

From: Tull, Lori  
Sent: Thursday, May 12, 2016 10:19 AM  
To: Wouter Van't Hof (wvanthof@clevelandcordblood.org)  
Subject: Clinical Information request for Cleveland Cord Blood BLA

Hi Wouter,

Would you please respond to the following request our clinical reviewer?  
As discussed in the FDA letter dated 05/28/2014, the BLA should contain a statement (see below) specifying your post-marketing surveillance plan; however, we haven't been able to

locate the information about your post-marketing surveillance plan in the BLA. Please either

indicate where this information is located in the BLA, or submit an amendment stating that you

agree to conduct the following post-marketing surveillance if Cleveland HPC, Cord Blood is

licensed in the U.S.:

a. Implement a safety outcomes monitoring and analysis plan. This plan will include: 1)

maintenance of an observational database to include, for all HPC, Cord Blood units released, information including but not limited to, time to neutrophil recovery, graft

failure, survival, cause of death, infusion reactions, and other adverse experiences; 2)

aggregate analyses of interval and cumulative adverse experience reports; and 3) safety

outcomes analyses of interval and cumulative data that address early mortality, graft

failure-related mortality, graft failure, time to neutrophil recovery, infusion-related

events, and other adverse experiences. Reports will include a description of the population analyzed, results of the analyses, whether outcomes indicators were triggered and, if so, what actions were implemented as a result.

b. Submit to FDA a 15-day "alert report" for each serious infusion reaction associated with

administration of HPC, Cord Blood.

Best Regards,

Lori Tull

Team Lead

Regulatory Management Staff

Office of Cellular, Tissue, and Gene Therapies

Center for Biological Evaluation and Research

(240) 402-8361

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