

Mid-cycle Meeting

Application type and number: BLA STN 125594/0

Product name: HPC, Cord Blood

Proposed Indication: Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System

Applicant: Cleveland Cord Blood Center

Meeting date & time: Thursday, January 14, 2016

Committee Chair: Yong Fan, MD

RPM: Lori Tull, Jean Gildner

Attendees: Yong Fan, Joydeep Ghosh, Safa Karandish, Fatima Abbasi, Steven Oh, Kimberly Benton, Raj Puri, Stephanie Simek, Atm Hoque, Alex Bailey, Mercedes Serabian, Steve Winitsky, Changting Haudenschild, Bruce Schneider, Ilan Irony, Wilson Bryan, Lori Tull, Jean Gildner, Patrick Riggins, Chad Burger, Marion Michaelis, Qiao Bobo, Laurie Norwood, Stan Lin, Lisa Stockbridge, Shiojjen Lee

Report and Discuss:

1. Reviewer Reports (each discipline listed below should discuss the following):
 - a. Any significant issues/major deficiencies identified by the review committee to date
 - b. Information regarding major safety concerns.
 - c. Preliminary review committee thinking regarding risk management
 - d. Any information requests sent and not received
 - e. Any new information requests to be communicated
 - i. *CMC* –
 - PI – final volume issue
 - Stability – CCB sent proposal but need to redraft protocol
 - Dry Shipper validation requalification
 - Sterility – 2 information requests
 - Flo cytometry – sending CCB an email for a few clarifications
 - Medical history questionnaires, donor screening SOPs – CCB working on
 - ISBT exemption request needed, have to give us a facility ID code and product code – CCB understands
 - ii. *DMPQ* –

Inspection was in December 483 - 9 observations waiting for responses

iii. *Pharm/tox* -

No issues

iv. *Clinical* -

There are no major deficiencies noted in the clinical data. No major safety concerns have been identified. The sponsor provided adequate responses to two additional information requests regarding discrepancies in the clinical data. No new information requests need to be communicated.

v. *Stats* -

Working on data analysis from response to IR

vi. *Labeling* -

1. PNR: (b) (4) was found unacceptable on Oct 15, 2015. I'm not aware of a new name review request being submitted. Keep in mind that they don't need a proprietary name for approval.
 2. Labeling review: not yet started. I will start my review after CMC and clinical team complete the majority of their review.
2. Determine whether Postmarketing Commitments (PMCs), Postmarketing Requirements (PMRs) or a Risk Evaluation Mitigation Strategy (REMS) are needed.

Nothing at this time

3. National Drug Code (NDC) assignments to product/packaging.
Need to give company a goal date for ISBT 128
4. Proper naming convention.
The proper name is HPC, Cord Blood
5. Status of inspections (GMP, BiMo, GLP) including issues identified that could prevent approval.

Confirm

6. Components Information Table was obtained and notification to the Data Abstraction Team (DAT) if discrepancies were found per *SOPP 8401.5: Processing Animal, Biological, Chemical Component Information Submitted in Marketing Applications and Supplements*. If not complete, indicate date it will be completed.
7. New facility information is included in the application, requiring implementation of regulatory job aid *JA 910.01: Facility Data Entry*. If not complete, indicate date it will be completed.

8. Status of decisions regarding lot release requirements, such as submitting samples and test protocols and the lot release testing plan.
9. Unique ingredient identifier (UNII) code process has been initiated. See regulatory job aid *JA 900.01: Unique Ingredient Identifier (UNII) Code* for additional information.

Need to make sure we have the all codes

Review

10. Major target and mile stone dates from RMS/BLA.
 - Draft reviews due to TL April 9, 2016
 - Labeling Target – May 9, 2016
 - PMC Study Target – May 9, 2016
 - First Action Due – June 9, 2016
11. Establish a labeling review plan and agree on future labeling meeting activities.
 - Schedule biweekly meetings after April 9.