

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 Biological Evaluation and Research
(240) 402-8361

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have