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

### 2. Application Information
- **Application Type:** BLA
- **Application Number:** 125742

### 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

<table>
<thead>
<tr>
<th>Material Type (use FDA codes)</th>
<th>Dissemination/Publication Date</th>
<th>Material ID Code</th>
<th>Material Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>www-website</td>
<td>10/06/2021</td>
<td>PP-CVV-USA-0442</td>
<td>Comirnaty US HCP Website Authorized Use Statement Update</td>
</tr>
</tbody>
</table>

**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.**

### 8. Applicant’s (or Agent’s) Return Address
- **An der Goldgrube 12**
- **Mainz**
- **Germany**

### 9. Responsible Official’s (or Agent’s)
- **Telephone Number (Include area code):** (484) 865-5035
- **FAX Number (Include area code):** (845) 474-3500
- **Email Address:** Donna.Boyce@pfizer.com
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