

# Filing Review, May 5, 2009 - Laviv

Our STN: BL 125348/0

May 5, 2009

Isolagen Technologies, Inc.  
Attention: Dr. Jeanne M Novak  
2905 Wilderness Place, Suite 202  
Boulder, CO 80301

Dear Dr. Novak:

This letter is in regard to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act.

We have completed an initial review of your application dated March 6, 2009 for Autologous Cultured Fibroblasts to determine its acceptability for filing. Under 21 CFR 601.2(a) we have filed your application today. The review goal date is January 4, 2010. This acknowledgment of filing does not mean that we have issued a license nor does it represent any evaluation of the adequacy of the data submitted.

We will contact you regarding your proposed labeling no later than December 5, 2009. If postmarketing study commitments (506B) are required, we will contact you no later than December 5, 2009.

At this time, we have not identified any potential review issues. Our filing review is only a preliminary review, and deficiencies may be identified during substantive review of your application. Following a review of the application, we shall advise you in writing of any action we have taken and request additional information if needed.

If you have any questions, please contact the Regulatory Project Manager, Lori Tull, at (301) 827-5102.

Sincerely yours,

Raj K. Puri, M.D., Ph.D.  
Director  
Division of Cellular and Gene Therapies  
Office of Cellular, Tissue, and Gene Therapies  
Center for Biologics Evaluation and Research

Page Last Updated: 07/19/2011

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