

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: STN 125582/0
Office: OBRR
Product: Coagulation Factor IX (Recombinant), Albumin Fusion Protein
Applicant: CSL Behring Recombinant Facility AG

Telecon Date / Time: July 24, 2015 at 10:30 a.m. Initiated by FDA? Yes
Telephone Number: (b) (4) with passcode
Communication Category: Other

Drafted: Edward Thompson
Revised: Mikhail Ovanesov,
Lisa Faulcon

Telecon Summary: To provide FDA's decision for the (b) (4)

FDA Participants:

Bindu George, MD, Acting Branch Chief, Clinical Review Branch, Division of Hematology Clinical Review, OBRR
Mikhail Ovanesov, PhD, Senior Staff Fellow, Division of Hematology Research and Review, OBRR
Lisa Faulcon, MD, Medical Officer, Division of Hematology Clinical Review, OBRR
Edward Thompson, RPM, OBRR

Non-FDA Participants:

CSL Behring Recombinant Facility AG

Kevin Darryl White, MBA, RAC, Senior Director, Global Regulatory Affairs, Head Region North America
Hartmut Landgrebe, PhD, Associate Director, Global Regulatory Affairs, Global Regulatory Lead
Christine Voigt, PhD, Principal Global Clinical Scientist
Monica Richardson, Manager, Global Regulatory Affairs, Regional Lead

Telecon Body:

The FDA communicated to CSL Behring Recombinant Facility AG that their request for the (b) (4)

CSL Behring Recombinant Facility AG understands the decision and further documentation will be provided in the final action letter.

End