

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125432/0 Office: OCTGT

Product:HPC, Cord Blood

Applicant:LifeSouth Community Blood Centers, Inc.

Telecon Date/Time: 02-Nov-2012 09:53 AM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s):1. Information Request

Author: MOHAMMED HEIDARAN

Telecon Summary:The sponsor followed-up with information regarding ISBT labeling

FDA Participants: None

Non-FDA Participants: Jill Evans

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:See attached email

From: [Heidaran, Mohammad](#)
To: ["Evans, Jill A."](#)
Cc: [Jarvis, Candace](#); [Dollins, Eric](#)
Subject: FW: Product Code
Date: Friday, November 02, 2012 9:53:04 AM
Attachments: [image001.png](#)
[ICCBA standard page 112.pdf](#)
[emfalert.txt](#)

We can discuss this in our upcoming telecon. The main question relates to the package label. You indicate that bar codes will be used for DIN and product code on the package label. Do you plan to use bar codes for other information required to be on the package label? You may want to prepare a mock package label as you have done so for the container label below for further discussion.

Again lets discuss this in our upcoming telecon.

Thanks,
Mo

From: Evans, Jill A. [mailto:JAEvans@lifesouth.org]
Sent: Thursday, November 01, 2012 3:58 PM
To: Heidaran, Mohammad
Subject: Product Code

Hi Mo,
Yes, we can produce a barcode for the package label.
Jill

Here is Lori's explanation:

ICCBA standards allow for the product code to be eye readable in cases where the container label size is too small to include linear bar codes for both the DIN and the product code. Our container label does not have enough space to accommodate the product code as a linear bar code. We have added it as eye-readable (see below/attached label)

Also, see the attached page from ICCBA standards, which includes the information about the product code. Note that Item 4 on this page does state that if the container label does not include a bar code product code, that the attached documentation must include the DIN and product code as bar codes. We can accommodate this requirement on our package label.

In other words, our container label will have a bar code DIN and eye readable product code. Our Package Label can have both a bar code DIN and a bar code product code.



Jill Evans

Vice President of Quality



4039 Newberry Road

Gainesville, FL 32607

Phone: 1-888-795-2707 Ext: 41634

www.lifesouth.org

Connecting our donors to our patients

LifeSouth Community Blood Centers, Inc. is not responsible for errors or omissions in this e-mail message. This message (and any associated files) is intended only for the use of the individual or entity to which it is addressed and may contain information that is confidential, subject to copyright or constitutes a trade secret. If you are not the intended recipient you are hereby notified that any dissemination, copying or distribution of this message, or files associated with this message, is strictly prohibited. If you have received this message in error, please notify us immediately by replying to the message and deleting it from your computer. Messages sent to and from us may be monitored. Internet communications cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. Therefore, we do not accept responsibility for any errors or omissions that are present in this message, or any attachment, that have arisen as a result of e-mail transmission. If verification is required, please request a hard-copy version. Any views or opinions presented are solely those of the author and do not necessarily represent those of LifeSouth Community Blood Centers, Inc.

To assist in label design, if more than one linear bar code is to be placed in a quadrant, e.g., Expiration Date and Special Testing, some adjustment of the absolute position of bar codes other than those for Data Structures 001, 002, 003 and 005 is permissible. Additionally, depending on the amount of text that is required, it may be necessary to reduce bar code height in accordance with bar code height requirements described 6.1.3, beginning on page 101.

A library of example labels from different countries is posted on the ICCBBA Website.

7.5.2 Small Final Label

Some containers may require a smaller final label. In designing such labels the principles outlined in this chapter should be applied to the extent possible.

If the design includes use of linear bar codes with an X dimension of <0.25 mm, care should be taken to ensure that all scanners that will be used to read the label are able to do so.

At a minimum,

- 1) Every ISBT 128-labeled product shall carry an electronically readable Donation Identification Number and Product Code
- 2) Every ISBT 128-labeled product shall carry an eye-readable text Donation Identification Number and Product Code
- 3) These (1 and 2 above) should appear on the affixed label whenever possible
- 4) If linear bar codes are used and the affixed label is too small to carry both bar codes, then the DIN bar code shall appear on the affixed label, along with eye-readable DIN and Product Code text. The DIN and Product Code bar codes shall also be carried together on an attached label or on accompanying documentation (*Note: For traceability, both the ISBT 128 DIN and Product Code, which includes both the Product Description Code and the division/pack code, are required.*)

7.6 Printing Label Text

7.6.1 Eye-Readable Text for Linear Bar Codes

The eye-readable text is the representation of the data characters in a bar code that is printed left justified immediately below a linear bar code, unless otherwise specified (see Figure 10, page 147).

Every Code 128 bar code on a container label shall be accompanied by eye-readable text. Bar code data identifiers are non-data characters and therefore shall appear only in the bar codes, not in the eye-readable text.

7.6.1.1 Donation Identification Number [001]

The eye-readable text for a Donation Identification Number is unique in that it is the sole means of presenting the data content of the bar code,