

MEMORANDUM

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

Date: April 19, 2018

From: CAPT Jean Makie

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Associate Director, Safety and Communications
Office of Compliance and Biologics Quality (OCBQ)

Through: Anita Richardson
Associate Director, Policy, OCBQ

To: Virginia Ocampo, Regulatory Project Manager
FDA/OMPT/CBER/OTAT

Subject: Linear Barcode Exemption Request
MD Anderson Cord Blood Bank
BLA STN: 125657/0

A. Introduction

On April 16, 2018, MD Anderson Cord Blood Bank submitted a formal request for an exemption from the linear bar code requirements under 21 CFR 201.25 and 610. The targeted PDUFA date for this application is June 26, 2018.

In their barcode exemption request letter, MD Anderson Cord Blood Bank requested an exemption under 21 CFR 201.25(d)(ii) an alternative regulatory program or method of product use renders the bar code unnecessary for patient safety from the linear barcode requirement under 21 Part CFR 201.25. They proposed the use of an alternative regulatory program for cord blood labeling, known as ISBT 128, which 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, they explained that 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.

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.

MD Anderson Cord Blood Bank proposed that their licensed HPC, Cord Blood will product bear the ISBT 128 standard label machine-readable format, accompanied by a human-readable ISBT number, in lieu of the linear barcode requirements specified under 21 CFR 201.25.

B. Background

Under 21 Part CFR 201.25(c) *What does the bar code look like? Where does the bar code go?*: (1) Each drug product described in paragraph (b) of this section must have a bar code that contains, at a minimum, the appropriate National Drug Code (NDC) number in a linear bar code that meets European Article Number/Uniform Code Council (EAN.UCC) or Health Industry Business Communications Council (HIBCC) standards. Additionally, the bar code must:

(i) Be surrounded by sufficient blank space so that the bar code can be scanned correctly; and

(ii) Remain intact under normal conditions of use.

(2) The bar code must appear on the drug's label as defined by section 201(k) of the Federal Food, Drug, and Cosmetic Act.

C. OCBQ Review of Barcode Exemption Request

OCBQ reviewed MD Anderson Cord Blood Bank 's barcode exemption request. Under 21 CFR 201.25(d), an exemption request must document why: (i) compliance with the barcode requirement would adversely affect the safety, effectiveness, purity or potency of the drug or 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 (ii) an alternative regulatory program or method of product use renders the bar code unnecessary for patient safety.

D. OCBQ Conclusion:

OCBQ believes that MD Anderson Cord Blood Bank has adequately documented that their use of the alternative regulatory program, ISBT 128, to label their licensed HPC, Cord Blood product satisfies 21 CFR 201.25(d)(ii).

OBCQ will issue its letter to the applicant granting a linear barcode exemption on the same day as the action date, which is currently targeted for June 26, 2018. The signed letter will be uploaded at that time to the BLA in the EDR for mailing to the applicant by the OTAT RPM. In the interim, OCBQ suggests that OTAT inform MD Anderson Cord Blood Bank that the exemption is tentatively granted pending approval of their BLA and that they may submit draft labels that bear the ISBT 128 standard label machine-readable format, accompanied by a human-readable ISBT number, in lieu of the linear barcode requirements specified under 21 CFR 201.25.