

FDA IN BRIEF

FDA In Brief: FDA Authorizes Longer Time for Refrigerator Storage of Thawed Pfizer-BioNTech COVID-19 Vaccine Prior to Dilution, Making Vaccine More Widely Available

For Immediate Release:

May 19, 2021

The following quote is attributed to Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research

Making COVID-19 vaccines widely available is key to getting people vaccinated and bringing the pandemic to an end. Pfizer Inc. submitted data to the FDA to support storage of undiluted, thawed vials of its COVID-19 vaccine for up to one month at refrigerator temperatures. This change should make this vaccine more widely available to the American public by facilitating the ability of vaccine providers, such as community doctors' offices, to receive, store and administer the vaccine.

Additional Information

- Based on a review of recent data submitted by Pfizer Inc. today, the U.S. Food and Drug Administration is authorizing undiluted, thawed Pfizer-BioNTech COVID-19 Vaccine vials to be stored in the refrigerator at 2°C to 8°C (35°F to 46°F) for up to 1 month. Previously, thawed, undiluted vaccine vials could be stored in the refrigerator for up to 5 days.
- Pfizer Inc. submitted data to the FDA to demonstrate that undiluted, thawed vials of its COVID-19 vaccine are stable at refrigerator temperatures for up to 1 month.
- The updated [Fact Sheet for Healthcare Providers Administering Vaccine](https://www.fda.gov/media/144413/download) (<https://www.fda.gov/media/144413/download>) (Vaccination Providers) is intended to help frontline workers understand the revised storage time. The Fact Sheet is available on the FDA's web site.
- [Emergency Use Authorization for Vaccines to Prevent COVID-19](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19) (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19>).

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