Our STN: BL 125742/860

SUPPLEMENT APPROVAL
RELEASE FROM 506B POSTMARKETING COMMITMENT
NEW 506B POSTMARKETING COMMITMENT

August 27, 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 June 3, 2026, 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-Sint-Amands Belgium; (b) (4) facilities, to include the 2026-2027 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 Patient Package Insert, and the draft carton labels submitted under amendment 2, dated June 8, 2026, and the container labels submitted under amendment 1, dated June 4, 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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert and Patient Package Insert, submitted on June 8, 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 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 June 8 and June 4, 2026, respectively, 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 the Advertising and Promotional Labeling Branch 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 commitments as described in your correspondences of August 14, 2026 and August 21, 2026, which state you will conduct an assessment of Cohort 1, as outlined below:

1. Prospectively designed study C4591083 to evaluate the safety and immunogenicity of COMIRNATY (COVID-19 Vaccine, mRNA) (2026-2027 Formula) in participants 65 years of age and older and in participants 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19

Final Protocol Submission:	July 31, 2026 (Submitted)
Study Initiation:	August 31, 2026
Interim Results:	February 26, 2027
Study Completion:	April 20, 2027
Final Report Submission:	June 15, 2027

2. Prospectively designed study C4591083 to evaluate the safety and immunogenicity of COMIRNATY (COVID-19 Vaccine, mRNA) (2026-2027 Formula) in participants 5 years through 11 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

Final Protocol Submission:	July 31, 2026 (Submitted)
Study Initiation:	August 31, 2026
Interim Results:	September 17, 2027
Study Completion:	April 20, 2027
Final Report Submission:	December 31, 2027

Please submit clinical protocols and interim results to your IND 19736, and a cross-reference letter to BLA STN BL 125742, explaining that these protocols and interim results were submitted to the IND.

If the information in the final report supports a change in the labeling, the final 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.

RELEASE FROM POSTMARKETING COMMITMENT

We also refer to your submission received August 27, 2026, requesting release from the following postmarketing commitment (PMC) identified in the August 27, 2025, supplement approval letter.

STN: BL 125742/656

PMC 4 A prospective, exploratory, placebo-controlled, randomized study to evaluate detection of circulating SARS-COV-2 spike antigen and self-reported symptoms of post-COVID-19 vaccination syndrome or Long COVID symptoms at Month 1, 3, 6, and 12 in vaccine and control arms

We have completed the review of your submission and conclude that you are released from the above PMC because of operational and feasibility challenges that impacted the conduct of this study as originally designed.

The above PMC will be replaced by the new PMCs described below.

NEW POSTMARKETING COMMITMENTS SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

3. A nonclinical study to assess biodistribution and persistence of COVID-19 vaccine-derived Spike protein following COMIRNATY administration

   Analytical Method Characterization

Final Protocol Submission:	September 11, 2026
Study Initiation:	September 14, 2026
Study Completion:	December 18, 2026
Final Report Submission:	January 11, 2027

   Organ/Tissue-Level Characterization of Spike Persistence

Final Protocol Submission:	December 18, 2026
Study Initiation:	January 12, 2027
Study Completion:	May 14, 2027
Final Report Submission:	June 15, 2027

4. A Phase 4 Retrospective Integrated Analysis of COMIRNATY Clinical Trial Data: Evaluation of Symptom Clusters Potentially Consistent with Post-COVID Vaccination Syndrome as Described in Published Literature

Final Protocol Submission:	December 17, 2026
Study Initiation:	January 15, 2027
Final Report Submission:	June 15, 2027

Please submit protocols to your IND 19736, and a cross-reference letter to this BLA 125742, explaining that these protocols were 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**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment – Final Study Report**

When you have fulfilled your commitment, submit your final report as **Postmarketing Commitment – Final Study Report** or **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 days of the

anniversary date of the approval of the BLA until all Requirements and Commitments subject to the reporting requirements of section 506B of the 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,

David C. Kaslow, MD
Director, Office of Vaccines Research and Review
For (b) (6)
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research