Our STN: BL 125742/684

SUPPLEMENT APPROVAL
February 20, 2026

BioNTech Manufacturing GmbH
Attention: Leslie Sands
Pfizer, Inc.
66 Hudson Boulevard East
New York, NY 10001

Dear Ms. Sands:

We have approved your request received April 24, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for COVID-19 Vaccine, mRNA (COMIRNATY) to revise the Package Insert to include information in Section 8 Use in Specific Populations from Study C4591015 of COMIRNATY administered during pregnancy (with the first dose at 24 to 34 weeks gestation) and from Study C4591024 of COMIRNATY administered to immunocompromised individuals 5 years of age and older.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: NCT04754594 and NCT04895982.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 29, dated February 19, 2026.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at https://www.fda.gov/industry/fda-data-standards-advisory-board/structured-product-labeling-resources. Content of labeling must be identical to the Package Insert submitted on February 19, 2026. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/spl-standard-content-labeling-technical-qs.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125742 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the (b) (6) at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the change approved today.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

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Office of Vaccines Research and Review
Center for Biologics Evaluation and Research