

Email - Labeling, May 2,2012 - HPC Cord Blood

From: Sista, Ramani V
Sent: Wednesday, May 02, 2012 1:59 PM
To: 'Miller, Sharon'
Cc: Freed, Brian; Fan, Yong
Subject: BLA 125391 - Labeling

Importance: High

Attachments: PI draft 02May2012.doc; Label comments.pdf

Hi Sharon,

Please see attached Labeling - package insert (PI) and changes to carton and container labels, for hematopoietic progenitor cells, cord blood (HPC, CORD BLOOD). The content of the PI is very similar to New York Blood's Hemacord, since they all fall in the same class. Some of the clinical information and instructions for use at the end of PI in your label will be different from Hemacord, as this information is specific to your file. As you can see from the comments in the document we are working on the clarification of your data sources in the clinical sections. Please review the PI and let us know by Monday, May 7, 2012, if you have concerns or issues. The instructions for use are not included in this version of PI since our CMC team is still working on it.

We would like to schedule a call next week, either Monday or Tuesday, to discuss the changes for the carton and container labeling.

Please also note that there will be no pre-marketing commitments or requirements for this file.

Please acknowledge receipt and let me know if you have questions.

Thanks,
Ramani

Ramani Sista, PhD, RAC
Regulatory Project Manager
Office of Cellular Tissue & Gene Therapies
CBER, FDA
Phone: 301-827-5152

Fax: 301-827-9796
Ramani.Sista@fda.hhs.gov

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 received this document in error, please immediately notify the sender immediately by e-mail or phone.