

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)
 07/01/2022

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 Gosia Mineo, Director, Global Regulatory Affairs - Vaccines (b) (6)	Telephone Number (Include area code) (b) (6)
	FAX Number (Include area code) (b) (6)
	Email Address (b) (6)
	U.S. Agent DUNS

PRODUCT DESCRIPTION 7. NDA, ANDA, or BLA Application Number 125742
 8. Supplement Number (If applicable) 45

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
 Revised USPI in response to FDA 29 June 2022 request for replacement to date of 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)		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 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) _____
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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, DMF 012683, DMF 031786, DMF 15911

Contin. Page for #29

30. This application contains the following items (Select all that apply)

<input 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 29 June 2022 request for replacement to date of 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 Gosia Mineo, Director, Global Regulatory Affairs - Vaccines	32. Date (mm/dd/yyyy) 07/01/2022
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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) (b) (6)	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 Digitally signed by Gosia Mineo DN: o=Pfizer Inc, cn=Gosia Mineo Date: 2022 07 01 10:12:11 -04'00'	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		Registration (FEI) Number 1000654629	
Address 1 (Street address, P.O. box, company name c/o) Rijksweg 12		MF Number	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Establishment DUNS Number 370156507	
City Puurs	State/Province/Region N/A		
Country Belgium	ZIP or Postal Code 2870		
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)
	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? <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		Registration (FEI) Number 1222181	
Address 1 (Street address, P.O. box, company name c/o) 1 Burt Road		MF Number	
Address 2 (Apartment, suite, unit, building, floor, etc.)		Establishment DUNS Number 174350868	
City Andover	State/Province/Region MA		
Country United States	ZIP or Postal Code 01810		
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)
	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? <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			
Address 1 (Street address, P.O. box, company name c/o) 875 Chesterfield Parkway West		Registration (FEI) Number 1940118	
Address 2 (Apartment, suite, unit, building, floor, etc.)		MF Number	
City Chesterfield	State/Province/Region MO		
Country United States	ZIP or Postal Code 63017		Establishment DUNS Number 004954111
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			
Address 1 (Street address, P.O. box, company name c/o) Grange Castle Business Park Clondalkin		Registration (FEI) Number 3004145594	
Address 2 (Apartment, suite, unit, building, floor, etc.)		MF Number	
City Dublin 22	State/Province/Region N/A		
Country Ireland	ZIP or Postal Code N/A		Establishment DUNS Number 985586408
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.		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 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)	
		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) _____	

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 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)	
		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) _____	
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)

(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

Yes

No

N/A

for inspection?

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)

(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

Yes

No

N/A

for inspection?

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			
Address 1 (Street address, P.O. box, company name c/o) Vollmersbachstrasse 66		Registration (FEI) Number 3014049480	
Address 2 (Apartment, suite, unit, building, floor, etc.)		MF Number	
City Idar-Oberstein	State/Province/Region		
Country Germany	ZIP or Postal Code 55743		Establishment DUNS Number 537365801
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	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 BioNTech Manufacturing GmbH			
Address 1 (Street address, P.O. box, company name c/o) An der Goldgrube		Registration (FEI) Number 3015003158	
Address 2 (Apartment, suite, unit, building, floor, etc.)		MF Number	
City Mainz	State/Province/Region		
Country Germany	ZIP or Postal Code 55131		Establishment DUNS Number 314382536
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 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? <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 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

Telephone Number (Include area code)

(b) (6)

(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)

Telephone Number (Include area code)

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

(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