

Dehdashti, Seameen (Jean)

From: Dehdashti, Seameen (Jean)
Sent: Tuesday, December 11, 2018 2:50 PM
To: 'BDV (Barbara Davies)'
Cc: Dehdashti, Seameen (Jean)
Subject: FDA Information Request - Clinical: 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 close of business tomorrow, Wednesday, December 12, 2018, if possible.

FDA Information Request (IR) – Clinical:

You state on page 87/1561 of Study 3859 Body Report that: “All bleeding endpoints were evaluated based on bleeding episodes requiring treatment with N8-GP. Non-treatment requiring bleeding episodes that coincided with regular prophylaxis doses was not included.”

1. Please clarify if “Non-treatment requiring bleeds” were included or excluded in the ABR analyses and/or in the treatment of bleeding analyses. Please clarify if this pertains to all other studies as well.
2. If “Non-treatment requiring bleeds” were excluded from the ABR analyses, please justify the reason for their exclusion.

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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