

From: Ocampo, Virginia
Sent: Wednesday, March 28, 2018 11:17 AM
To: Wilson,Jeffrey (jmwilson@mdanderson.org)
Subject: BLA 125657 MD Anderson Cord Blood Bank_ Information request for linear bar code exemption

Dear Jeff,

Please note that MD Anderson Cord Blood Bank has not formally requested an exemption from the linear barcode rule. Your submission under section 2.3.P.1 Description and Composition of the Drug Product [HPC, Cord Blood, Injectable Suspension in your original application only requested an exemption from the use of an NDC number (“MD Anderson Cord Blood Bank requests an NDC code exemption because we use ISBT 128 compliant labeling.”). 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.

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.

Please submit a formal request for an exemption from the linear barcode rule. For example, you may consider such language as:

MD Anderson Cord Blood Bank requests 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. We propose 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. 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 proposes that our licensed HPC, Cord Blood 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.

Kindly acknowledge receipt.

Thank you,
Virginia
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