FDA shortens wait for COVID-19 vaccine booster to 5 months, expands eligibility down to age 12

Major changes were authorized this morning to increase access to booster shots for the COVID-19 vaccine from Pfizer-BioNTech by the US Food and Drug Administration (FDA).

There are three main changes: (1) the time between completion of the primary vaccine series until eligible for a booster shot has been reduced to five months from the prior six months, (2) booster shots are authorized for ages 12 to 15 under the same conditions as for those 16 and older, and (3) children ages 5 to 11 who are unusually immunocompromised are eligible for an additional third dose as part of their primary vaccine sequence.

The FDA said in a statement, "The agency has determined that the protective health benefits of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine to provide continued protection against COVID-19 and the associated serious consequences that can occur including hospitalization and death, outweigh the potential risks in individuals 12 through 15 years of age." The FDA said the decision relied upon safety and effectiveness data, including a study of 6,300 Israelis ages 12 to 15, that showed no appreciable risk of adverse reactions, and in particular "The data shows there are no new safety concerns following a booster in this population. There were no new cases of myocarditis or pericarditis reported to date in these individuals."

"Throughout the pandemic, as the virus that causes COVID-19 has continuously evolved, the need for the FDA to quickly adapt has meant using the best available science to make informed decisions with the health and safety of the American public in mind," said Acting FDA Commissioner Janet Woodcock, MD, in a statement. "With the current wave of the omicron variant, it's critical that we continue to take effective, life-saving preventative measures such as primary vaccination and boosters, mask wearing and social distancing to in order to effectively fight COVID-19."

"Based on the FDA's assessment of currently available data, a booster dose of the currently authorized vaccines may help provide better protection against both the delta and omicron variants. In particular, the omicron variant appears to be slightly more resistant to the antibody levels produced in response to the primary series doses from the current vaccines," said Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research. "With this in mind, the FDA has extended the range of individuals eligible to receive a booster, shortened the length of time between the completion of the Pfizer primary series for individuals to receive a booster and is authorizing a third protective vaccine dose for some of our youngest and most vulnerable individuals."

The three-dose primary vaccine for young children is a very unusual situation, the FDA emphasized: "Children 5 through 11 years of age who have undergone solid organ transplantation, or who have been diagnosed with conditions that are considered to have an equivalent level of immunocompromise, may not respond adequately to the two-dose primary vaccination series. Thus, a third primary series dose has now been authorized for this group. This will now allow these children to receive the maximum potential benefit from vaccination… Children 5 through 11 years of age who are fully vaccinated and

are not immunocompromised do not need a third dose at this time, but the FDA will continue to review information and communicate with the public if data emerges suggesting booster doses are needed for this pediatric population." When appropriate, this third primary series dose would be administered at least 28 days after the second dose.

UPDATE Wed, Jan 5, 2022: The RI Department of Health issued a statement that practices in the state will adopt the new FDA guidance for the Pfizer vaccine: "The booster interval recommendations for people who received the Johnson & Johnson vaccine (two months) or the Moderna vaccine (six months) have not changed."