

Dehdashti, Seameen (Jean)

From: Dehdashti, Seameen (Jean)
Sent: Thursday, December 13, 2018 3:19 PM
To: 'BDV (Barbara Davies)'
Cc: Dehdashti, Seameen (Jean)
Subject: FDA Information Request - Statistical/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, Thursday, December 20, 2018, if possible.

FDA Information Request (IR) – Statistical/Clinical:

Please provide updated results including the non-treatment required bleeds for the following tables:

Trial 3859 main part report: **Table 11-1, 14.2.87-14.2.91**
 Table 11-2, 14.2.17-14.2.20
 Table 14.2.21-14.2.25

Trial 3859 extension part 1 report: **Table 11-1, 14.2.216-14.2.219**
 Tables 14.2.220-14.2.224

Trial 3885 main part report: **Table 11-1**
 Table 11-4, 14.2.21, 14.2.22

Trial 3885 extension part report: **Table 11-1**
 Table 11-5, 14.2.21, 14.2.22

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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