

**From:** Tull, Lori  
**Sent:** Monday, March 14, 2011 10:27 AM  
**To:** 'Jeanne Novak'; 'Dana Weinberger'  
**Subject:** Request for clarification

Hi Jeanne and Dana,

Would you please help us clarify the following:

Subject -(b)(6)- received Placebo (see Table below in red ink) during study 006 according the assignment chart below; however, you stated that the subject received three treatments of azficel-t instead of placebo in study 006 in Amendment 35 (see paragraph on page 6 of amendment 35 below in red ink).

"On 25 June 2010 the subject received 0.2 mL azficel-T intradermally in his right arm and 0.2 mL placebo (saline) in his left arm as part of the Fibrocell IT-H-001 clinical study. (Note: Previously, subject had received three treatments, five weeks apart of 1.15 mL azficel-T to his face for the treatment of nasolabial fold wrinkles in 2007 as part of the Fibrocell IT-R-006 clinical study)".

[illegible]

(b)(6)		----- (b)(6) -----		N/A
(b)(6)		----- (b)(6) -----		N/A
IT-R-006	(b)(6)	Placebo	(b)(6)	----- (b)(6) -----
Placebo		(b)(6)	----- (b)(6) -----	
Placebo		(b)(6)	----- (b)(6) -----	
Placebo		(b)(6)	----- (b)(6) -----	
IT		(b)(6)	----- (b)(6) -----	
IT		(b)(6)	----- (b)(6) -----	
IT		(b)(6)	----- (b)(6) -----	
Placebo		(b)(6)	----- (b)(6) -----	
Placebo		(b)(6)	----- (b)(6) -----	
IT		(b)(6)	----- (b)(6) -----	
IT		(b)(6)	----- (b)(6) -----	
IT		(b)(6)	----- (b)(6) -----	
Placebo		(b)(6)	----- (b)(6) -----	

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