

# Telecon with Isolagen, June 1, 2009 - Laviv

Date: 6-1-09 Time 2:00pm

A telecon was convened to inform Isolagen that a pre-license inspection (PLI) will be conducted at their Exton, PA facility from Aug. 31 to Sept. 4, 2009.

The sponsor was informed that the CBER inspection team will include:

Dr. Gang Wang (Lead), Biologist, OCBQ/DMPQ  
Dr. Randa Melhem, CSO, OCBQ/DMPQ  
Dr. John Thomas, Biologist, OCTGT/DCTG  
Dr. Donald Fink, Biologist, OCTGT/DCTG

The Inspection team may also include an inspector from the PA District Office, ORA upon confirmation.

A list of Information Request related to the PLI will be provided to the sponsor at least two weeks prior to the inspection.

With regard to manufacturing the sponsor was informed that the following would be required to be observed during the period of inspection:

- Biopsy receipt/processing – -----(b)(4)-----
- Harvesting of bulk Drug Substance – -----(b)(4)-----
- A fully operational QC lab running various lot release tests
- Drug Product-Injection – -----(b)(4)----- and final container filling procedures
- The sponsor agreed to provide for the above requirements and would submit a proposed manufacturing schedule to the inspection team for review and approval. The sponsor will attempt to stagger the major processing steps described above so that each will be available for inspection.

## FDA Participants

Lori Tull  
Terrig Thomas  
Gang Wang

## Isolagen Participants

Jeanne Novak, Ph.D., Authorized Regulatory Representative  
Kevin Hennegan, M.A., Regulatory/Scientific Consultant  
Jessica Allmond, M.A.S., RAC, Clinical/Regulatory Consultant  
Declan Daly, CEO, Isolagen  
John Maslowski, M.S., CQA, VP Operations, Isolagen  
Karen Donhauser, Director of Quality, Isolagen