

From: Wilson,Jeffrey <jmwilson@mdanderson.org>
Sent: Friday, June 08, 2018 6:18 PM
To: Ocampo, Virginia
Cc: Reioux,Donna K; Eaton,Erin N
Subject: RE: BLA 125657/0 MD Anderson Cord Blood Bank_ Edited Prescribing Information
Attachments: MDA product insert_20180608.docx; smime.p7s; ATT00001.txt; ATT00002.htm

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Virginia,

We have addressed Mercy's comments and accepted her changes. Attached is the updated document. Regarding her comment about Figure 8, we believe that she may have thought that the supernatant bag was not empty because of the manufacturer's base label attached to the opposite side of the transfer pack. I am also including the updated picture of the tie tag attached to the canister.

Thanks,
Jeff

From: Ocampo, Virginia [mailto:Virginia.Ocampo@fda.hhs.gov]
Sent: Friday, June 08, 2018 1:20 PM
To: Wilson,Jeffrey
Subject: BLA 125657/0 MD Anderson Cord Blood Bank_ Edited Prescribing Information
Importance: High

Dear Jeff,

Please see attached the revised PI in tracked changes. Please review to address comments and accept changes.

Comment regarding the picture showing how the tie tag label is attached to the product at shipping: figure will look more complete if the whole label showed in the photo (show a product with full label); only a part of the label shows in the current photo.

Please send us back the updated version of PI as soon as possible.

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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