DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL LABELING FOR DRUGS AND BIOLOGICS FOR HUMAN USE

Form Approved: OMB No. 0910-0001
Expiration Date: March 31, 2024
See PRA Statement on last page.

1. Date Submitted
09/08/2021

2. Application Information
Application Type: BLA
Application Number: 125742 /

× Single product Multiple products

For multiple products, submit completed form and specimen of advertising/promotional materials to one application of choice, and attach separate sheet addressing items 3-5 for remainder of products. Refer to No. 3 on instruction sheet.

NOTE: Form FDA 2253 is required by law. Reports are required for approved NDAs, ANDAs (21 CFR 314.81), and BLAs (601.12(f)(4))

3. Proprietary Name	4. Established Name
COMIRNATY	[COVID-19 mRNA Vaccine (nucleoside modified)] Product Code No.:
5. Package Insert Date and ID Number (Latest final printed labeling) 08/21 LAB-1448-1.0	6. Manufacturer Name License No. (Biologics):

7. **Advertisement / Promotional Labeling Materials**

a. **Please check only one:** × Professional Consumer

Material Type (use FDA codes) b.	Dissemination/ Publication Date c.	Material ID Code d.	Material Description e.	
www-website	09/08/2021	PP-CVV-USA-0408	COMIRNATY HCP Website EUA/BLA August Readiness August 2021 V2	Delete Row

To delete a row, click the "Delete Row" button for that row (or press the enter key if you've tabbed into the button). You cannot delete the last remaining row. **Add New Row**

f. Comments

PP-CVV-USA-0408 is an updated version of PP-CVV-USA-0357 previously filed 08/26/2021. The code will be updated throughout the entire site to PP-CVV-USA-0408 when it goes live.

,

8. Applicant's (or Agent's) Return Address		9. Responsible Official's (or Agent's)
Address 1 *(Street address, P.O. box, company name c/o)* An der Goldgrube 12		a. Telephone Number *(Include area code)* (484) 865-5035
Address 2 *(Apartment, suite, unit, building, floor, etc.)*		b. FAX Number *(Include area code)* (845) 474-3500
City Mainz	State/Province/Region N/A	c. Email Address Donna.Boyce@pfizer.com
Country Germany	ZIP or Postal Code 55131	

10. Typed Name and Title of Responsible Official or Agent	11. Signature of Responsible Official or Agent	12. Date
Donna Boyce M.S., Senior Vice President, Global Regulatory Affairs, Global Product Development	(b) (6) Sign	09/08/2021

13. For CBER Products Only *(Check one)*

Draft ☒ Final

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 2 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."