U.S. FOOD & DRUG ADMINISTRATION

Memorandum

DATE: May 11, 2022

TO: Ramachandra Naik, OMPT/CBER/OVRR/DVRPA
Laura Gottschalk, OMPT/CBER/OVRR/DVRPA
Michael Smith, OMPT/CBER/OVRR/DVRPA
Susan Wollersheim, Medical Officer, OMPT/CBER/OVRR/DVRPA

FROM: Oluchi Elekwachi, Regulatory Reviewer
OCBQ/DCM/APLB

THROUGH: Lisa Stockbridge, Branch Chief
OCBQ/DCM/APLB

SUBJECT: COMIRNATY (COVID-19 vaccine, mRNA)
Suspension for intramuscular injection
BLA 125742/245

Sponsor: Pfizer Inc.

The sponsor submitted:

☐	Original Application
☐	Major Amendment
☐	Prior Approval Supplement (PAS)
☒	Changes Being Effected (CBE) Supplement

Submission contains:

☒	Prescribing Information (PI) – version submitted on December 16, 2021
☐	Patient Package Insert (PPI)
☐	Package and Container - labels

BACKGROUND

On December 16, 2021, BioNTech Manufacturing GmbH (in partnership with Pfizer, Inc.) submitted an efficacy supplement for COMIRNATY to extend the indication to adolescents 12 through 15 years of age. The action due date (ADD) is June 17, 2022.

On April 20, 2022, FDA requested prescribing information revisions. The sponsor submitted a revised Package Insert (PI) on April 29, 2022, concluding an extensive iterative review between the review team and the sponsor. APLB has participated in reviewing the revised PI and all revisions submitted to date. At this time, we offer the following comments from a promotional and comprehension perspective.

GENERAL

- Use active voice and command language whenever possible.
- Do not bullet when there only is one concept. Over-bulleting deemphasizes the importance of a concept and reduces readability.
- Do not bold headings, subheadings, or statements unless required by the regulations. Underline or italics may be used for additional subheadings (use consistent style throughout).
- Avoid using research terms, such as “Phase I” or “Phase 3” studies.

FULL PRESCRIBING INFORMATION: CONTENTS

Ensure any changes in the table of contents are consistent with the FULL PRESCRIBING INFORMATION.

FULL PRESCRIBING INFORMATION

17 PATIENT COUNSELING INFORMATION

Include the following statement:

Prior to administering the vaccine, give the vaccine recipient the Vaccine Information Fact Sheet for Recipients and Caregivers about COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) for Use in Individuals 12 Years of Age and Older. The Vaccine Information Fact Sheet for Recipients and Caregivers is available at www.cvdvaccine.com.

If you have any questions regarding this review, please contact CAPT Oluchi Elekwachi, PharmD, MPH, Regulatory Review Officer at 240-402-8930.

Firm: Pfizer Inc.
STN: 125742/45

Document type: Review Memorandum

Bcc: OElekwachi
APLB Chronologic File
APLB Historical File

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Concurrence box:

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APLB	Oluchi Elekwachi -S Digitally signed by Oluchi Elekwachi -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9 2342.19200300.100.1.1=1300216724, cn=Oluchi Elekwachi -S Date: 2022.05.11 11:42:41 -04'00'
APLB	Lisa L. Stockbridge -S Digitally signed by Lisa L. Stockbridge -S Date: 2022.05.11 13:22:18 -04'00'