

Transmittal Memo

TO: Lorrie McNeill
Director, OCOB

FROM: Doran Fink, M.D., Ph.D. Doran Fink -S
Acting Deputy Director
Office of Vaccines Research and Review

Digitally signed by Doran Fink -S
Date: 2022.07.08 13:52:09 -04'00'

RE: Action Package for: STN 125742/45, COVID-19 Vaccine, mRNA (COMIRNATY)

DATE: July 8, 2022

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

Please update the following information on CBER's Approval Web page for the product referenced above:

Proper Name: COVID-19 Vaccine, mRNA

Tradename: COMIRNATY

Manufacturer: BioNTech Manufacturing GmbH

Indication: For active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 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 provided via e-mail with this transmittal memo comprise the official Action Package for Posting for this supplement approval.

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

Web page	Post? (Add "X" if Yes)
CBER's Pediatric Labeling 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)	
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)	

Web page	Post? (Add "X" if Yes)
Infectious Disease Testing https://www.fda.gov/vaccines-blood-biologics/infectious-disease-tests)	
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)	
Approved Risk Evaluation and Mitigation Strategies (REMS) https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm	