Transmittal Memo

TO: Lorrie McNeill
Director
Office of Communication, Outreach and Development

FROM: Marion F. Gruber, Ph.D.
Director
Office of Vaccines Research and Review

Marion F. Gruber -S

Digitally signed by Marion F. Gruber -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300077111, cn=Marion F. Gruber -S
Date: 2021.08.23 08:22:53 -04'00'

RE: Action Package for: STN 125742/0, COVID-19 Vaccine, mRNA (COMIRNATY)

DATE: August 23, 2021

Office Point of Contact: Laura Gottschalk, Ph.D.

Please include the following information for posting on Web pages:

Proper Name: COVID-19 Vaccine, mRNA
Tradename: COMIRNATY
Manufacturer: BioNTech Manufacturing GmbH
Indication: COMIRNATY is a vaccine indicated 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.

Please review and redact the documents indicated in the options below and post on CBER's Approval Web page. Additional WORD documents (including labeling) are provided via e-mail to '*CBER-OCOD-Action Packages'* on the date of approval.

The documents identified as "Post to Web" in CBER regulatory systems comprise the official Action Package for Posting under Section 916 of FDAAA for original BLAs/NDAs.

Please add the following information to CBER's Approval Web page:
Demographic Subgroup Information – COVID-19 Vaccine, mRNA (COMIRNATY)

Refer to Section 1.1 of the Clinical Review Memo for information about participation in the clinical trials and any analysis of demographic subgroup outcomes that is notable.

In addition, please post appropriate documents on the Web pages indicated in the following table.

Web page	**Post?** (Add "X" if Yes)
FDA's PREA Web page https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/biologics-prea-reviews-and-labeling-changes	X
Vaccines Licensed for Use in the United States (https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states)	X
Approved Cellular and Gene Therapy Products (https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products)	

Web page	**Post?** (Add "X" if Yes)
Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays (https://www.fda.gov/vaccines-blood-biologics/complete-list-donor-screening-assays-infectious-agents-and-hiv-diagnostic-assays) [IF SELECTED, PROVIDE THE APPLICABLE ASSAY TABLE AND DATA TO BE INCLUDED IN TABLE]	
Infectious Disease Testing (http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/InfectiousDisease/default.htm)	
Testing Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Donors for Relevant Communicable Disease Agents and Diseases (https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/testing-human-cells-tissues-and-cellular-and-tissue-based-product-hctp-donors-relevant-communicable)	