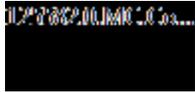


From: Thompson, Edward
Sent: Thursday, June 18, 2015 7:37 AM
To: 'Kevin Darryl (KD) White (Kevin.White@cslbehring.com)'
Cc: Monica.Richardson@cslbehring.com
Subject: FDA Mid-Cycle Communication Summary for BL 125582/0

Contacts: Kevin Darryl (KD) White - CSL Behring

Dear Mr. White,

Please find attached the Mid-Cycle Communication Summary for BL 125582/0 for the teleconference conducted on May 22, 2015 at 11 am.



Please contact me if you require clarification concerning this document.

Sincerely,
Edward Thompson
Regulatory Project Manager
FDA/CBER
Office of Blood Research and Review
(240) 402-8443
email: edward.thompson@fda.hhs.gov
10903 New Hampshire Avenue
WO71-4212
Silver Spring, MD 20993-0002

Mid-Cycle Communication Summary

Application type: Original BLA

Tracking number: STN 125582/0

Product name: Coagulation Factor IX (Recombinant), Albumin Fusion Protein

Proposed Indication: To treat patients with hemophilia B (congenital Factor IX deficiency) for (1) Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; (2) Control and prevention of bleeding episodes; and (3) Control and prevention of bleeding in perioperative setting

Applicant: CSL Behring Recombinant Facility AG

Meeting date & time: 22 May 2015, Friday at 11:00 AM

Committee Chair: Mikhail Ovanesov, PhD

RPM: Edward Thompson

FDA Attendees:

Mikhail Ovanesov, PhD, CBER/OBRR/DHRR/LH
Edward Thompson, RPM, CBER/OBRR

Other Attendee:

Christopher Sese, Independent Assessor, Eastern Research Group

CSL Behring Recombinant Facility AG Attendee:

Monica Richardson, Global Regulatory Affairs Regional Manager, North America
Kevin Darryl White, MBA, RAC, Senior Director, Global Regulatory Affairs, Head
Regional North America
Hartmut Landgrebe, PhD, Associate Director, Global Regulatory Affairs, Development
Products Regional Lead
Debra Bensen-Kennedy, MD, Global Therapeutic Area Head, Clinical R&D
Iris Jacobs, MD, Senior Global Clinical Program Director, Clinical R&D
Yanyan Li, Global Statistical Scientist, Clinical R&D
Christine Joch, Director, Clinical Safety Physician, Clinical R&D
Jay Newman, Director, CMC Lead, R&D

Discussion Summary:

1. No significant issues or major deficiencies have been identified by the review committee to date.
2. The review of the clinical data to date did not raise major safety concerns. The current thinking of the review committee is that a *Risk Evaluation and Mitigation Strategy* (REMS) is not required.
3. With regard to risk management, routine pharmacovigilance is recommended.
4. The current thinking of the review committee is that this BLA will not be presented at the *Blood Products Advisory Committee* meeting.
5. Information requests (IRs) sent but responses from CSL Behring have not been received:
 - FDA sent two IRs about Endotoxin assay methods on 04 May 2015 and 11 May 2015, and is expecting CSL Behring's response by 22 May 2015.
 - FDA sent an additional IR about validation of analytical methods for Factor IX Activity, (b) (4), Purity and Residual Water Content on 07 May 2015, and is expecting CSL Behring's response by 01 June 2015.
6. FDA will send CSL Behring another IR on the characterization of the albumin moiety by (b) (4) in May 2015. Please note that the review is ongoing and additional information may be requested as the need arises.
7. The following facility is currently scheduled for a pre-license inspection on 27 May 2015 to 4 June 2015: CSL Behring GmbH, FEI: 3003098680, DUNS: 326530474; Address: Emil-von-Behring-Str. 76, D-35041 Marburg, Germany.
8. The late-cycle face-to-face meeting is scheduled on 25 August 2015, Tuesday from 1:30 PM to 3:30 PM.
9. The action due date for this submission is Friday, 4 December 2015.

Additional Discussions

1. FDA went over the 9 items stated above and CSL Behring did not have any questions regarding them. In addition, FDA updated CSL Behring on impending IRs, including additional ones not presented in the 19 May 2015 Mid-cycle Communication.
2. CSL Behring informed FDA that all pre-inspection documents will be available for the FDA inspectors next week.

End