

## COVID-19 Vaccine Information Brief

August 31, 2021

Changes to the document from the previous version are highlighted in yellow.

### **Pfizer-BioNTech Vaccine Expiration Extension and Beyond Use Date**

The FDA has approved an amendment to the EUA for Pfizer-BioNTech extending the expiration dates of COVID-19 Vaccine from six to nine months. CDC has issued further clarification of the Beyond Use Date noted below.

*The approved extended expiration date applies to all currently available batches that have not yet expired and which have been stored within recommended storage conditions between 90°C to -60°C (-130°F to -76°F). Vaccines stored in the Freezer (-25°C to -15°C) and Refrigerator [2°C to 8°C (35°F to 46°F)] are eligible for expiration date extension consistent with the parameters for the storage unit (Freezer - 2 weeks, Refrigerator 31 days) beyond use date. Please see scenarios below for beyond use date extension for individual storage units.*

### **Ultra-Cold Freezer**

Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as authorized storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained. Please note: the ultra cold temperature range has been broadened to include -90° C (-130°F).

### **Freezer**

Undiluted vials, which were stored according to the approved storage conditions and then moved to the freezer (-25°C to -15°C), may also be used until the extended expiry date. The vaccine stored in the freezer (-25°C to -15°C) should not be used beyond the 2 week period or the 3-month extension, whichever is earlier. For example, vaccine with a printed expiry date of August 2021 has an extended expiry date of November 2021 (i.e., November 30, 2021). Vaccine stored at (-25°C to -15°C) may be used for 2 weeks and would not need to be discarded on August 31, 2021. At the end of the 2 week period in the freezer, the vaccine can then be stored in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 31 days.

### **Refrigerator**

Undiluted vials, which were stored according to the approved storage conditions and then moved to the refrigerator [2°C to 8°C (35°F to 46°F)], may also be used until the extended expiry date. The vaccine stored in the refrigerator [2°C to 8°C (35°F to 46°F)] should not be used beyond the 31-day period or the 3-month extension, whichever is earlier. For example, vaccine with a printed expiry date of August 2021 has an extended expiry date of November 2021 (i.e., November 30, 2021). Vaccine stored at 2°C to 8°C on August 23<sup>rd</sup> may be used for 31 days and would not need to be discarded on August 31, 2021.

Please refer to the current [EUA Fact Sheet for information](#). Additional information on Pfizer storage and handling may be found at: [Administration Overview for Pfizer-BioNTech COVID-19 Vaccine](#) | CDC

**It is important for healthcare providers to update vaccine expiration dates in IRIS. Questions regarding IRIS vaccine inventory and adjusting expirations dates can be directed to the IRIS Helpdesk at 800-374-3958.**

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## **Beyond Use Date Case Scenarios: Pfizer-BioNTech COVID-19 Vaccine Expiration Extension**

With the Pfizer-BioNTech COVID-19 Vaccine expiration date extension, there have been questions about how this might impact beyond-use date. To prevent vaccine from inadvertently being discarded, providers should ensure the new expiration date is indicated, i.e., label the tray or post on the unit.

- **Case scenario #1: A vial of Pfizer vaccine was moved from freezer storage to the refrigerator on August 15<sup>th</sup>. It is marked with the expiration date of August 2021 (August 31, 2021). Can this vaccine be stored for the full 31 days allowed for refrigeration storage, or does it need to be administered by August 31, 2021?**
  - Yes, this vaccine vial can be stored for the full 31 days (i.e., through September 15, 2021). The recent expiration date extension changes the expiration date to November 2021. The Beyond Use Date replaces the manufacturer's expiration date (now November/2021) and should be noted on the label along with the initials of the person making the calculation.
- **Case scenario #2: A vial of Pfizer vaccine is moved from ultracold storage to the freezer on August 23<sup>rd</sup>. It is marked with the expiration date of August 2021 (August 31, 2021). Can this vaccine be stored for the full 2 weeks allowed in the freezer? After that time, can the vaccine still move it to the refrigerator and store for an additional 31 days?**
  - Yes, the vaccine vial may be stored for the full 2 weeks in the freezer (through September 6, 2021), moved to the refrigerator, and stored for an additional 31 days (October 7, 2021). The recent expiration date extension changes the expiration date to November 2021. The Beyond Use Date replaces the manufacturer's expiration date (now November 2021) and should be noted on the label along with the initials of the person making the calculation.
- **Case scenario #3: A vial of Pfizer-BioNTech COVID-19 vaccine is moved from the freezer to the refrigerator on August 1, 2021. Since the expiration date has been extended, can this vial be stored in the refrigerator through November 31, 2021?**
  - No, this vial cannot be stored through the extended expiration date. A vial can be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 1 month (31 days) regardless of the expiration date extension.

Clinical guidance and resources for storing, preparing and administering the vaccine, including labels to assist with tracking the Beyond Use Date can be found here:

[www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html)