

Health Information Compliance Alert

FDA Gives Pfizer Vaccine Full Approval

This may alleviate COVID vaccination mandate stress.

If your organization is swamped with COVID-19 vaccine questions, prepare yourself. One recent update may quadruple patient - and staff - inquiries.

Why? On Aug. 23, the Food and Drug Administration (FDA) moved the Pfizer-BioNTech COVID-19 Vaccine from its emergency use authorization (EUA) status to fully approved for individuals 16 and up. The vaccine is rebranded under a new name, "Comirnaty," which may confuse consumers.



But: The Pfizer vaccine will retain its EUA status for "individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals," an FDA release said.

"While millions of people have already safely received COVID-19 vaccines, we recognize that for some, the FDA approval of a vaccine may now instill additional confidence to get vaccinated," said Acting FDA Commissioner **Janet Woodcock, MD**, in a release on the change.

Experts suggest that this may decrease vaccine hesitancy. "Full approval may be welcome news to some employers, as EUA status has reportedly been a driver of hesitancy among some 30 percent of unvaccinated employees," explain attorneys **Jennifer Nelson Carney, Christopher Page**, and **James Petrie** with law firm Bricker & Eckler LLP. "Full approval also reduces employers' legal risk in mandating vaccines," Nelson Carney, Page, and Petrie point out in online legal analysis.

The FDA, in coordination with the Centers for Disease Control and Prevention (CDC), plans to continue its extensive safety monitoring of the Comirnaty COVID-19 Vaccine, but assures the "public and medical community [they] can be confident that although we approved this vaccine expeditiously, it was fully in keeping with our existing high standards for vaccines in the U.S.," indicated **Peter Marks, MD, PhD**, director of FDA's Center for Biologics Evaluation and Research, in the FDA release.

Resource: See the timeline and find more information on the Comirnaty COVID-19 Vaccine at www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine.