

From: Giordano, Erica
To: ["Patel, Manisha"](#)
Cc: [Ahmed, Narin](#)
Subject: RE: BL 125646 Primary Container Label
Date: Wednesday, August 23, 2017 9:49:00 AM
Attachments: [image003.png](#)
[image009.png](#)
Sensitivity: Confidential

I am confirming receipt.

Thanks
Erica

From: Patel, Manisha [<mailto:manisha.patel@novartis.com>]
Sent: Tuesday, August 22, 2017 10:12 PM
To: Giordano, Erica
Cc: Ahmed, Narin
Subject: RE: BL 125646 Primary Container Label
Sensitivity: Confidential

Hi Erica, please see attached.

As a heads up, we plan to submit the version of the label sent on August 17 to the BLA (not the attached). These attachments are for reference, and are not elements that would be considered by Novartis as part of established conditions of BLA 125646.

Kind regards,
Manisha

From: Giordano, Erica [<mailto:Erica.Giordano@fda.hhs.gov>]
Sent: Tuesday, August 22, 2017 9:36 PM
To: Patel, Manisha <manisha.patel@novartis.com>
Subject: RE: BL 125646 Primary Container Label
Sensitivity: Confidential

Hi Manisha,

As a follow-up request; could you please provide the final container label in the detailed format that includes the patient and product information such as shown below?



NOT the abbreviated one (no product and patient specific information) sent in the e-mail on August

17, 2017, such as shown below:



Thanks
Erica

From: Giordano, Erica
Sent: Tuesday, August 22, 2017 9:15 PM
To: 'Patel, Manisha'
Subject: RE: BL 125646 Primary Container Label
Sensitivity: Confidential

Thanks very much for letting me know.

Erica

From: Patel, Manisha [<mailto:manisha.patel@novartis.com>]
Sent: Tuesday, August 22, 2017 5:06 PM
To: Giordano, Erica
Subject: RE: BL 125646 Primary Container Label
Sensitivity: Confidential

Hi Erica, the submission is gateway submission is planned for Thursday.

Kind regards,
Manisha

From: Giordano, Erica [<mailto:Erica.Giordano@fda.hhs.gov>]
Sent: Tuesday, August 22, 2017 3:57 PM
To: Patel, Manisha <manisha.patel@novartis.com>
Subject: RE: BL 125646 Primary Container Label
Sensitivity: Confidential

Hi Manisha,

Please let me know when you plan to submit this response through the gateway.

Thanks
Erica

From: Patel, Manisha [<mailto:manisha.patel@novartis.com>]
Sent: Thursday, August 17, 2017 3:18 PM
To: Giordano, Erica; Ahmed, Narin
Cc: Riggins, Cindy
Subject: RE: BL 125646 Primary Container Label
Sensitivity: Confidential

Dear Erica,

Please see below and attached response. I will submit a copy through the gateway.

FDA comment 1: Please modify the labels as show below (see FDA attachment)

Novartis response: The font size of “tisagenlecleucel” has been increased. Novartis confirms the spelling of ‘modified’ is correct. Please see attached.

FDA comment 2: Please clarify if there is a label on the (b) (4) that holds the infusion bag within the dry shipper.

Novartis response: There is no label on the (b) (4) that holds the infusion bag within the dry shipper.

Kind regards,
Manisha

From: Giordano, Erica [<mailto:Erica.Giordano@fda.hhs.gov>]
Sent: Tuesday, August 15, 2017 8:28 PM
To: Ahmed, Narin <narin.ahmed@novartis.com>; Patel, Manisha <manisha.patel@novartis.com>
Cc: Riggins, Cindy <cindy.riggins@novartis.com>
Subject: RE: BL 125646 Primary Container Label
Sensitivity: Confidential

Good evening,

Please see the attached response regarding the primary container label and provide a response by 4 pm on August 17th.

Please confirm receipt.

Thank you,
Erica Giordano
Regulatory Project Manager
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
Tel: 240-402-8298
Erica.Giordano@fda.hhs.gov



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From: Ahmed, Narin [<mailto:narin.ahmed@novartis.com>]
Sent: Thursday, August 10, 2017 4:56 PM
To: Giordano, Erica; Patel, Manisha
Cc: Riggins, Cindy
Subject: RE: BL 125646 Primary Container Label
Sensitivity: Confidential

Dear Erica,

Please find attached the Novartis response to FDA's comments on the Kymriah primary container label.

Please note that Appendix 2, 3, 4 and 5 are not elements that would be considered by Novartis as part of established conditions of BLA 125646.

This will be submitted to BLA 125646 tomorrow.

Best regards,
Narin

Narin Ahmed (Hussain), Pharm.D.
Sr. Associate Director, Regulatory Affairs

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www.novartis.com

From: Giordano, Erica [<mailto:Erica.Giordano@fda.hhs.gov>]
Sent: Friday, August 04, 2017 2:00 PM
To: Patel, Manisha <manisha.patel@novartis.com>
Cc: Riggins, Cindy <cindy.riggins@novartis.com>; Ahmed, Narin <narin.ahmed@novartis.com>
Subject: BL 125646 Primary Container Label
Sensitivity: Confidential

Good afternoon,

Please see the attached feedback regarding the primary container label and provide a response

by COB on August 8, 2017.

Please confirm receipt.

Thank you,

Erica Giordano

Regulatory Project Manager

Center for Biologics Evaluation and Research

Office of Tissues and Advanced Therapies

U.S. Food and Drug Administration

Tel: 240-402-8298

Erica.Giordano@fda.hhs.gov



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