

From: Karandish, Safa
Sent: Tuesday, December 22, 2015 11:54 AM
To: wvanthof@clevelandcordblood.org
Cc: Tull, Lori
Subject: BLA 125594- Information Request (follow-up)

Dear Dr. Van't Hof:

This is a follow-up email regarding couple of topics that you and I discussed during the pre-licensure inspection.

1- Use of ISBT 128 Labeling system- As I explained, in order to use the ISBT 128 Labeling system in lieu of the NDC, you need to provide us with the manufacturer code (referred to as facility identification number) and the product code assigned to you by ICCBBA. Based on your response letter submitted on 11/23/15, I understand that you assign a different ISBT facility identifier (Prefix WXXXX) to each collection hospital, and you currently do not have a facility identifier assigned to CCBC. Please note that you need to address this issue if you wish to use ISBT 128 identification and labeling system in lieu of an NDC. One option that you may wish to consider is to use a facility identifier that is assigned to your cord blood bank as part of the DIN instead of using a number that is assigned to each collection site. You may contact ICCBBA for additional information.

2- [REDACTED] FDA Registration [REDACTED]
The number that you provided in the BLA (section 31.4A, page 10) appears to be the facility's FDA blood registration number. Please submit the laboratory's FDA registration number for testing HCT/Ps.

Please contact me if you have any questions. I wish you a very happy holiday season.

Best regards,

Safa

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time, but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received

17_IR email 20151222.pdf.txt

this document in
error, please immediately notify the sender by e-mail or phone.