

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

October 18, 2021

Dear Colleague,

We expect the Pfizer pediatric COVID-19 vaccine will be authorized for use in children ages 5 to 11 years in coming weeks and we are writing to help you prepare for this expansion. The independent advisory committee to the U.S. Food and Drug Administration (FDA) will review Pfizer's application for Emergency Use Authorization for this age group on October 26, 2021 and the FDA's decision is expected shortly after. If FDA authorization is granted, the Advisory Committee on Immunization Practices will meet November 2-3, 2021 to advise the Centers for Disease Control and Prevention (CDC) about policy recommendations. **Providers should be ready to vaccinate children ages 5 to 11 years as early as November 4, 2021, pending FDA authorization and CDC recommendations.** 

New York City providers will be able to pre-order Pfizer vaccine for children ages 5 to 11 years in the <u>Citywide Immunization Registry</u>, Online Registry, starting today, October 18, 2021. The Pfizer vaccine for children ages 5 to 11 must be ordered separately from Pfizer vaccine for people ages 12 years and older. The Pfizer vaccine for people ages 12 years and older cannot be used to vaccinate younger children. Orders for vaccine for children 5 to 11 years will be in increments of 100 doses. The first wave of deliveries will likely arrive after FDA authorization, but before CDC recommendations. As a reminder, providers cannot administer COVID-19 vaccine to children ages 5 to 11 years until the CDC issues a recommendation for vaccination in this age group.

The Pfizer vaccine order will include diluent and other ancillary supplies configured specifically for use in children 5 to 11 years. Reconstitution will use a different volume of diluent than the formulation for people ages 12 years and older. The vaccine for children ages 5 to 11 can be stored in the refrigerator for up to 10 weeks and in an ultra-cold freezer (between -90°C to -60°C) for up to six months. Regular freezers cannot be used with the new formulation. Once punctured, the vials must be used within six hours. A guidance document outlining the differences between the Pfizer vaccine for children 5-11 year and people 12 years and older is attached.

In anticipation of the resources required for the pediatric rollout, Pfizer COVID-19 vaccine orders for people ages 12 years and older (1,170 dose trays) will be suspended between October 29 and November 4. Please order enough vaccine before October 29 to ensure you have sufficient supply for first, second, third and booster doses for people ages 12 years and older during this period.

If you have any questions, please email <u>COVIDVax@health.nyc.gov</u>. Thank you for your work to vaccinate New Yorkers and keep our city healthy.

Sincerely,

Jone R. Zichen

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

## **Pfizer-BioNTech COVID-19 Vaccines** PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL

Description	Current Adult/Adolescent Formulation (1170 and 450 packs)	Future Pediatric Formulation
	Dilute Prior to Use	Dilute Prior to Use
Age Group	12 years and older	5 to <12 years**
Vial Cap Color	PURPLE	ORANGE
Dose	30 mcg	10 mcg
Injection Volume	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	1.3 mL
Amount of Diluent* Needed per Vial	1.8 mL	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	10 doses per vial (after dilution)
Storage Conditions		
ULT Freezer (-90°C to -60°C)	9 months	6 months
Freezer (-25°C to -15°C)	2 weeks	N/A
Refrigerator (2°C to 8°C)	1 month	10 weeks

*Q*: Can the current adult/adolescent formulation (purple cap) be used to vaccinate children 5 to <12 years old once the vaccine is authorized for this age group?

A: No. For children under 12 years of age, you cannot use the current formulation and will need to use the future pediatric (orange cap) formulation.

Purple Cap – Adult/Adolescent: Authorized only for aged 12 years and older



**Orange Cap** – Pediatric: Future authorization for aged 5to 12 years. A separate vaccine formulation specific for a 10mcg dose will be introduced.



<u>NOTE</u>: Use of the current adult/adolescent formulation (purple cap) to prepare doses for children 5 to <12 years would result in an injection volume for the 10mcg dose of 0.1mL, which is both generally considered too small for typical IM injections and has not been studied.

\*Diluent: 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic; DO NOT USE OTHER DILUENTS

\*\*The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 5 to <12 years old