

21_Requesting response regarding issues in Filing letter.txt
From: Tull, Lori
Sent: Tuesday, November 17, 2015 1:36 PM
To: Wouter Van't Hof (wvanthof@clevelandcordblood.org)
Subject: Requesting response regarding issues in Filing letter

Hi Wouter,

Thanks very much for your response regarding the facilities question I sent earlier. I also have a follow-up question regarding when you will be able to respond to our requests from the filing letter. For your reference, the questions were:

Donor Eligibility and Collection

1. Please clarify whether you are using a treponemal or non-treponemal screening test for syphilis. In section 3.1.4A, Table 4A-3 and in SOP-L0025, you have listed [REDACTED] (non-treponemal test), but in Table 4-A-8, you have listed [REDACTED] (treponemal test). In SOP-L008, you refer to both tests. Furthermore, if you are using a non-treponemal screening test [REDACTED], please provide the test kit manufacturer information and explain how you determine the donor eligibility for donors who test reactive with the non-treponemal screening test.
2. Please submit the following documents:
 - a. Maternal Medical and Family History questionnaires and any associated decision or action guides.
 - b. Forms used for documentation of maternal consent and pre-screening, medical record review, labor and delivery information, maternal and infant donor linkage, and cord blood collection.
3. Please submit the SOP(s) that describes how findings related to the clinical and physical evidence of communicable diseases are factored in to the final donor eligibility determination. In SOP-H0012 you only describe the information that you document.
4. Please submit the SOP (including the training materials) that you use to train the cord blood collectors and the staff responsible for screening the birth mothers and the infant donors for relevant communicable diseases.
5. It appears that you intend to use ISBT 128 system. Please note that BLA applicants, who wish to use ISBT 128 identification and labeling standards in lieu of an NDC number, may submit an exemption request from the barcode labeling requirements. The agency will consider the exemption request if the BLA applicant has fully implemented the ISBT 128 labeling systems.

Sterility Test Method Validation:

6. We note that you have cross-referenced the [REDACTED] [REDACTED] in your application for the sterility test method validation.

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- a. Please specify the sections of the MF that you are cross-referencing by submitting a table indicating the titles of the MF chapters/sections with the respective submission dates, volumes and page numbers.
- b. Please clarify if you are cross-referencing this MF for the validation of specificity, limit of detection, ruggedness and robustness of both the sterility test incubation/detection instrument [REDACTED] and your used media [REDACTED]. If so, specify the respective sections of the MF as explained under the previous bullet-point.

7. Please provide the following details on your actual incubation/detection instrument [REDACTED]

- a. Model number
- b. Software version currently loaded and a clarification on if the same version of the software was used during the actual validation studies.
- c. The installation qualification (IQ), operation qualification (OQ) and performance qualification (PQ) documents/data and a clarification on if [REDACTED] has performed those studies.

Flow Cytometry

8. Please explain your back up plan to determine CD34 count for lot release in the case of malfunction of the [REDACTED].
9. Please provide validation data for your viability test.

Regards,
Lori Tull
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Regulatory Management Staff
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