

Packing Label Email, August 8, 2012 - Ducord

From: Gavin, Denise K

Sent: Wednesday, August 08, 2012 6:08 PM

To: Rebecca Durham; Davidson, Mark

Cc: Davidson, Mark; Bruce Burnett, Ph.D.

Subject: RE: Packing label

Attachments: Ducord PI Infusion Instructions comments 8-8-12.docx.html

Hi Becky,

We would like to discuss the Instructions for Preparation for Infusion that accompany the Package Insert in our t-con on Friday. To that end, I wanted to give you a heads up regarding our questions. Please see attached comments and edited PI.

1) Please provide data that establishes expiries for the post-thaw products (washed and 'diluted only') as these values are indicated on the Package Insert (PI). If you do not have this data a stability study of the thawed product will need to be conducted to establish post thaw expiration.

a. In the DRAFT PI (submitted May 31, 2012 with amendment 8) under section 16 How Supplied/Storage and Handling states that the thawed and washed product should be stored at 4-8oC until time of infusion and -----(b)(4)----- to infusion. Once DUCORD is thawed and washed it should be infused with in (b)(4) hrs.

b. In section 2 under Dosage and Administration the PI indicates that DUCORD should be infused -----(b)(4)-----, thaw and dilute (1 hr) and thaw and wash (4 hr).

2) The Instructions for Preparation for Infusion procedures are based on CCBB DIST-028, has the SOP CCBB-DIST-028 rev 03 Effective Date: 21 Dec 2011 been revised? Was this the version of the SOP used for the validation studies?

3) The Instructions for Preparation for Infusion procedures based on CCBB DIST-028 make reference to a number of Duke specific job aides and forms.

a. For instance: some requisite forms (i.e. JA1 Thawing Job Aide and FORM2 Thawing and Infusion Worksheet, FRM2 Thawing and reinfusion Worksheet, Hematopoietic Progenitor Cell Infusion Form, FORM1 Carolina CBB CBU Thawing Form, FRM1Hematopoietic Progenitor Assay Worksheet, Cryopreservation of Back-up cells from Original UCB Reinfusion) are referred to in the thawing instructions but were not submitted to the BLA.

b. Since they appear to be necessary to make calculations and verify aspects of the procedure, these forms must accompany the Instructions sent with the Package Insert. Is this your plan?

4) We recommend that the Instructions be revised to make them more applicable to accompany Ducord to all transplant centers. Some recommendations for formatting and language revisions, which are attached.

Thank you,
Denise

From: Rebecca Durham [mailto:rebecca.durham@duke.edu]
Sent: Wednesday, August 08, 2012 8:26 AM
To: Gavin, Denise K
Cc: Davidson, Mark; Bruce Burnett, Ph.D.
Subject: RE: Packing label

We are working on this today along with the other responses.
Becky

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From: Gavin, Denise K [mailto:Denise.Gavin@fda.hhs.gov]
Sent: Tuesday, August 07, 2012 6:10 PM
To: Bruce Burnett, Ph.D.; Rebecca Durham; Davidson, Mark
Cc: Amanda Parrish, Ph.D.
Subject: Packing label

Hi Becky

Please send a copy or mock up version of the propose ISBT package labels for the cryobag (smaller label) and tag tie (larger standard ISBT label) and/or other full container label if there is one. Please ensure that the photograph or other representations are large enough to see each aspect of the label.

And please detail the elements that are contained on each label if additional labels will accompany the product.

Please send by Wednesday August 8, 2012. .

Thank you for your cooperation!

Denise

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