LATE-CYCLE MEETING MATERIALS

BLA 125606/0

CSL Behring GmbH
Attention: Kevin Darryl White, MBA, RAC
CSL Behring LLC
1020 First Avenue
PO Box 61501
King of Prussia, PA 19406-0901

Dear Mr. White:

Please refer to your Biologic License Application (BLA) submitted under section 351(a) of the Public Health Service Act for C1 Esterase Inhibitor Subcutaneous (Human) [HAEGARDA™], a white lyophilized powder supplied in single-use vials containing 2000 or 3000 International Units (IU) of C1-INH.

Attached are our meeting materials, including our agenda, for the Late-Cycle Meeting (LCM) scheduled for March 13, 2017.

If you have any questions, please contact the Regulatory Project Manager, 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

ENCLOSURE:
Late-Cycle Meeting Materials

Late-Cycle Meeting Materials

Meeting Date and Time:	March 13, 2017 at 10:00 AM
Meeting Location:	WO-71 Conference Room 1208/1210 Food and Drug Administration Center for Biologics Evaluation and Research 10903 New Hampshire Ave. Silver Spring, MD 20993-0002
Application Number:	BL 125606/0
Product Name:	C1 Esterase Inhibitor Subcutaneous (Human)
Indication:	For routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients
Applicant Name:	CSL Behring GmbH

INTRODUCTION

The purpose of a Late-Cycle Meeting (LCM) is to share information and to discuss any substantive review issues that we have identified to date, Advisory Committee (AC) meeting plans (if scheduled), and our objectives for the remainder of the review. The application has not yet been fully reviewed by the signatory authorities, division directors, and application Chair. Therefore, the meeting will not address the final regulatory decision for the application. We are sharing this material to promote a collaborative and successful discussion at the meeting.

During the meeting, we may discuss additional information that could be submitted to address any identified issues. We may also discuss whether the submission of such information would be expected to trigger an extension of the PDUFA goal date if the review committee should decide, upon receipt of the information, to review it during the current review cycle.

Please note: if you submit any new information in response to the issues identified in this background package prior to this LCM or the AC meeting, if an AC meeting is planned, we may not be prepared to discuss that information at this meeting.

1. Discipline Review Letters

No Discipline Review letters have been issued to date.

2. Substantive Review Issues to be discussed during the LCM

At this time we do not have any substantive review issues.

For inspections: Facility inspections are waived.

Amendment: We acknowledge your amendments submitted and received on February 28, 2017. A review of these amendments is ongoing and a final decision of these issues is pending.

3. Advisory Committee Meeting

An Advisory Committee meeting is not planned.

4. Risk Management Actions (e.g., REMS)

We have not identified any issues related to risk management. We do not believe that a risk management action is needed at this time.

LCM AGENDA

1. Introductory Comments – 5 minutes (RPM/Chair)

   Welcome, Introductions, Ground rules, Objectives of the meeting

2. Information Requests – 5 minutes

   Recent Information Requests (IR):

   - CMC/Facility IR sent on February 24, 2017. Response is requested by March 3, 2017.
   - Clinical Pharmacology IR sent on February 13, 2017. Response to item #1 has been extended to March 7, 2017.
   - Request for samples of the product (Lots (b) (4) sent February 18, 2017. Response is requested by March 7, 2017.

   We will send you an additional information request by March 13, 2017.

3. Risk Management Actions (e.g., REMS) – 1 minute

   We have not identified any issues related to risk management. We do not believe that a risk management action is needed at this time.

4. Postmarketing Requirements/Postmarketing Commitments – 1 minute

   There is no anticipation of PMRs/PMCs at this time.

5. Major labeling issues – 1 minute

   There are no labeling issues identified at this time.

6. Review Plans – 5 minutes

   - Finalizing the review of the already submitted material
   - Review of the responses to the recent IRs
   - Evaluation of the product samples
   - Finalizing the review of labeling

7. Applicant Questions –5 minutes
8. Wrap-up and Action Items – 5 minutes