Jesse Goodman, former FDA chief scientist, called the approach the agency finally settled on very sensible, but said it was a "really badly done process" to get there.

If FDA had strong ethical concerns about the design of the trial it should have intervened before Moderna ran the study, Goodman said.

Pending approval, Moderna said it expects to make its flu shot available for the 2026/2027 flu season.

News Source:

<https://pharma.economictimes.indiatimes.com/news/regulatory-update/us-fda-reverses-course-will-review-modernas-flu-vaccine-application/128534169>

