

**From:** Gottschalk, Laura  
**Sent:** Saturday, August 21, 2021 10:45 AM  
**To:** Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>  
**Cc:** Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>  
**Subject:** RE: [EXTERNAL] RE: STN 125742/0: Comment regarding vial labels

Dear Elisa,

We acknowledge that additional information regarding the diluent name will not fit on the vial labels but is included on the carton labels. Therefore, you do not need to provide a response to our August 20, 2021 comment regarding the vial labels.

Best,  
Laura

*Laura Gottschalk, PhD | Regulatory Project Manager/Primary Reviewer*

**From:** Gottschalk, Laura  
**Sent:** Friday, August 20, 2021 5:02 PM  
**To:** Harkins Tull, Elisa <[Elisa.HarkinsTull@pfizer.com](mailto:Elisa.HarkinsTull@pfizer.com)>  
**Cc:** Devlin, Carmel M <[Carmel.Devlin@pfizer.com](mailto:Carmel.Devlin@pfizer.com)>; Aghajani Memar, Neda <[Neda.AghajaniMemar@pfizer.com](mailto:Neda.AghajaniMemar@pfizer.com)>; Smith, Michael (CBER) <[Michael.Smith2@fda.hhs.gov](mailto:Michael.Smith2@fda.hhs.gov)>; Naik, Ramachandra <[Ramachandra.Naik@fda.hhs.gov](mailto:Ramachandra.Naik@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] RE: STN 125742/0: Comment regarding vial labels

Hi Elisa,

Thanks for the update. We'll provide a response soon.

Best,  
Laura

*Laura Gottschalk, PhD | Regulatory Project Manager/Primary Reviewer*

**From:** Harkins Tull, Elisa <[Elisa.HarkinsTull@pfizer.com](mailto:Elisa.HarkinsTull@pfizer.com)>  
**Sent:** Friday, August 20, 2021 3:57 PM  
**To:** Gottschalk, Laura <[Laura.Gottschalk@fda.hhs.gov](mailto:Laura.Gottschalk@fda.hhs.gov)>  
**Cc:** Devlin, Carmel M <[Carmel.Devlin@pfizer.com](mailto:Carmel.Devlin@pfizer.com)>; Aghajani Memar, Neda <[Neda.AghajaniMemar@pfizer.com](mailto:Neda.AghajaniMemar@pfizer.com)>; Smith, Michael (CBER) <[Michael.Smith2@fda.hhs.gov](mailto:Michael.Smith2@fda.hhs.gov)>; Naik, Ramachandra <[Ramachandra.Naik@fda.hhs.gov](mailto:Ramachandra.Naik@fda.hhs.gov)>  
**Subject:** [EXTERNAL] RE: STN 125742/0: Comment regarding vial labels

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Hi Laura,

I just got done meeting with the graphic artists who manage our vial and carton artwork. The additional information about the diluent that CBER proposed for us to add will definitely not fit on the vial label. That information is, however, already on the carton label. Given this, does CBER still need us to formally respond to this request?

Best regards,  
Elisa

**From:** Gottschalk, Laura <[Laura.Gottschalk@fda.hhs.gov](mailto:Laura.Gottschalk@fda.hhs.gov)>

**Sent:** Friday, August 20, 2021 3:11 PM

**To:** Harkins Tull, Elisa <[Elisa.HarkinsTull@pfizer.com](mailto:Elisa.HarkinsTull@pfizer.com)>

**Cc:** Devlin, Carmel M <[Carmel.Devlin@pfizer.com](mailto:Carmel.Devlin@pfizer.com)>; Aghajani Memar, Neda <[Neda.AghajaniMemar@pfizer.com](mailto:Neda.AghajaniMemar@pfizer.com)>; Smith, Michael (CBER) <[Michael.Smith2@fda.hhs.gov](mailto:Michael.Smith2@fda.hhs.gov)>; Naik, Ramachandra <[Ramachandra.Naik@fda.hhs.gov](mailto:Ramachandra.Naik@fda.hhs.gov)>

**Subject:** [EXTERNAL] STN 125742/0: Comment regarding vial labels

Dear Elisa,

Our review of the information provided in your BLA STN 125742/0 for COMIRNATY (COVID-19 Vaccine, mRNA), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older, is ongoing. We refer you to the revised carton and container labels that were submitted to you BLA in amendment 63 (seq 0064, dated August 19, 2021).

Please see the attached pdf of your vial label that contains our comment. Please respond to our comment by **EOD today, August 20, 2021**, and follow up with a submission to the BLA.

Please acknowledge receipt of this message and let me know if you have any questions.

Best,  
Laura

**Laura Gottschalk, PhD**

*Regulatory Project Manager/Primary Reviewer*

**Center for Biologics Evaluation and Research  
Office of Vaccines Research and Review**

**U.S. Food and Drug Administration**

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