



Our STN: BL 125742/41

**MATERIAL THREAT MEDICAL COUNTERMEASURE  
PRIORITY REVIEW VOUCHER – GRANTED**

January 27, 2022

BioNTech Manufacturing GmbH  
Attention: Kathleen Collins, M.S.  
Pfizer, Inc.  
500 Arcola Road  
Collegeville, PA 19426

Dear Ms. Collins:

Please refer to your Biologics License Application (BLA) submitted, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA and approved on August 23, 2021.

We also refer to your December 3, 2021 submission, received on December 3, 2021, requesting a material threat medical countermeasure priority review voucher (PRV).

We inform you that you have been granted a material threat medical countermeasure PRV, as provided under section 565A of the Food, Drug and Cosmetic Act (FDCA). This PRV has been assigned a tracking number, PRV BLA 125742. All correspondence related to this voucher should refer to this tracking number.

This voucher entitles you to designate a single human drug application submitted under section 505(b)(1) of the FDCA or a single biologic application submitted under section 351(a) of the PHS Act as qualifying for a priority review. Such an application would not have to meet any other requirements for a priority review. The list below describes the sponsor responsibilities and the parameters for using and transferring a material threat medical countermeasure PRV.

- The sponsor who redeems the PRV must notify FDA of its intent to submit an application with a PRV at least 90 days before submission of the application and must include the date the sponsor intends to submit the application. This notification should be prominently marked, **“Notification of Intent to Submit an Application with a Material Threat Medical Countermeasure Priority Review Voucher.”**
- This PRV may be transferred, including by sale, by you to another sponsor of a human drug or biologic application. If the PRV is transferred, the sponsor to whom the PRV has been transferred should include a copy of this letter and proof that the PRV was transferred. When redeeming this PRV, you should refer to this letter as an official record of the voucher.

For additional information regarding the PRV, see FDA's draft guidance, *Material Threat Medical Countermeasure Priority Review Voucher Program* at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/material-threat-medical-countermeasure-priority-review-vouchers-draft-guidance-industry>. This guidance when finalized, will represent the current thinking of FDA on this topic.

If you have any questions, please contact the (b) (6)  
(b) (6) at (b) (6) or by email at  
(b) (6)

Sincerely,

Peter Marks, M.D., Ph.D.  
Acting Director  
Office of Vaccines Research and Review  
Center for Biologics Evaluation and Research