

Pfizer Tris Shelf-Life Extension Approved

The Food & Drug Administration has approved an amendment to the EUA for Pfizer Tris COVID-19 vaccine extending the shelf-life of the following Pfizer product formulations **from 9 to 12 months**:

- Pfizer Tris Pediatric vaccine (Orange Cap for ages 5 through 11, with diluent)
- Pfizer Adult Tris (**Gray Cap** for ages 12+, no diluent)

Vials stored consistently in an ultra-low temperature freezer at -90oC to -60oC (-130°F to -76°F) may remain in use **for up to 12 months beyond the date of manufacture** printed on the vials and cartons. Vials stored in refrigerated vials (2°C to 8°C) are **NOT** eligible for extension, regardless of the expiration date. Additional information on Pfizer storage and handling may be found at <u>Administration Overview for Pfizer-BioNTech COVID-19 Vaccine | CDC</u>.

Pfizer Orange and Gray Cap Tris Vaccine expiry dates based on 12 months from the date of the manufacture are shown below and at Expiry Information for Pfizer COVID-19 Vaccines

Printed Manufacturing Date	12-Month Expiry Date
06/2021	31-May-2022
07/2021	30-Jun-2022
08/2021	31-Jul-2022
09/2021	31-Aug-2022
10/2021	30-Sep-2022
11/2021	31-Oct-2022
12/2021	30-Nov-2022
01/2022	31-Dec-2022
02/2022	31-Jan-2023
03/2022	28-Feb-2023

No changes have been made to the vaccine itself to enable extension of expiry dating. This change is based on stability data submitted by the manufacturer to the FDA.

Reminders:

- Do not use Pfizer Tris products beyond 12 months from manufacture date.
- Expiration dates for the Pfizer TRIS products are **NOT** printed on the vaccine cartons or vials
- Do not store Pfizer vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed, they should not be refrozen.

For more information, please review the updated FDA Factsheets:

Fact Sheet for Healthcare Providers Administering Vaccine (Gray Cap/Adult)

Fact Sheet for Healthcare Providers Administering Vaccine (Orange Cap/PEDS)

COVID-19 vaccines authorized under an EUA do not have fixed expiration dates, and expiration dates may be extended as more stability data is collected. Always check Expiry Information for Pfizer COVID-19 Vaccines to obtain the most up-to-date expiration dates for the Pfizer COVID-19 vaccines you have in inventory.

Please send questions to COVIDVaccines@dhec.sc.gov.