From: Cagungun, Nannette
Sent: Thursday, June 15, 2017 3:45 PM
To: Michele.Walsh@cslbehring.com
Subject: Information Request: Postmarketing Commitments

Importance: High

Our Reference: BL 125606/0

Dear Ms. Walsh:

We are reviewing your June 30, 2016 biologics license application (BLA) for C1 Esterase Inhibitor Subcutaneous (Human). We request that you make the following postmarketing commitments:

1. CSLB commits to re-evaluate HAEGARDA release specifications after the first (b) (4) lots of the product are manufactured. A final study report will be submitted as a Postmarketing Commitment - Final Study Report by [Please insert the date; our estimated date is July 1, 2018].

2. CSLB commits to establish (b) (4) for the HAEGARDA process which has a (b) (4) characterized in Study Report IR-617-001-02. Final study report will be provided as a Postmarketing Commitment - Final Study Report by January 1, 2018.

3. CSL Behring commits to perform (b) (4) The final study report will be submitted as a as a Postmarketing Commitment - Final Study Report by March 1, 2018.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

Please submit your response to this information request as an amendment to this file by June 16, 2017 referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

The action due date for this file is June 30, 2017.

If you have any questions, please contact me at (240) 402-8267 or at nannette.cagungun@fda.hhs.gov.

Sincerely,
Nannette Cagungun, MS, PD, RAC

Regulatory Project Manager
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
Tel: 240-402-8267
nannette.cagungun@fda.hhs.gov.