

19\_IR email 20151203.txt

From: Tull, Lori  
Sent: Thursday, December 03, 2015 8:56 AM  
To: Wouter Van't Hof (wvanthof@clevelandcordblood.org)  
Subject: FDA request for information for BLA STN 125594/0

Importance: High

Hi Wouter,

Would you please provide the additional information requested below? You may submit the response by email but please also submit the information as an official Amendment to the BLA.

STN 125594 - Sterility Test and Method Validation:

1. A copy of the SOP for the Sterility Test.
2. Information on the gauge sizes of the needles used for inoculating the [REDACTED] and [REDACTED] media bottles during the validation study. Please confirm that the same needle gauges will be used during the actual sterility test.
3. Clarify how you will be qualifying the incoming lots of the [REDACTED] and [REDACTED] media in future (qualification method based just on manufacturer's certificate of analysis is not acceptable). Please provide a copy of the SOP for that qualification test.

Regards,  
Lori Tull  
Team Lead  
Regulatory Management Staff  
Office of Cellular, Tissue, and Gene Therapies  
Center for Biologicals Evaluation and Research  
(240) 402-8361

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