From: Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Sent: Wednesday, August 18, 2021 5:20 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Cc: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>
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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