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From: Cagungun, Nannette
Sent: Tuesday, June 20, 2017 9:43 AM
To: Michele.Walsh@cs Behring.com
Subject: HAEGARDA: Information Request Lot release protocol template

Importance: High

Our Reference: BL 125606/0

Dear Ms. Walsh:

We note a discrepancy between HAEGARDA appearance specification in Section 2.3.P.5 (Table 4) and Section 3.2.P.5.1 (Table 1) which is "Colorless, clear to slightly opalescent solution" and in the Lot Release Protocol template submitted in Amendment 28 dated 6/12/17, which is "colourless and clear solution."

- a. Please correct the specification and resubmit the Lot Release Protocol.
- b. Please resubmit Lot Release Protocols submitted for lots that are used for product launch.

Please submit your response to this request by COB today. 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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