

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

Center for Biologics and Evaluation
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration

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