



## FDA Considers Revoking Pfizers COVID-19 Authorization



*The main entrance of FDA's Building 1, which houses the Commissioner's and Senior Staff's offices. The FDA campus is located at 10903 New Hampshire Ave., Silver Spring, MD 20993.*

*Photo courtesy of: The U.S. Food and Drug Administration*

WASHINGTON, D.C. – On Wednesday, August 13, 2025, the Food and Drug Administration (“**FDA**”) declared that they are considering revoking the authorization given to Pfizer’s COVID-19 vaccine for healthy children younger than 5 years of age. This could make the upcoming winter season much more difficult for parents, as it would create another barrier for them to access the vaccine for their children during peak respiratory virus season. Currently, this vaccine is available for use under an emergency use authorization (“**EUA**”) as a measure to protect children during the COVID pandemic.

In a statement released by Pfizer, the company stated the FDA’s consideration has nothing to do with the safety or efficacy of the vaccine, and that it expects approval for using their vaccine for children ages 5 to 11, just as Moderna and Novavax. Furthermore, Pfizer’s COVID-19 vaccine has been approved for children 12 or older since 2022.

However, it must be noted that it is not unusual for the FDA to revoke EUA authorizations if there are competitors with similar products that have gained approval, and Pfizer specifically has yet to apply for full approval for their COVID-19 vaccine.