

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: October 20, 2015 at 2:15 p.m. Initiated by FDA? No

Communication Category: 1. Advice

Drafted: Edward Thompson
Revised: Mikhail Ovanesov

Telecon Summary: Telecon requested by CSLB to discuss the FDA decision to issue Major Amendment letter on October 16, 2015.

FDA Participants:
Tim Lee, PhD, Acting Chief, CBER/OBRR/DHRR/LH
Mikhail Ovanesov, PhD, CBER/OBRR/DHRR/LH
Edward Thompson, RPM, CBER/OBRR

Non-FDA Participants:
CSL Behring
Hartmut Landgrebe, PhD, Associate Director, Global Regulatory Affairs, Global Regulatory Lead
Monica Richardson, Manager, Global Regulatory Affairs, Regional Lead
Kevin Darryl White, MBA, RAC, Senior Director, Regional Head North America, Global Regulatory Affairs

Telecon Body:

CSL Behring (CSLB) requested an informal teleconference to discuss the FDA Major Amendment Acknowledgment (MAA) letter issued on October 16, 2015.

CSLB inquired on FDA's decision to issue the MAA letter. FDA stated that the justification is outlined in the letter for the decision.

CSLB inquired if the office management provided their concurrence to this action. The FDA stated that this decision was deliberated and accepted by the office and division level directors.

CSLB inquired about the timeline of issuance of an MAA letter. FDA responded that the Agency is to inform the applicant promptly but no specific timeline is mandated. Due to

the internal discussion that led to this decision, it took some time for the issuance of the MAA letter after the receipt of the various amendments.

CSLB requested if the FDA can commit to the approval at an earlier date than the action due date posted in the MAA letter. FDA stated that this commitment cannot be provided. FDA further stated that the review is on-going and issues may be added, expanded upon, or modified as we continue the review.

CSLB requested an update on the review of the package insert. FDA stated that this review is currently on-going and that revisions are pending with no specific date at this time to be issued to the CSLB.

End