

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE Dave A. Chokshi, MD, MSc Commissioner

August 24, 2021

Dear Colleague,

The New York City (NYC) Department of Health and Mental Hygiene (Health Department) is pleased to report that **on August 23, 2021, the U.S. Food and Drug Administration (FDA) fully approved the Pfizer COVID-19 vaccine for individuals 16 years of age and older.** The vaccine will now be marketed as Comirnaty<sup>®</sup>. The vaccine also continues to be available under emergency use authorization (EUA) specifically for individuals 12 through 15 years of age and for the administration of a third dose in <u>certain immunocompromised individuals</u>.

Following approval, the FDA released a <u>Fact Sheet for Healthcare Providers Administering Vaccine</u>, a <u>Fact</u> <u>Sheet for Recipients and Caregivers</u>, and a <u>Frequently Asked Questions</u> webpage. Providers are responsible for adhering to all requirements outlined in the Centers for Disease Control and Prevention (CDC) <u>COVID-19</u> <u>Vaccination Program Provider Agreement</u>. This applies to both EUA and FDA approved COVID-19 vaccines. Accordingly, use of these products outside of those that have been approved and authorized by FDA (often referred to as "off-label use") is not recommended and would violate the CDC COVID-19 vaccine agreement.

The Advisory Committee on Immunization Practice (ACIP) will hold its <u>next meeting</u> August 30-31 to review the latest data on COVID-19 vaccines and to consider policy recommendations, including booster doses. Please stay on the lookout for updates from the NYC Health Department after this meeting.

In addition, the expiration dates for the Pfizer COVID-19 vaccine have been extended from six to nine months. Cartons and vials of Pfizer COVID-19 vaccine with an expiration date of August 2021 through February 2022 printed on the label may remain in use for three months beyond the printed date as long as the vaccine has been properly stored under ultra-cold storage conditions between -90°C to -60°C (-130°F to -76°F). Frozen vials stored at -25°C to -15°C and refrigerated vials (2°C to 8°C) are NOT eligible for extension of the expiration date. The expiration date extension does NOT apply to vials dated July 2021 and earlier. Additional information on Pfizer storage and handling may be found <u>here</u>.

Please continue to report all COVID-19 vaccine doses administered to the Citywide Immunization Registry (CIR) within 24 hours. Patient consent is not required. It is critical to enter all demographic information including race, ethnicity, patient phone numbers and email addresses in CIR. Cell phone and e-mail is critical to enable linkage with CIR, My Vaccine Record and Excelsior Pass Plus.

Finally, we urge you to leverage the Pfizer approval to talk to your patients about COVID-19 vaccination and to offer vaccination at every opportunity. Your strong recommendation can play a crucial role in vaccination decisions. For the latest information on COVID-19 vaccines in NYC, visit our <u>website</u>. Thank you for your continued efforts in protecting New Yorkers from COVID-19.

Sincerely,

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Jane R. Zucker, MD, MSc Assistant Commissioner Bureau of Immunization