**From:** Smith, Michael (CBER)
**Sent:** Monday, August 16, 2021 1:22 PM
**To:** Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
**Cc:** Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
**Subject:** STN 125742.0: Second set of comments and questions on the carton and container labels

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 Amendment 46 of your BLA (dated August 13, 2021) in which you responded to our August 9, 2021 comments on your carton and container labels. We have the following additional requests for information regarding your proposed carton and container labels:

**Regarding the Diluent Labeling:**

1. In our August 9, 2021 communication, we requested that you provide the vial labels for the diluent; however, no vial labels were submitted. We continue to request that you submit vial labels for the diluents as this information should be included in your BLA.

2. In your original BLA submission, you included a single picture of the outside of each multi-vial diluent carton. Please provide copies of the full carton labels for the diluent manufactured at both Fresenius Kabi and Hospira as this information should be included in your BLA. Each carton label should include a lot number and expiration date for the packaged diluent.

3. In Amendment 46, you included a "Diluent Sticker." Our understanding is this sticker is the same as the previously submitted "Fresenius Kabi Diluent Stamp" and the "Hospira Diluent Label". Please confirm. For each diluent carton, please provide a graphical presentation of the carton label and clearly show where the sticker/stamp will be located.

4. In our August 9, 2021 communication we requested that the "Fresenius Kabi Diluent Stamp" and the "Hospira Diluent Label" include the proper name of the diluent, the lot number, and expiration date. However, revised labels were not submitted. Please provide a revised stamp and label for our review. See also comment 3 above.

**Regarding the COMIRNATY Carton Labels:**

5. The placement of the QR code in the center of the label for the 195-vial container from Kalamazoo competes with and distracts from the information provided on the label. Please revise the label to place the QR code such that it does not compete with, distract from, interrupt, or distort the required or recommended content on the carton labeling (see the draft guidance for industry: *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (April 2013). When final, this guidance will represent the Agency's current thinking on this topic). For example, placement of the QR code on the lower left of the label (such as on the carton for the 195-vial container from Puurs) would be acceptable.

6. Please include on the cartons the following instructions, "Please see prescribing information for additional details including instructions for preparation, dosage and administration."

7. Please revise the temperatures for storage prior to dilution so that they are consistent with the prescribing information by changing:

   -90°C to -60°C (-130°F to -76°F)

   to

   -80°C to -60°C (-112°F to -76°F).

Please provide your responses in an amendment to STN 125742/0 by 12:00 PM on Tuesday, August 17, 2021. We recommend that you restate each item and follow it with your explanation or clarification. Use of this format helps organize

the relevant information and provides a self-contained document that facilitates future reference.

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

Regards,

Mike

**Mike Smith, Ph.D.**
**Captain, USPHS**

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