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U.S. DISTRICT COURT
N.D. OF ALABAMA

Marks Declaration
Exhibit 3

U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125742/36 **SUPPLEMENT APPROVAL**

BioNTech Manufacturing GmbH
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

December 16, 2021

Dear Mr. Patel:

We have approved your request submitted and received on November 18, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for COVID-19 Vaccine, mRNA (COMIRNATY), to include a new 30 microgram dose formulation (Tris/Sucrose) of COMIRNATY manufactured at the Pfizer Manufacturing Belgium NV, Puurs, Belgium (Pfizer, Puurs) facility.

LABELING

We hereby approve the draft content of labeling including the Package Inserts submitted under amendment 10, dated December 13, 2021, and the draft carton and container labels submitted under amendment 6, dated December 9, 2021.

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 Inserts submitted on December 13, 2021. 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 December 9, 2021, 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)).

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

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

Sincerely,

Jerry P. Weir, Ph.D.
Director
Division of Viral Products
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research