

Fibrocell Resubmission Email, January 5, 2011 - Laviv

From: Thomas, John

Sent: Wednesday, January 05, 2011 11:21 AM

To: Tull, Lori; Fink, Donald; Haudenschild, Changting; Hoque, Atm S.; Lee, Shiohjen; Lim, Agnes; Melhem, Randa; Ou, Alan C.; Stockbridge, Lisa L; Wang, Gang; White, Janet; Zhu, Yao-Yao; Zinderman, Craig E; Buckler, Aileen

Cc: Wonnacott, Keith; Simek, Stephanie; Puri, Raj K. (FDA/CBER); Benton, Kimberly; Witten, Celia (CBER); Bryan, Wilson; Schneider, Bruce; Serabian, Mercedes; Wise, Robert

Subject: RE: Fibrocell BLA STN 125348 Resubmission

Lori,

The CMC portion of the resubmission is complete.

Also, can you set up a review team meeting so we can discuss timelines etc for completing the review of this resubmission?

Thanks,

Terrig

From: Tull, Lori

Sent: Wednesday, December 22, 2010 8:55 AM

To: Thomas, John; Fink, Donald; Haudenschild, Changting; Hoque, Atm S.; Lee, Shiohjen; Lim, Agnes; Melhem, Randa; Ou, Alan C.; Stockbridge, Lisa L; Wang, Gang; White, Janet; Zhu, Yao-Yao; Zinderman, Craig E

Cc: Wonnacott, Keith; Simek, Stephanie; Puri, Raj K. (FDA/CBER); Benton, Kimberly; Witten, Celia (CBER); Bryan, Wilson; Schneider, Bruce; Serabian, Mercedes; Syin, Chiang; Waites, Nancy; Norwood, Laurie; Crim, James; Wise, Robert; Holobaugh, Patricia

Subject: Fibrocell BLA STN 125348 Resubmission

Hello all,

We have received Fibrocell's resubmission for their BLA 125348. The final study report for the histology study is in the EDR (amendment 34). Amendments 28, 30, and 33 are also in the EDR and contain additional responses to the CR letter.

Please let me know by 1/7/11 if you agree that the resubmission is complete. If so, this will be a class 2 resubmission with a due date of June 22, 2011. I need to send a confirmation letter to the company no later than 1/11/11.

Thanks,

Lori

Lori A. Tull, RAC

Regulatory Project Manager

Office of Cellular, Tissue, and Gene Therapies
Center for Biologics Evaluation and Research
(301) 827-5359

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