

# Fibrocell BLA 125348 Review Team Meeting, February 23, 2011 - Laviv

## Review updates

### Product

Telecon with Sponsor 2-16-2011 - concerns discussed and resolved  
Revised container label needs to be submitted

### Clinical

Biopsy study and SAE report of leukocytoclastic vasculitis  
Inter-center consultation – update  
Advisory committee

### OBE/DE

Post-licensure registry study PMR proposal

### APLB

Labeling issues  
Proprietary name review – Laviv

### Administrative

Labeling meetings scheduled

### Participants

Celia Witten	Kimberly Benton
Stephanie Simek	Keith Wonnacott
Wilson Bryan	Lori Tull
Randa Melhem	Patrick Riggins
Gang Wang	Shiowjen Lee
Janet White	
Craig Zinderman	
Yao-Yao Zhu	
Agnes Lim	
Bruce Schneider	
Mark Borgini	
John Thomas	
Donald Fink	

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