

From: Ocampo, Virginia
Sent: Monday, May 07, 2018 4:12 PM
To: 'Wilson,Jeffrey'
Subject: RE: BLA 125657/0 MD Anderson Cord Blood Bank_ Prescribing Information edits in tracked changes

Dear Jeff,

The Clinical Review team accepted your previous definitions for time to neutrophil and platelet recovery. There are no other edits from clinical review team at this time.

Thank you,
Virginia
Virginia Ocampo, MT (ASCP)
Regulatory Project Manager
Center for Biologics Evaluations and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
Tel: (301) 348-3949
virginia.ocampo@fda.hhs.gov

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From: Wilson,Jeffrey [mailto:jmwilson@mdanderson.org]
Sent: Thursday, May 03, 2018 5:28 PM
To: Ocampo, Virginia <Virginia.Ocampo@fda.hhs.gov>
Cc: Eaton,Erin N <ENEaton@mdanderson.org>; Reieux,Donna K <DKReieux@mdanderson.org>
Subject: RE: BLA 125657/0 MD Anderson Cord Blood Bank_ Prescribing Information edits in tracked changes

Hi Virginia,

We have accepted the all of the changes submitted by the reviewers with the exception of our definitions for time to neutrophil and platelet recovery the same as our previous. submission.

Thanks,
Jeff

Jeffrey Wilson
Assistant Director

MD Anderson Cord Blood Bank
jmwilson@mdanderson.org
T 713-794-1908
F 713-563-3468

From: Ocampo, Virginia [mailto:Virginia.Ocampo@fda.hhs.gov]
Sent: Thursday, May 03, 2018 1:11 PM
To: Wilson,Jeffrey
Subject: RE: BLA 125657/0 MD Anderson Cord Blood Bank_ Prescribing Information edits in tracked changes

Hi Jeff,

Please send your response via email by tomorrow 5/4 COB. There may be more comments from the review team with regards to labeling.

Thanks again,
Virginia
Virginia Ocampo, MT (ASCP)
Regulatory Project Manager
Center for Biologics Evaluations and Research
Office of Tissues and Advanced Therapies
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From: Wilson,Jeffrey [mailto:jmwilson@mdanderson.org]
Sent: Thursday, May 03, 2018 2:01 PM
To: Ocampo, Virginia <Virginia.Ocampo@fda.hhs.gov>
Cc: Reioux,Donna K <DKReioux@mdanderson.org>; Eaton,Erin N <ENEaton@mdanderson.org>
Subject: RE: BLA 125657/0 MD Anderson Cord Blood Bank_ Prescribing Information edits in tracked changes

Hi Virginia,

We have received the communication. Do they want the definitions in an email, or as part of the prescribing information due by COB tomorrow?

Thanks,
Jeff

Jeffrey Wilson
Assistant Director
MD Anderson Cord Blood Bank
jmwilson@mdanderson.org
T 713-794-1908
F 713-563-3468

From: Ocampo, Virginia [mailto:Virginia.Ocampo@fda.hhs.gov]
Sent: Thursday, May 03, 2018 12:54 PM
To: Wilson,Jeffrey
Subject: RE: BLA 125657/0 MD Anderson Cord Blood Bank_ Prescribing Information
edits in tracked changes

Dear Jeff,

Here is the comment form the Clinical review team:

Thank you for your comments and we are discussing the edit regarding neutrophil recovery and will provide a response soon. In the meantime, please provide your definitions for “time to neutrophil recovery” and “neutrophil recovery.

Please acknowledge receipt.

Best regards,
Virginia
Virginia Ocampo, MT (ASCP)
Regulatory Project Manager
Center for Biologics Evaluations and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
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From: Wilson,Jeffrey [mailto:jmwilson@mdanderson.org]
Sent: Wednesday, May 02, 2018 4:28 PM
To: Ocampo, Virginia <Virginia.Ocampo@fda.hhs.gov>
Cc: Reioux,Donna K <DKReioux@mdanderson.org>; Eaton,Erin N
<ENEaton@mdanderson.org>
Subject: RE: BLA 125657/0 MD Anderson Cord Blood Bank_ Prescribing
Information edits in tracked changes

Hi Virginia,

We have received the edited Prescription Information. After a brief review of the edits, most are understandable/acceptable, however there is one change that does not make sense to me regarding the edits made. We feel that the language we originally submitted was in line with the language used by other licensed banks. Can you please provide us with some additional guidance regarding this edit?

MD Anderson Cord Blood Bank Original Text:

Neutrophil recovery is defined as the time from transplantation to an absolute neutrophil count more than 500 cells/?L. Platelet recovery is the time to a platelet count more than 20,000 cells/?L without a platelet transfusion for the preceding seven days. Erythrocyte recovery is the time to a reticulocyte count greater than 30,000 cells/?L.

FDA Edited Text:

Neutrophil recovery is defined as achieving an absolute neutrophil count (ANC) more than 500 cells/?L at Day 42 after transplantation. Platelet recovery is defined as achieving a platelet count more than 20,000 cells/?L at Day 100 after transplantation without a platelet transfusion for the preceding seven days. Erythrocyte recovery is the time to a reticulocyte count greater than 30,000 cells/?L

Other Licensed Cord Blood Banks:

Bank 1 (DUCORD):

Neutrophil recovery is defined as the time from transplantation to an absolute neutrophil count more than 500 per microliter. Platelet recovery is the time to a platelet count more than 20,000 per microliter. Erythrocyte recovery is the time to a reticulocyte count greater than 30,000 per microliter.

Bank 2 (CLEVECORD):

Neutrophil recovery is defined as the time from transplantation to an absolute neutrophil count more than 500 per microliter. Platelet recovery is the time to a platelet count more than 20,000 per microliter. Erythrocyte recovery is the time to a reticulocyte count greater than 30,000 per microliter.

Thanks,
Jeff

From: Ocampo, Virginia [mailto:Virginia.Ocampo@fda.hhs.gov]
Sent: Wednesday, May 02, 2018 3:02 PM
To: Wilson,Jeffrey

Subject: BLA 125657/0 MD Anderson Cord Blood Bank_ Prescribing Information
edits in tracked changes
Importance: High

Dear Jeff,

Please find attached Prescription Information with edits in tracked changes.

Please respond to us on Friday, May 4, 2018 by COB.

Kindly acknowledge receipt and let me know if you have any questions.

Thank you,
Virginia
Virginia Ocampo, MT (ASCP)
Regulatory Project Manager
Center for Biologics Evaluations and Research
Office of Tissues and Advanced Therapies
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