

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)
 08/11/2021

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 | | Email Address Ruben.Rizzi@biontech.de | |
| Address 2 (Apartment, suite, unit, building, floor, etc.) | | Applicant DUNS 117645848 | |
| City Mainz | State/Province/Region N/A | U.S. License Number if previously issued 2229 | |
| Country Germany | ZIP or Postal Code 55131 | | |

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

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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

Response to 10 August 2021 Information Request Regarding Comments Received for the Postmarketing Safety Study(ies)

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

(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) _____

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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)

| | |
|--|--|
| <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): <u>Response to 10 August 2021 Information Request Regarding Comments Received for the Postmarketing Safety Study(ies)</u> | |

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 Elisa Harkins, Global Regulatory Lead, Global Regulatory Affairs - Vaccines, Pfizer Inc. | 32. Date (mm/dd/yyyy) 08/11/2021 |
|--|-------------------------------------|

| | | |
|---|---|---|
| 33. Telephone Number (Include country code if applicable and area code) 215-280-5503 | 34. FAX Number (Include country code if applicable and area code) 845-474-3500 | 35. Email Address 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 Neda Aghajani Memar <small>Digitally signed by Neda Aghajani Memar DN cn=Neda Aghajani Memar, o, ou, email=neda.aghajanimemar@pfizer.com, c=US Reason I am signing on behalf of applicant responsible party. Date 2021.08.11 10 40 43 -04'00'</small> | Sign | 38. Countersignature of Authorized U.S. Agent | Sign |
|---|-------------|---|-------------|

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Food and Drug Administration
Office of Operations
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PRAStaff@fda.hhs.gov

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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