



Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center of Biologics Evaluation and Research

Pharmacology/Toxicology Review
Mid-cycle BLA Memorandum
Division of Hematology
Office of Blood Research & Review

To: File STN: 125506/0/0 (Cross reference: IND 14235)
Reviewer: M. Keith Wyatt, PhD, Pharmacologist, DH, OBRR, CBER
Through: Anne M. Pilaro, PhD, Supervisory Toxicologist, CBER/OBRR/DH
Applicant: Bio Products Laboratories, Inc. (BPL)

Product: Coagulation Factor X (Human, REPLAFAC[®]TEN)

Purpose: To review results from nonclinical studies to support licensure of Coagulation Factor X (Human) for the treatment of bleeding episodes, and prevention of bleeding during surgery in patients with hereditary deficiency of coagulation factor X.

Date received: July 15, 2013

Information should be sent to the Applicant

Application type and number: STN: 125506/0/0

Product Name: Coagulation Factor X (Human, REPLAFAC[®]TEN)

Proposed indications: Treatment of bleeding episodes and prevention of bleeding during surgery in patients with hereditary deficiency of coagulation factor X.

Applicant: Bio Products Laboratory, LLC (BPL)

Reviewer Name: Michael (Keith) Wyatt

Discipline: Pharmacology/Toxicology (PT)

a. Reviewer's assigned areas *not* completely reviewed to-date

All nonclinical study reports submitted in Module 4 of STN: 125506/0/0 have been reviewed.

b. Outstanding Information Requests

There are no comments or outstanding information requests related to the nonclinical program to be conveyed to the Applicant at this time.

c. Date reviewer will complete the primary discipline review, if not complete.

The final Pharmacology/Toxicology primary review memorandum for STN 125506/0/0 will be completed, with supervisory concurrence, by December 5, 2013.

d. Key findings and substantive issues with the information and data in the application.

There are no outstanding or substantive nonclinical issues at the present time that would prevent approval of STN 125506/0/0 for BPL's Coagulation Factor X for the intended indications. Additionally, there are no Pharmacology/Toxicology post-marketing commitments or requirements that have been identified at the current time.

e. Potential impact the substantive issues have on the review especially those which could prevent approval and impact the review timeline

There are no substantive nonclinical issues at the present time that would prevent approval of STN: 125506/0/0 for BPL's Coagulation Factor X for the intended indications.

f. Plan for addressing issues and the reason for the suggested approach

Not applicable