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From: Cagungun, Nannette
Sent: Thursday, December 29, 2016 8:58 AM
To: Michele.Walsh@csllab.com
Subject: Information Request_Stat_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 determined that the following information is necessary to continue our review:

1. For study CSL830_3001, please provide the subgroup analyses for the time-normalized number of HAE attacks (number/day and number/month) and the percentage of responders

for the following subgroups (please follow the result format of Table 14.2.15 and Table

14.2.2.3 in CSL830_3001 CSR):

- * Type I vs Type II HAE
- * Country
- * Female subjects vs male subjects for each country
- * Female subjects vs male subjects for US and non-US

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 the requested information as an amendment to the file by Friday, January 13, 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.

Sincerely,
Nannette Cagungun, MS, PD, RAC
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