Our Reference: BL 125606/0 December 16, 2016

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

Dear Mr. White:

Attached is a copy of the agenda for your December 20, 2016, Mid-Cycle Communication Teleconference with CBER.

Please include a reference to BL 125606/0 in your future submissions related to the subject product.

If you have any questions, please contact Nannette Cagungun at (240) 402-8267.

Sincerely,

Basil Golding, MD
Director
Division of Plasma Protein Therapeutics
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Mid-Cycle Communication Teleconference Agenda

Application type and number: BL 125606/0
Product name: C1 Esterase Inhibitor Subcutaneous (Human)
Proposed Indication: For routine prophylaxis against Hereditary Angioedema in adolescent and adult patients.
Applicant: CSL Behring GmbH
Meeting date & time: December 20, 2016 at 10:00 AM
Committee Chair: Felice D'Agnillo, PhD
RPM: Nannette Cagungun, MS, PD, RAC

Agenda:

To discuss the progress of the review.

Discussion Summary:

1. Any significant issues/major deficiencies, categorized by discipline, identified by the review committee to date.

   The review team has no significant issues/major deficiencies to communicate at this time. Further information/clarification will be requested to assist with the review of the CMC section of your application.

2. Information regarding major safety concerns.

   The review team has not identified any major safety concerns at this time.

3. Preliminary review committee thinking regarding risk management.

   The review team has no comments regarding risk management at this time.

4. Any information requests sent and responses not received

   We sent a CMC/Facility information request on December 16, 2016 for which we requested a response by January 6, 2017.

5. Any new information requests to be communicated

   - CMC Information Request
     - Assessment of (b) (4)
     - Timeline for additional updated stability data
     - Information regarding process validation studies and in-process testing of the (b) (4)

- Update on clinical studies ongoing at time of BLA submission
- Sample request for three vials of final product from each of the (b) (4) conformance lots (b) (4)

6. Proposed date for the Late-Cycle meeting (LCM)

The LCM between you and the review committee is currently scheduled for March 13, 2017.

We intend to send the LCM meeting materials to you approximately 10 days in advance of the LCM.

If these timelines change, we will communicate updates to you during the course of the review.

7. Updates regarding plans for the AC meeting

There are no plans to present this BLA to BPAC at this time.

8. Other projected milestone dates for the remainder of the review cycle, including changes to previously communicated dates.

Labeling Target Date: May 31, 2017

PMC Target Date: May 31, 2017