



December 8, 2023

Pfizer Inc.
Attention: (b) (6)
66 Hudson Boulevard East
New York, NY, 10001

Re: EUA 27034 - Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine, Reissued on September 11, 2023, under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3); Request in Amendments submitted and received on November 27, 2023, December 6, 2023 and December 7, 2023, to Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine, Bivalent (2023-2024 Formula), For 6 Months Through 11 Years of Age

Dear (b) (6) :

This letter is to notify you that we have reviewed the requested changes and that your request is granted.

We concur with your request to revise section 2.1 of the Fact Sheet for Healthcare Providers Administering Vaccine to clarify preparation for administration instructions as indicated below:

2.1 Preparation for Administration

There are 2 presentations of Pfizer-BioNTech COVID-19 Vaccine:

Vial Cap and Vial Label Border Color	Age of Recipient	Vial Type	Dilution Required
Yellow	6 months through 4 years of age	Multiple dose	Yes
Blue	5 through 11 years of age	Single dose	No

Pfizer-BioNTech COVID-19 Vaccine vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.

If vials are frozen, they must be thawed prior to use [for thawing instructions, see *How Supplied/Storage and Handling (16)*].

For multiple dose vials with yellow caps and labels with yellow borders:

- **Dilute** prior to use:

- Check the contents of the vial during preparation. The liquid should be clear to slightly opalescent with no visible particles. Do not use if liquid is discolored or if particles are observed.
- Add 1.1 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.
- Before removing the needle from the vial, equalize vial pressure by withdrawing air into the empty diluent syringe.
- Gently invert the vaccine vial 10 times to mix. Do not shake.
- Record the date and time of dilution on the vial label.
- Store at 2°C to 25°C (35°F to 77°F) and discard after 12 hours.
- After dilution, multiple-dose vials contain 3 doses of 0.3 mL each.
- If the amount of vaccine in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

For single dose vials with blue caps and labels with blue borders:

- **Do Not Dilute.**
- Prior to withdrawing the dose, mix by inverting the vial gently 10 times. Do not shake.
- Withdraw a single 0.3 mL dose.
- Discard vial and any excess volume.

By submitting these amendments for review and concurrence by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the September 11, 2023 letter authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine.

Sincerely,

David C. Kaslow, M.D.
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and
Research