

# Record of Telephone Conversation, September 8, 2009 - Laviv

Submission Type: BLA   Submission ID: 125348/0   Office: OCTGT  
Product:  
Autologous Cultured Fibroblasts

Applicant:  
Fibrocell Technologies, Inc.

Telecon Date/Time: 08-Sep-2009 02:00 PM   Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s):

1. Information Request

Author: LORI TULL  
Telecon Summary:  
Clinical information requested  
FDA Participants: Yao-Yao Zhu, Lori Tull  
Non-FDA Participants: Jessica Allmond  
Trans-BLA Group: No

Related STNs: None  
Related PMCs: None

Telecon Body:

FDA stated that there were some patients that still had ongoing cases and requested CRFs for patients -----(b)(6)-----, and for any other patients with ongoing cases. FDA asked Isolagen to provide their version of the ongoing cases from the integrated safety and provide subject numbers and CRFs for studies 001, 002 and 007. FDA noted that there were inconsistencies with ITR002. The AE table of side effects was inconsistent with the database and asked Isolagen to explain this inconsistency.