From: DeCiero, Daniel
Sent: Thursday, August 19, 2021 12:48 PM
To: Zubkova, Iryna
Cc: Peters, Lori; Naik, Ramachandra; Smith, Michael (CBER); Gottschalk, Laura; Ertel, Donald; Sausville, Robert; Anderson, Maria (CBER); Mendoza, Melissa; Malarkey, Mary
Subject: RE: Request for Compliance Check BLA STN 125742/0

- **Applicant Name:** *BioNTech Manufacturing GmbH*
- **Product Names:** *125742/0 - COVID-19 mRNA Vaccine (COMIRNATY)*
- **License Number:** *2229*
- **Address:** *BioNTech Manufacturing GmbH,* An der Goldgrube 12 Mainz, , GERMANY
- **Application #:** 125742/0
- **Submission type:** *BLA*
- **Projected Approval Date/Action Due Date:** *August 20, 2021*

Summary: For a*ctive immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals ≥16 years of age*

List only those manufacturing locations requiring inspection for an original application approval. List all manufacturing locations affected by the change(s) identified in a supplement:

Manufacturing/ Testing activities	Inspection? Waiver? Not Required?	Compliance check required for approval?	RMS-BLA entry required?	Comments/ Inspection history
Manufacturing of (b) (4) Drug Substance Release and Stability Testing Drug Product Release and Stability Testing **Facility**: Pfizer Inc. 875 Chesterfield Parkway West Chesterfield, MO 63017 **FEI#:** 1940118	Waiver	Yes	Yes	ORA surveillance inspection NAI, 08/19/2019 – 08/20/2019
Manufacture of BNT162b2 drug substance (b) (4) Drug Substance Release and Stability Testing (Buildings (b) (4) Drug Product Release and Stability Testing (Buildings (b) (4) **Facility**: Wyeth BioPharma	Inspection	Yes	Yes	CBER pre-license inspection July 19 – 23, 2021

Manufacturing/ Testing activities	Inspection? Waiver? Not Required?	Compliance check required for approval?	RMS-BLA entry required?	Comments/ Inspection history
Division of Wyeth Pharmaceuticals LLC[a] 1 Burtt Road Andover, MA 01810 **FEI#:** 1222181				
LNP production and bulk drug product formulation Fill and finish Primary packaging Secondary packaging Drug Product Release and Stability testing **Facility:** Pharmacia & Upjohn Company LLC[b] 7000 Portage Road Kalamazoo, MI 49001 **FEI#:** 1810189	Waiver	Yes	Yes	ORA/OBPO surveillance inspection VAI, 05/11/2021 – 05/20/2021
LNP production and bulk drug product formulation Fill and finish Primary packaging Secondary packaging Drug Product Release and Stability testing **Facility:** Pfizer Manufacturing Belgium NV Rijksweg 12 Puurs, 2870 Belgium **FEI#:** 1000654629	Inspection	Yes	Yes	BNT162b2 will be filled in the (b) (4) building ((b) (4) area) and Vaccine Building. The (b) (4) syringe line was previously FDA inspected but not the (b) (4) vial filling line. The Vaccine Building was not previously FDA inspected. CBER pre-license inspection June 24 - July 2, 2021
Drug Product Release and Stability Testing **Facility:** Pfizer Ireland Pharmaceuticals Grange Castle Business Park Clondalkin, Dublin 22 Ireland **FEI#:** 3004145594	Waiver	Yes	Yes	ORA/OBPO surveillance inspection VAI, 11/04/2019 – 11/12/2019
Drug Product Release Testing	Waiver	Yes	Yes	CDER preapproval

Manufacturing/ Testing activities	Inspection? Waiver? Not Required?	Compliance check required for approval?	RMS-BLA entry required?	Comments/ Inspection history
(Sterility) **Facility:** Hospira Zagreb Ltd.[c] Prudnička cesta 60 10291 Prigorje Brdovečko Croatia **FEI#:** 3010630287				inspection VAI, 11/14/2019 – 11/22/2019
Drug Product Release Testing (Sterility) **Facility**: SGS Lab Simon SA Vieux Chemin du Poète 10 Wavre, 1301 Belgium **FEI#:** 3004186644	Waiver	Yes	Yes	ORA surveillance inspection VAI, 09/25/2017 – 09/27/2017
Manufacture, testing and release (of 2 mL size diluent vials) **Facility:** Fresenius-Kabi USA, LLC (b) (4) **FEI#** (b) (4)	Not Required	Yes	Yes	ORA surveillance inspection VAI, (b) (4)
Manufacture, testing and release (of 10 mL size diluent vials) **Facility:** Hospira, Inc (b) (4) **FEI#** (b) (4)	Not Required	Yes	Yes	ORA surveillance inspection VAI, (b) (4)
Manufacture, testing and release (of 10 mL size diluent vials) Facility: Pfizer Healthcare India Pvt. Ltd.[**] (b) (4)	Not Required	Yes	Yes	ORA surveillance inspection OAI, (b) (4)

Manufacturing/ Testing activities	Inspection? Waiver? Not Required?	Compliance check required for approval?	RMS-BLA entry required?	Comments/ Inspection history
FEI# (b) (4)				

** Please note the removal of the Pfizer Healthcare India Pvt. Ltd. (b) (4) facility from the original request as a result of BLA amendment 125742.0.56.

There are no ongoing or pending investigations or compliance actions with respect to the above facilities or their product(s). Therefore, the Office of Compliance and Biologics Quality, Division of Case Management does not object to the approval of this BLA.

Daniel DeCiero
Consumer Safety Officer
OCBQ/DCM/BDDCB
WO71, Room 5011B
240-402-1666

From: Zubkova, Iryna <Iryna.Zubkova@fda.hhs.gov>
Sent: Friday, August 13, 2021 5:46 PM
To: DeCiero, Daniel <Daniel.DeCiero@fda.hhs.gov>
Cc: Peters, Lori <Lori.Peters@fda.hhs.gov>; Zubkova, Iryna <Iryna.Zubkova@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Ertel, Donald <Donald.Ertel@fda.hhs.gov>
Subject: Request for Compliance Check BLA STN 125742/0
Importance: High

Hello Daniel!

Please execute the Compliance Check for BLA 125742/0.
The PDUFA ADD is January 16, 2022. But the **internal** ADD is **August 20, 2021 or August 27, 2021**.
Facilities table has been updated and Inspection waiver is attached.
EIR's will be submitted when they are available.

<< File: BLA 125742-0_08-09-2021_Inspection Related_Inspect.pdf >>

Thank you,
Iryna

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Manufacture of BNT162b2 drug substance (b) (4) Drug Substance Release and Stability Testing (Buildings (b) (4) and (b) (4) Drug Product Release and Stability Testing (Buildings (b) (4) and (b) (4) **Facility**: Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC[a] 1 Burtt Road Andover, MA 01810 **FEI#:** 1222181	Inspection	Yes	Yes	CBER pre-license inspection July 19 – 23, 2021
LNP production and bulk drug product formulation Fill and finish Primary packaging Secondary packaging Drug Product Release and	Waiver	Yes	Yes	ORA/OBPO surveillance inspection VAI, 05/11/2021 – 05/20/2021

Manufacturing/ Testing activities	Inspection? Waiver? Not Required?	Compliance check required for approval?	RMS-BLA entry required?	Comments/ Inspection history
Stability testing **Facility:** Pharmacia & Upjohn Company LLC[b] 7000 Portage Road Kalamazoo, MI 49001 **FEI#:** 1810189				
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Drug Product Release Testing (Sterility) **Facility:** Hospira Zagreb Ltd.[c] Prudnička cesta 60 10291 Prigorje Brdovečko Croatia **FEI#:** 3010630287	Waiver	Yes	Yes	CDER preapproval inspection VAI, 11/14/2019 – 11/22/2019
Drug Product Release Testing (Sterility) **Facility**: SGS Lab Simon SA	Waiver	Yes	Yes	ORA surveillance inspection VAI, 09/25/2017 – 09/27/2017

Manufacturing/ Testing activities	Inspection? Waiver? Not Required?	Compliance check required for approval?	RMS-BLA entry required?	Comments/ Inspection history
Vieux Chemin du Poète 10 Wavre, 1301 Belgium **FEI#:** 3004186644				
Manufacture, testing and release (of 2 mL size diluent vials) **Facility:** Fresenius-Kabi USA, LLC (b) (4) **FEI#** (b) (4)	Not Required	Yes	Yes	ORA surveillance inspection VAI, (b) (4)
Manufacture, testing and release (of 10 mL size diluent vials) **Facility:** Hospira, Inc (b) (4) **FEI#** (b) (4)	Not Required	Yes	Yes	ORA surveillance inspection VAI, (b) (4)
Manufacture, testing and release (of 10 mL size diluent vials) Facility: Pfizer Healthcare India Pvt. Ltd. (b) (4) **FEI#** (b) (4)	Not Required	Yes	Yes	ORA surveillance inspection OAI (b) (4)

Iryna Zubkova, Ph.D.
Regulatory Project Manager

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