DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

January 28, 2016

Dr. Rebecca Haley, M.D.
Medical Director
Bloodworks Cord Blood Services
921 Terry Avenue
Seattle, WA 98104-1256

Dear Dr. Haley,

This is in response to your letter dated December 17, 2014, in which you request an exemption from the bar code requirements for your HPC, Cord Blood product filed under the following original Biologics License Application:

STN: BL125585

The regulations at 21 CFR 201.25 and 610.67 require bar codes on the labels of most prescription drugs, biologics, and OTC drug products that are dispensed pursuant to an order and are commonly used in hospitals. Under 21 CFR 201.25(d)(1), in response to a written request from a manufacturer, repacker, relabeler, or private label distributor, FDA may exempt a drug product from the barcode label requirements, provided certain criteria are met. A manufacturer, repacker, relabeler or private label distributor who requests an exemption under § 201.25(d)(1) must document why:

- compliance with the bar code requirement would adversely affect the safety, effectiveness, purity or potency of the drug or would not be technologically feasible, and the concerns underlying the request could not reasonably be addressed by measures such as package redesign or use of overwraps, or
- an alternative regulatory program or method of product use would render the use of the barcode unnecessary for patient safety.

As noted in the preamble to the final rule, we will not consider written requests that are based on other reasons such as financial reasons, a claimed low rate of medication errors, or a claim that the product is somehow unique such that medication errors do not occur or rarely occur (see 69 FR 9120, 9131 (February 26, 2004). Nor will we consider written requests that are based on small vials or containers, but firms may alternatively modify the drug's immediate container to accommodate a label bearing a bar code (response to comment 27, 69 FR 9120 at 9131).

You exemption request is based on an alternative regulatory program or method of product use that renders the bar code unnecessary for patient safety. Specifically, your request is for the use of an alternative regulatory program for cord blood labeling, known as ISBT 128. ISBT 128 is a recognized, global standard for the identification, labeling and information transfer of human blood, cell, tissue and organ products across international borders and disparate health care systems. Further, ISBT 128 is a machine-readable standard designed to ensure the highest levels of accuracy, safety, and efficiency for the benefit of donors, patients, health care professionals, and facilities worldwide. You state that ISBT 128 specifies:

- a donation numbering system that ensures globally unique identification;
- the information to be transferred, using internally agreed reference tables,
- an international product reference base
- the data structures in which the information is placed
- a barcoding system for the transfer of the information on the product label'
- a standard layout for the product label; and
- a standard reference for use in electronic messaging.

Licensed HPC, Cord Blood manufactured by Bloodworks Cord Blood Services will bear the ISBT 128 standard in a human and machine-readable format on the drug's label in lieu of the bar code specified under 21 CFR 201.25.

We approve your exemption request for HPC, Cord Blood, because the ISBT 128 standard represents an alternative regulatory program or method of product use that renders the bar code unnecessary for patient safety.

If you have any questions concerning this letter, please feel free to contact Anita Richardson at (240) 402-9065.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Research and Review