

From: Cagungun, Nannette
Sent: Friday, February 17, 2017 12:26 PM
To: Michele.Walsh@csllab.hhs.gov
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 comments and request for additional information:

1. Reference your response to Question #1 (125606/0.12 received 13 Jan 2017 to Information Request on 21 Dec 2016):

a. Please provide a summary of the microbial testing performed as part of the CV re-validation (that you reference) for the (b) (4). Please include the sampling method, acceptance criteria, and a summary of the results (and any deviations).

b. CV-689-001-01 (that was provided in the application) for CV of (b) (4) does not include data for microbial testing (bioburden). Was microbial testing performed as part of the CV for the (b) (4)? If so, please provide the sampling method, acceptance criteria, and a summary of the results (and any deviations).

2. Please provide a description of the (b) (4). You may use diagrams or images of rooms and equipment to support your response, as needed.

Please submit the requested information in an amendment to the file by Tuesday, February 28, 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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