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
   b. Material Type (use FDA codes)
   c. Dissemination/Publication Date
   d. Material ID Code
   e. Material Description
      Comirnaty.com Booster Pop-up

   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

   PP-CVV-USA-0430 is an updated version of PP-CVV-USA-0349 filed 08/27/2021.
8. Applicant’s (or Agent’s) Return Address

| Address 1 (Street address, P.O. box, company name c/o) | address | An der Goldgrube 12 |
| Address 2 (Apartment, suite, unit, building, floor, etc.) | City | Mainz | State/Province/Region | N/A | Country | Germany | ZIP or Postal Code | 55131 |

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

| a. Telephone Number (Include area code) | (617) 855-5035 |
| b. FAX Number (Include area code) | (617) 855-3500 |
| 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

| (b) (6) | Sign |

12. Date

| 09/28/2021 |

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 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:

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