

**From:** Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>  
**Sent:** Monday, July 19, 2021 11:40 AM  
**To:** Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>  
**Cc:** Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Rohlfing, Paul <Paul.Rohlfing@pfizer.com>  
**Subject:** BLA STN 125742/0 – COMIRNATY - COVID-19 mRNA Vaccine - Issuance of BLA license number in advance of approval

Dear Ms. Harkins,

Reference is made to your request in the cover letter to the first roll of your BLA for COMIRNATY dated May 6, 2021, for the US License Number for BioNTech Manufacturing GmbH with the agreement that it will not be used until after the BLA is approved.

At this time, we are providing a US License Number of 2229 to facilitate product labelling in advance of approval during the declared Public Health Emergency. Provision of this number does not constitute any determination by FDA on the application.

Please confirm receipt of this email and let me know if you have any questions or need additional information.

Regards,  
Ram

**Ramachandra S. Naik, Ph.D.**  
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