

From: Tull, Lori
Sent: Tuesday, February 02, 2016 2:26 PM
To: Wouter Van't Hof (wvanthof@clevelandcordblood.org)
Subject: FW: IR for STN 125594

Importance: High

Hi Wouter,

The CMC reviewer has the following request for information. Would you please respond by email and follow with an official amendment to the BLA by 2/16/16?

1. We note that although you have cross-referenced the [REDACTED] you have used [REDACTED] gauge needles to inoculate the [REDACTED] bottles for your validation studies (the [REDACTED] media package insert recommends that you use [REDACTED] gauge needles for the inoculation of [REDACTED] bottles). Please clarify your rationale for using [REDACTED] gauge needles (as using a larger gauge needle may compromise the seal of the [REDACTED] bottles and the sterility test for the strict anaerobic microorganisms). Also, please clarify if you will be switching to [REDACTED] gauge needles for the [REDACTED] bottle inoculation for the actual sterility test (if applicable please update and submit the respective SOP) of HPC, Cord Blood.

2. Reference - Qualification of new lots of test media: Please change (based on the data from your Sterility Test method validation) the "expected outcomes" to "All tests Positive for Growth in [REDACTED] days" for [REDACTED] and "All tests Positive for Growth in [REDACTED] days" for [REDACTED].

Regards,
Lori Tull
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Regulatory Management Staff
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