

Review Team Meeting Agenda Minutes, March 19 2009 - Laviv

Participants: Donald Fink, John Thomas, Ashok Batra, Gang Wang, Stephanie Simek, Bo Zhen, Ghanshyam Gupta, Michael Yao, Allen Ou, Raj Puri, Lisa Stockbridge, Atm Hoque, Keith Wonnacott, Kimberly Benton, Robert Wise, Lori Tull, Craig Zinderman, Janet White

Isolagen BLA 125348 First Committee Meeting

Introduction of Review Team

Terrig Thomas (Product)

Donald Fink	(Product)
Atm Hoque	(Pre-clinical)
Michael Yao	(Clinical)
Gang Wang	(DMPQ)
Shiowjen Lee	(Statistics)
Craig Zinderman	(Epidemiology)
Alan Ou	(Epidemiology)
Janet White	(Bioresearch Monitoring)
Lisa Stockbridge	(Labeling)
Lori Tull	(RPM)

Outline of Submission

Autologous Fibroblasts (human, dermal, Isolagen Technologies, Inc.) Expanded ex vivo, Administered Intradermally for the Treatment of Rhytids.

History Summary

Major Review Milestones

First committee meeting - 3/20/09
Filing meeting - 4/17/09
Filing action (letter) - due by 5/5/09
Deficiencies identified (letter) - due by 5/19/09
Labeling Target - due by 12/5/09
PMC Study Target - due by 12/5/09
First action due - 1/4/10

Review Expectations

Good Review Management Principles (GRMP) Guidance

Sponsor Communications

How often – will schedule as needed, Mid cycle in August
Who initiates?
Who participates – as needed
How are they documented – Lori drafts emails for comments from team

Inspections

Timing for DMPQ (June or August) and BiMo Inspections
Product reviewer credentialing (Don and Terrig)

Need for Advisory Committee Meeting – Yes

Overview of upcoming Filing/Planning meeting – Lori to email checklist

Action Items

Formal consult from CDRH and CDER
PVP – possible REMS or PMR
Set up eroom