NEWS BRIEF

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FDA Says Johnson & Johnson COVID-19 Vaccine Is Safe and Effective

The U.S. Food and Drug Administration (FDA) recently released an <u>analysis</u> that found that Johnson & Johnson's COVID-19 vaccine is safe and effective. According to the FDA, the vaccine meets requirements for an Emergency Use Authorization (EUA).

The vaccine, developed by Janssen Biotech Inc., a subsidiary of Johnson & Johnson, has been found to have 72% efficacy in the United States, while proving less effective in Latin America and South Africa, where a highly contagious variant is behind most new cases. The vaccine has also demonstrated 86% efficacy against severe forms of COVID-19 in the United States, with 82% against severe outcomes in South Africa.

According to the FDA, there were no specific safety concerns identified in subgroup analyses by age, race, ethnicity, medical comorbidities or prior SARS-CoV-2 infection.

This analysis confirms that Americans will likely soon have a third effective coronavirus vaccine. Importantly, the Johnson & Johnson COVID-19 vaccine is for individuals age 18 and older, and notably, requires only one dose, as opposed to the Moderna and Pfizer-BioNTech vaccines, which require two doses. The vaccine can also be stored at standard refrigeration temperatures for at least three months, while other vaccines approved for emergency use have stricter refrigeration and storage requirements.

Johnson & Johnson COVID-19 Vaccine Approval and Distribution

On Feb. 4, 2021, a request for an EUA for the Johnson & Johnson vaccine was submitted to the FDA. After these findings, the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet on Friday, Feb. 26 to discuss an EUA for the vaccine. The FDA is largely expected to issue an EUA, and could do so as soon as Saturday, Feb. 27, depending on its vote from its vaccine advisory panel, which would recommend an EUA for the vaccine.

If the vaccine receives an EUA, there are around 4 million doses ready to be distributed immediately. Johnson & Johnson plans on providing 20 million shots in the next month and 100 million over the summer.

Employers should continue to monitor updates from local officials for vaccine availability. Kinloch Consulting Group, Inc. will keep you updated on any noteworthy developments.



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