



Our STN: BL 125742/175

SUPPLEMENT APPROVAL

BioNTech Manufacturing GmbH
Attention: (b) (6)
Pfizer Inc.
4300 Oak Park Road
Sanford, NC 27330

August 25, 2022

Dear (b) (6)

We have approved your request received on June 10, 2022, to supplement your Biologics License Application (BLA) 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 the introduction of the Monovalent Tris/Sucrose (30 mcg) Single Dose Vial with 0.48 mL Fill Volume to be filled on (b) (4) (b) (4) and (b) (4) filling lines at the Puurs, Belgium location, and associated labeling changes.

LABELING

We hereby approve the draft content of labeling including the Package Insert submitted under amendment 5, dated August 25, 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 August 25, 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 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 (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)).

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.

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

Sincerely,

(b) (6)

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