

Food and Drug Administration
Center for Biologics Evaluation and Research
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September 17, 2020

Our internal reference : **B4013** update 1

DMF#: 10953

Holder: Datwyler Pharma Packaging Belgium NV

Subject : Rubber Compounds

Letter of Authorization for:


- **compound FM457/0**, located in record # 026, Update 3, pages 1-7, dated April 21, 2020.

Dear DMF Staff:

Datwyler Pharma Packaging Belgium NV hereby authorizes **Pfizer Inc. as US Agent for BioNTech RNA Pharmaceuticals GmbH** to incorporate by reference information regarding **compound FM457/0** in DMF 10953 into a **BLA** application filed by Pfizer Inc. as US Agent for BioNTech RNA Pharmaceuticals GmbH, 500 Arcola Road, Collegeville, PA, 19436, USA, for their product **SARS-COV-2-mRNA Vaccine**. We also authorize the FDA to review the aforementioned specific information in DMF 10953 when considering a BLA application filed by Pfizer Inc. as US Agent for BioNTech RNA Pharmaceuticals GmbH.

Datwyler Pharma Packaging Belgium NV states that DMF 10953 is current and Datwyler Pharma Packaging Belgium NV will comply with the statements made within it. Datwyler Pharma Packaging Belgium NV will notify FDA through an amendment to DMF 10953 of any addition, change, or deletion of information in the DMF. Datwyler Pharma Packaging Belgium NV will also notify in writing Pfizer Inc. as US Agent for BioNTech RNA Pharmaceuticals GmbH that an addition, change, or deletion of information has been made to the DMF.

Sincerely,


Digitally signed
by Tabassam
Sharif
Date:
2020.09.17
16:13:25 +02'00'

Tabassam Sharif

Manager Regulatory Affairs

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