

(System Info - 127399 TULL LORI 04/29/2010 09:59:31 TULL)

From: Benton, Kimberly
Sent: Thursday, April 29, 2010 9:48 AM
To: 'Kim, Helen'
Cc: Tull, Lori
Subject: RE: SPL

Helen,

The appropriate units have not been entered into the SPL system as of 9 am EDT. We have been assured that this is in progress but I do not have a definitive date of completion. In the interim you should enter information for sipuleucel-T but be aware that it will not pass validation. Not passing validation is not a show-stopper. FDA is aware that this will be entered and will not pass validation until the system has updated applicable units of measure. CBER's lead on SPL is CDR Vada Perkins and you may contact him at <vada.perkins@fda.hhs.gov>.

As we discussed in our previous telecon, please use as unit of measure "50 million CD54+ cells in 250 mL".

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From: Kim, Helen [<mailto:hkim@Dendreon.com>]
Sent: Wednesday, April 28, 2010 6:44 PM
To: Tull, Lori; Benton, Kimberly
Cc: Gaynor, Jonathan
Subject: SPL

Importance: High

Hi Lori and Kim ?

I was just checking on the status of the unit of measure for sipuleucel-T? Has this been finalized yet with FDA? We have been checking on our end and have not seen it yet on the FDA web site.

Helen Kim

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