

Information Request, November 2, 2011 - Hemacord

From: Thomas, Terrolyn

To: Driscoll, Chris; "Quinley, Eva";

Subject: INFORMATION REQUEST: NYBC- revisions for container and package labels/DUE FRIDAY, NOVEMBER 4, 2011

Date: Wednesday, November 02, 2011 4:32:54 PM

Please note the revisions that are needed for the container and package labels as shown below. If they need clarification on any points we can work on setting up a short call tomorrow. As with everything else, we'd like the revision submitted on Friday.

Thanks.

Container Label – affixed to the cryobag

The following revisions are needed:

- Provide more prominence to the proper name "Hematopoietic Progenitor Cells, Cord Blood". The current presentation gives the most prominence to "National Cord Blood Program."
- Move the name, address and license number of the manufacturer to the bottom of the label.
- Delete the label version since the information is irrelevant to the product.

Package Label – (the sheet titled "LABEL FOR LICENSED HPC-C AT RELEASE FOR TRANSPLANTATION.")

The following revisions are needed:

- Delete the text box containing the statement "LABEL FOR LICENSED HPC-C AT RELEASE FOR TRANSPLANTATION."
- Delete the logo for National Cord Blood Program.
- To give more prominence to the product's names, please present the manufacturer information, i.e., name, address, and license number, at the bottom of the label.
- Place the proper name of the product ("Hematopoietic Progenitor Cells, Cord Blood") above the proprietary name of the product (HEMACORD).
- The point size and typeface of the proper name shall be at least as prominent as the point size and typeface used in designating the proprietary name.
- Separate the dosage form from the proper name. Dosage form, i.e., Injectable Suspension, may be presented as a separate line beneath the product names.
- Move the statements "Do not irradiate", "Rx only", and "For Intravenous Administration Only" to the upper portion of the label to provide more emphasis. Please note that "Intravenous" should be used instead of "IV."
- Ensure that the NDC number is placed prominently in the top third of the label. Instead of appearing in the top third of the label, the NDC number may appear as part of and contiguous to any bar-code symbol for the product if following two conditions are met.

- The symbol appears prominently in a conspicuous location. This condition is not satisfied by the appearance of the symbol only on the natural bottom of a container or wrapper.
- The bar-code symbol is compatible with the NDC, i.e., the symbol provides a format capable of encoding the numeric characters of an NDC Number.
- The source of the product for safe administration should be included. In this case, since HEMACORD is made from human cord blood, the risk of transmitting infectious agents should be addressed. For example, "Warning: This product is made from human cord blood. The risk of transmitting infectious agents is present. Careful donor selection and available laboratory tests do not eliminate the hazard."
- Use precise and concrete terms. For example, use "Volume" instead of "Volume of product," and "Storage temperature" instead of "Recommended storage temperature."

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