From: Cagungun, Nannette
Sent: Wednesday, April 19, 2017 3:43 PM
To: Michele.Walsh@cslbehring.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:

In reference to your (b) (4) test:

1. SOP, Q-52-A07, that you provided an amendment, does not include test parameters specific to the C1-INH (b) (4) vial filled units. Please provide the following for both vial sizes:

* The specific program (test cycle) used
* The amount of (b) (4) applied
* The defined period of time that the (b) (4) is monitored
* The specified (b) (4) reference values that would indicate a (b) (4) if exceeded

2. Please confirm that the (b) (4) test for the C1-INH (b) (4) vial filled units had been validated, and that testing parameters and acceptance limits are defined in a working document.

Please submit the requested information in an amendment to the file by Monday, April 24, 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,
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