

Record of Telephone Conversation August 26, 2009 - Laviv

Submission Type: BLA Submission ID: 125348/0 Office: OCTGT

Product:
Autologous Cultured Fibroblasts

Applicant:
Fibrocell Technologies, Inc.

Telecon Date/Time: 26-Aug-2009 02:00 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):
1. Advice

Author: LORI TULL

Telecon Summary:
Discussion regarding indication statement

FDA Participants: Changting Haudenschild, Agnes Lim, Bruce Schneider, Lori Tull

Non-FDA Participants: Jeanne Novak, Jessica Allmond, David Hines

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

FDA suggested a change in the indication from treatment to “indicated for the temporary improvement of moderate to severe nasolabial fold wrinkles”. Isolagen responded that there was the potential for long term improvement and “temporary” would be contrary to their data. FDA stated that only 6 months of efficacy data was available. Isolagen replied that they understood, but the intention of the treatment was long-term. Isolagen requested that “for at least 6 months” or “up to 6 months” be used. FDA responded that they would discuss the issue internally and get back to Isolagen.