



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

Our Reference: BLA BL 125523/0

ProFibrix BV
Attention: Linda Zuckerman, PhD
The Medicines Company
1144 Eastlake Ave East, Suite 700
Seattle, WA 98109

Dear Dr. Zuckerman:

Please refer to your Biologics License Application (BLA) submitted under the Public Health Service Act for Fibrin Sealant (Human) [Raplixa].

Attached are our briefing materials, including our agenda, for the Late-Cycle Meeting (LCM) scheduled for April 2, 2015.

If you have any questions, please call Sonday L. Kelly, MS, RAC, Regulatory Project Manager, at (240) 402-8410.

Sincerely,

Basil Golding, MD
Director
Division of Hematology Research and Review
Office of Blood Research and Review
Center for Biologics
Research and Review

ENCLOSURE:
Late-Cycle Meeting Materials

Late-Cycle Meeting Materials

Meeting Date and Time: April 2, 2015, 2:30 – 3:30 p.m., EDT

Meeting Location: Building 75, Room 1535
Federal Research Center
10903 New Hampshire Avenue
Silver Spring, MD 20993

Application Number: BL 125523/0

Product Name: Fibrin Sealant (Human) [Raplixa]

Indication: An aid to surgical hemostasis for mild to moderate bleeding from small vessels when control of bleeding by standard surgical techniques is ineffective or impractical

Applicant Name: ProFibrix BV

INTRODUCTION

The purpose of a Late-Cycle Meeting (LCM) is to share information and to discuss any substantive review issues/major deficiencies that we have identified to date and our objectives for the remainder of the review. The application has not yet been fully reviewed by the signatory authorities, division directors, and application chair. Therefore, the meeting will not address the final regulatory decision for the application. We are sharing this material to promote a collaborative and successful discussion at the meeting.

1. Discipline Review Letters

No Discipline Review letters have been issued to date.

2. Substantive Review Issues/Major Deficiencies to be discussed during the LCM

At this time, we do not have any substantive review issues or major deficiencies.

For inspections: Inspections are complete. A final recommendation is pending at this time. However, if we learn of any issues from the outstanding facility inspections, the agenda will be modified accordingly.

3. Advisory Committee Meeting

An Advisory Committee meeting is not planned.

4. REMS or Other Risk Management Actions

We have not identified any issues related to risk management, and do not believe that a *Risk Evaluation and Mitigation Strategies* (REMS) is needed at this time.

LCM AGENDA

1. Introductory Comments – 5 minutes (RPM/Chair)

Welcome, Introductions, Ground rules, Objectives of the meeting

2. Review Plans – 5 minutes

- Receipt of Complete Response to the Additional Information Letter for the 510(k), BK140119, Fibrospray should occur on April 2, 2015.

3. Applicant Questions – 45 minutes

4. Wrap-up and Action Items – 5 minutes

END