

From: Smith, Michael (CBER)

Sent: Monday, August 9, 2021 3:18 PM

To: 'Aghajani Memar, Neda' <Neda.AghajaniMemar@pfizer.com>; 'Harkins Tull, Elisa' <Elisa.HarkinsTull@pfizer.com>; 'Devlin, Carmel M' <Carmel.Devlin@pfizer.com>

Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>

Subject: STN 125742.0: Comments on the Carton and Container labels

Neda,

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 have the following requests for additional information regarding your proposed Carton and Container Labels and the review team has requested a response as soon as possible:

Regarding the Diluent Labeling:

1. When referring to the proper name, please revise to, "COVID-19 Vaccine, mRNA."
2. Please provide the vial labels for the diluent.
3. For the "Fresenius Kabi Diluent Stamp," and the "Hospira Diluent Label," please include the following:
 - a. The proper name of the diluent,
 - b. The lot number, and
 - c. The expiration date.

Regarding the COMIRNATY Carton Labels:

4. When referring to the proper name, please revise to, "COVID-19 Vaccine, mRNA."
5. Please confirm that the cartons will contain the Product Identifier as described in the Drug Supply Chain Security Act (DSCSA).

6. Please include the License Number on all COMIRNATY carton labels.
7. Please clarify where the lot number and expiry will be presented on the cartons that will contain 25 vials from Puurs.
8. Please revise the prominence (point size and type face) of the proper name to ensure that it is at least as prominent as the trade name.
9. Please remove the graphic to the left of the trade name as it is adversely affecting the prominence of the proper name.
10. Please include on the cartons the following instructions, "Please see prescribing information for preparation, dosage and administration."
11. Please revise the storage conditions to be consistent with the prescribing information.
12. For the 25 vial carton labels, please include the following language under *Dosage and Administration* on the side panel, "Diluent (sterile 0.9% Sodium Chloride Injection, USP) supplied separately. Use the provided diluent or an alternate brand of sterile 0.9% Sodium Chloride Injection, USP." Delete the parenthetical "supplied separately" on the main panel.
13. Please make applicable changes to the 195 vial carton labels.

Regards,

Mike

- Please confirm receipt of this e-mail and let us know if you have any questions.

Mike Smith, Ph.D.
Captain, USPHS

Senior Regulatory Review Officer
Food and Drug Administration

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