

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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