From: Karandish, Safa
Sent: Thursday, October 01, 2015 12:05 PM
To: BeckyH@BloodWorksNW.org
Cc: Sista, Ramani V
Subject: BLA 125585- Information Requested

Dear Dr. Haley:
Below is the list of items that we discussed in our phone conversation yesterday. I understand that you
will include most of this information with the documents that you are planning to submit before the end
of the month.
Please contact me if you have any questions.
Best regards,
Safa

1. Please provide a complete list (including addresses) of your current collection sites and partners.
We've noted the following discrepancies in your submitted documents:
Collection sites
a. Module 2, 2.3.S.1, page 4 & Module 3, 3.2.S.2.1.2, Pages 7-8:
17 sites
b. Module 3, 3.2.P.3.1.1, page 4, table P.3.1.1-1:
16 sites
c. Module 1, Response to March 26, 2015 FDA letter, page 20:
18 sites
Collection partners
d. Module 1, response to July 18, 2014 FDA letter, page 30 and Module 2, 2.3.S.1, Page 4:
- Hawaii Cord Blood Bank
- Inland Northwest Blood Center
- Oregon Health and Science University
e. Module 1, Response to March 26, 2015 FDA letter, page 21:
- Hawaii Cord Blood Bank
- Inland Northwest Blood Center
2. Please clarify the following discrepancy regarding the DIN assigned to maternal samples:
- Module 3, 3.2.P.5.&.4: DINs with prefix (b) (4)
- Submitted batch records (e.g. (b) (4) ), DIN with prefix (b) (4)

3. We understand that the HPC, Cord Blood Unit Information (Form 25-9-006) is sent to the
transplant centers with the cord blood units. The terms "conforming" and "non-conforming"
used on this form are not consistent with the FDA's donor eligibility determination terminology
("eligible" and "ineligible"). Please revise and submit the updated form.
4. Draft SOP CBP 7020 describes the list of records and forms that accompany CB units that are
shipped to the transplant centers but it doesn't specify which documents are applicable to
licensed products. Please revise and submit the updated SOP.
5. In SOP CBP 8040, you have included the following note: "Test results received after Medical
Director release to inventory are reviewed by the Medical Director prior to CBU release (i.e. HLA
results) per (b) (4) Please note that in order to determine the licensure status of a unit, all
the test results must be reviewed before the unit is released to the available inventory for
search. Please revise and submit the updated SOP.
6. You have listed b) (4) as the manufacturer of the test for syphilis. Please clarify whether the test is

(b) (4), which is currently the only FDA cleared non-treponemal donor screening test. We also suggest that your refer to the latest guidance regarding the acceptable donor screening tests for syphilis (published Sept 2015): http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM373311.pdf

7. Please address the following discrepancies regarding the minimum acceptable volume for collected cord blood units:

a. Draft SOP 1060: (b) (4)

b. Module 3, section 3.2S.2.4: (b) (4)

c. CBU Initial Receipt Form (25-9-203): (b) (4) for Hawaii, (b) (4) for non-Hawaii units (if this is the current criteria, please explain the rational for the different acceptable volumes)

8. According to instruction on page 2 of Form 25-9-021, cord blood should not be collected in presence of certain complications during birth or pregnancy, but on the 1st page of the same form, you indicate that the donor may still donate regardless of the response to the question related to such findings. Please clarify.

9. In draft SOP CBP 1060 (page 3), you state that allogeneic units with “repeat” reactive or positive test results, excluding CMV, on blood samples obtained from the donor mother will be discarded. In our phone conversation, you explained that “reactive” is referring to the test kits manufacturers algorithm that the testing facility uses before making the final interpretation of the test results . You confirmed that negative results with repeated tests would not override the initial reactive results reported by the testing facility. We suggest that the you clarify the statement in the SOP.

10. Please submit the finalized versions of the following draft SOPs & forms: CBP 1060, CBP 7020, QARA 420, 25-9-180 QSU HPC, Cord blood Shipping Verification

11. The summary of collection validation that you have submitted does not include pre-defined expectations related to acceptable volume or contamination. Please submit the applicable information.