MEMORANDUM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

Date: September 14, 2012

From: Loan Nguyen, Regulatory Review Officer
OCBQ/DCM/APLB, HFM-602

Through: Lisa Stockbridge, Branch Chief
OCBQ/DCM/APLB, HFM-602

To: Mark Davidson, RPM, OCTGT, RMS (HFM-700)
Denise Gavin, Chair, Product, CBER, OCTGT, DCGT, GTB (HFM-720)

Subject: Labeling Review - Comments on product labeling (Instructions for Preparation and container and package labels)

Product: **DUCORD (HPC, Cord Blood)**
BLA STN: **125407/0**
Sponsor: Duke University School of Medicine, Carolinas Cord Blood Bank

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Background

The sponsor submitted:

☒ New Approval

☐ Major Amendment

☐ Prior Approval Supplement (PAS)

☐ Changes Being Effected (CBE) Supplement

Submission contains:

☐ Prescribing Information (PI)

☐ Patient Package Insert (PPI)

☒ Carton and/or container labels

☒ Other: Instructions for Preparation for Infusion

The PDUFA due date for this original application is October 8, 2012.

This labeling review is for the revised Instructions for Preparation for Infusion and the container labels provided by OCTGT on September 11, 2012.

APLB Comments/Recommendations

Review of Container Labels

- General
  - With this revision, the sponsor intends to use the small ISBT 128 label on the

cryobag and the full standard ISBT 128 with 4 quadrant barcode on the tie tag that will be attached to the product just prior to shipment to a transplant center (see figure 1 for final configuration).

Figure 1

- Ensure that the font used on the labels must be a minimum of 6 points.

- Small ISBT 128 label (see figure 2):

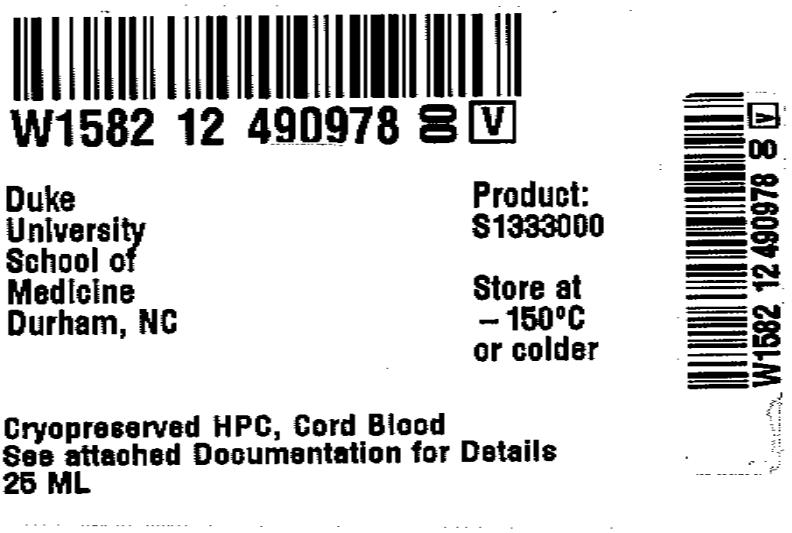

Figure 2

- This small label is considered to be a partial container label according to 21 CFR §610.60(c). With the proper name of the product, the name of the

manufacturer, and the ISBT unique donation identifier and the product code in place of the lot number and other lot identification, it has the minimum required elements for a partial label.

- Since the proper name of the product is HPC, Cord Blood and "cryopreserved" is not part of the proper name, APLB recommends presenting them in separate lines. For example,

  Cryopreserved
  HPC, Cord Blood

- Full standard ISBT 128 label (see figure 3):

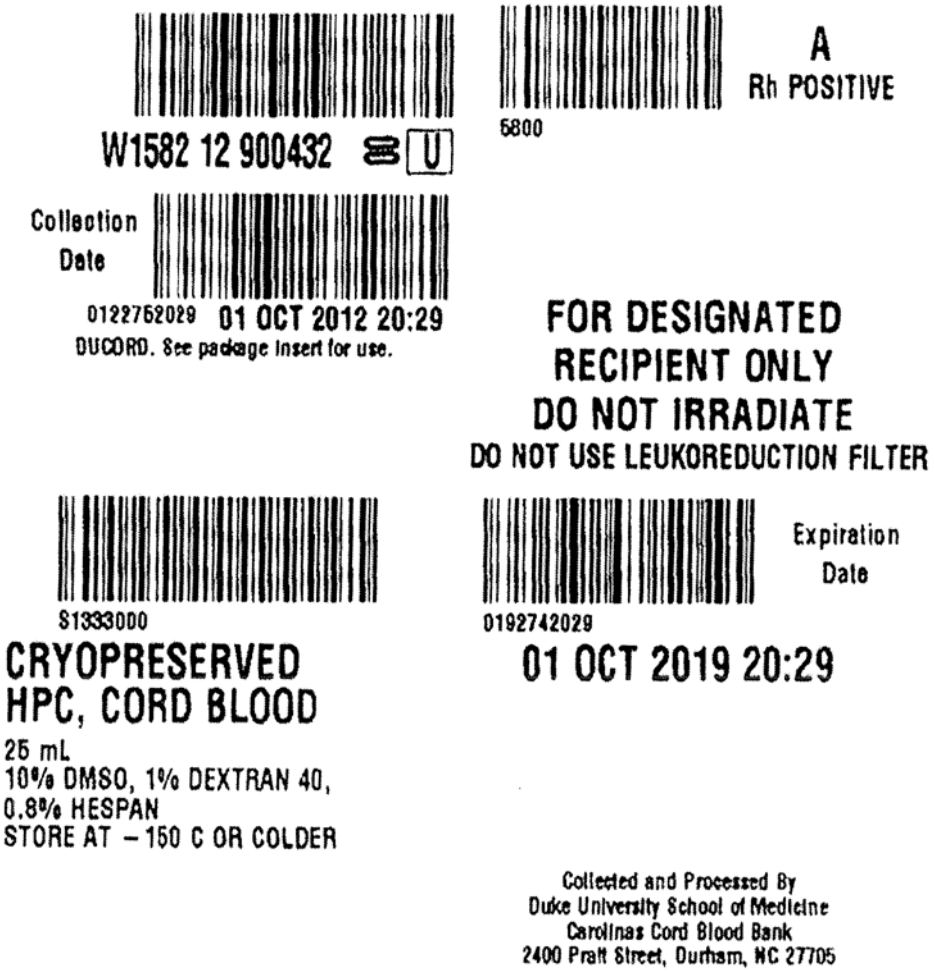

Figure 3

- This full ISBT 128 label is considered to be a full container label. Since the product does not have a package label, this full container label should include all the required elements of a package label according to 21 CFR 61.60 (b) & 61. Please add the following required elements:
  - license number of the manufacturer
  - route of administration
  - "Rx Only" statement

- Delete "DUCORD. See package insert for use" from underneath the collection date barcode. The proprietary name, if presented on the product label, should be right beneath the proper name (see 21 CFR 610.62). Since ISBT does not allow proprietary name on the label and proprietary name is not a required element of the full container label, APLB recommends not including DUCORD on the label. Having DUCORD by itself only creates confusion.
- Add the statement "See package insert for full prescribing information and instructions for preparation" as space permits.

Review of the Instructions for Preparation for Infusion

- The Instructions for Preparation for Infusion is not a section of the FULL PRESCRIBING INFORMATION (FPI). Do not present it as section 18.
- Reorganize the instructions so that it is easier to follow. Currently, the instructions have 2 sections and the second section, Procedure, has 15 subsections. APLB recommends the following outline:

INSTRUCTIONS FOR PREPARATION FOR INFUSION

I. MATERIALS AND EQUIPMENT

1. Materials

2. Equipment

II. PREPARATION

1. General Preparation Information

2. Prepare Thawing Solution (Dextran-Albumin Solution)

3. Assembly the Closed System

4. Assembly of Reagents and Supplies in Hood

III. DUCORD THAWING

IV. DUCORD DILUTING

V. DUCORD WASHING

1. Centrifugation of Thawed/Diluted DUCORD

2. Removal of Supernatant

3. Centrifugation of Supernatant

VI. PREPARATION FOR TRANSPLANTATION

1. Bag Method for Adult Recipients

2. Syringe Method for Pediatric Recipients

VII. QUALITY CONTROL TESTS

VIII. EMERGENCY PRODUCT RECOVERY IN THE EVENT OF A CONTAINER FAILURE

- Use command language consistently.
- Do not use trade/brand names when referring to other products. For example, do not use "Gentran" as it is a brand of Dextran 40.

- Use USP standard for materials. For example,

  Albumin (Human) 25%, USP

  Dextran 40 in Sodium Chloride Injection, USP

- Present the US license number with the manufacturer information.
- Ensure the information of the manufacturer is accurately and consistently presented. For example, the license holder is Duke University School of Medicine, which has the Carolinas Cord Blood Bank; therefore, the manufacturer information should be

  Duke University School of Medicine
  Carolinas Cord Blood Bank
  North Pavilion Building, Suite 1400
  2400 Pratt Street
  Durham, NC 27705

  US License #

- Do not include issued date at the end of the document since this is part of the prescribing information and the issued date is already presented in the HIGHTLIGHTS section.

If you have any questions regarding this review please contact Loan Nguyen, Pharm.D., Regulatory Review Officer at 301-827-6333.

Firm: Duke University School of Medicine

STN: 125407/0

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Bcc: HFM-602 L. Nguyen
HFM-602 APLB Chronologic File
HFM-602 APLB Historical File

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Concurrence box:

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