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FDA Approves Updated Moderna and Pfizer COVID-19 Vaccines for 2023-2024 Season

Coronavirus / **Published On September 12, 2023 07:00 AM /**

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The U.S. Food and Drug Administration announced on Monday the approval and emergency use authorization of updated Covid-19 mRNA vaccines for the 2023-2024 season.

Manufactured by Moderna and Pfizer, these vaccines have been revised to target the currently circulating variants, including the Omicron variant XBB.1.5. The aim is to enhance protection against severe outcomes such as hospitalization and death, the FDA said.

Individuals aged 5 and older, regardless of prior vaccination status, can receive a single dose of the updated mRNA vaccine at least two months after their last Covid-19 vaccine dose, according to the FDA. For children aged 6 months to 4 years who have previously been vaccinated, one or two doses of the updated vaccine may be administered, depending on the type of previous vaccine

received. Unvaccinated children in the same age group are eligible for three doses of the updated authorized Pfizer-BioNTech vaccine or two doses of the Moderna vaccine.

Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, emphasized the critical role of vaccination in public health. "The public can be assured that these updated vaccines have met the agency's rigorous scientific standards for safety, effectiveness, and manufacturing quality. We very much encourage those who are eligible to consider getting vaccinated," he said.

The updated mRNA vaccines are approved for individuals aged 12 and older and are authorized for emergency use in those aged 6 months to 11 years. As part of today's announcement, the previous versions of the Moderna and Pfizer-BioNTech vaccines are no longer authorized for use in the United States.

The updated vaccines have undergone rigorous evaluation based on manufacturing data and immune response studies. The FDA states that the vaccines are expected to be effective against the current variants of the virus. Unless a significantly more virulent variant emerges, annual updates to the vaccine composition may be expected, similar to seasonal influenza vaccines.

The U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices is set to meet today to discuss further clinical recommendations, including considerations for specific populations like the immunocompromised and older individuals.

Manufacturers have announced that the updated vaccines should be available this fall. This comes as part of the FDA's ongoing effort to adapt to the evolving pandemic, supported by data from studies and hundreds of millions of prior vaccine administrations.

Specific updates include a change to a single dose for Comirnaty (COVID-19 Vaccine, mRNA) for individuals 12 years and older, and a single dose of Spikevax (COVID-19 Vaccine, mRNA) for individuals 18 years and older. Additional doses have also been authorized for certain immunocompromised individuals between the ages of 6 months and 11 years.

The approval for the updated Comirnaty formula was granted to BioNTech Manufacturing GmbH, while the emergency use amendment was issued to Pfizer Inc. ModernaTX Inc. received both the approval for the updated Spikevax formula and the emergency use amendment.