

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

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

Product:

Autologous Cultured Fibroblasts

Applicant:

Fibrocell Technologies, Inc.

Telecon Date/Time: 08-Jul-2009 01:00 PM   Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s): 1. Information Request

Author: LORI TULL

Telecon Summary:

Request for clarification of statistical datasets

FDA Participants: Changting Haudenschild, Shiojjen Lee, Agnes Lim, Yao-Yao Zhu, Lori Tull

Non-FDA Participants: Jessica Allmond, Barbara Ellishoff

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

FDA noted that the integrated dataset was in a different format and asked if the Isolagen could use the same format that was used for the individual datasets. Isolagen responded that they used SDTM format. FDA stated that CBER does not accept SDTM. Isolagen responded that they would work on it.

FDA noted that there were 2 CRFs from the 005 study that were blank when opened. Isolagen responded that they would check on the problem.

FDA noted a discrepancy of efficacy results between the 005 and 006 studies. FDA suggested that there could have been intra or inter reader inconsistency and asked if Isolagen had an analysis regarding variability. Isolagen responded that there was not a specific analysis. Investigators were trained and evaluated. FDA asked if there was QA at the sites. Isolagen responded no. Isolagen stated that they would clarify this issue in their response to the 74-day letter.

FDA asked when Isolagen would send their 12 month data. Isolagen responded that the safety update would be submitted at the end of August or early September.

FDA informed Isolagen that there may be PMCs regarding long term safety beyond 12 months, tumor formation, lifespan of the cells, and overgrowth. There may be a PMC needed for non Caucasian populations especially African Americans, older patients, and male patients.

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