

Dehdashti, Seameen (Jean)

From: Dehdashti, Seameen (Jean)
Sent: Thursday, September 20, 2018 12:06 PM
To: 'BDV (Barbara Davies)'
Cc: Dehdashti, Seameen (Jean)
Subject: FDA Information Request (IR): BLA 125671/0

Importance: High

Dear Barbara,

We are reviewing your BLA submission for Antihemophilic Factor (Recombinant), GlycoPEGylated, turoctocog alfa pegol (STN 125671) and have the following information request (IR), outlined below in **bold text**, regarding Validation of Analytical Procedure (b) (4) Potency by Chromogenic Assay (b) (4). Please send us your response by Monday, October 15, 2018. If you feel that you will not be able to meet this timeline, please propose the date by which you can provide the requested data.

FDA Information Request (IR):

- 1. While reviewing of your accuracy data, we noted that you determined nominal (expected) and measured potencies using the same method. We do not agree that the results support accuracy of your method. The accuracy should be demonstrated by either comparing results obtained using (b) (4) methods or from (b) (4) experiments, in which an authoritative standard (e.g., WHO International Standard) of known assigned potency value is (b) (4) /product under consideration and measured to evaluate accuracy (b) (4). Please provide data obtained by either of these two approaches to demonstrate accuracy of your method.**
- 2. In your validation report, you provided linearity data for test samples only. You did not provide data such as correlation coefficient, slope and intercept; and the acceptance criteria for the standard curves. Please provide system suitability results (as per section 11 of your test procedure (b) (4) obtained during experiments carried out for method validation. This should include data for standard and control, and formulae and results of analysis used to show parallelism and equivalence between reference curve, control and test samples.**

Please confirm receipt of this communication, and do not hesitate to contact me, should you have any questions and/or concerns.

Warm regards,

Jean Dehdashti, MSc, RAC
Regulatory Project Manager

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