

From: Cagungun, Nannette
Sent: Friday, February 24, 2017 2:28 PM
To: Michele.Walsh@csllab.com
Subject: Information Request_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. A summary of the validation (PQ) of the (b)(4) depyrogenation of the (b)(4). Please ensure to include the following:
 - > reference to the equipment used for (b)(4) depyrogenation, and
 - reference to associated
 - equipment qualification documents
 - > dates of the validation studies
 - > acceptance criteria
 - > summary of the results and any deviations
2. A copy of (b)(4) Test Instruction Q-52-A07 for review.
3. In table format, all steps of the process where (b)(4) is monitored as an in-process test. Please provide the applied limit at that step, and the justification/ rationale for the limit.

Please submit the requested information in an amendment to the file by Friday, March 3, 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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