

From: Cagungun, Nannette  
Sent: Friday, May 05, 2017 11:32 AM  
To: Michele.Walsh@csllabhring.com  
Subject: Information Request\_CMC\_C1INH/CSL830

Our Reference: BL 125606/0

Dear Ms. Walsh:

We are reviewing your June 30, 2016, biologics license application for C1 Esterase Inhibitor Subcutaneous (Human) for routine prophylaxis to prevent Hereditary Angioedema attacks in adult and adolescent patients. We have the following request for additional information:

1. In your amendment received 02/28/17: Reference your Attachment 1, CV-680-002-01R06, page 2 of 11- please provide your scientific rationale for why Factor I products represent the worst case scenario for cleaning.
  2. In your amendment received 03/03/17: Reference your Attachment 1, Extract of the Detailed PQ Documentation-
    - a. For the cleaning of vials in (b) (4), you reference the (b) (4) (b) (4) vials. Please explain how this study is relevant to cleaning of (b) (4), and provide your scientific your scientific rationale for any worst case loads.
    - b. For the depyrogenation of vials in (b) (4), you reference the worst case load of (b) (4) vials. Please provide your scientific rationale for this worst case load.
    - c. Have you physically performed any qualification runs for (b) (4) vial cleaning or depyrogenation, or do plan to?
- Please submit the requested information in an amendment to the file by Thursday, May 11, 2017, referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact me immediately so a new response date can be identified.

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

Sincerely,  
Nannette Cagungun, MS, PD, RAC  
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Center for Biologics Evaluation and Research  
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