2. Application Information
   Application Type: BLA
   Application Number: 125742
   \(\times\) Single product
   \(\times\) 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)]

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: \(\times\) Professional Consumer
      
      | Material Type (use FDA codes) | Dissemination/ Publication Date | Material ID Code | Material Description |
      |-------------------------------|--------------------------------|------------------|---------------------|
      | www-website                   | 08/26/2021                     | PP-CVV-USA-0357  | COMIRNATY HCP Website EUA/BLA August Readiness August 2021 V2 |

   f. Comments

   PP-CVV-USA-0357 will be used with these previously filed educational pieces under the EUA:

   PP-CVV-USA-0177 filed 22-Feb-21
   PP-CVV-USA-0202 filed 23-Mar-21
   PP-CVV-USA-0273 filed 15-Jun-21
   PP-CVV-USA-0283, PP-CVV-USA-0286 & PP-CVV-USA-0302 filed 02-Jun-21
   PP-CVV-USA-0307 filed 13-Jul-21
   PP-CVV-USA-0310 & PP-CVV-USA-0312 filed 28-Jun-21
   PP-CVV-USA-0313 & PP-CVV-USA-0314 filed 15-Jun-21
   PP-CVV-USA-0322 filed 28-Jul-21
   PP-CVV-USA-0323 & PP-CVV-USA-0325 filed 28-Jul-21
   PP-CVV-USA-0326 filed 13-Jul-21
   PP-CVV-USA-0330 filed 28-Jul-21
   PP-CVV-USA-0343 & PP-CVV-USA-0344 filed 4-Aug-21
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@hhs.gov

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