



Our STN: 125582/0

PROPRIETARY NAME ACCEPTANCE

CSL Behring Recombinant Facility AG
Attention: Mr. Kevin D. White
CSL Behring
1020 First Avenue
PO Box 61501
King of Prussia, PA 19406-0901

Dear Mr. White:

We have reviewed your submission dated December 5, 2014 with your biologics license application (BLA) for Coagulation Factor IX (Recombinant), Albumin Fusion Protein requesting a proprietary name review.

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB) we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, IDELVION, is acceptable at this time.

We will perform another proprietary name review of IDELVION closer to the time of the action due date to ensure that we have not approved a conflicting proprietary name for another product in the interim.

If you have any questions, please contact Edward Thompson at (240) 402-8443.

Sincerely,

Basil Golding, MD
Director
Division of Hematology Research and Review
Office of Blood Research and Review
Center for Biologics Evaluation and Research