Moderna Asks FDA to Authorize Fourth COVID Vaccine Dose for Adults 18 and Older



Moderna asked the U.S. Food and Drug Administration (FDA) on Thursday to <u>amend Emergency Use Authorization</u> (EUA) of its COVID-19 vaccine to include a fourth dose for adults 18 and older.

The <u>request</u> is broader than Pfizer's, who earlier this week asked the agency to authorize a fourth dose of its COVID vaccine for adults 65 and older based on non-peer-reviewed data from Israel.

In a <u>press release</u>, Moderna said the request to include adults over 18 was made "to provide flexibility for the U.S. Centers for Disease Control and Prevention and healthcare providers to determine the appropriate use of an additional booster dose of mRNA-1273, including for those at higher risk of COVID-19 due to age or comorbidities."

Moderna <u>said its decision</u> to seek FDA approval was based on

studies from the U.S. and Israel about the Omicron variant but didn't provide further information. Booster doses of Moderna are half the dose of the first and second doses.

The <u>Centers for Disease Control and Prevention</u> currently recommends a primary series of two doses of the Moderna vaccine and a booster dose six months after completing the primary series. Moderately to severely immunocompromised people are supposed to get an additional primary shot (third dose) at least 28 days after their second shot, followed by a booster (fourth dose).

There is no long-term data on the safety or efficacy of COVID booster doses.