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FDA Approves Pfizer COVID-19 Boosters for Older and At-Risk People

Today, 23 September, the US FDA amended the EUA for the Pfizer-BioNTech COVID-19 Vaccine to permit a booster dose for those who are 65 years and older, who are at risk for severe disease, and whose professions bring them occupational exposure. This booster dose can be administered at least six months after completion of the primary two-dose regimen.

In an FDA press release, acting FDA Commissioner, Dr Janet Woodcock, said: “After considering the totality of the available scientific evidence and the deliberations of our advisory committee of independent, external experts, the FDA amended the EUA for the Pfizer-BioNTech COVID-19 Vaccine to allow for a booster dose in certain populations such as health care workers, teachers and daycare staff, grocery workers and those in homeless shelters or prisons, among others.”

Last Friday, 17 September, the FDA solicited independent scientific and public health expert advice on Pfizer’s supplement application for the booster. Pfizer and the FDA presented supporting data and the analysis in a public meeting. The FDA also invited international and US agencies and groups, including the Israeli Ministry of Health, the University of Bristol, UK, and the Centers for Disease Control and Prevention, to present recent data on vaccine booster use, COVID-19 epidemiology, and real-world data evidence on vaccine effectiveness.

The FDA analysed safety and immune response data from a cohort of original clinical trial participants of the Pfizer-BioNTech COVID-19 Vaccine to support the authorisation and real-world data on the vaccine’s efficacy over time. Analysis of participants’ immune responses (ages 18 to 55) who received a single booster dose six months after their second dose indicated a booster response. Neutralising antibodies one month after the booster shot were compared to those one month after completing the initial regimen in the same participants. Analysis of the COVID-19 incidence during the Delta surge among the trial participants demonstrated a modest decrease in the vaccine’s efficacy among those that completed the primary vaccine sequence earlier.

Like the primary two-dose series results, commonly reported booster side-effects included injection site pain, redness, and swelling, as well as fatigue, headache, muscle or joint pain and chills. Swollen underarm lymph nodes were more often observed after receiving the booster dose than the primary two-dose series.

The Pfizer-BioNTech COVID-19 Vaccine original FDA EUA authorisation on 11 December 2020 indicated use for ages 16 years and up, but the age threshold was lower to 12 years on 10 May 2021. A third dose was authorised only for specific immunocompromised individuals aged 12 and up on 12 August 2021.

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