U.S. FOOD & DRUG ADMINISTRATION

LABELING REVIEW MEMORANDUM

To: The File

Date: August 2, 2022

STN: 125742/45

Supplement Type: Efficacy

Applicant: BioNTech Manufacturing GmbH (in partnership with Pfizer, Inc.)

Product: COVID-19 Vaccine, mRNA (COMIRNATY)

Michael J. Smith -S4 Digitally signed by Michael J. Smith -S4 Date: 2022.08.02 12:59:27 -04'00'

From: Laura Gottschalk, Ph.D. and CAPT Mike Smith, Ph.D.
OVRR/DVRPA/RRB3

Through: Elizabeth M. Sutkowski, Ph.D.
OVRR/DVRPA/RRB3

Elizabeth M. Sutkowski -S Digitally signed by Elizabeth M. Sutkowski -S Date: 2022.08.02 13:47:31 -04'00'

Summary:
COMIRNATY was originally approved on August 23, 2021 (STN 125742/0) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. In the current application, BioNTech has submitted an Efficacy Supplement to the Biologics License Application (sBLA) to include use in adolescents 12 through 15 years of age.

The product labeling submitted to the sBLA included new Package Inserts (PIs) for the Tris/Sucrose formulation and the PBS/Sucrose formulation.

Revisions to the proposed labeling for the PIs were communicated to BioNTech as indicated below in Table 1, and the corresponding amendments that were received are described in Table 2. BioNTech's responses to CBER's suggested revisions were submitted in Amendments 8 and 12. The final draft labels were submitted in Amendment 13 dated July 1, 2022. The principal reviewers of the labels were those in the Clinical Review Team, Advertising and Promotional Labeling Branch, the OVRR Immediate Office of the Director, and the Regulatory Project Managers.

Table 1. Labeling Review History

Date	Action
04/08/2022	Internal labeling meeting.
04/20/2022	Internal labeling meeting.
04/20/2022	First set of labeling comments on the PIs were sent to the applicant.

05/10/2022	Second set of labeling comments on the PIs were sent to the applicant.
06/29/2022	Third set of labeling comments on the PIs were sent to the applicant. The only change requested was to replace “M/YYYY” with “7/2022” for the date under "recent major changes" and "revision date."
7/05/2022	BioNTech was notified that the PIs submitted in Amendment 13, dated 07/01/2022, are considered the Final Draft Labels.

Table 2. Labeling Amendments

Date	Amendment	Summary
04/29/2022	STN 125742/45.8	Response to the first set of comments on the PI dated 04/20/2022.
05/13/2022	STN 125742/45.12	Response to the second set of comments on the PIs dated 05/10/2022.
07/01/2022	STN 125742/45.13	Response to the third set of comments on the PIs dated 06/29/2022. Final Draft Labels.

Regarding BioNTech’s Amendments containing revisions to the PI:
BioNTech submitted to CBER two versions of the PIs (as amendments to the sBLA) in response to CBER’s comments. BioNTech’s responses to CBER’s suggested revisions regarding the PIs were submitted in Amendments 125742/45.8, 125742/45.12 and 125742/45.13. The clean copies of the PIs submitted on July 1, 2022 (Amendment 13) were considered the Final Draft PIs for approval. BioNTech was notified on July 5, 2022, that CBER considered the PIs included in Amendment 13 as the Final Draft PIs for approval.

Review of National Drug Codes:
A review of the National Drug Codes was not done for this supplement since the product presentations and how supplied are the same as those approved in the original BLA STN 125614/0 and Post Approval Supplement STN 125742/36.

Recommendation:
The discipline reviewers mentioned above have reviewed the relevant labeling documents and found the PIs received in Amendment 13 dated July 1, 2022 to be acceptable as Final Draft Labeling for approval. As the Regulatory Project Manager, I concur with their recommendation. The Final Draft PIs were provided to the Office of Communication, Outreach and Development as part of the approval package for web posting.