

**From:** Gottschalk, Laura <[Laura.Gottschalk@fda.hhs.gov](mailto:Laura.Gottschalk@fda.hhs.gov)>  
**Sent:** Wednesday, August 18, 2021 5:20 PM  
**To:** Harkins Tull, Elisa <[Elisa.HarkinsTull@pfizer.com](mailto:Elisa.HarkinsTull@pfizer.com)>  
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**Subject:** [EXTERNAL] STN 125742/0 – COMIRNATY (COVID-19 Vaccine, mRNA) - Comments regarding inclusion of draft carton and container labels in a single amendment

Dear Ms. Harkins,

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.

For the sake of referencing in the Approval Letter, please submit, in a single amendment, all the draft labels listed in the below amendments:

- Amendment 46 (Seq 0046, dated 08/13/2021)
  - COMIRNATY Vial Label (Kalamazoo)
  - COMIRNATY Vial Label (Puurs)
  - Diluent Sticker (Hospira)
  
- Amendment 53 (Seq 0054, dated 08/17/2021)
  - COMIRNATY Carton – 25 Vial (Kalamazoo)
  - COMIRNATY Carton – 25 Vial (Puurs)
  - COMIRNATY Carton – 195 Vial (Kalamazoo)
  - COMIRNATY Carton – 195 Vial (Puurs)
  - Diluent Vial (Fresenius Kabi)
  - Diluent Vial (Hospira)
  - Diluent Carton – 25 Vial (Fresenius Kabi)
  - Diluent Carton – 25 Vial (Hospira)
  
- Unsubmitted
  - Diluent stamp (Fresenius Kabi) – revised version

Please submit these labels as soon possible, but no later than 12:00pm, August 19, 2021.

Please acknowledge receipt of these comments and let me know if you have any questions.

Thanks,  
Laura

**Laura Gottschalk, PhD**

*Regulatory Project Manager/Primary Reviewer*

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