

Dehdashti, Seameen (Jean)

From: Dehdashti, Seameen (Jean)
Sent: Wednesday, November 14, 2018 12:44 PM
To: 'BDV (Barbara Davies)'
Cc: Dehdashti, Seameen (Jean)
Subject: FDA Information Request - Clinical: 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**. Please send us your response by close of business, Monday, November 19, 2018.

FDA Information Request (IR) - Clinical:

- 1. Please provide, in a tabular format, a list of all subjects (with subject IDs) in Study 3859 who were randomized to Q7D dosing in Ext 1 and who started on Q7D in Ext 2 but switched to Q4D at any time during Ext 2.**
- 2. Please provide the relative Day (relative to start of Ext2) of all bleeding events that occurred in these subjects, Day when they switched to Q4D dosing, and the reason for switching.**

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
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