

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)
 08/20/2021

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:

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
 Response to FDA 20 August 2021 Information Request Regarding Identification of BLA Compliant Lots Graphic and Dear HCP Letter

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

Establishment Name Pharmacia and Upjohn Company LLC (Pfizer)		Registration (FEI) Number 1810189	
Address 1 (Street address, P.O. box, company name c/o) 7000 Portage Road		MF Number	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Establishment DUNS Number 618054084	
City Kalamazoo	State/Province/Region MI	Country USA	ZIP or Postal Code 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 (b) (6)	Telephone Number (Include area code) (b) (6)
(b) (6)	FAX Number (Include area code) (b) (6)
(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? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If No, when will site be ready? (mm/dd/yyyy) _____
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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)

<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) <input type="checkbox"/> B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request) <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): <u>Response to FDA 20 August 2021 IR Regarding Identification of BLA Compliant Lots Graphic and Dear HCP Letter</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 <u>Elisa Harkins, Global Regulatory Lead, Global Regulatory Affairs - Vaccines, Pfizer Inc.</u>	32. Date (mm/dd/yyyy) <u>08/20/2021</u>
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33. Telephone Number (Include country code if applicable and area code) <u>215-280-5503</u>	34. FAX Number (Include country code if applicable and area code) <u>845-474-3500</u>	35. Email Address <u>Elisa.HarkinsTull@pfizer.com</u>
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36. Address of Applicant's Responsible Official			
Address 1 (Street address, P.O. box, company name c/o) <u>500 Arcola Road</u>			
Address 2 (Apartment, suite, unit, building, floor, etc.)			
City <u>Collegeville</u>	State/Province/Region <u>PA</u>		
Country <u>United States of America</u>	ZIP or Postal Code <u>19426</u>		

37. Signature of Applicant's Responsible Official or Other Authorized Official Elisa Harkins Tull <small>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: 2021.08.20 17:11:06 -04'00'</small>	Sign	38. Countersignature of Authorized U.S. Agent	Sign
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Food and Drug Administration
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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		Registration (FEI) Number 1940118	
Address 1 (Street address, P.O. box, company name c/o) 875 Chesterfield Parkway West		MF Number	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Establishment DUNS Number 004954111	
City Chesterfield	State/Province/Region MO		
Country United States	ZIP or Postal Code 63017		
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 (b) (6)	Telephone Number (Include area code) (b) (6)
(b) (6)	FAX Number (Include area code) (b) (6)
(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? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If No, when will site be ready? (mm/dd/yyyy) _____
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Establishment Name Pfizer Ireland Pharmaceuticals		Registration (FEI) Number 3004145594	
Address 1 (Street address, P.O. box, company name c/o) Grange Castle Business Park Clondalkin		MF Number	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Establishment DUNS Number 985586408	
City Dublin 22	State/Province/Region N/A		
Country Ireland	ZIP or Postal Code N/A		
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 (b) (6)	Telephone Number (Include area code) (b) (6)
(b) (6)	FAX Number (Include area code) (b) (6)
(b) (6)	Email Address (b) (6)

Manufacturing Steps and/or Type of Testing Drug product testing	Is the site ready for inspection? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If No, when will site be ready? (mm/dd/yyyy) _____
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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.		Registration (FEI) Number 3010630287	
Address 1 (Street address, P.O. box, company name c/o) Prudnicka cesta 60		MF Number	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Establishment DUNS Number 500625201	
City Prigorje	State/Province/Region Brdovecko		
Country Croatia	ZIP or Postal Code 10291		
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 (b) (6)	Telephone Number (Include area code) (b) (6)
(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? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If No, when will site be ready? (mm/dd/yyyy) _____
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Establishment Name SGS Lab Simon SA		Registration (FEI) Number 3004186644	
Address 1 (Street address, P.O. box, company name c/o) Vieux Chemin du Poete 10		MF Number	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Establishment DUNS Number 283063907	
City Wavre	State/Province/Region N/A		
Country Belgium	ZIP or Postal Code 1301		
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 (b) (6)	Telephone Number (Include area code) (b) (6)
(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? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If No, when will site be ready? (mm/dd/yyyy) _____
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Add Fourth Continuation Page for #28

FOURTH CONTINUATION PAGE FOR ITEM 28 – Establishment Information

Provide information for additional establishments below, as needed.

Establishment Name
Fresenius Kabi USA LLC

(b) (4)
[Redacted Address and Registration Information]

Withdrawn

Establishment Contact Information at the site/facility

Name of Contact for the Establishment
Anthony Giessert

Telephone Number (Include area code)

(b) (4), (b) (6)

FAX Number (Include area code)

N/A

Email Address

(b) (6)

(b) (4), (b) (6)

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) _____

Establishment Name
Hospira Inc.

(b) (4)
[Redacted Address and Registration Information]

Withdrawn

Establishment Contact Information at the site/facility

Name of Contact for the Establishment
Paul Lucas

Telephone Number (Include area code)

(b) (4), (b) (6)

FAX Number (Include area code)

(b) (4), (b) (6)

Email Address

(b) (6)

(b) (4), (b) (6)

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) _____

Add Fifth Continuation Page for #28