HUGE: FDA Recommended Authorizing Novavax C-19 Vaccine Regardless Of Myocarditis Risks!

Description

USA: The US FDA panel experts suggested authorizing the Novavax C-19 vaccine in a federal advisory committee this Tuesday.

The advisers didn't pay attention to the latest assessment released by the agency. Previously the FDA shared a report about the causal relationship between the Novavax vaccine and heart inflammation or myocarditis.

In the FDA documents, we can see that there were reported many events of myocarditis/pericarditis after the Novavax vaccine application, raising concern about a possible risk of heart inflammation from the vaccine.

"Multiple events of myocarditis/ pericarditis were reported in temporal relationship to NVX-CoV2373 administration, similar to myocarditis following mRNA COVID-19 vaccines and raising concern for a causal relationship to NVX-CoV2373. Events of lymphadenopathy were infrequent but reported by a higher proportion of participants in the NVX arm, with the highest rate observed after Dose 2 (0.2%). Review of the data also identified small imbalances in certain thromboembolic events, including cardiac and neurovascular events, hypersensitivity events, cholecystitis, uveitis, cardiac failure, and cardiomyopathy," according to the documents.

"Data from passive surveillance during post-authorization use in other countries also indicate a higher-than-expected rate of myocarditis and pericarditis (mainly pericarditis) associated with the vaccine," the documents added.

The FDA's panel experts voted 21-0 to give the shot an authorization for use among adults 18+ in the US. The committee voted this way, stating the benefits outweigh the risks of developing myocarditis.

CNBC has more:

The FDA's committee of independent vaccine experts voted 21 to 0 with one abstention to recommend authorization of the shot for use in the U.S. after an all-day public meeting in which they weighed safety and effectiveness data. The FDA usually follows the committee's recommendations, though it is not obligated to do so. The agency could clear Novavax's vaccine for distribution in the U.S. as soon as

this week.

The Centers for Disease Control Prevention would still need to sign off on the shots before pharmacies and other health-care providers can start administering them to people.

Novavax's shot would be the fourth Covid vaccine authorized for use in the U.S. The Maryland biotech company's shots are based on protein technology that's been in use for decades in vaccines against hepatitis B and HPV. The technology differs from Pfizer and Moderna's shots, which were the first ones using messenger RNA technology to receive FDA approval.

Dr. Peter Marks, who leads the FDA office responsible for reviewing vaccine safety and effectiveness, said Novavax's vaccine would potentially appeal to people who have not gotten immunized yet because they would rather receive a shot that is not based on the mRNA technology used by Pfizer and Moderna. Though Johnson & Johnson's shot is also available, the CDC has restricted its use due to a risk of blood clots primarily in women.

by Addison Wilson

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