DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

MEMORANDUM

Date: August 18, 2021

From: Marie J. Anderson, MS, PhD
Division of Biological Standards and Quality Control (DBSQC)
Office of Compliance and Biologics Quality (OCBQ)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

To: Biologics License Application Submission Tracking Number 125742

Subject: Review of Lot Release Protocol (LRP) Template for COVID-19 mRNA Vaccine

Through: Maryna Eichelberger, PhD, Director DBSQC/OCBQ/CBER/FDA
Mary A. Malarkey, Director OCBQ/CBER/FDA

Cc: Ramachandra Naik, PhD, Chair, BLA Review Committee, DVP/OVRR/CBER/FDA
Michael Smith, PhD, RPM, DVRPA/OVRR/CBER/FDA
Laura Gottschalk, PhD, RPM, DVRPA/OVRR/CBER/FDA

Applicant: BioNTech Manufacturing GmbH (BioNTech)

Product: COVID-19 mRNA Vaccine

Trade Name: COMIRNATY

Executive Summary: The LRP template for COVID-19 mRNA Vaccine submitted in amendment 125742/0.50 on August 16, 2021 is acceptable for use.

1 General Information

1.1 CMC Review Identifiers and Dates

1.1.1 **Biologics License Application (BLA) Submission Tracking Number (STN):** 125742

1.1.2 **Submission received by CBER:** May 18, 2021

1.1.3 **Review completed:** August 17, 2021

Material Reviewed: BLA 125742

1.1.4 **Related Master File, INDs and BLAs:** N/A

2 Review

2.1 Documents Reviewed

Lot release documentation package submitted on May 18, 2021 in amendment 125742/0.1

Response and lot release documentation submitted on July 9, 2021 in amendment 125742/0.10

Response and LRP template submitted on July 20, 2021 in amendment 125742/0.14

Response and LRP template submitted on August 11, 2021 in amendment 125742/0.40

LRP template received via e-mail on August 14, 2021

Response and LRP template (identical to template submitted August 14, 2021) submitted on August 16, 2021 in amendment 125742/0.50

2.2 Review

BioNTech submitted BLA 125742 on May 6, 2021. A lot release documentation package was submitted in amendment 125742/0.1 on May 18, 2021.

This documentation did not qualify as an LRP template. An IR for an LRP template was sent on June 25, 2021. A response was submitted in amendment 125742/0.10 on July 9, 2021. The response stated the LRP that included the

assays performed and acceptance criteria was previously provided with the initial submission. The same lot release documentation was submitted.

An IR for a LRP template (additional information provided) was requested on July 16, 2021. A response was submitted in amendment 125742/0.14 on July 20, 2021. The LRP template was reviewed by OVRR/DVP, OCBQ/DBSQC and OCBQ/DMPQ/PRB with comments.

An IR for a revised LRP template was sent to Pfizer/BioNTech on August 4, 2021. This IR also included templates to document assay results. A response was submitted in amendment 125742/0.40 on August 11, 2021. The response and LRP template were reviewed by OVRR/DVP, OCBQ/DBSQC and OCBQ/DMPQ/PRB.

The majority of CBER's requested revisions were made to the LRP template. However, Pfizer/BioNTech requested clarifications to some CBER comments and issues regarding the submission of requested (b) (4) .

An IR for additional revisions to the LRP template and clarifications was sent to Pfizer/BioNTech on August 13, 2021. A revised LRP template was submitted via e-mail on August 14, 2021. This template was reviewed by OCBQ/DBSQC with no comments.

An e-mail stating the LRP template was acceptable for use was sent via e-mail to Pfizer/BioNTech on August 14, 2021. This message also stated (b) (4) for each lot must be provided as previously requested.

An amendment (containing the identical lot release protocol template and information in the body of the e-mail) was submitted to 125742/0.50 on August 16, 2021. This response and LRP template were reviewed by DBSQC. There were no changes from the e-mail submission of August 14, 2021.

3 Conclusions

The LRP template for COVID-19 mRNA Vaccine submitted in amendment 125742/0.50 on August 16, 2021 is acceptable for use. This template may be used for future lot release submissions. This BLA was under an expedited review and the LRP template may require additional revisions in the future.