

From: Sista, Ramani V
Sent: Thursday, January 15, 2015 10:04 AM
To: 'Heather Pratt'
Subject: RE: NDA 125552 - IR
Attachments: Attachment F - Sterility Testing Report PROT CPD (b) (4) PDF

Importance: High

Hi Heather,
The reviewer is looking for information below regarding the attached:

Conformance lots are lots manufactured in support of the BLA application. If you have sterility results on any lots of collection bags for MSC1207DD and MSC1208DD, that would work.

The attached sterility test validation submitted for sterility test was translated from Polish and looks like missed some information. Could you please ask for the clarification?

1. Please confirm the inoculum/ colony forming units for each microorganism used in sterility test validation (protocol no. (b) (4) 01);
2. Please provide (b) (4) results for microorganisms used in the sterility test validation.

Thanks,
Ramani
Ramani Sista, PhD, RAC, CQA
RPM
OCTGT/CBER/FDA
Phone: 240 402 8354

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From: Heather Pratt [mailto:heather@macopharmausa.com]
Sent: Wednesday, January 14, 2015 2:55 PM
To: Sista, Ramani V
Subject: RE: NDA 125552 - IR

Dear Ramani,

I received your email below requesting sterility test results, however, can you please clarify what you mean by "conformance lots"?

Thanks,
Heather

Best Regards,
Heather Pratt

Listen • Understand
• Provide Solutions

Heather Pratt
Manager, Regulatory & Clinical
Affairs
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From: Sista, Ramani V [mailto:Ramani.Sista@fda.hhs.gov]
Sent: Wednesday, January 14, 2015 10:39 AM
To: Heather Pratt
Subject: NDA 125552 - IR
Importance: High

Hi Heather,
Please provide the information below by COB tomorrow.

Please provide sterility test results of conformance lots for cord blood sterile collection bags with anticoagulant Citrate Phosphate Dextrose (CPD).

Please let me know if you have questions.
Thanks,
Ramani

Ramani Sista, PhD, RAC, CQA
RPM
Office of Cellular Tissue & Gene Therapies
CBER, FDA
Phone: 240 402
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Ramani.Sista@fda.hhs.gov

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