FDA, CDC Authorize ‘Mix and Match’ Novavax COVID Booster for Adults, Bypass Advisory Panels

The U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) on Wednesday authorized a first booster dose of Novavax’s COVID-19 vaccine for adults, including those who received Pfizer, Moderna or Johnson & Johnson as their primary series.

The FDA, in a factsheet for healthcare providers, said adults ages 18 and older can receive Novavax as their third shot six months after completion of the primary series of another COVID-19 vaccine.

Just hours later the CDC signed off on the FDA’s decision without a debate or vote from its vaccine advisory panel that met Wednesday to discuss COVID-19 vaccines.

“This action gives people ages 18 years and older the option

to receive a Novavax monovalent booster instead of an updated (bivalent) Pfizer-BioNTech or Moderna booster if they have completed primary series vaccination but have not previously received a COVID-19 booster—and if they cannot or will not receive mRNA vaccines," the CDC said in a press release.

The agency said the FDA's authorization of Novavax COVID boosters is an important step forward in "our country's comprehensive vaccination program" that has "helped provide increased protection for all Americans COVID-19 disease and death."

Novavax targets the original strain of the virus no longer circulating in the U.S, whereas updated booster shots from Moderna and Pfizer target both the original strain and circulating Omicron subvariants.

To date, Novavax has not presented real-world efficacy data on how its vaccine performs against BA.5, the most common circulating strain of COVID-19. Pfizer and Moderna also do not have real-world data on how their bivalent boosters perform against BA.5.

The FDA's decision to authorize Novavax as a first booster dose was based only on UK clinical trial data conducted by the company. The company claims the data show its booster is "effective" because it increased antibodies in those who received Novavax or an mRNA vaccine as a primary series.

The FDA may not have convened its vaccine advisors because, at previous meetings, the FDA's Vaccines and Related Biological Products Advisory Committee admitted antibody levels are not an accurate indicator of whether a shot will provide actual protection against the disease or its severity.

In addition, the potential safety concerns of receiving an additional booster of Novavax and the long-term effects of mixing mRNA vaccines with Novavax were entirely overlooked.

According to a press release published Wednesday by Novavax, the incidence of "Grade 3 or higher" adverse events remained "relatively low," although it was not disclosed what these types of adverse events consist of. The company also said that safety reporting of reactogenicity events showed an increasing incidence across all three doses of Novavax.

"Among participants 18 years of age and older, solicited adverse reactions following administration of a booster dose of the Novavax COVID-19 Vaccine, Adjuvanted were injection site pain/tenderness (81.1%), fatigue/malaise (63.4%), muscle pain (63.0%), headache (52.9%), joint pain (30.3%), nausea/vomiting (14.7%), injection site swelling (8.4%), injection site redness (6.3%), and fever (6.3%)," the company said.

Only about 35,000 doses of the Novavax vaccine have been administered in the U.S. so far, according to CDC data, compared to more than 600 million doses of primary messenger RNA vaccines Pfizer and Moderna.

Novavax was one of the original participants in the U.S. race to develop a COVID-19 vaccine in 2020 and received $1.8 billion in taxpayer funds.