DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

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
   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)  Dissemination/Publication Date  Material ID Code  Material Description
      b.  c.  d.  e.

   www-links  10/01/2021  PP-CVV-USA-0424  Comirnaty BLA COVID-19 Vaccine DTC SEM DTC Recommendation - Headline Update

   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.

   f. Comments

FORM FDA 2253 (04/21) PREVIOUS EDITION IS OBSOLETE  Page 1 of 2
### Applicant’s (or Agent’s) Return Address

<table>
<thead>
<tr>
<th>Address 1 (Street address, P.O. box, company name c/o)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>An der Goldgrube 12</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Address 2 (Apartment, suite, unit, building, floor, etc.)</th>
<th></th>
</tr>
</thead>
</table>

### 8. Applicant’s (or Agent’s) Return Address

- **An der Goldgrube 12**

### 9. Responsible Official’s (or Agent’s)

- **a. Telephone Number (Include area code)**
  - (484) 865-5035
- **b. FAX Number (Include area code)**
  - (845) 474-3500
- **c. Email Address**
  - Donna.Boyce@pfizer.com

### 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

![Signature](signature.png)

### 12. Date

- **10/01/2021**

### 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.*