

CLINICAL PHARMACOLOGY BLA REVIEW

Division of Hematology
Office of Blood Review & Research

BLA 125523/0

Product: Raplixa^T (Fibrocaps, human fibrinogen and human thrombin)
Sponsor: ProFibrix BV (subsidiary of The Medicines Company Inc.)
Indication: Aid to surgical hemostasis for mild to moderate bleeding from small vessels when control of bleeding by standard surgical techniques is ineffective or impractical.
Date Received: January 31, 2014
Reviewer: Carl-Michael Staschen, M.D., Ph.D.
RPM: Tracy Tilghman
Through: Salim Haddad, M.D.

Background

Fibrocaps (b) (4) is developed as a dry-powder fibrin sealant made of a single, pre-mixed blend of human plasma-derived fibrinogen and thrombin. Fibrocaps contains FDA-licensed, human plasma-derived fibrinogen and human plasma-derived thrombin obtained from (b) (4) (b) (4)

The company is seeking approval in the U.S. for the following target indications for Fibrocaps (human plasma-derived fibrinogen and thrombin):

- an adjunct to haemostasis in patients undergoing surgical procedures when control of mild or moderate bleeding by conventional surgical techniques including suture, ligature and cautery is ineffective or impractical,
- (b) (4)

Specific clinical pharmacology or formal pharmacokinetic studies of Fibrocaps have not been performed as Fibrocaps is applied topically, acts locally and as such there is little to no biodistribution to other tissues including blood.

CLINICAL PHARMACOLOGY LABELING COMMENTS

The Clinical Pharmacology labeling section (12) only consists of the Mechanism of Action of Fibrocaps. This is acceptable from a Clinical Pharmacology perspective.

RECOMMENDATION

There is no Clinical Pharmacology issue in this BLA submission.

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