

20_IR email 20151117.txt

From: Tull, Lori
Sent: Tuesday, November 17, 2015 11:40 AM
To: Wouter Van't Hof (wvanthof@clevelandcordblood.org)
Subject: FW: IR for STN 125594 CCBC

Importance: High

Hi Wouter,

Would you please provide a response to this information request from our facilities reviewer by Nov. 23?

Please indicate if to your knowledge there are any extraordinary circumstances that exist that would warrant the preparation of an environmental assessment due to the manufacture of HPC, Cord Blood per 21 CFR §25.15(d).

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

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