DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our STN: BL 125606/0

BLA FILING NOTIFICATION

CSL Behring GmbH
Attention: Kevin D. White, MBA, RAC
CSL Behring LLC
1020 First Avenue
P.O. Box 61501
King of Prussia, PA 19406-0901

Dear Mr. White:

This letter is in regard to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act.

We have completed an initial review of your application dated June 30, 2016, for C1 Esterase Inhibitor (Human) to determine its acceptability for filing. Under 21 CFR 601.2(a) we have filed your application today. The review classification for this application is Standard. Therefore, the review goal date is June 30, 2017. This acknowledgment of filing does not mean that we have issued a license nor does it represent any evaluation of the adequacy of the data submitted.

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which include the timeframes for FDA internal milestone meetings. We plan to hold our internal mid-cycle review meeting on December 12, 2016. Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process.

We will contact you regarding your proposed labeling no later than May 31, 2017. If post marketing study commitments (506B) are required, we will contact you no later than May 31, 2017.

We are not currently planning to hold an advisory committee meeting to discuss this application.

At this time, we have not identified any potential review issues. Our filing review is only a preliminary review, and deficiencies may be identified during substantive review of your application. Following a review of the application, we shall advise you in writing of any action we have taken and request additional information if needed.

If you have any questions, please contact the Regulatory Project Manager, Ms. Nannette Cagungun, at (240) 402-8267 or at nannette.cagungun@fda.hhs.gov.

Sincerely,

Iliana Valencia, MS, MCPM
Chief
Regulatory Project Management Staff
Office of Blood Research and Review
Center for Biologics Evaluation and Research