

<b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b> Food and Drug Administration <b>APPLICATION TO MARKET A NEW OR ABBREVIATED NEW DRUG OR BIOLOGIC FOR HUMAN USE</b> <i>(Title 21, Code of Federal Regulations, Parts 314 &amp; 601)</i>	Form Approved: OMB No. 0910-0338 Expiration Date: March 31, 2020 <i>See PRA Statement on page 3.</i>
	1. Date of Submission (mm/dd/yyyy) 05/13/2022

<b>APPLICANT INFORMATION</b>	2. Name of Applicant BioNTech Manufacturing GmbH
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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
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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 Kathleen Collins, Senior Director, Global Regulatory Affairs <div style="background-color: #cccccc; height: 100px; width: 100%;"></div>	Telephone Number (Include area code) <div style="background-color: #cccccc; padding: 2px;">(b) (6)</div> FAX Number (Include area code) <div style="background-color: #cccccc; padding: 2px;">(b) (6)</div> Email Address <div style="background-color: #cccccc; padding: 2px;">(b) (6)</div> U.S. Agent DUNS

<b>PRODUCT DESCRIPTION</b>	7. NDA, ANDA, or BLA Application Number 125742	8. Supplement Number (If applicable) 45
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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
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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.)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If yes, provide the Orphan Designation number for this indication: <input type="text"/>
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**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

<b>APPLICATION INFORMATION</b>	16. Application Type (Select one) <input type="checkbox"/> New Drug Application (NDA) <input checked="" type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Abbreviated New Drug Application (ANDA)
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17. If an NDA, identify the type <input type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2)	18. If a BLA, identify the type <input checked="" type="checkbox"/> 351(a) <input type="checkbox"/> 351(k)
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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 type="checkbox"/> Original <input type="checkbox"/> Labeling Supplement <input type="checkbox"/> CMC Supplement <input checked="" type="checkbox"/> Efficacy Supplement <input type="checkbox"/> Annual Report <input type="checkbox"/> Product Correspondence <input type="checkbox"/> REMS Supplement <input type="checkbox"/> Postmarketing Requirements or Commitments <input type="checkbox"/> Periodic Safety Report <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 Revised USPI in response to FDA 10 May 2022 request for revisions to Package Insert for COMIRNATY in Individuals 12 Years of Age and Older			
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		Registration (FEI) Number 1810189	
Address 2 (Apartment, suite, unit, building, floor, etc.)		MF Number	
City Kalamazoo	State/Province/Region MI		
Country USA	ZIP or Postal Code 49001		Establishment DUNS Number 618054084
Is the establishment new to the application? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		What is the status of the establishment? <input type="checkbox"/> Pending <input checked="" 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) _____	
		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, DMF 012683, DMF 031786, DMF 15911			
			Contin. Page for #29
30. This application contains the following items (Select all that apply)			
<input checked="" type="checkbox"/> 1. Index	<input checked="" type="checkbox"/> 2. Labeling (Select one): <input checked="" 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): Revised USPI in response to FDA 10 May 2022 request for revisions to PI for COMIRNATY in Individuals ≥ 12yo	

**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 Kathleen Collins, Senior Director, Global Regulatory Affairs	32. Date (mm/dd/yyyy) 05/13/2022
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33. Telephone Number (Include country code if applicable and area code) (b) (6)	34. FAX Number (Include country code if applicable and area code)	35. Email Address (b) (6)
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36. Address of Applicant's Responsible Official (b) (6)
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37. Signature of Applicant's Responsible Official or Other Authorized Official  Kathleen Collins <small>Digitally signed by Kathleen Collins DN: o=Pfizer Inc, cn=Kathleen Collins Reason: I attest to the accuracy and integrity of this document Date: 2022 05 13 08:29:24 -04'00'</small>	<b>Sign</b>	38. Countersignature of Authorized U.S. Agent	<b>Sign</b>
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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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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		Registration (FEI) Number 1000654629	
Address 2 (Apartment, suite, unit, building, floor, etc.)		MF Number	
City Puurs	State/Province/Region N/A		
Country Belgium	ZIP or Postal Code 2870		Establishment DUNS Number 370156507
Is the establishment new to the application? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		What is the status of the establishment? <input type="checkbox"/> Pending <input checked="" type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Withdrawn	

<i>Establishment Contact Information at the site/facility</i>	
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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Establishment Name Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC			
Address 1 (Street address, P.O. box, company name c/o) 1 Burt Road		Registration (FEI) Number 1222181	
Address 2 (Apartment, suite, unit, building, floor, etc.)		MF Number	
City Andover	State/Province/Region MA		
Country United States	ZIP or Postal Code 01810		Establishment DUNS Number 174350868
Is the establishment new to the application? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		What is the status of the establishment? <input type="checkbox"/> Pending <input checked="" type="checkbox"/> Active <input type="checkbox"/> Inactive <input type="checkbox"/> Withdrawn	

<i>Establishment Contact Information at the site/facility</i>	
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 Manufacture of drug substance, 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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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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No			What is the status of the establishment? <input type="checkbox"/> Pending <input checked="" 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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No			What is the status of the establishment? <input type="checkbox"/> Pending <input checked="" 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.

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

FOURTH CONTINUATION PAGE FOR ITEM 28 – Establishment Information

Provide information for additional establishments below, as needed.

Establishment Name  
Fresenius Kabi USA LLC

(b) (4)

Establishment Contact Information at the site/facility

Name of Contact for the Establishment  
Anthony Giessert

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

Telephone Number (Include area code)

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

FAX Number (Include area code)

N/A

Email Address

(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)

Establishment Contact Information at the site/facility

Name of Contact for the Establishment  
Paul Lucas

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

Telephone Number (Include area code)

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

FAX Number (Include area code)

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

Email Address

(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

FIFTH CONTINUATION PAGE FOR ITEM 28 – Establishment Information

Provide information for additional establishments below, as needed.

Establishment Name

BioNTech Manufacturing GmbH

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

Emil-von-Behring-Str. 76

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

City

Marburg

State/Province/Region

N/A

Country

Germany

ZIP or Postal Code

35041

Registration (FEI) Number

3011406957

MF Number

Establishment DUNS Number

313270335

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

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

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

Establishment Name

Labor LS SE & Co KG

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

Mangelsfeld 4,5,6

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

City

Bad Bocklet

State/Province/Region

Country

Germany

ZIP or Postal Code

97708

Registration (FEI) Number

3002807481

MF Number

Establishment DUNS Number

314929072

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 (Bioburden)

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

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

Add Sixth Continuation Page for #28



SIXTH CONTINUATION PAGE FOR ITEM 28 – Establishment Information

Provide information for additional establishments below, as needed.

Establishment Name BioNTech Innovative Manufacturing Services (BNT IMFS) GmbH		Registration (FEI) Number 3014049480	
Address 1 (Street address, P.O. box, company name c/o) Vollmersbachstrasse 66		MF Number	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Establishment DUNS Number 537365801	
City Idar-Oberstein	State/Province/Region		
Country Germany	ZIP or Postal Code 55743		

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)
(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

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

Establishment Name BioNTech Manufacturing GmbH		Registration (FEI) Number 3015003158	
Address 1 (Street address, P.O. box, company name c/o) An der Goldgrube		MF Number	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Establishment DUNS Number 314382536	
City Mainz	State/Province/Region		
Country Germany	ZIP or Postal Code 55131		

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 Christoph Prinz	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

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

Add Seventh Continuation Page for #28

SEVENTH CONTINUATION PAGE FOR ITEM 28 – Establishment Information

Provide information for additional establishments below, as needed.

Establishment Name

Hospira, Inc

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

1776 North Centennial Drive

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

City

McPherson

State/Province/Region

Kansas

Country

United States

ZIP or Postal Code

67460

Registration (FEI) Number

1925262

MF Number

Establishment DUNS Number

030606222

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

Ian MacKellar

(b) (6)

Telephone Number (Include area code)

(b) (6)

FAX Number (Include area code)

N/A

Email Address

(b) (6)

Manufacturing Steps and/or Type of Testing

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

Sandoz GmbH

(b) (4)

Establishment Contact Information at the site/facility

Name of Contact for the Establishment

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

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

Telephone Number (Include area code)

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

FAX Number (Include area code)

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

Email Address

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

Manufacturing Steps and/or Type of Testing

(b) (4)

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

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

Add Eighth Continuation Page for #28