

Dehdashti, Seameen (Jean)

From: Dehdashti, Seameen (Jean)
Sent: Thursday, November 01, 2018 2:54 PM
To: 'BDV (Barbara Davies)'
Cc: Dehdashti, Seameen (Jean)
Subject: FDA Information Request (IR): BLA 125671/0

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**. Please send us your response by Thursday, November 15, 2018.

FDA Information Request (IR):

We have reviewed your response (125671/0.36 received on 10/23/2018) to our IR dated October 16, 2018. We have the following information request regarding the data submitted in Table 1-3 for in response to our CMC Question #2:

- **You showed (b) (4) replicate results each for potency of your secondary standard (b) (4) by the chromogenic and one-stage clotting assays. Please provide details of how the data were obtained, including how many independent sample preparations, analysts, instruments, and laboratories were involved in this study.**

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

**Center for Biologics and Evaluation Office
of Tissues and Advanced Therapies
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