

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

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

1. Date Submitted
 10/11/2021

2. Application Information

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.

Application Type: BLA

Application Number: 125742 /

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
 COMIRNATY

4. Established Name
 [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. | |
|--|---|------------------------|--|------------|
| Promotional Labeling | 10/18/2021 | PP-CVV-USA-0431 | COMIRNATY LDV Resource Sheet Booster Update | Delete Row |
| Promotional Labeling | 10/11/2021 | PP-CVV-USA-0432 | COMIRNATY EUA/BLA 16+ Checklist Booster Update | Delete Row |
| Promotional Labeling | 10/11/2021 | PP-CVV-USA-0391 | COMIRNATY BLA 16+ Dry Ice Replenishment Sheet US August 2021 | 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

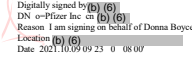

f. Comments

PP-CVV-USA-0431 is an updated version of PP-CVV-USA-0389 filed 09/24/2021.

PP-CVV-USA-0432 is an updated version of PP-CVV-USA-0387 filed 09/24/2021.

PP-CVV-USA-0391 is an updated version of PP-CVV-USA-0311 which is non-reportable.

| | | | |
|---|------------------------------|---|--|
| 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 Donna Boyce M.S., Senior Vice President, Global Regulatory Affairs, Global Product Development | 11. Signature of Responsible Official or Agent (b) (6)   | 12. Date 10/09/2021 |
|---|--|------------------------|

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.”