Mid-cycle Communication Teleconference

Application type and number:	BLA STN 125523/0
Product name:	Fibrin Sealant, Human Fibrinogen Human Thrombin
Proposed Indication:	Aid to surgical hemostasis for mild to moderate bleeding from small vessels
Applicant:	ProFibrix BV
Meeting date & time:	July 30, 2014, 10:30 am - 12:30 pm
Committee Chair:	Alexey Khrenov, PhD
RPM:	Tracy Tilghman, MPH

FDA Attendees:
Alexey Khrenov, PhD, CMC Reviewer, CBER/OBRR/DHRR/LH
Tracy Tilghman, MPH, Regulatory Project Manager, CBER/OBRR/DBCD

ProFibrix Attendees:
Linda Zuckerman, Ph.D. VP Regulatory Affairs
Eliane Schutte, MSc., VP Global Product Development
Sabine Snaar, Ph.D., Director, Quality Assurance
Laurens van Pinxteren, Ph.D. Director Clinical Manufacturing
Sabrina Gu, Regulatory Affairs Specialist II
Jan Ohrstrom, SVP EU Regional Engagement Leader

Discussion Summary:

1. No significant issues with the data submitted in the BLA have been identified by the review committee to date.

2. The review of the clinical data to date did not raise any major safety concerns

3. Information Requests were sent to the Applicant on May 30 and June 24, 2014: for analytical methods and their validations. Applicant committed to respond by September 30th, 2014.

4. AIR letter was sent to the Applicant regarding the Fibrospray device 510(k) application. Applicant was advised to submit the response within 90 days of the Action Due Date for the BLA.

5. The Pre-License Inspection for (b) (4)

6. The current thinking of the review committee is that this BLA will not be presented at Blood Products Advisory Committee meeting.

7. The late-cycle meeting will be scheduled for mid-October 2014. The format of the meeting (i.e., a face-to-face meeting or a teleconference) will be determined in the course of the next two months

END