

Bioresearch Monitoring Mid-Cycle Review, August 11, 2009 - Laviv

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE August 11, 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 Mid-Cycle Review
BLA: STN 125348/0
Sponsor: Isolagen Technologies, Inc.
Product: Autologous Human Fibroblasts (Isolagen Therapy™)

1. ----- Information withheld per Privacy Act-----
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Janet K. White
Consumer Safety Officer

Page Last Updated: 09/24/2013

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