Our STN: BL 125742/698

SUPPLEMENT APPROVAL
June 25, 2025

BioNTech Manufacturing GmbH
Attention: Heather Hufnagel, MS
Pfizer, Inc.
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Hufnagel:

We have approved your request received May 13, 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), manufactured at the Pfizer Manufacturing Belgium NV, Puurs, Belgium (Pfizer, Puurs) and Pharmacia & Upjohn Company LLC, Kalamazoo, Michigan (Pfizer, Kalamazoo) facilities, to include new safety information (NSI) regarding the risks of myocarditis and pericarditis following administration of mRNA COVID-19 vaccines in the "Warnings and Precautions", "Adverse Reactions" and "References" sections of the Package Insert and in the Patient Package Insert in accordance with section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (FDCA).

The review of this supplement was associated with our April 17, 2025, SAFETY LABELING CHANGE NOTIFICATION LETTER, notifying you, under Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (FDCA), of NSI that we determined should be included in the labeling for COMIRNATY. This information pertains to (1) data from the Biologics Effectiveness and Safety System on the estimated unadjusted incidence of myocarditis and/or pericarditis following administration of the 2023-2024 Formula of mRNA COVID-19 vaccines, and (2) results from an observational study [Jain et al. https://doi.org/10.1016/j.eclinm.2024.102809] in patients with COVID-19 vaccine-associated myocarditis showing persistence of abnormal cardiac magnetic resonance imaging findings that are a marker for myocardial injury at a median follow-up of approximately 5 months.

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 submitted under amendment 2, dated June 18, 2025.

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 18, 2025. 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.

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.

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

Sincerely,

R. Douglas Pratt, MD, MPH
Deputy Director
Division of Clinical and Toxicology Review
Office of Vaccine Research and Review
Center for Biologics Evaluation and Research