EXHIBIT 2

U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125742/45

SUPPLEMENT APPROVAL
PMR FULFILLED

BioNTech Manufacturing GmbH
Attention: Gosia Mineo, M.S.
Pfizer, Inc.
1 Pfizer Way 190/004/4405
Pearl River, NY 10965

July 8, 2022

Dear Ms. Mineo:

We have approved your request received on December 16, 2021, 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), Pharmacia & Upjohn Company LLC, Kalamazoo, Michigan (Pfizer, Kalamazoo) and Hospira, Inc., McPherson, Kansas (Pfizer, McPherson) facilities, to include use in adolescents 12 through 15 years of age for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

The review of this supplement was associated with the following National Clinical Trial number: 04368728.

LABELING

We hereby approve the draft content of Package Insert labeling, submitted under amendment 13, dated July 1, 2022.

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 submitted on July 1, 2022. 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 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)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

FULFILLED POSTMARKETING REQUIREMENT

This submission fulfills your postmarketing requirement #1 identified in the August 23, 2021, approval letter for BLA STN 125742/0 for COVID-19 Vaccine, mRNA. The requirement addressed in this submission is as follows:

1. Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age.

   Final Protocol Submission: October 7, 2020

   Study Completion: May 31, 2023

   Final Report Submission: October 31, 2023

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for ages 12 through 15 years for this application.

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

Sincerely,

Doran Fink, M.D., Ph.D.
Acting Deputy Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research