

BNT162b2 (COMIRNATY)

BLA STN 125742/0

Response to 16 August 2021 CBER Information Request

Regarding Diluent Packaging Labels

August 2021

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1. INTRODUCTION

Reference is made to BLA STN 125742/0 for the Pfizer-BioNTech COVID-19 Vaccine for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals ≥ 16 years of age.

The purpose of this document is to respond to CBER's Information Request (IR) communicated from Captain Michael Smith, PhD (CBER) to Elisa Harkins (Pfizer Inc.) via email on 16 August 2021, with questions regarding proposed diluent packaging labels.

CBER's comments/requests in *bold italics* are followed by the Sponsor's responses below.

2. CBER REQUESTS

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:

2.1. CBER Request Regarding the Diluent Vial and Carton Labels:

2.1.1. CBER Request 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.

Response

The [vial label](#) for Hospira diluent and the [vial label](#) for Fresenius Kabi diluent are provided in Module 1.14.1.1.

2.1.2. CBER Request 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.

Response

The [carton label](#) for Hospira diluent and the [carton label](#) for Fresenius Kabi diluent are provided in Module 1.14.1.1. Both carton labels include a lot number and expiration date for the packaged diluent.

2.1.3. CBER Request 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.

Response

The “Diluent Sticker” provided in Amendment 46 is the updated “Hospira Diluent Label”. This is the sticker that will be placed on top of the shrink-wrapped vials within a carton of Hospira diluent. Please refer to the [Hospira Diluent Carton picture](#) submitted in Sequence 0002 of the initial application. The sticker will be placed on the shrink wrap on top of the packaged carton, not on the carton label itself.

For the Fresenius Kabi diluent, Fresenius Kabi will update the stamp that will be placed on their carton to contain the same information as that included in the “Diluent Sticker” provided in Amendment 46, though it will be in black text. Please refer to the [Fresenius Kabi Diluent Carton picture](#) submitted in Sequence 0002 of the initial application and the [carton label](#) for Fresenius Kabi diluent that is provided in Module 1.14.1.1 of the present submission. The stamp will be on the opposite end of the carton from Fresenius Kabi’s diluent carton label.

2.1.4. CBER Request 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.

Response

Pfizer/BioNTech acknowledges CBER’s request. The purpose of the “Fresenius Kabi Diluent Stamp” and the “Hospira Diluent Label” is specifically to indicate that the product is designated for use with COMIRNATY. The vials labels and carton labels for both diluent products contain the lot number and expiration date for that product. Please see the responses to Items 1 and 2 of this submission. In addition, for the Fresenius Kabi diluent, the “Fresenius Kabi Diluent Stamp” will be applied to the actual carton which already contains the lot number and expiration date. For the Hospira diluent, the “Hospira Diluent Label” will be manually applied from a roll of labels, thus it will not be possible to include the lot number and expiration date. It will be placed in such a way that does not obscure the lot and expiry information already printed on the carton label. As the lot number and expiration date will be clearly visible on the carton labels, to avoid potential confusion due to redundancy, it is preferred to not include this information on the diluent stamp/label.

2.2. CBER Request Regarding the COMIRNATY Carton Labels:

2.2.1. CBER Request 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.

Response

The carton labels have been updated accordingly and are provided in Module 1.14.1.1.

2.2.2. CBER Request 6

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

Response

The carton labels have been updated accordingly and are provided in Module 1.14.1.1.

2.2.3. CBER Request 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).

Response

On 16 August 2021, Pfizer/BioNTech submitted updated prescribing information that corrected the temperatures for storage prior to dilution to “**-90°C to -60°C (-130°F to -76°F)**”. Therefore, the carton labels do not need to be revised.

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