Next Page | Export Data | Import Data | Reset Form

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)*: 05/06/2021

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)*: 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

Email Address: Ruben.Rizzi@biontech.de

Applicant DUNS: 117645848

U.S. License Number if previously issued:

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

Authorized U.S. Agent Name: Elisa Harkins, Global Regulatory Lead, Pfizer Global Regulatory Affairs - Vaccines

Address 1 *(Street address, P.O. box, company name c/o)*: 500 Arcola Road

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

City: Collegeville

State: PA

ZIP Code: 19426

Telephone Number *(Include area code)*: 215-280-5503

FAX Number *(Include area code)*: 845-474-3500

Email Address: Elisa.HarkinsTull@pfizer.com

U.S. Agent DUNS:

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)* ☑ Original ☐ Labeling Supplement ☐ CMC Supplement ☐ Efficacy Supplement ☐ Annual Report ☐ Product Correspondence ☐ REMS Supplement ☐ Postmarketing Requirements or Commitments ☐ Periodic Safety Report ☐ Request for Proprietary Name Review ☐ Other *(Specify)*: _____

22. Submission Sub-Type ☑ Presubmission ☐ Amendment ☐ Initial Submission ☐ Resubmission

23. If a supplement, identify the appropriate category. ☐ CBE ☐ Prior Approval (PA) ☐ CBE-30

24. For Originals and all Supplements, is the product a combination product (21 CFR 3.2(e))? ☐ Yes ☑ No

Combination Product Type *(See instructions)*

Request for Designation (RFD) Number

25. Does the submission contain: *Only* Pediatric data? ☐ Yes ☑ No

Human factors information? ☐ Yes ☑ No

26. Proposed Marketing Status *(Select one)* ☑ Prescription Product (Rx) ☐ Over-The-Counter Product (OTC)

27. Reasons for Submission

Rolling Submission 0001 for STN/BL 125742

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? ☑ Pending ☐ Active ☐ Inactive ☐ Withdrawn

Establishment Contact Information at the site/facility

Name of Contact for the Establishment
Christopher S. Nagra

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

Telephone Number *(Include area code)*
269-720-1003

FAX Number *(Include area code)*
269-833-8707

Email Address
christopher.s.nagra@pfizer.com

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)(vi)(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 (j)(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 (l)(3))*	☑ 18. User Fee Cover Sheet *(PDUFA Form FDA 3397, GDUFA Form FDA 3794, BsUFA Form FDA 3792, or MDUFA Form FDA 3601)*
☑ 19. Financial Disclosure Information *(21 CFR Part 54)*	
☐ 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.
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	32. Date *(mm/dd/yyyy)*
Elisa Harkins, Global Regulatory Lead, Global Regulatory Affairs - Vaccines, Pfizer Inc.	05/05/2021

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

36. Address of Applicant's Responsible Official

Address 1 *(Street address, P.O. box, company name c/o)*: 500 Arcola Road		
Address 2 *(Apartment, suite, unit, building, floor, etc.)*:		
City: Collegeville	State/Province/Region: PA	
Country: United States of America	ZIP or Postal Code: 19426	

37. Signature of Applicant's Responsible Official or Other Authorized Official	38. Countersignature of Authorized U.S. Agent
Sign	Sign
Elisa Harkins Tull Digitally signed by Elisa Harkins Tull DN: o=Pfizer Inc, cn=Elisa Harkins Tull Reason: I attest to the accuracy and integrity of this document Date: 2021 05 05 18:43:29 -04'00'	

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@fda.hhs.gov

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

Remove Continuation Page | Return to Form

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
Sofie Depuydt

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

Telephone Number *(Include area code)*
+ 32 (0)4 778 098 00

FAX Number *(Include area code)*
+ 32(0)3 889 65 32

Email Address
sofie.depuydt@pfizer.com

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 Burtt 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
Nicole Barrera

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

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

City
Andover

State/Province/Region
MA

Country
United States

ZIP or Postal Code
01810

Telephone Number *(Include area code)*
(978) 247-3717

FAX Number *(Include area code)*
(212) 338-1872

Email Address
nicole.barrera@pfizer.com

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

Remove Continuation Page | Return to Form

Remove Continuation Page | Return to Form

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
Edward Bourneuf

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

Telephone Number *(Include area code)*
(636) 247-8253

FAX Number *(Include area code)*
(845) 474-4618

Email Address
ed.v.bourneuf@pfizer.com

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
Ciaran Tobin

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

Telephone Number *(Include area code)*
+353 876380768

FAX Number *(Include area code)*
+353 (0) 1469 4001

Email Address
ciaran.tobin@pfizer.com

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

Remove Continuation Page | Return to Form

Remove Continuation Page | Return to Form

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
Marko Vuleticm

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

Telephone Number *(Include area code)*
+385 164122202

FAX Number *(Include area code)*
+385 1 641 2299

Email Address
Marko.Vuletic@pfizer.com

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
Stani Litwinski

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

Telephone Number *(Include area code)*
+32 10 42 11 13

FAX Number *(Include area code)*
+32 10 42 11 00

Email Address
stani.litwinski@sgs.com

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

Remove Continuation Page | Return to Form