

Telecon, November 7, 2011 - Hemacord

DATE: November 7, 2011
Time: 3:00 -4:00 PM EST
Sponsor: New York Blood Center
BLA #: BLA 125397
Product: Hematopoietic stem/progenitor cells, cord (HPC-C)

FDA Attendees: Quagraine, Mercy; Benton, Kimberly; Thomas, Terrolyn; Loan, Nygen

Sponsor: Eva Quinley, Ludy Dobrila, Christine Driscoll, Andromachi Scaradavou

Summary of Discussion:

FDA requested a tcon to discuss the following outstanding issues:

1. New York Blood Center, Inc as their name.

CBER stated New York Blood Center, Inc was used as the applicant's name on 356h form, and this is the name on the existing FDA license. Therefore CBER intends to use New York Blood Center, Inc. NYBC agreed.

2. Container and package labels, and proposal for container label on the overwrap at the time of shipping

CBER and NYBC discussed the word document CBER sent by email with revision to their container and package labels. NYBC agreed to both labels. NYBC explained the plan for affixing container label to the overwrap at the time of shipment of a licensed unit. CBER agreed to this proposal, and explained that the differences between these 2 labels should be limited. For the cryobag the name "HEMACORD" and license number would not be present, because NYBC will not know at the time of cryopreservation whether a unit meets licensure criteria. NYBC requested that the label version number be included on the cryobag label according to FACT standards.

NYBC agreed to provide pictures of a unit with the cryobag and overwrap labels.

3. Need for formatting revisions for Instructions for Preparation for Infusion
CBER explained that the Instructions for Preparation for Infusion need to be reformatted for ease of reading and for compatibility with SPL. SPL cannot accept more than 2 levels of headings. The number of text boxes of notes and cautions should be reduced for readability. CBER provided by email a version of the document with a start on reformatting. NYBC agreed to continue the reformatting and provide a version to CBER by midday Tuesday.

4. Withdrawal of original indication statement

CBER asked about status of submission of letter to withdrawal the original indication statement. NYBC stated this was submitted in amendment approximately 12 pm November 8, 2011.

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