Amit Patel, Director, Pfizer Global Regulatory Affairs - Vaccines  
235 East 42nd Street  
New York NY  
10017  
214-918-5262  
845-474-3500  
Amitkumar.Patel@pfizer.com

[COVID-19 mRNA Vaccine (nucleoside modified)]  
COMIRNATY

- **Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals ≥16 years of age**

15B. SNOMED CT Indication Disease Term (Use continuation page for each additional indication and respective coded disease term)
COVID-19; SARS-CoV-2; Disease caused by severe acute respiratory syndrome coronavirus 2; SARS-CoV-2 vaccination; COVID-19 vaccination
Request for Comments and Advice for Pfizer/BioNTech’s Plan for Reporting Adverse Events

Pharmacia and Upjohn Company LLC (Pfizer)
7000 Portage Road
Kalamazoo MI
USA 49001

1810189
618054084

LNP production and bulk drug product formulation, Fill and finish, Primary packaging, Secondary packaging, Drug product testing

IND 19736, DMF 012683, DMF 9543, DMF 15209, DMF 011793, DMF 011820, DMF 011321, DMF 10953

28. Establishment Information (Full establishment information should be provided in the body of the application.)

Establishment Name
Pharmacia and Upjohn Company LLC (Pfizer)

Address 1 (Street address, P.O. box, company name c/o)
7000 Portage Road

Address 2 (Apartment, suite, unit, building, floor, etc.)

City
Kalamazoo
State/Province/Region
MI

Country
USA
ZIP or Postal Code
49001

Registration (FEI) Number
1810189

MF Number

Establishment DUNS Number
618054084

Is the establishment new to the application?
[ ] Yes [ ] No

What is the status of the establishment?
[ ] Yes [ ] No
[ ] Pending [ ] Active [ ] Inactive [ ] Withdrawn

Contact Information at the site/facility

Name of Contact for the Establishment
(b) (6)

Telephone Number (Include area code)
(b) (6)

FAX Number (Include area code)
(b) (6)

Email Address
(b) (6)

Manufacturing Steps and/or Type of Testing
LNP production and bulk drug product formulation, Fill and finish, Primary packaging, Secondary packaging, Drug product testing

Is the site ready for inspection? [ ] Yes [ ] No [ ] N/A
If No, when will site be ready? (mm/dd/yyyy)

Continuation Page for #28

29. Cross References (List related BLAs, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, MAFs, and DMFs referenced in the current application.)

IND 19736, DMF 012683, DMF 9543, DMF 15209, DMF 011793, DMF 011820, DMF 011321, DMF 10953

Contin. Page for #29

30. This application contains the following items (Select all that apply)

[ ] 1. Index [ ] 2. Labeling (Select one): [ ] Draft Labeling [ ] Final Printed Labeling [ ] 3. Summary (21 CFR 314.50 (c))

[ ] 4. Chemistry Section [ ] A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
[ ] B. Samples (21 CFR 314.50(e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA’s request)
[ ] C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)

[ ] 5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)
[ ] 6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)

[ ] 7. Clinical microbiology section (e.g., 21 CFR 314.50(d)(4))
[ ] 8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)

Item 30 continued on page 3
30. This application contains the following items (Continued; select all that apply)

- 9. Safety update report (e.g., 21 CFR 314.50(d)(5)(v)(b); 21 CFR 601.2)
- 10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
- 11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
- 12. Case report forms (e.g., 21 CFR 314.50(f)(2); 21 CFR 601.2)
- 13. Patent information on any patent that claims the drug/ biologic (21 U.S.C. 355(b) or (c))
- 14. A patent certification with respect to any patent that claims the drug/biologic (21 U.S.C. 355(b)(2) or (f)(2)(A))
- 15. Establishment description (21 CFR Part 600, if applicable)
- 16. Debarment certification (FD&C Act 306 (k)(1))
- 17. Field copy certification (21 CFR 314.50 (f)(3))
- 18. User Fee Cover Sheet (PDUFA Form FDA 3397, GDUFA Form FDA 3794, BsufA Form FDA 3792, or MDUFA Form FDA 3601)
- 20. Other (Specify): ______________________________

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to, the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211, or applicable regulations, Parts 606, and/or 820.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state, and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

31. Typed Name and Title of Applicant's Responsible Official

Amit Patel, Director, Global Regulatory Affairs - Vaccines, Pfizer Inc.

32. Date (mm/dd/yyyy)

09/07/2021

33. Telephone Number (Include country code if applicable and area code)

214-918-5262

34. FAX Number (Include country code if applicable and area code)

845-474-3500

35. Email Address

Amitkumar.Patel@pfizer.com

36. Address of Applicant's Responsible Official

Address 1 (Street address, P.O. box, company name c/o)

235 East 42nd Street

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

New York

State/Province/Region

NY

Country

United States of America

ZIP or Postal Code

10017

37. Signature of Applicant's Responsible Official or Other Authorized Official

Amit Patel

Digitally signed by Amit Patel

Reason: I attest to the accuracy and integrity of this document

Date: 2021 09 07 16:44:25 -05’00’

38. Countersignature of Authorized U.S. Agent

Sign

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 24 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 the address to the right:

“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.”

Department of Health and Human Services

Food and Drug Administration

Office of Operations

Paperwork Reduction Act (PRA) Staff

PRAStaff@fdasehs.gov

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.
### Pfizer Manufacturing Belgium NV

**Address 1** (Street address, P.O. box, company name c/o)  
Rijksweg 12

**City**  
Puurs

**Country**  
Belgium

**Address 2** (Apartment, suite, unit, building, floor, etc.)

**Registration (FEI) Number**  
1000654629

**MF Number**

**Establishment DUNS Number**  
370156507

**Is the establishment new to the application?**  
☑ Yes  
☐ No

**What is the status of the establishment?**  
☑ Pending  
☐ Active  
☐ Inactive  
☐ Withdrawn

### Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC

**Address 1** (Street address, P.O. box, company name c/o)  
1 Burtt Road

**City**  
Andover

**Country**  
United States

**Registration (FEI) Number**  
1222181

**MF Number**

**Establishment DUNS Number**  
174350868

**Is the establishment new to the application?**  
☑ Yes  
☐ No  
☐ N/A

**Manufacturing Steps and/or Type of Testing**

- LNP production and bulk drug product formulation, Fill and finish, Primary packaging, Secondary packaging, Drug product testing

**Is the site ready for inspection?**  
☑ Yes  
☐ No  
☐ N/A

**If No, when will site be ready? (mm/dd/yyyy)**
<table>
<thead>
<tr>
<th>Establishment Name</th>
<th>Pfizer Inc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address 1 (Street address, P.O. box, company name c/o)</td>
<td>875 Chesterfield Parkway West</td>
</tr>
<tr>
<td>City</td>
<td>Chesterfield</td>
</tr>
<tr>
<td>State/Province/Region</td>
<td>MO</td>
</tr>
<tr>
<td>Country</td>
<td>United States</td>
</tr>
<tr>
<td>ZIP or Postal Code</td>
<td>63017</td>
</tr>
<tr>
<td>Is the establishment new to the application?</td>
<td>Yes</td>
</tr>
<tr>
<td>Phone Number</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>FAX Number</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>Email Address</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>Manufacturing Steps and/or Type of Testing</td>
<td>Drug substance testing, Drug product testing</td>
</tr>
<tr>
<td>Is the site ready for inspection?</td>
<td>Yes</td>
</tr>
<tr>
<td>If No, when will site be ready? (mm/dd/yyyy)</td>
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</tr>
</tbody>
</table>

<table>
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<tr>
<th>Establishment Name</th>
<th>Pfizer Ireland Pharmaceuticals</th>
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<tr>
<td>Address 1 (Street address, P.O. box, company name c/o)</td>
<td>Grange Castle Business Park Clondalkin</td>
</tr>
<tr>
<td>Address 2 (Apartment, suite, unit, building, floor, etc.)</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td>Dublin 22</td>
</tr>
<tr>
<td>State/Province/Region</td>
<td>N/A</td>
</tr>
<tr>
<td>Country</td>
<td>Ireland</td>
</tr>
<tr>
<td>ZIP or Postal Code</td>
<td>N/A</td>
</tr>
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<td>Is the establishment new to the application?</td>
<td>Yes</td>
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<tr>
<td>What is the status of the establishment?</td>
<td>Pending</td>
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<td>(b) (6)</td>
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<tr>
<td>Manufacturing Steps and/or Type of Testing</td>
<td>Drug product testing</td>
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<tr>
<td>Is the site ready for inspection?</td>
<td>Yes</td>
</tr>
<tr>
<td>If No, when will site be ready? (mm/dd/yyyy)</td>
<td></td>
</tr>
</tbody>
</table>
### Third Continuation Page for Item 28 - Establishment Information

#### Hospira Zagreb Ltd.

**Address 1 (Street address, P.O. box, company name c/o)**
Prudnicka cesta 60

**Address 2 (Apartment, suite, unit, building, floor, etc.)**

**City**
Prigorje

**State/Province/Region**
Brdovecko

**Country**
Croatia

**ZIP or Postal Code**
10291

**Registration (FEI) Number**
3010630287

**MF Number**

**Establishment DUNS Number**
500625201

**Is the establishment new to the application?**
✓ Yes  ☐ No

**What is the status of the establishment?**
✓ Pending  ☐ Active  ☐ Inactive  ☐ Withdrawn

#### Establishment Contact Information at the site/facility

**Name of Contact for the Establishment**
(b) (6)

**Telephone Number (Include area code)**

**FAX Number (Include area code)**

**Email Address**

#### Manufacturing Steps and/or Type of Testing

Drug Product Release Testing (Sterility)

Is the site ready for inspection?
✓ Yes  ☐ No  ☐ N/A

If No, when will site be ready? (mm/dd/yyyy)

---

#### SGS Lab Simon SA

**Address 1 (Street address, P.O. box, company name c/o)**
Vieux Chemin du Poete 10

**Address 2 (Apartment, suite, unit, building, floor, etc.)**

**City**
Wavre

**State/Province/Region**
N/A

**Country**
Belgium

**ZIP or Postal Code**
1301

**Registration (FEI) Number**
3004186644

**MF Number**

**Establishment DUNS Number**
283063907

**Is the establishment new to the application?**
✓ Yes  ☐ No  ☐ N/A

**What is the status of the establishment?**
✓ Pending  ☐ Active  ☐ Inactive  ☐ Withdrawn

#### Establishment Contact Information at the site/facility

**Name of Contact for the Establishment**
(b) (6)

**Telephone Number (Include area code)**

**FAX Number (Include area code)**

**Email Address**

#### Manufacturing Steps and/or Type of Testing

Drug Product Release Testing (Sterility)

Is the site ready for inspection?
✓ Yes  ☐ No  ☐ N/A

If No, when will site be ready? (mm/dd/yyyy)

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<p>| Add Fourth Continuation Page for #28 |</p>
<table>
<thead>
<tr>
<th>Establishment Name</th>
<th>Telephone Number (Include area code)</th>
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</thead>
<tbody>
<tr>
<td>Fresenius Kabi USA LLC</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td>Anthony Giessert</td>
<td>FAX Number (Include area code)</td>
</tr>
<tr>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Email Address</td>
</tr>
<tr>
<td></td>
<td>(b) (6)</td>
</tr>
</tbody>
</table>

**Manufacturing Steps and/or Type of Testing**

- manufacture, testing and release of diluent (0.9% Sodium chloride Injection, USP)

**Is the site ready for inspection?** Yes [ ] No [ ] N/A [ ]

**If No, when will site be ready? (mm/dd/yyyy)**

---

<table>
<thead>
<tr>
<th>Establishment Name</th>
<th>Telephone Number (Include area code)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospira Inc.</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td>Paul Lucas</td>
<td>FAX Number (Include area code)</td>
</tr>
<tr>
<td></td>
<td>N/A</td>
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<tr>
<td></td>
<td>Email Address</td>
</tr>
<tr>
<td></td>
<td>(b) (6)</td>
</tr>
</tbody>
</table>

**Manufacturing Steps and/or Type of Testing**

- manufacture, testing and release of diluent (0.9% Sodium chloride Injection, USP)

**Is the site ready for inspection?** Yes [ ] No [ ] N/A [ ]

**If No, when will site be ready? (mm/dd/yyyy)**