

Filing Meeting Summary

Date: July 13, 2014

Time: 1:30 PM

From: LT Thomas J. Maruna, USPHS, MSc, MLS(ASCP)^{CM}

To: STN 125591/0

Re: Filing Meeting for CSL Behring's Antihemophilic Factor (Recombinant), Single Chain

CBER Participants:

Chair/Product	Alexey Khrenov
CMC/Product	Ze Peng
Clinical	Victor Baum
Pharm/Tox	Anne Pilaro
Pharm/Tox	Yolanda Branch
Clin Pharm	Carl-Michael Staschen
BIMO	Haecin Chun
BIMO	Christine Drabick
DMPQ Facility Inspector	Donald Ertel
Biostatistician	Renee Rees
Biostatistician	Jessica Hu
Testing Plan & Lot Release	Not Present – Exempt
Regulatory Management Officer	Thomas J. Maruna
OBRR/IO/RPMS	Lorraine Wood
Epidemiology/Pharmacovigilance	Adamma Mba-Jonas
APLB	Loan Nguyen
OBRR/DHCR	Howard Chazin
OCBQ/DMPQ	Carolyn Renshaw
OBRR/DHRR/LH	Timothy Lee

Background:

CSL Behring Recombinant Facility, license number 2009, has submitted to the FDA for review an original Biologics License Application (BLA), STN 125591/0. This BLA arrived to the Agency on May 29, 2015. The cross-reference to Investigational New Drug (IND) application is IND 14791. CSL Behring has requested review of proprietary names (b) (4) (primary) and AFSTYLATM (alternate). CSL Behring has requested Lot Release exemption. Priority review has not been requested. The product was not granted Orphan status as requested by applicant; however, the applicant has submitted a request for refund of the User-Fee and has stated it will submit an amendment providing justification for Orphan designation. The applicant expects the refund request to be granted if Orphan designation is approved. No amendment has been received to date.

Summary: Sponsor	CSL Behring Recombinant Facility (CSL Behring), License #2009
STN	125591/0
References	CRMTS 9127, 9649 IND 14791
Product	Antihemophilic Factor (Recombinant), Single Chain
Proposed Indication	Control and prevention of bleeding episodes, routine prophylaxis and perioperative management in adults and children with hemophilia A (congenital Factor VIII deficiency)
Review Priority	Standard
Orphan Status	Not Granted – User fee paid (refund requested) On 9 April 2015, CSLB received feedback that FDA was unable to grant orphan designation at that time. In response to FDA's feedback, CSLB plans to submit an amendment.
Proposed Proprietary Name	Primary: (b) (4) Alternate: AFSTYLA
Lot Release	Exemption Requested

Discussion:

- All reviewers/disciplines noted that the submission appears complete and no information appears to be omitted.
- No substantive deficiencies or issues have been identified that have significant impact on the ability to complete the review of the application. There are no Refuse to File (RTF) issues according to 21 CFR §601.2 for this BLA.
- APLB reviewer noted that the proprietary name review is ongoing, but the applicant's proposed primary name, (b) (4), has been found unacceptable; AFSTYLATM was considered acceptable at the time of the meeting.
- Bioresearch Monitoring has selected the following three sites for inspection:

FACTS 11547811

Site # 7100001

14 Subjects – South Africa

FACTS #11547814

Site # 6160014

11 Subjects - Poland

FACTS # 11547818

Site # 6080001

8 Subjects - Philippines

- This product will be exempt from lot release testing.

- No Deficiencies Identified letters will be issued.
- This application will be reviewed under a standard review schedule.
- No Advisory Committee meeting will be required.
- This application may be filed (confirmed with all review disciplines)

Action Items:

Issue a Filing action letter

END