

Review Team Meeting Minutes, August 20, 2009 - Laviv

Participants: Donald Fink, John Thomas, Yao-Yao Zhu, Gang Wang, Stephanie Simek, Shiohjen Lee, Changting Haudenschild, Raj Puri, Lisa Stockbridge, Craig Zinderman, Atm Hoque, Keith Wonnacott, Kimberly Benton, Lori Tull, Jane Liedtka, Janette Alexander, Charles Durfor
Isolagen BLA 125348 Review Team Meeting Agenda (8-20-09)

1. Administrative

- Briefing Dr. Midthun
- USAN proprietary name ballot received. USAN working group will review

2. Sponsor Communication

- Response to the May 19th letter

3. Review Status

- Update of new information

4. Advisory Committee (CTGTAC)

- **Meeting date – October 9th**
- **AC briefing document**
- CMC and Clinical sections due to Division Directors – Aug. 26th
- Draft version of full document due to Dr. Witten – Sept. 2nd
- Final briefing document to be sent out to AC panel – Sept.9th
- **Questions – Discussion**
- Two standardized voting questions for safety and efficacy.

Draft voting questions for Isolagen CTGTAC Panel

21 CFR 601.25(c)(1) states that safety of a licensed biological product means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition recipient at the time. Proof of safety shall consist of adequate tests by methods reasonably applicable to show the biological product is safe under the prescribed conditions of use, including results of significant human experience during use. Considering the data in the BLA, please comment on whether there is a reasonable assurance that the product is safe.

21 CFR 601.25(c)(2) states that effectiveness of a licensed biological product means a reasonable expectation that, in a significant portion of the target population, the pharmacological or other effect of the biological product, when used under adequate directions, for use and warnings against unsafe use, will serve a clinically significant function in the diagnosis, cure, mitigation treatment, or

prevention of disease in man. Proof of effectiveness shall consist of controlled clinical investigations. Considering the data in the BLA, is there reasonable assurance that the product is effective?

- CMC – No questions
- Clinical – Please provide

Previous CDER AC questions provided by Jane Liedka

5. PVP/REMS - update

Page Last Updated: 07/20/2011