

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125523/0 Office: OBRR

Product:

Fibrin Sealant, Human Fibrinogen Human Thrombin

Applicant:

ProFibrix, BV.

Telecon Date/Time: 24-Mar-2014 04:00 PM Initiated by FDA? Yes

Telephone Number: (b) (4)

Communication Category(ies):

1. Other - to alert ProFibrix of incomplete information in the BLA

Author: TRACY TILGHMAN

Telecon Summary:

The purpose of this teleconference is to discuss with ProFibrix the incomplete facility information in the BLA on multiple aspects related to equipment, systems, facilities, and contractual responsibilities, and verify the availability of this information.

FDA Participants:

Natalya Ananyeva

Alexey Khrenov

Carolyn Renshaw

Tracy Tilghman

Susan Yu

Non-FDA Participants:

ProFibrix/The Medicines Company:

Eliane Schutte, MSc. VP Global Product Development


Laurens van Pinxteren, Ph.D. Director Manufacturing and Supply

Sabine Snaar, Ph.D., Director Quality Assurance

Linda Zuckerman, Ph.D. VP Clinical Development

Sabrina Gu, Manager, Regulatory Affairs

(b) (4), (b) (6)



Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

The purpose of this teleconference was to discuss with ProFibrix and Nova (b) (4) (b) (4) incomplete information that cannot be found in the BLA. The FDA referred ProFibrix to the “Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products” and “Guidance for Industry: for the Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products” regarding the incomplete information. The incomplete information included information on the equipment use, equipment and component sterilization, the facility cleanroom validation, complete information regarding water systems and other areas. The complete list of information will be provided as information request to ProFibrix. FDA asked whether the information discussed in this telecon could be submitted to the BLA within a two week timeframe. ProFibrix stated that this is a reasonable request and they should be able to make this deadline.

The FDA asked ProFibrix to provide a manufacturing production schedule in order to schedule a pre-license inspection. ProFibrix stated that the spray-drying of fibrinogen and thrombin and filling of the drug product were separated by approximately (b) (4) gap. The spray-drying will be performed in June 2014 and the filling will be performed in (b) (4) (b) (4). Additional information will be provided on the specific manufacturing dates by ProFibrix.

Following clarifications were given by (b) (4) during telecon:

1. There are no (b) (4) sterilizers a (b) (4); only (b) (4) sterilization is performed.
2. “Contract employees” performing the (b) (4) employees.
3. FDA inspection was performed in (b) (4)

In the future, ProFibrix would like to be part of any communications FDA has with (b) (4) (b) (4) in regards to ProFibrix product.