

GOVERNMENT

FDA grants full approval to COVID-19 vaccine

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Based on results from the clinical trial, the Comirnaty vaccine was 91 percent effective in preventing COVID-19 disease. Image credit: U.S. Center for Disease Control

By LUXURY DAILY NEWS SERVICE

The **U.S. Food and Drug Administration** (FDA) has fully approved the first COVID-19 vaccine, the Pfizer-BioNTech inoculation.

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The dose will now be marketed as the Comirnaty vaccine, which will be used for people 16 and older to prevent COVID-19. This is the first vaccine to move beyond emergency use status in the United States, and comes in tandem with several organizations, hospitals and businesses implementing vaccine requirements and/or policies.

"The FDA's approval of this vaccine is a milestone as we continue to battle the COVID-19 pandemic," said Janet Woodcock, M.D., acting FDA commissioner, in a statement. "While this and other vaccines have met the FDA's rigorous, scientific standards for emergency use authorization, as the first FDA-approved COVID-19 vaccine, the public can be very confident that this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product."

Vaccines and moving forward

The Pfizer-BioNTech COVID-19 vaccine has been available under emergency use authorization (EUA) since December 2020. The **FDA** can implement EUAs during public health emergencies to provide access to medical products that may be effective in preventing, diagnosing or treating a disease, after the FDA determines the benefits of that product outweigh any perceived risks.

In the FDA's review for approval, the agency reviewed data from the clinical trial and included a follow-up in a larger clinical trial population. The agency analyzed effectiveness data from approximately 20,000 vaccine and 20,000 placebo recipients ages 16 and older who did not have evidence of the COVID-19 virus infection within a week of receiving the second dose.

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The first FDA-approved vaccine comes on the heels of rising global concern regarding the delta variant of the virus. With most of the United States experiencing high or substantial rates of COVID-19 transmission, shifts in consumer sentiment and spending may have fallout for the luxury retail sector.

In a matter of weeks, the state of the pandemic has worsened in the U.S. to the point that more cities and businesses have turned to new mask mandates or vaccination requirements. Major companies, including tech giants and banks, have also pushed back plans to reopen offices further threatening the tenuous economic recovery ([see story](#)).

Disparate states, organizations and companies have also begun to implement specific masks and vaccination policies, with some requiring proof of vaccination in order to gain entry.



Equinox Hotels will be requiring proof of COVID-19 vaccination. Image credit: Equinox

Equinox Hotels, the hospitality arm of luxury fitness club Equinox, will be requiring proof of COVID-19 vaccination for all guests starting next month.

The move is in line with New York's new indoor vaccine mandate, announced on Aug. 3. As the delta variant contributes to rising COVID-19 cases and hospitalizations, more hospitality brands, retailers and other businesses are requiring proof of vaccination or reinstating mask policies ([see story](#)).