

## IMPORTANT PRESCRIBING INFORMATION

**Subject: Pfizer BioNTech COVID-19 Vaccine  
and Pfizer BioNTech COVID-19 Vaccine, Bivalent –  
Change in Third Dose of 3-Dose Primary Series for Individuals 6 months through 4 Years  
of Age**

Dear Healthcare Provider,

The purpose of this letter is to inform you that on December 8, 2022, the US Food and Drug Administration authorized emergency use of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine, Bivalent, for use in individuals 6 months through 4 years of age as the third dose in the 3-dose primary series, to help prevent COVID-19 caused by the Omicron variant of SARS-CoV-2. The Pfizer-BioNTech COVID-19 Vaccine, a monovalent vaccine, is no longer authorized for use as the third dose of the primary series in individuals 6 months through 4 years of age.

Therefore, Pfizer-BioNTech COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine, Bivalent are authorized for use in individuals 6 months through 4 years of age to provide a 3-dose primary series as follows:

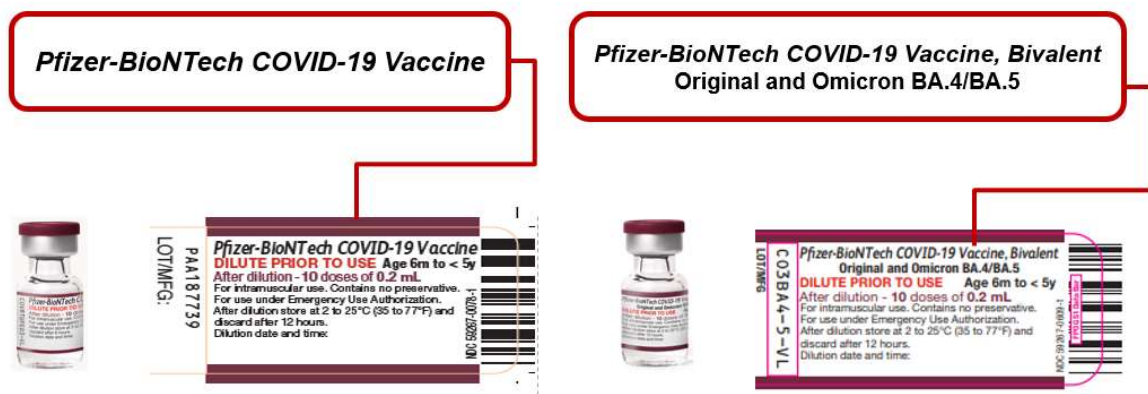
**Dose 1:** Pfizer-BioNTech COVID-19 Vaccine

**Dose 2:** Pfizer-BioNTech COVID-19 Vaccine

**Dose 3:** Pfizer-BioNTech COVID-19 Vaccine, Bivalent

The Pfizer-BioNTech COVID-19 Vaccine for individuals 6 months through 4 years of age, and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, for individuals 6 months through 4 years of age are both supplied in multiple dose vials with maroon caps and labels with maroon borders and **MUST BE DILUTED PRIOR TO USE**.

It is important to carefully read the labels to differentiate between the vaccines to ensure individuals 6 months through 4 years of age receive the appropriate vaccine for each dose.



Storage and handling requirements for these vaccines are identical.

Vaccination providers must report certain information associated with the administration of the vaccine to VAERS in accordance with the authorized Fact Sheet.

Should you have any questions about the use of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, you can either contact Pfizer at 1(877) 829 2619 or visit [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com) for additional resources.

This letter is not intended as a complete description of the benefits and risks related to the use of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for children 6 months through 4 years of age. Please refer to the authorized Fact Sheet for Pfizer-BioNTech COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Sincerely,



Alejandro Cane, MD, PhD

North America Vaccines Medical Scientific Affairs Lead