

**From:** Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>  
**Sent:** Wednesday, July 28, 2021 2:16 PM  
**To:** Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>  
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**Subject:** STN 125742/0 - COMIRNATY (COVID-19 Vaccine, mRNA) - Preliminary comments on Package Insert

Dear Ms. Harkins,

Inserted in the attached please find preliminary requested changes and comments on the draft Package Insert for COMIRNATY. Please note that we have not reviewed Section 6 (Adverse reactions) or Section 14 (Clinical Studies). Comments on these sections will be provided after review. Please submit a revised draft of the Package Insert to include the revisions requested by COB Monday, August 2, 2021.

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.**

*Biologist (Regulatory) / Primary Reviewer*  
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