

From: [Patel, Manisha](#)
To: [Giordano, Erica](#)
Cc: [Riggins, Cindy](#); [Ahmed, Narin](#)
Subject: RE: BL 125646 Clinical Information Request
Date: Monday, March 20, 2017 4:47:48 PM
Sensitivity: Confidential

Dear Erica,

Novartis confirms that study CCTL019B2202 patient (b) (6) received two bags of CTL019 dose on August 4, 2015. The CTL019 final product produced for this patient was filled into two bags (each at the same dose of 1×10^6 transduced viable cells/kg body weight) based on the manufacturing filling process in place at the time. Individually, the single bags did not meet the minimum release criteria of 2×10^6 transduced viable T cells/kg body weight in place at that time. Therefore, Novartis submitted a product deviation request (approved by FDA on July 24, 2015) requesting that both bags be released and infused in order to meet the minimum defined dose requirement.

Kind regards,
Manisha

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Thursday, March 16, 2017 1:06 PM
To: Patel, Manisha <manisha.patel@novartis.com>
Cc: Riggins, Cindy <cindy.riggins@novartis.com>; Ahmed, Narin <narin.ahmed@novartis.com>
Subject: BL 125646 Clinical Information Request
Sensitivity: Confidential

Good afternoon,

Please see the information request below and provide a response by 5 pm ET on March 20, 2017.

In the case report forms for (b) (6), the same identical dose of CTL019 is reported as being given twice on August 4, 2015. Please confirm that the subject did in fact receive two separate doses on the same day. Please provide an explanation (e.g. dose divided into two infusion bags).

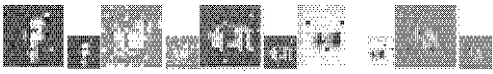
Thank you,

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
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