Our STN: BL 125742/564 **SUPPLEMENT APPROVAL**

BioNTech Manufacturing GmbH August 28, 2024
Attention: (b) (6)
Pfizer, Inc.
66 Hudson Boulevard East
New York, NY 10001

Dear (b) (6)

Please refer to your supplement to your Biologics License Application (BLA) received June 26, 2024, submitted under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA (COMIRNATY).

We also refer to our supplement approval letter dated August 22, 2024, which contained the following error:

> The date of the final printed carton and container labels was incorrectly listed as June 26, 2024 in the "CARTON AND CONTAINER LABELS" section, when it should have been listed as July 23, 2024.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain August 22, 2024, the date of the original supplement approval letter.

We have approved your request received June 26, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for COVID-19 Vaccine, mRNA (COMIRNATY), manufactured at the Pfizer Manufacturing Belgium NV (Puurs, Belgium), Pharmacia and Upjohn Company LLC (Kalamazoo, Michigan) and (b) (4) facilities, to include the 2024-2025 Formula and associated labeling revisions.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft content of labeling: Package Insert and FDA-approved patient labeling submitted under amendment 1, dated July 1, 2024, and the draft carton and container labels submitted under amendment 3, dated July 23, 2024.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert, Patient Package Insert submitted on July 1, 2024. 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 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on July 23, 2024, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

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 (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 changes approved today.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitment as described in your correspondences of August 9, 2024, and August 21, 2024, as outlined below:

1. Study C4591054, Substudy C, to evaluate immune responses following a single dose of COMIRNATY (2024-2025 Formula) in individuals 18 years of age and older.

   Final Protocol Submission: August 31, 2024 (Submitted)

   Topline Results (Substudy C, Cohort 3) Submission: February 28, 2025

   Study Completion Date: March 31, 2025

   Final Report Submission: August 31, 2025

Please submit the clinical protocol to your IND 19736, and a cross-reference letter to BLA STN BL 125742 explaining that this protocol was submitted to the IND.

If the information in the final study report supports a change in the labeling, the final study report must be submitted as a supplement. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Correspondence Status Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment Final Study Report**

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of the approval of BLA STN BL 125742 until all requirements and commitments subject to the reporting requirements of section 506B of

the Federal Food, Drug, and Cosmetic Act (FDCA) are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

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

Sincerely,

For (b) (6)

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