

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE November 10, 2009

FROM Janet White, Bioresearch Monitoring Branch, HFM-664
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

THROUGH Patricia Holobaugh, Bioresearch Monitoring Branch Chief, HFM-664

TO John Thomas, HFM-730, Chair, BLA Committee
Lori Tull, HFM-705, RPM, BLA Committee

SUBJECT Bioresearch Monitoring Inspection Results
BLA: STN 125348/0
Sponsor: Fibrocell Technologies, Inc.
(formerly Isolagen Technologies, Inc.)
Product: Autologous Human Fibroblasts
(Azfibrocel-T, previously known as Isolagen Therapy™)

SUMMARY STATEMENT

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