

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
 Food and Drug Administration  
**APPLICATION TO MARKET A NEW OR ABBREVIATED NEW DRUG OR BIOLOGIC FOR HUMAN USE**  
*(Title 21, Code of Federal Regulations, Parts 314 & 601)*

Form Approved: OMB No. 0910-0338  
 Expiration Date: March 31, 2020  
 See PRA Statement on page 3.

1. Date of Submission (mm/dd/yyyy)  
 07/28/2021

**APPLICANT INFORMATION** 2. Name of Applicant  
 BioNTech Manufacturing GmbH

3. Telephone Number (Include country code if applicable and area code) +49 (0) 6131 9084-7593  
 4. Facsimile (FAX) Number (Include country code if applicable and area code) +49 (0) 6131 9084-390

5. Applicant Address

|   |                              |  |  |
|---|------------------------------|--|--|
| Address 1 (Street address, P.O. box, company name c/o)<br>An der Goldgrube 12 |                              | Email Address<br>Ruben.Rizzi@biontech.de         |  |
| Address 2 (Apartment, suite, unit, building, floor, etc.)                     |                              | Applicant DUNS<br>117645848                      |  |
| City<br>Mainz   | State/Province/Region<br>N/A | U.S. License Number if previously issued<br>2229 |  |
| Country<br>Germany  | ZIP or Postal Code<br>55131  |  |  |

6. Authorized U.S. Agent (Required for non-U.S. applicants)

|  |             |  |  |
|--|-------------|--|--|
| Authorized U.S. Agent Name<br>Elisa Harkins, Global Regulatory Lead, Pfizer Global Regulatory Affairs - Vaccines |             | Telephone Number (Include area code)<br>215-280-5503 |  |
| Address 1 (Street address, P.O. box, company name c/o)<br>500 Arcola Road  |             | FAX Number (Include area code)<br>845-474-3500       |  |
| Address 2 (Apartment, suite, unit, building, floor, etc.)  |             | Email Address<br>Elisa.HarkinsTull@pfizer.com        |  |
| City<br>Collegeville   | State<br>PA | U.S. Agent DUNS                                      |  |
| ZIP Code<br>19426  |             |  |  |

**PRODUCT DESCRIPTION** 7. NDA, ANDA, or BLA Application Number 125742  
 8. Supplement Number (If applicable)

9. Established Name (e.g., proper name, USP/USAN name)  
 [COVID-19 mRNA Vaccine (nucleoside modified)]

10. Proprietary Name (Trade Name) (If any)  
 COMIRNATY

11. Chemical/Biochemical/Blood Product Name (If any)  
 COVID-19 Vaccine (BNT162, PF-07302048)

12. Dosage Form Liquid  
 13. Strengths 30 mcg  
 14. Route of Administration Intramuscular

15A. Proposed Indication for Use  
 Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals ≥16 years of age

Is this indication for a rare disease (prevalence <200,000 in U.S.)?  Yes  No

Does this product have an FDA Orphan Designation for this indication?  Yes  No

If yes, provide the Orphan Designation number for this indication:

**Continuation Page for #15**

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

**APPLICATION INFORMATION** 16. Application Type (Select one)  New Drug Application (NDA)  Biologics License Application (BLA)  
 Abbreviated New Drug Application (ANDA)

17. If an NDA, identify the type  505(b)(1)  505(b)(2)  
 18. If a BLA, identify the type  351(a)  351(k)

19. If a 351(k), identify the biological reference product that is the basis for the submission.  
 Name of Biologic: \_\_\_\_\_ Holder of Licensed Application: \_\_\_\_\_

20. If an ANDA, or 505(b)(2), identify the listed drug product that is/are the basis for the submission.  
 Name of Drug: \_\_\_\_\_ Application Number of Relied Upon Product: \_\_\_\_\_

Indicate Patent Certification:  P1  P2  P3  P4  Section viii - MOU  Statement of no relevant patents

|  |                             |   |  |
|--|-----------------------------|---|--|
| 21. Submission (See instructions) <input checked="" type="checkbox"/> Original <input type="checkbox"/> Labeling Supplement <input type="checkbox"/> CMC Supplement <input type="checkbox"/> Efficacy Supplement <input type="checkbox"/> Annual Report<br><input type="checkbox"/> Product Correspondence <input type="checkbox"/> REMS Supplement <input type="checkbox"/> Postmarketing Requirements or Commitments <input type="checkbox"/> Periodic Safety Report<br><input type="checkbox"/> Request for Proprietary Name Review <input type="checkbox"/> Other (Specify): _____ |                             |   |  |
| 22. Submission Sub-Type <input type="checkbox"/> Presubmission <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Initial Submission <input type="checkbox"/> Resubmission   |                             | 23. If a supplement, identify the appropriate category. <input type="checkbox"/> CBE <input type="checkbox"/> Prior Approval (PA) <input type="checkbox"/> CBE-30                         |  |
| 24. For Originals and all Supplements, is the product a combination product (21 CFR 3.2(e))? <input type="checkbox"/> Yes <input type="checkbox"/> No  |                             | Combination Product Type (See instructions)   | Request for Designation (RFD) Number   |
| 25. Does the submission contain: Only Pediatric data? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  |                             | Human factors information? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  | 26. Proposed Marketing Status (Select one) <input checked="" type="checkbox"/> Prescription Product (Rx) <input type="checkbox"/> Over-The-Counter Product (OTC) |
| 27. Reasons for Submission<br>Follow-up Response to 22 July 2021 Information Request regarding clinical study shell tables for study C4591001  |                             |   |  |
| 28. Establishment Information (Full establishment information should be provided in the body of the application.)  |                             |   |  |
| Establishment Name<br>Pharmacia and Upjohn Company LLC (Pfizer)  |                             |   |  |
| Address 1 (Street address, P.O. box, company name c/o)<br>7000 Portage Road  |                             | Registration (FEI) Number<br>1810189  |  |
| Address 2 (Apartment, suite, unit, building, floor, etc.)  |                             | MF Number   |  |
| City<br>Kalamazoo  | State/Province/Region<br>MI |   | Establishment DUNS Number<br>618054084   |
| Country<br>USA   | ZIP or Postal Code<br>49001 |   |  |
| Is the establishment new to the application? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No   |                             | What is the status of the establishment? <input checked="" type="checkbox"/> Pending <input type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Withdrawn |  |
| Establishment Contact Information at the site/facility   |                             |   |  |
| Name of Contact for the Establishment<br>(b) (6)   |                             | Telephone Number (Include area code)<br>(b) (6)   |  |
| (b) (6)  |                             | FAX Number (Include area code)<br>(b) (6)   |  |
|  |                             | Email Address<br>(b) (6)  |  |
|  |                             | (b) (6)   |  |
| Manufacturing Steps and/or Type of Testing<br>LNP production and bulk drug product formulation, Fill and finish, Primary packaging, Secondary packaging, Drug product testing  |                             | Is the site ready for inspection? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A<br>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.)<br>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)  |                             |   |  |
| <input checked="" type="checkbox"/> 1. Index <input type="checkbox"/> 2. Labeling (Select one): <input type="checkbox"/> Draft Labeling <input type="checkbox"/> Final Printed Labeling <input type="checkbox"/> 3. Summary (21 CFR 314.50 (c))  |                             |   |  |
| <input type="checkbox"/> 4. Chemistry Section <input type="checkbox"/> A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)<br><input type="checkbox"/> B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)<br><input type="checkbox"/> C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)   |                             |   |  |
| <input type="checkbox"/> 5. Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(2); 21 CFR 601.2)  |                             | <input type="checkbox"/> 6. Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)  |  |
| <input type="checkbox"/> 7. Clinical microbiology section (e.g., 21 CFR 314.50(d)(4))  |                             | <input type="checkbox"/> 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)

|  |  |
|--|--|
| <input type="checkbox"/> 9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)  | <input type="checkbox"/> 10. Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)   |
| <input type="checkbox"/> 11. Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)   | <input type="checkbox"/> 12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)  |
| <input type="checkbox"/> 13. Patent information on any patent that claims the drug/biologic (21 U.S.C. 355(b) or (c))  | <input type="checkbox"/> 14. A patent certification with respect to any patent that claims the drug/biologic (21 U.S.C. 355 (b)(2) or (j)(2)(A)) |
| <input type="checkbox"/> 15. Establishment description (21 CFR Part 600, if applicable)  | <input type="checkbox"/> 16. Debarment certification (FD&C Act 306 (k)(1))   |
| <input type="checkbox"/> 17. Field copy certification (21 CFR 314.50 (l)(3))   | <input type="checkbox"/> 18. User Fee Cover Sheet (PDUFA Form FDA 3397, GDUFA Form FDA 3794, BsUFA Form FDA 3792, or MDUFA Form FDA 3601)        |
| <input type="checkbox"/> 19. Financial Disclosure Information (21 CFR Part 54)   |  |
| <input checked="" type="checkbox"/> 20. Other (Specify): Follow-up Response to 22 July 2021 Information Request regarding clinical study shell tables for study C4591001 |  |

**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.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
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<br>Elisa Harkins, Global Regulatory Lead, Global Regulatory Affairs - Vaccines, Pfizer Inc. | 32. Date (mm/dd/yyyy)<br>07/27/2021 |
|--|-------------------------------------|

|   |   |   |
|---|---|---|
| 33. Telephone Number (Include country code if applicable and area code)<br>215-280-5503 | 34. FAX Number (Include country code if applicable and area code)<br>845-474-3500 | 35. Email Address<br>Elisa.HarkinsTull@pfizer.com |
|---|---|---|

|   |  |                             |  |
|---|--|-----------------------------|--|
| 36. Address of Applicant's Responsible Official                           |  |                             |  |
| Address 1 (Street address, P.O. box, company name c/o)<br>500 Arcola Road |  |                             |  |
| Address 2 (Apartment, suite, unit, building, floor, etc.)                 |  |                             |  |
| City<br>Collegeville  |  | State/Province/Region<br>PA |  |
| Country<br>United States of America                                       |  | ZIP or Postal Code<br>19426 |  |

|  |             |   |             |
|--|-------------|---|-------------|
| 37. Signature of Applicant's Responsible Official or Other Authorized Official<br><b>Elisa Harkins Tull</b><br><small>Digitally signed by Elisa Harkins Tull<br/>DN: o=Pfizer Inc, cn=Elisa Harkins Tull<br/>Reason: I attest to the accuracy and integrity of this document<br/>Date: 2021 07 27 15:36:14 -04'00'</small> | <b>Sign</b> | 38. Countersignature of Authorized U.S. Agent | <b>Sign</b> |
|--|-------------|---|-------------|

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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:

Department of Health and Human Services  
Food and Drug Administration  
Office of Operations  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

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**DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.**

FIRST CONTINUATION PAGE FOR ITEM 28 – Establishment Information

Provide information for additional establishments below, as needed.

Establishment Name  
Pfizer Manufacturing Belgium NV

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

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

City  
Puurs

State/Province/Region  
N/A

Country  
Belgium

ZIP or Postal Code  
2870

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

Establishment 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)

Establishment Name

Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC

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

1 Burt Road

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

City  
Andover

State/Province/Region  
MA

Country  
United States

ZIP or Postal Code  
01810

Registration (FEI) Number  
1222181

MF Number

Establishment DUNS Number  
174350868

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)

(b) (6)

FAX Number (Include area code)

(b) (6)

Email Address

(b) (6)

Manufacturing Steps and/or Type of Testing

Manufacture of drug substance, Drug substance testing, Drug product testing

Is the site ready for inspection?

Yes  No  N/A

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

Add Second Continuation Page for #28

SECOND CONTINUATION PAGE FOR ITEM 28 – Establishment Information

Provide information for additional establishments below, as needed.

Establishment Name

Pfizer Inc

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

875 Chesterfield Parkway West

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

City

Chesterfield

State/Province/Region

MO

Country

United States

ZIP or Postal Code

63017

Registration (FEI) Number

1940118

MF Number

Establishment DUNS Number

004954111

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)

(b) (6)

FAX Number (Include area code)

(b) (6)

Email Address

(b) (6)

Manufacturing Steps and/or Type of Testing

Drug substance testing, Drug product testing

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

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

Establishment Name

Pfizer Ireland Pharmaceuticals

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

Grange Castle Business Park Clondalkin

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

City

Dublin 22

State/Province/Region

N/A

Country

Ireland

ZIP or Postal Code

N/A

Registration (FEI) Number

3004145594

MF Number

Establishment DUNS Number

985586408

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)

(b) (6)

FAX Number (Include area code)

(b) (6)

Email Address

(b) (6)

Manufacturing Steps and/or Type of Testing

Drug product testing

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

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

Add Third Continuation Page for #28

THIRD CONTINUATION PAGE FOR ITEM 28 – Establishment Information

Provide information for additional establishments below, as needed.

Establishment Name

Hospira Zagrab 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)

(b) (6)

FAX Number (Include area code)

(b) (6)

Email Address

(b) (6)

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) \_\_\_\_\_

Establishment Name

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

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)

(b) (6)

FAX Number (Include area code)

(b) (6)

Email Address

(b) (6)

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) \_\_\_\_\_

Add Fourth Continuation Page for #28